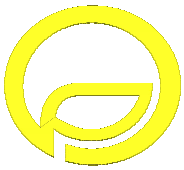

ÖBIG

Pharmaceutical Pricing and Reimbursement Information

SWEDEN

June 2007

Commissioned by
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Pharmaceutical Pricing and Reimbursement Information

SWEDEN

Pharma Profile

Final version, June 2007

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Executive summary

Background

NHS – covers all residents

The Swedish healthcare system is a National Health Service system. 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 emphasizes 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 healthcare. The overall goals and policies are decided at the national level, but the actual provision of services is done by the local authorities.

Financed through taxation

The healthcare system is primarily funded through taxation. Both the county councils and the municipalities levy proportional income taxes on the population to cover the services that they provide. The county councils and the municipalities also generate income through state subsides and user charges.

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), an independent government authority, has a supervisory function over the county councils, acting as the government's central advisory and supervisory agency for health and social services.

County councils run hospitals and primary care centers

The 21 county councils own and run most of the healthcare facilities, such as hospital and primary care centers. There are few private hospitals, and the number of private physicians and health centers varies widely between counties. 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.

Pharmaceutical system

The pharmaceutical system is based on two main acts. The legislative framework for the production, registration and distribution of pharmaceuticals in Sweden is the Medicinal Products Act (Läkemedelslagen), which is based on EU directives. The Act on Pharmaceutical Benefits etc. (Lag om läkemedelsförmåner m.m.) builds the overall legal framework for the pricing and reimbursement of pharmaceuticals.

The LFN decides on reimbursement and prices

The Medical Products Agency (Läkemedelsverket, MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products. Pricing and reimbursement decisions on pharmaceuticals used in out-patient care are made by the Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN). Both the MPA and the LFN are independent government authorities answering to the Ministry of Health and Social Affairs.

Pharmaceutical committees support doctors

It is the county councils which bear the costs for pharmaceuticals in both in-patient and out-patient care. Most county council activities are financed by taxes which they have a right to levy. However, to finance expenditure for pharmaceuticals in out-patient care the county councils receive a subsidy from the state. In each county council there is at least one Pharmaceutical Committee. The committees for example 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.

In Sweden there are two wholesalers, Kronans Droghandel (Oriola KD) and Tamro (Phoenix group), with a roughly equal market share. 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.

Pharmacies are state-owned

All Swedish pharmacies are fully owned by the state and are organised as a pharmacy chain called the National Corporation of Swedish Pharmacies (Apoteket). Apoteket has the exclusive right to sell medicines to Swedish customers/patients. Apoteket is responsible for all 850 community pharmacies.

In 2004 the total pharmaceutical expenditure in Sweden was SEK 28,795 million / € 3,102 million, out of which about 70 percent was public expenditure and about 30 percent private expenditure. Total pharmaceutical expenditure increased relatively rapidly at the end of 1990s and the first couple of years of the new decade. However, the annual increase rate has dropped dramatically since 2002. The main reason for this development is the introduction of generic substitution in October 2002.

Pricing

Pricing and reimbursement processes are combined

The LFN decides whether an out-patient pharmaceutical should be reimbursed and sets its price. Reimbursement and pricing processes are combined and an application from a pharmaceutical company results in a joint reimbursement and price decision by the LFN.

Prices are not negotiated

One important aspect of the Swedish reimbursement system is that the LFN does not negotiate prices. It looks upon the price as an integral part of the cost-effectiveness analysis. If the price is too high, the pharmaceutical will not be cost-effective. Then the Board will reject the application in question. The company will have to decide if they should apply again and suggest a lower price.

The LFN also has the responsibility of deciding on price changes of pharmaceuticals which are already included in the benefit scheme.

Competition between suppliers of generic medicines

To boost competition between the pharmaceutical companies the LFN has introduced a simplified process for price-decisions concerning pharmaceuticals subject to generic substitution. If the new price, which a company applies for, is lower or the same as the highest price within a group of substitutable medicines, the LFN allows both price cuts and price rises without further investigation. The LFN made over 9,000 decisions during 2006. About 70 percent of these were price cuts.

The LFN makes decisions on price changes once a month and a company does not know which price its competitors have applied for. Because of generic substitution the company which can offer the lowest price will get the vast majority of sales during the following month. This procedure creates a robust price competition.

Companies can also apply for price rises for non-substitutable pharmaceuticals, but these are only accepted under exceptional conditions.

Free pricing on products outside the benefit scheme

Pharmaceuticals not included in the reimbursement scheme, i.e. most OTC products, as well as prescription medicines not included in the benefit scheme, may be priced freely by the manufacturers.

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.

For reimbursed pharmaceuticals prices are set by the LFN the pharmacy purchase price level. In other words, that is what a pharmacy buys a pharmaceutical for. The price which the pharmacies charge the patients, the pharmacy retail price, is the pharmacy purchase price plus a mark-up.

The LFN decides the pharmacy margin

The pharmacy retail margin for reimbursed pharmaceuticals is decided by the LFN. The margin consists of two parts:

- A flat fee per prescription. However, depending on the price of the pack this fee can be of three different sizes.
- A fee depending on the price of the pack.

The wholesale margin is not regulated by the government but based on free agreements between manufacturers and the two wholesalers. These agreements are not public.

The standard VAT rate is 25 percent for products in Sweden. However, with the exception of OTC products, pharmaceuticals are exempt from VAT.

Reimbursement

The aim of the system: rational and cost-effective use of medicines

The overall aim of the Pharmaceutical Benefits Scheme is to achieve a rational and cost-effective public use of medicines.

The LFN decides whether an out-patient medicine should be reimbursed and sets its price. Reimbursement and pricing processes are combined and an application from a pharmaceutical company results in a joint reimbursement and price decision by the LFN.

Sweden has a system with a positive list indicating which medicines are reimbursed for out-patient use.

Three criteria are weighed together

Three principles summarise the eligibility criteria for reimbursement laid out in the Act on Pharmaceutical Benefits, etc.:

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

The above-mentioned criteria for reimbursement eligibility should all be considered and weighed together by the LFN when making its decision on reimbursement.

Cost-effectiveness from a societal perspective: a different approach

In the Swedish reimbursement system cost-effectiveness is analysed from a societal perspective. This means that all relevant costs and revenues for treatment and ill health should be considered, regardless of who pays or benefits – be they state, county council, municipality or patient. This broad societal approach to cost-effectiveness analysis differs from some other national systems which also use pharmaco-economics in decision-making. In these systems a narrower approach is applied, taking into account e.g. only cost and revenues which occur in the healthcare sector.

The cost-effectiveness analysis is done to show whether or not the use of a pharmaceutical costs citizens a reasonable amount of money in relation to the health gains it offers the patients. The actual size of the health bill is not a good measure of whether we are using the right amount of pharmaceuticals or even the right kind of pharmaceuticals. The crucial aspect here is instead that

a pharmaceutical is cost-effective, and not just for the healthcare sector, but for society as a whole.

Tighter target for reimbursement decisions applies in Sweden

In 2006 it took on average 91 days for a new pharmaceutical to obtain reimbursement. Since the LFN was set up in October 2002, all decisions have been made within 180 days, i.e. in accordance with the Transparency Directive. The Swedish Government has set a tighter target when it comes to the time-limit for decisions on pricing and reimbursement in Sweden. The LFN has to announce decisions within 120 days.

A product-oriented, not indication based, system

In Sweden medicines are not grouped together into certain reimbursement categories. The reimbursement system is mainly product-oriented.

This means that medicines are either granted reimbursement status for the whole of its approved area of use or not at all. In exceptional cases the LFN can circumvent this and choose to restrict the reimbursement of a medicine to a limited area of use or to a particular patient group.

The reimbursement rate is calculated based on the pharmacy retail price of each pharmaceutical and depends on the consumption of each patient and not on the product. The reimbursement rate ranges from 0% (for patients with expenses below a threshold of SEK 900 / € 96.96) to 100% (for patients who have reached a 12-month co-payment ceiling of SEK 1,800 / € 193.91).

In Sweden there is no reference price system in place anymore. However, within the system for generic substitution, substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation.

Patients pay a maximum of SEK 1,800 per year

The Swedish reimbursement system contains no social clauses, e.g. for old age pensioners or unemployed persons, which covers private pharmaceutical expenses. However, individuals who use large amounts of medicines are protected from high costs. The patient pays the full price for reimbursed medicines up to a certain level (cost ceiling), after which they obtain different amounts of reductions in the additional cost. The maximum amount payable by the patient during a 12 month period is SEK 1,800 /€ 193.91.

No fixed co-payments, for example prescription fees, are used within the Swedish reimbursement system.

County councils pay for hospital medicines

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 pharmaceuticals used for in hospitals. This is a part of their overall responsibility for providing healthcare. Patients pay a fee of SEK 80 /€ 8.62 for every day in hospital care and this fee covers costs for pharmaceuticals as well as all other treatments.

All medicines are reviewed for reimbursement

The LFN is currently conducting a review of the entire list of medicines that were eligible for reimbursement when the new Pharmaceutical Benefits Scheme came into force in October 2002.

At the time of the transition to the new system it was impossible to confirm overnight that all medicines conformed to the new regulations. Therefore the pharmaceuticals which had been reimbursed in the old system were allowed to keep their reimbursement status until a review of these products had been carried out.

The LFN has started an overall review of these products in order to see if they fulfil the new criteria for reimbursement or not. Each and every medicine will be reviewed according to the new regulations.

Rational use of pharmaceuticals

The pharmacy shall substitute with cheapest available copy

Generic substitution is mandatory in Sweden. If a pharmaceutical included in the Pharmaceutical Benefits Scheme has been prescribed and there is one or more less expensive, substitutable medicine available at the pharmacy – be it a generic, parallel import or even the original brand – the pharmaceutical shall be substituted with the least expensive pharmaceutical available.

A pharmaceutical shall not be substituted if the doctor has objected substitution on medical grounds. Nor shall a pharmaceutical be substituted if the patient pays the difference between the price set for the prescribed pharmaceutical and the corresponding price for the least expensive substitutable pharmaceutical available out-of pocket.

Sharp drop in prices after the introduction of generic substitution

Market prices for generic pharmaceuticals have fallen by approximately 40 percent since generic substitution was introduced in October 2002. The accumulated savings in the pharmaceutical budget have been almost SEK 7 billion / approximately € 760 million.

When applying for reimbursement a pharmaceutical company shall prove a medicine's cost-effectiveness by submitting a pharmaco-economic analysis to the LFN. Since pharmaco-economic analysis can be done in a number of ways the LFN has published general guidelines for economic evaluations submitted with applications for reimbursement.

County councils decentralize responsibility for costs

The responsibility for out-patient pharmaceutical expenditure has been pushed further out in the organisation by more and more county councils. Only 3 out of 21 county councils have a centralised responsibility for these costs. Others have either decentralized the cost responsibility to a middle level (for example to primary care areas within the county) or to primary care centres or hospital clinics.

County councils use incentive agreements

There is at least one Pharmaceutical Committee in each county council. The committees support doctors in their choice of medicines by publishing an annual list of medicines recommended as the first choice treatment for a range of common diseases.

As a complement to the recommendation lists, and as a way to further promote effective pharmaceutical prescribing, many Pharmaceutical Committees produce various forms of prescription targets, e.g. simvastatin should make up 80 percent of statin prescriptions. Ten county councils have also designed, to a varying degree, extensive incentive agreements. Some county councils have incentive agreements where both adherence of doctors to the budget and prescription targets result in a reward.

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.

Current challenges and future development

Difficult to prioritise

One future challenge for the pharmaceutical system is to manage the increasing number of applications for orphan drugs. More and more medicines for rare and serious diseases (orphan drugs) are entering the market. In contrary to the rules for market authorisation of medicines, there are no specific rules for orphan drugs in place when it comes to reimbursement. How should a society with finite resources prioritise between orphan drugs and other urgent treatments which in many cases are more cost-effective?

Competition in the pharmacy market

The Swedish pharmacy system is facing enormous change. The new government which took office after the election in autumn 2006 aims to deregulate the pharmacy market by abolishing the state pharmacy monopoly. The objective are to guarantee a safe and secure supply of medicines, increase accessibility and the degree of service as well as to increase price pressure. The government has appointed a special investigator to propose how a new pharmacy system can be created. The investigator shall submit his proposal before the end of 2007.

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List of Tables and Figures

Abbreviations

Apoteket	Apoteket AB / The National Corporation of Swedish Pharmacies
BMI	Body Mass Index
BMGFJ	Bundesministerium für Gesundheit, Familie und Jugend / Austrian Federal Ministry for Health, Family and Youth
EU	European Union
DDD	Defined Daily Dose
EMEA	European Medicines Agency
FGL	Föreningen för generiska läkemedel / The Swedish Generic Medicines Association
FPL	Föreningen för parallelldistributörer av läkemedel / The Swedish Association for Parallel distributors of Medicines
GDP	Gross Domestic Product
GGE	General Government Expenditure
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG
IHE	Institutet för hälso- och sjukvårdsekonomi / The Swedish Institute for Health Economics
IML	Innovativa mindre läkemedelsföretag / Swedish Association for small and medium-sized companies active in R&D
INN	International Non-proprietary Name
LIF	Läkemedelsindustriföreningen / The Swedish Association of the Pharmaceutical Industry
LFN	Läkemedelsförmånsnämnden / The Pharmaceutical Benefits Board (Sweden)
MPA	Läkemedelsverket / The Medical Products Agency (Sweden)
Mio.	Million
n.a	Not available
n.apl.	Not applicable
NEPI	Nätverk för läkemedelepidemiologi / Network for Pharmaceutical Epidemiology

NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-Counter Pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-only Medicines
PPP	Pharmacy Purchase Price
PPRI	Pharmaceutical Pricing and Reimbursement Information Project
PRP	Pharmacy Retail Price
R&D	Research and Development
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
SALAR	Sveriges kommuner och landsting / The Swedish Association of Local Authorities and Regions
SBU	Statens Beredning för Medicinsk Utvärdering / Swedish Council on Technology Assessment in Healthcare
SEK	Svenska kronor / Swedish Crowns
SFS	Svensk författningssamling / Swedish Code of Statutes
SOU	Statens Offentliga Utredningar / Reports of the Government's Commission
VAT	Value-added Tax
Vinnova	The Swedish Governmental Agency for Innovation Systems
WHO	World Health Organisation
QALY	Quality Adjusted Life Year

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at http://ppri.oebig.at. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 NHS – covers all residents and financed through taxation

The Swedish healthcare system is a National Health Service system. The most important law regulating the provision of healthcare is the Health and Medical Services Act of 1982 (SFS 1982). The law not only incorporates equal access to services on the basis of need, it also emphasizes a vision of equal health for all.

According to the Health and Medical Services Act, the Swedish system provides coverage for all residents of Sweden, regardless of nationality. In addition, emergency coverage is provided to all patients from EU/European Economic Area countries and nine other countries with which Sweden has bilateral agreements.

In Sweden, there are three independent governmental levels – the national government, the county councils and the municipalities – and they are all involved in healthcare. The overall goals and policies are decided at the national level, but the actual provision of services is done by the local authorities.

The health system is primarily funded through taxation. Both the county councils and the municipalities levy proportional income taxes on the population to cover for the services that they provide. The county councils and the municipalities also generate income through state subsidies and user charges.

1.2 Several agencies involved at the national level

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 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 Ministry of Health and the National Board of Health and Welfare collaborate with other central government bodies. The most important are 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 Pharmaceutical Benefits Board (Läkemedelsförmånsnämnden, LFN) and the National Institute of Public Health (Folkhälsoinstitutet).

Table 1.1: Sweden – Key figures on the healthcare system 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005	Source
Total population	8,837.496	8,882.792	8,909.128	8,940.788	8,975.670	9,011.392	9,047.752	Statistics Sweden 2006
Life expectancy at birth, total	78.8	79.7	79.8	79.9	80.2	80.6	80.6	Statistics Sweden 2006
Life expectancy at birth, females	81.4	82.0	82.1	82.1	82.4	82.7	82.8	Statistics Sweden 2006
Life expectancy at birth, males	76.2	77.4	77.6	77.7	77.9	78.4	78.4	Statistics Sweden 2006
GDP in Million SEK	1,787.889	2,217.290	2,288.351	2,371.606	2,459.413	2,573.176	2,673.064	OECD Health Data 2006
GDP in Million €	193,757	262,457	247,237	258,937	269,522	281,992	287,977	OECD Health Data 2006
GGE in Million SEK	1,199.338	1,259.751	1,292.842	1,373.663	1,430.602	1,458.198	n.a	OECD Health Data 2006
GGE in Million €	129,974	149,115	139,681	149,980	156,777	159,803	n.a	OECD Health Data 2006
THE in Mio. SEK	144,125	185,305	199,772	216,725	228,667	233,450	n.a	OECD Health Data 2006
THE in Mio. €	15,619	21,934	21,584	23,663	25,059	25,584	n.a	OECD Health Data 2006
Public Health Expenditure in Mio. SEK	124,884	157,306	169,556	184,460	195,251	198,274	n.a	OECD Health Data 2006
Public Health Expenditure in Mio. €	13,534	18,620	18,319	20,140	21,397	21,729	n.a	OECD Health Data 2006
Private Health Expenditure in Mio. SEK	19,241	27999	30,216	32,265	33,416	35,176	n.a	OECD Health Data 2006
Private Health Expenditure in Mio. €	2,085	3,314	3,265	3,523	3,662	3,855	n.a	OECD Health Data 2006
Total number of hospitals[1]	98	80	77	80	81	80	n.a	SALAR
No. of acute care beds	26,848	21,725	20,857	20,378	19,985	20,022	n.a	OECD Health Data 2006
Total number of doctors	25,213	27,268	28,224	29,126	29,763	n.a	n.a	OECD Health Data 2006
No. of visits to GPs per patient per year	n.a	2.84	2.88	2.87	2.77	2.75	2.75	SALAR[2]
Exchange rate (SEK per €)	9.2275	8.4482	9.2557	9.1590	9.1251	9.1250	9.2822	Swedish and Austrian National Bank 2006

GDP = Gross Domestic Product, GGE = General government expenditure, GP = General Practitioner, SALAR = The Swedish Association of Local Authorities and Regions, THE = Total Health Expenditure

[1] Geriatric and psychiatric hospitals are not included.

[2] Numbers of visits to doctors from the SALAR in relation to the figure of the total population from Statistics Sweden.

1.3 County councils run hospitals and primary care centers

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

Resource-allocation principles vary among the county councils. Most county councils have decentralised a great deal of the financial responsibility to healthcare districts, through global budgets. Activities such as psychiatry, geriatrics and emergency services are normally financed through global budgets. In about half of the county councils, payments to both hospitals and primary care centers are based on global budgets. Among the others, a smaller group of about five county councils continue to use per-case payment, with expenditure ceilings for some services (primarily hospitals) and capitation models for primary care. In another group of a similar size, payment for primary care is moving in the direction of capitation, whereas global budgets are used for all other services. The payments, whether they are based on fixed per-case payments, per-diem reimbursements, global budgets, fee-for-service methods or a combination of these systems, are traditionally based on full costs.

The majority of healthcare providers are publicly owned, and therefore physicians, dentists, pharmacists and other professional groups are mainly salaried employees.

Table 1.2: Sweden - Diseases with highest morbidity and the leading causes of mortality

No.	Top 5 diseases with highest morbidity[3] (1 = most common)	3-digit ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	3-digit ICD-10 code
1	Diseases of the circulatory system	I00-I99	1	Diseases of the circulatory system	I00-I99
2	Injury, poisoning and certain other consequences of external causes	S00-T98	2	Neoplasm	C00-D48
3	Symptoms, signs, abnormal findings, ill-defined causes	R00-R99	3	Diseases of the respiratory system	J00-J99
4	Complications of pregnancy, childbirth and puerperium	O00-O99	4	Injury, poisoning and certain other consequences of external causes	S00-T98
5	Diseases of the digestive system	K00-K93	5	Mental and behavioural disorders	F00-F99
Year: 2005			Year: 2003		

Source: The National Board of Health and Welfare (Socialstyrelsen)

[3] Defined as diseases with highest morbidity among persons in in-patient care

2 Pharmaceutical system

2.1 Organisation

In the following section the regulatory framework (legal basis, main authorities and their tasks) of the Swedish pharmaceutical system and the Swedish pharmaceutical market (data, key players) will be described. Figure 2.1 gives an overview of the system.

2.1.1 Regulatory framework

This section includes a description of the legal framework for the pharmaceutical policy, the principal authorities and important players in this framework and their roles.

The main player in the Swedish pharmaceutical system at the national level is the Ministry of Health and Social Affairs. The Ministry submits bills on the extension, development and reform of the healthcare and social systems, which are then debated and voted upon by the Parliament (riksdagen).

2.1.1.1 Policy and legislation

The Swedish parliament and government has adopted a set of acts which govern the pharmaceutical sector.

Sweden joined the EU in 1995 and has since harmonised its legislation regarding authorisation of pharmaceuticals etc. with that of the European Community. Therefore, Swedish legislation in this field is essentially the same as that of the rest of the EU. EC Directives are transposed into acts and ordinances by the Swedish parliament and government and into provisions by the MPA.

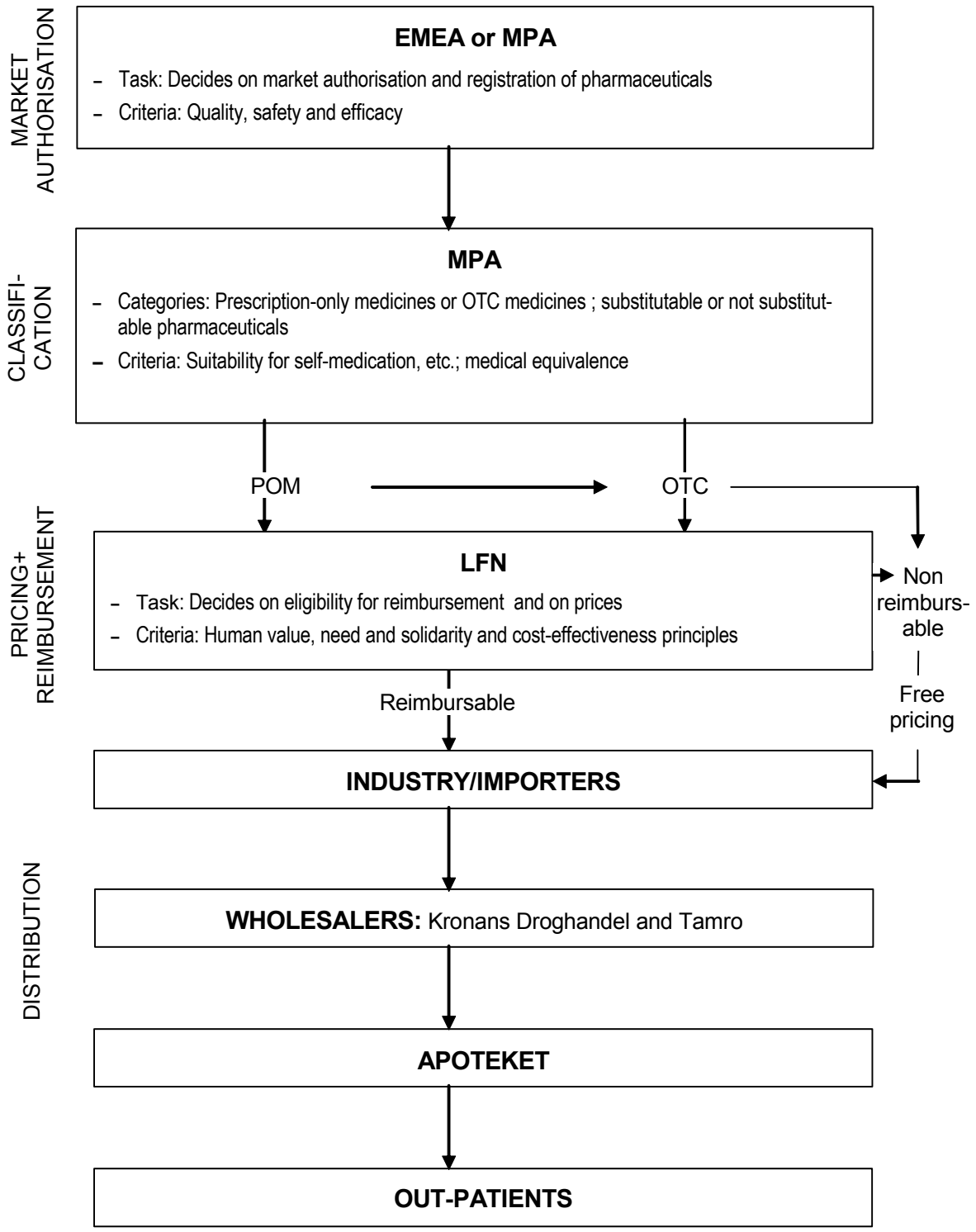
The legislative framework for the production, registration and distribution of pharmaceuticals is the Medicinal Products Act (Läkemedelslagen, SFS 1992). This is complemented by a government ordinance (SFS 2006) and by numerous provisions[4] by the MPA.

Guidelines for pharmaco-economic evaluations

The Act on Pharmaceutical Benefits etc. (Lag om läkemedelsförmåner m.m., SFS 2002a) builds the overall legal framework for the pricing and reimbursement of pharmaceuticals. In addition to this the government has adopted an ordinance (SFS 2002b) and the LFN has issued provisions which provide rules on applications to and decisions by the Board (LFN 2003b) and rules on non-prescription pharmaceuticals (LFN 2003a). Furthermore the LFN has published general guidelines for economic evaluations submitted with applications for the inclusion of a medicine in the Pharmaceutical Benefits Scheme (LFN 2003c) and for price increases of pharmaceuticals (LFN 2006a).

[4] http://www.lakemedelsverket.se/Tpl/NormalPage____4409.aspx

Figure 2.1: Sweden - Flowchart of the pharmaceutical system



Source: LFN 2007

2.1.1.2 Authorities

The 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 produces recommendations for medical treatment in various therapeutic areas. In these treatment recommendations the pharmaceutical treatment options are considered in regard to other measures such as changes in lifestyle or surgery. The agency is an authority subordinate to the Ministry of Health and Social Affairs and is primarily financed by fees.

The LFN decides on reimbursement and prices

The LFN is also an agency answering to the Ministry of Health and Social Affairs and it is 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 Board is appointed by the government to serve for a period of two years and has eleven members. Four of the members are taken from the county councils, four from authorities and other organisations with knowledge in pharmaceuticals and two from user groups.

Currently the Board consists of a chairperson who is a lawyer, six doctors (two clinical pharmacologists, two experts in medical ethics and one general practitioner), two health economists, a representative from the disability movement and a representative from the largest pensioner's organisation. When necessary, the Board can temporarily co-opt one or more experts with particular expertise. Co-opted experts do not take part in the decisions.

The agency's Director General makes the decisions which are not the responsibility of the Board. An example of this is that the Director General makes all decisions on price increases and decreases of medicines.

Pharmaceutical Committees support doctors

It is the county councils which bear the costs for pharmaceuticals in both in-patient and out-patient care. The 21 county councils are independent regional governmental bodies and are accountable for the majority of 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 (cf. 2.2.2).

In each county council there is at least one Pharmaceutical Committee. The committees for example 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.

The county councils have a right to deliberation with the LFN before the 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 smaller group of experts to manage communications with the LFN, called the Pharmaceutical Benefits Group for County Councils (Landstingens läkemedelsförmånsgrupp) (cf 4.1).The group has the right to communi-

cate its position for each reimbursement case once it has evaluated the application sent in from the pharmaceutical company in question.

Table 2.1: Sweden - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Socialdepartementet	The Ministry of Health and Social Affairs	Regulatory body	Overall planning and legislative authority.
Läkemedelsverket	The Medical Products Agency (MPA)	Government agency subordinate to the Ministry of Health and Social Affairs	In charge of market authorisation, classification, vigilance and monitoring of clinical trials.
Läkemedelsförmånsnämnden (LFN)	The Pharmaceutical Benefits Board	Government agency subordinate to the Ministry of Health and Social Affairs	Responsible for pricing and reimbursement decisions.
Landsting	The county councils	21 regional independent governmental bodies. The county councils have together with the 290 municipalities formed an interest organisation - The Swedish Association of Local Authorities and Regions (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 SALAR, deliberates with the LFN in pricing and reimbursement cases.
Statens beredning för medicinsk utvärdering (SBU)	The Council on Technology Assessment in Healthcare	Government agency subordinate to the Ministry of Health and Social Affairs	A HTA organisation responsible for assessing healthcare technology from medical, economic, ethical and social standpoints.
Socialstyrelsen	The National Board of Health and Welfare	Government agency subordinate to 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.

Source: LFN 2007

SBU produces systematic overviews of literature

At a national level there are two other agencies in the field of pharmaceuticals besides the LFN and the MPA. These are the SBU (the Swedish Council on Technology Assessment in Healthcare) and the National Board of Health and Welfare. The SBU has the mission of evaluating

various methods in healthcare from a medical, economic, ethical and social perspective. This is done through producing systematic overviews of the international scientific literature in various therapeutic areas. The National Board of Health and Welfare has, amongst many other responsibilities, the task of producing guidelines for care and treatment of patients with difficult, chronic diseases, which affect many people's lives and have a large drain on society's resources. Support for making decisions regarding prioritisation in healthcare is included in these guidelines.

2.1.2 Pharmaceutical market

This section gives an overview of the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

On 1 January 2006, a total of 8,504 pharmaceuticals were authorised in Sweden (counting different pharmaceutical forms, but excluding different dosages and pack sizes). Of these, around 90 percent were prescription-only medicines.

Table 2.2: Sweden - Number of pharmaceuticals 1995, 2000 - 2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised[2]	3,394	4,843	5403	6203	6942	7291	8047	8504
On the market	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Precription-only[2]	n.a	n.a	n.a	5690	6398	6722	7434	7844
Reimbursable[3]	n.a	n.a	n.a	4057	n.a	4665	n.a	5126
Generics	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Parallel traded[2]	0	601	912	1149	1553	1506	1674	1635
Hospital-only	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

[1]as of 1 January

[2]The data include different pharmaceutical forms but exclude different dosages and pack sizes

[3]Only reimbursed pharmaceuticals that had sales during respective year are counted in the table. The data include different pharmaceutical forms and dosages but exclude different pack sizes

Source: LVIS (MPA's database), Xplain (Apoteket's database)

The number of generics has increased

The number of reimbursed pharmaceuticals has increased substantially since the introduction of the new reimbursement system in October 2002 (cf. 4.2). As generic substitution was introduced at the same time, the increase of reimbursed pharmaceuticals is probably caused by an increased number of generic products.

In Sweden there is a national classification system of prescription-only medicines and OTC medicines, but there is no classification system regarding hospital-only medicines in place. The MPA decides on the prescription status of a pharmaceutical and on switches from a prescription-only status to OTC status.

Whether a pharmaceutical should be reimbursed or not is decided by the LFN after reviewing an application from the pharmaceutical company (cf. 4.2).

2.1.2.2 Market data

Table 2.3 presents pharmaceutical market data for Sweden for 1995 and for the years between 2000 and 2005. The growth rate of sales at pharmacy retail price level has more than halved since 2000. Between 2000 and 2001 sales rose by more than 6 percent, and between 2004 and 2005 the equivalent figure was less than 3 percent.

Table 2.3: Sweden - Market data 1995, 2000 - 2005

In million €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume in million	n.a	56,618	58,110	59,691	60,221	61,411	62,496
No. of annual prescriptions by value in pharmacy retail price	n.a	2,157.4	2,079.3	2,277.5	2,296.3	2,303.7	2,271.5
Pharmaceutical sales							
Sales at ex-factory price level[5]	1,375.4	2,080.5	2,223.0	2,387.9	2,432.8	2,489.1	2,596.6
Sales at wholesale price level	1,409.8	2,132.5	2,278.6	2,447.6	2,493.6	2,551.3	2,661.5
Sales at pharmacy retail price level	1,830.3	2,638.8	2,806.8	2,998.8	2,983.2	3,070.9	3,161.3
Sales at hospitals	221.1	352.2	370.5	368.7	304.2	364.1	429.4
Sales of generics	n.a.	229.1	247.1	270.7	301.6	312.0	342.2
Sales of parallel traded pharmaceuticals	n.a	184.1	211.7	219.5	220.9	265.8	317.5
Exports and imports[6]							
Total pharmaceutical exports	1,375.4	2,080.5	2,223.0	2,387.9	2,432.8	2,489.1	2,596.6
Total pharmaceutical imports	1,409.8	2,132.5	2,278.6	2,447.6	2,493.6	2,551.3	2,661.5

Source: Apoteket 2007 and IMS 2006

Generic substitution explains lower growth rate

The lower growth rate is mainly due to the fact that a system for generic substitution was introduced in 2002 and that this coincided with the patent expiry of some blockbuster pharmaceuticals. The share of generic pharmaceuticals has in terms of volume increased significantly since the introduction of generic substitution. However, mandatory generic substitution has only induced a moderate increase in the market share in terms of value. This is due to the fact that generic substitution of out-patient pharmaceuticals has led to a dramatic drop in prices on off-

[5] Estimated 81,5 % of wholesale price

[6] Finished products

patent medicines (cf. 5.5.1). Table 2.4 lists the top ten best selling pharmaceuticals by active ingredient, based on their turnover 2005.

Table 2.4: Sweden - Top 10 best selling pharmaceuticals, by active ingredient, 2005

Position	Pharmaceutical
1	Etanercept
2	Budesonid + Formoterol
3	Atorvastatin
4	Sertralin
5	Infliximab
6	Losartan
7	Olanzapin
8	Venlafaxin
9	Metoprolol
10	Omeprazol

Source: IMS 2006

2.1.2.3 Patents and data protection

The duration of patent for inventions is 20 years from the filing date of the patent application. The term may, however, be extended for pharmaceutical patents by a maximum of five years; the extension of the term of protection is called a Supplementary Protection Certificate (SPC). The protection extends to the active ingredient or ingredients found in an approved medicinal product in accordance with the EC Regulation in force in Sweden. The term of protection is calculated based on the date of the first approval for sale of the medicinal product within the European Economic Area (EEA) and the filing date of the patent application. The term of protection takes effect at the end of the lawful term of the basis patent. (PRV 2007)

2.1.3 Market players

This section describes the key players in the pharmaceutical system, except the authorities which have been introduced in section 2.1.1.2. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy making.

2.1.3.1 Industry

In 2004 there were approximately 330 enterprises in Sweden, within the field of pharmaceuticals and biotechnology[7]. These enterprises had about 27,400 employees. The largest enter-

[7] Including companies in biotechnical medical technology and biotechnical tools. Companies in diagnostics and medical technology are excluded. Companies with only marketing and sales representatives are included.

prises were AstraZeneca, Pfizer, GE Healthcare, Fresenius Kabi, Getinge and Biovitrum. (Vinnova 2004)

AstraZeneca is a major net exporter

More than a third of all employees in the Swedish pharmaceutical and biotechnology industry are employed by AstraZeneca.

The company has its headquarters in the UK, but the headquarters for R&D is still located in Sweden. Of AstraZeneca's total R&D investments 36 percent are made in Sweden, which equals SEK 10 billion / € 1.08 billion a year. However, only 1.5 percent of AstraZeneca's total sales revenues are generated on the Swedish market. In 2004 AstraZeneca accounted for about 20 percent of the total Swedish net export. (Government report 2005)

The pharmaceutical and biotechnology enterprises are to be found almost exclusively in regions that have universities and university colleges with strong life science research. Most employees are found in the Stockholm-Uppsala region. Other strong regions are Skåne and western Sweden close to Goteborg.

Table 2.5: Sweden - Key data on the pharmaceutical industry 1995 - 2005

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	n.a	n.a	n.a	n.a	n.a	333[16]	n.a
- research-oriented	n.a	n.a	n.a	n.a	n.a	n.a	n.a
- generic producers	n.a	n.a	n.a	n.a	n.a	n.a	n.a
- biotech	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Number of persons employed	n.a	n.a	n.a	n.a	n.a	27,400	n.a

Source: Swedish Governmental Agency for Innovation Systems (Vinnova)

Five different industry organisations

The research-oriented pharmaceutical industry in Sweden has two interest organisations: the Swedish Association of the Pharmaceutical Industry (LIF, Läkemedelsindustriföreningen) and the Swedish Association for small and medium-sized companies active in R&D (IML, Innovativa mindre läkemedelsföretag). The LIF has 64 member companies and IML 20. The Swedish Generic Medicines Association (FGL, Föreningen för generiska läkemedel) has 16 member companies. The Association for Parallel distributors of Medicines (FPL, Föreningen för parallelldistributörer av läkemedel) have 8 member companies. For biotechnology companies the association is SwedenBIO with 82 members. 10 LIF companies are also members of SwedenBIO.

The pharmaceutical industry has set up its own ethical rules and policies about pharmaceutical information, non-intervention studies, safety evaluation and contacts with patient organisations (cf. 5.3).

2.1.3.2 Wholesalers

In Sweden there are two wholesalers, Kronans Droghandel (Oriola KD) and Tamro (Phoenix group), with a roughly equal market share.

The wholesale market is divided between two companies

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. This means that Swedish wholesalers are logistics service providers rather than traditional wholesale dealers. Neither of the two are full line wholesalers and thus the pharmacies may only obtain certain products from one of the distributors.

There is no statutory wholesale margin. Instead Kronans Droghandel and Tamro negotiate their margins directly with the pharmaceutical companies.

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

Table 2.6: Sweden - Key data on pharmaceutical wholesale 1995 - 2005

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	2	2	2	2	2	2	2
Total number of outlets	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.

Source: LIF

2.1.3.3 Pharmaceutical outlets / retailers

Pharmacies are state-owned

All Swedish pharmacies are fully owned by the state and are organised as a pharmacy chain (limited company) called Apoteket[8]. Apoteket has the exclusive right to sell medicines to Swedish customers/patients. Apoteket is responsible for all 850 community pharmacies in Sweden and may also dispense medicines through mail order and Internet order. The county councils are allowed to run their own pharmacies in hospitals, but right now all county councils have agreements with Apoteket to do so.

Apoteket employs about 875 representatives stocking a small amount of non-prescription pharmaceuticals available for customers. Those representatives, for example grocer's stores, are mostly located in rural areas where there are long distances to community pharmacies. Apoteket also sends personally addressed packages with prescription medicines to customers

[8] Please note that the government has appointed a special investigator to propose how a new pharmacy system can be created. The investigator shall submit his proposal before the end of 2007. (cf. 6.2)

through these representatives. In order to increase the availability of pharmacy services Apoteket are developing new services as mail order and Internet order (cf 2.1.3.3.3).

Prices are the same all over Sweden

Community pharmacies in Sweden have to supply all pharmaceuticals that have been approved for sale in all parts of the country at the same price. The stock at the above mentioned representatives is 20-30 items of small packages of non-prescription medicines that could be needed in an acute situation. Apoteket also sells products that are closely related to healthcare. The last couple of years Apoteket has also opened about 30 stores called Apoteket shop. These stores only sell OTC medicines and other health products.

2.1.3.3.1 Pharmacies

The pharmaceutical services provided by the pharmacies are governed by an overall agreement between Apoteket and the government (the Ministry of Health and Social Affairs). Included in this agreement are all regular pharmaceutical services, provision of pharmaceutical information and some other commitments and responsibilities including management of the pharmaceutical reimbursement system.

Around 165,000 patients (primarily elderly in nursing homes) daily receive their medicines dose-dispensed in multi-dose sachets. These are prepared by special dispensing pharmacies.

Table 2.7: Sweden - Retailers of pharmaceuticals 1995, 2000 - 2006

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies	804	820	821	812	812	806	885	850
No. of private pharmacies	0	0	0	0	0	0	0	0
No. of public pharmacies	804	820	821	812	812	806	885	850
Number of hospital pharmacies for outpatients	90	86	84	82	81	77	0	0
Number of other POM dispensaries	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.
Total number of POM-dispensaries	894	906	905	894	893	883	885	850
No. of Internet pharmacies	0	0	0	0	0	0	0	1
No. of OTC dispensaries:								
- Apoteket Shop	n.apl.	n.apl.	n.apl.	n.apl.	n.apl.	6	15	29
- Apoteket representatives	n.a	n.a	n.a	n.a	n.a	950	844	875

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines

Source: Apoteket 2007

The LFN decides on the pharmacy margin

The community pharmacy retail margin for reimbursed pharmaceuticals is decided by the LFN. The margin consists of two parts (cf. 3.5.2):

- A flat fee per prescription. However, depending on the price of the pack this fee can be of three different sizes.
- A fee depending on the price of the pack.

Pharmacies are often located near shopping centres or in the close vicinity of a primary health-care centre or a hospital. In rural areas Apoteket employs pharmacy representatives to whom it sends medicines and where the patient can easily get access to medicines. Access to medicines is also enhanced by mail-order and Internet order. (cf 2.1.3.3 and 2.1.3.3.3)

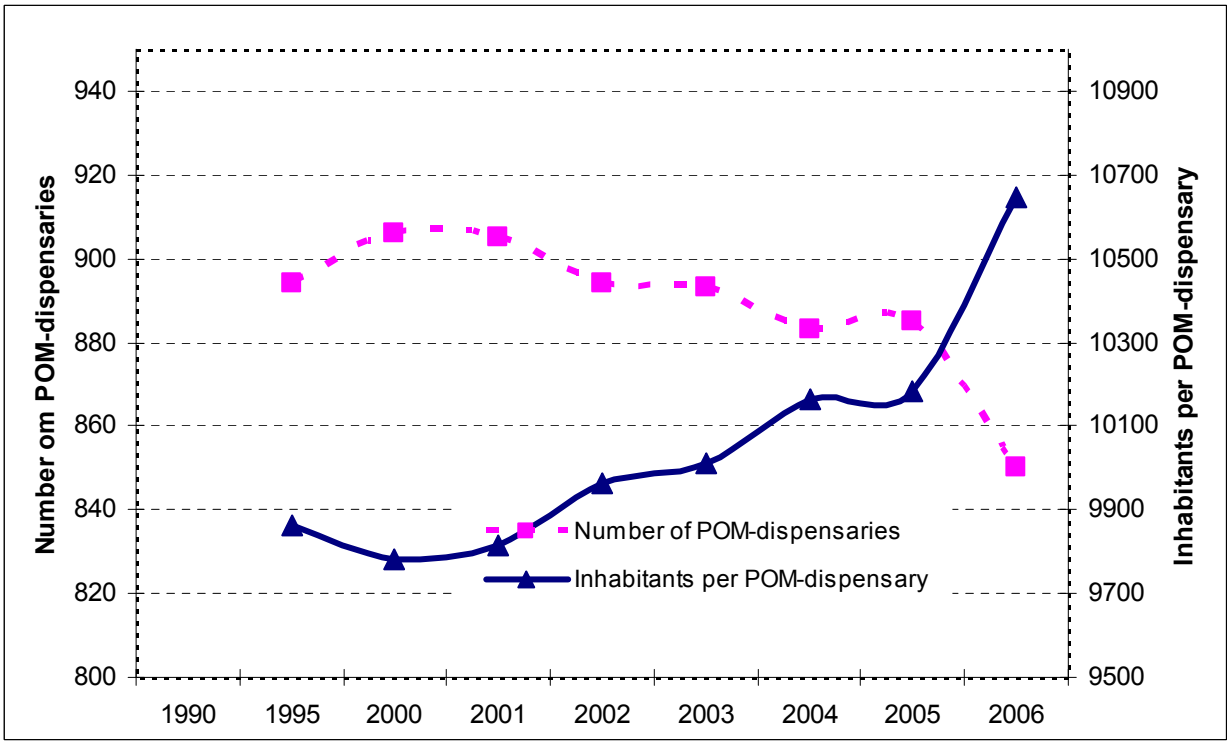
Discounts are paid only for hospital products

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 often are given discounts for medicines used in hospitals. Discounts are in general paid to the county council directly from the manufacturer based on the volume of products purchased during a certain period. This procurement procedure does not involve the community pharmacy system as such and it does not influence the community pharmacy prices.

There are two trade unions organising people working at Apoteket and they have more than 7000 members each. Almost 80 percent of the Swedish pharmacists are members of the Swedish Pharmaceutical Association (Sveriges Farmacevtförbund). The Pharmacy Employees' Union (Farmaciförbundet) organises many prescriptionists and most pharmacy technicians. Their primary task is to safeguard the professional and occupational interests of the pharmaceutical profession. As interest organisations they take part in the public debate and try to influence decision-makers concerning issues that are of importance for their members. Both associations have a seat on the Board of Apoteket.

In Sweden there are 850 pharmacies (not including Apoteket shops or representatives). That makes one pharmacy per 10,600 inhabitants (cf. Table 2.7 and Figure 2.2).

Figure 2.2: Sweden - Number of POM dispensaries and number of inhabitants per POM dispensary 1995 and 2000 – 2006



Source: Apoteket 2007, Statistics Sweden 2006

2.1.3.3.2 Other pharmacy outlets

In the beginning of 2006 an independent investigator commissioned by the government proposed that non-prescription nicotine replacement medicines should be allowed to be sold also by other retailers than Apoteket. This proposal is now under consideration by the government.

According to the proposal it is desirable that retail trade with these kinds of medicines can take place in different places, for example where tobacco is being sold and where alcohol is being served. However, to be able to start selling non-prescription nicotine replacement medicines the retailer will need a special permit from the MPA.

2.1.3.3.3 Internet pharmacies

Apoteket is the only enterprise which is allowed to sell pharmaceuticals in Sweden. Consequently, there exist no Internet pharmacies which are independent from Apoteket.

However, from August 2006 it is possible for patients to order both prescription-only medicines and OTC medicines from Apoteket via Internet or telephone and have them delivered by mail.

Mail-order costumers are offered pharma counselling

The first time a patient uses this new service he or she is offered pharmaceutical counselling, either via telephone or at a local pharmacy. Hereafter, the patient is offered booked counselling once a year. Information by telephone is always available 24 hours and 365 days a year via Apoteket's Customer Centre. Apoteket aims at having about 10 percent of all prescriptions dispensed via Internet or telephone by 2010.

2.1.3.3.4 Dispensing doctors

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

2.1.3.4 Hospitals

In principle, each full-service hospital has its own hospital pharmacy, which only serves for internal use. The hospital doctors are allowed to use any of the pharmaceuticals granted a marketing authorisation.

County councils procure medicines for hospital use

However, 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 use 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. Often, the prices are lower in hospital use than for the same products when prescribed to out-patients, due mainly to a more or less guaranteed sales volume.

2.1.3.5 Doctors

In Sweden there are two main organisations for doctors, the Swedish Society of Medicine (Svenska Läkaresällskapet) and the Swedish Medical Association (Sveriges läkarförbund).

The Swedish Society of Medicine is the scientific organisation of the Swedish medical profession. Its aim is to promote research, education and development in the healthcare sector. The Society is responsible, with the support of its sections, for the advanced training of Swedish physicians and it contributes more than SEK 20 million / € 2.15 million to medical research every year.

The Swedish Medical Association is the union and professional organisation for medical practitioners. Issues which are dealt with by the Association include doctors' work environment, salaries, working hours, training and research. The Association is frequently engaged in the public debate on how to organise and finance the healthcare sector. It is also often represented on

various commissions set down by the government to investigate different issues pertaining to the healthcare system.

2.1.3.6 Patients

The Swedish reimbursement system contains a high-cost threshold for reimbursed medicines. The patient pays for reimbursed medicines up to maximum SEK 1,800 /€ 193.91 for a period of 12 months. (cf. 4.4.2.2).

Medicine prices are available on the web

Apoteket has a retailing monopoly for all pharmaceuticals. This means that the prices of medicines are the same in every pharmacy. Patients may obtain information about prices of all medicines included in the Pharmaceutical Benefits Scheme at the LFN website www.lfn.se or at www.fass.se. Fass is published by the LIF and contains, besides from prices, useful information on for example recommended dosages, contra-indications, side-effects and is well-known to many patients.

The disability movement in Sweden consists of disability organisations and the Swedish Disability Federation. In total, the disability organisations have just over half a million members and display great variation between individual organisations.

Pensioner organisations have just over 830,000 members in Sweden. The largest organisations are the Swedish National Pensioners' Organisation (Pensionärernas Riksorganisation) and the Swedish Association for Senior Citizens (Sveriges Pensionärsförbund).

Several stakeholders in the pharmaceutical policy-making area, e.g. state authorities, county councils, the LIF and Apoteket, have user councils and other forms of collaboration with user organisations.

In 2005 the LIF appointed an investigator to review the collaboration between user organisations and the pharmaceutical industry. The report was published at the beginning of 2006 and it shows that the current collaboration between pharmaceutical companies and user organisations is extensive.

Wide range of collaboration between companies and patients

According to the LIF's calculations, pharmaceutical company support comprises 5-10 percent of the organisations' total finances. The collaboration is chiefly between pharmaceutical companies, disability organisations and patient associations. In a survey of the LIF's 61 member companies, 32 of the 44 respondents stated that they collaborated with user organisations. There is limited collaboration with associations for senior citizens. Not all disability organisations have collaborations with pharmaceutical companies. On the other hand, there are examples of both long-term and comprehensive collaborations. The content of the collaboration varies greatly and may relate to such things as information days, production of information material, contributing to exhibitions, statements of requirements and projects on accessible packaging. (LIF 2006)

The report suggests ways in which transparency in the collaboration between pharmaceutical companies and user organisations could be secured in combination with a number of ethical principles for the collaboration. These principles were adopted by the LIF Board of Directors in the autumn of 2006.

2.2 Funding

This section provides an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

Total pharmaceutical expenditure in Sweden increased relatively rapidly at the end of 1990s and the first couple of years of the new decade. This was due to an increase in volume in the number of purchased medicines and a gradual shift over time to a more expensive range of pharmaceuticals because of the introduction of many new products (SOU 2000).

Prices on generics has fallen dramatically

As is evident from table 2.8 the annual increase rate has dropped dramatically since 2002. The main reason for this development is the introduction of generic substitution in October 2002. Due to the generic substitution market prices of generic pharmaceuticals have fallen by approximately 40 percent (cf. 5.5.1).

Both the public pharmaceutical expenditure and the private pharmaceutical expenditure as shares of the total health expenditure have gone down since 2000.

Table 2.8: Sweden - Total pharmaceutical expenditure 1995, 2000 – 2005

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in million SEK	17,757	25,603	26,401	28,249	28,762	28,795	n.a
TPE in % of THE	12.3	13.8	13.2	13.0	12.6	12.3	n.a
TPE per capita in SEK	2009	2882	2963	3159	3204	3195	n.a
Public PE in % of THE	9.0	9.7	9.1	9.1	8.9	8.6	n.a
Private PE in % of THE	3.3	4.1	4.1	3.9	3.7	3.8	n.a

TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure, THE = Total Health Expenditure, SEK = Swedish Crowns

Source: OECD Health Data 2006

In 2003 total pharmaceutical expenditure both as a share of the GDP (1.2 percent) and a share of the total health expenditure (12.3 percent) was below the European average (1.5 percent and 17.9 percent).

2.2.2 Sources of funds

Medicines have three financial sources in Sweden. These are the county councils, the state and the patients.

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.

Government grant covers costs for out-patient medicines

Costs for out-patient pharmaceuticals are formally also financed by the county councils. However, when the county councils in 1998 took over the responsibility for expenditure for pharmaceuticals included in the Pharmaceutical Benefits Scheme from the state, a state subsidy was introduced to cover these costs. The government and the SALAR have reached an agreement concerning the subsidy for the years 2005 to 2007.

For 2005 the county councils received SEK 19.8 billion/ € 2.23 billion, for 2006 they got SEK 20.7 billion / € 2.23 billion and for 2007 SEK 21.5 billion / € 2.32 billion. If the actual costs substantially exceed the fixed subsidy the government and the SALAR together will decide whether the agreement should be re-negotiated or not. Unlike the 2002-2004 agreement, the current agreement includes no formal risk-sharing model setting out responsibility for covering excess spending. But in practice, if expenditure do not substantially exceed the subsidy they are covered by the county councils and if the expenses, like in 2005 and 2006, are below the subsidy then the remaining funds may be used by the county councils for other purposes.

Patients pay 30 percent of total expenditure

In 2004 the private pharmaceutical expenditure's share of the total expenditure on pharmaceuticals was slightly above 30 percent. As is evident from table 2.9 this share has been quite stable the last couple of years.

Table 2.9: Sweden – Public and private pharmaceutical expenditure as a share of the total pharmaceutical expenditure 1995, 2000 – 2005, percent

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
Public PE in % of TPE	73.4	70.0	68.9	70.0	70.4	69.4	n.a
Private PE in % of TPE	26.6	30.0	31.1	30.0	29.6	30.6	n.a

TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

Source: OECD Health Data 2006

About 70 percent of the private pharmaceutical expenses are out-of pocket payments of patients for prescription pharmaceuticals (cf. 4.4.2.2). The majority of the remaining 30 percent are direct payments for OTC products. However, patients face direct payments also if they refuse substitution of a medicine within the system for generic substitution (cf. 5.5.1) and if the doctor prescribes a non-reimbursed pharmaceutical.

At the moment the vast majority of prescription medicines are reimbursed. However, as the LFN progresses with its review of the reimbursement status of all reimbursed pharmaceuticals (cf. 4.6.5) it is likely that the share of not reimbursed medicines will grow.

2.3 Evaluation

In Sweden there is no centrally coordinated programme for evaluating the pharmaceutical policy. But state authorities, county councils, Apoteket and different university research units and research institutes do evaluate various aspects of the policy. This is done partly as a matter of course, and partly in the form of specially formed initiatives. Below *some examples* are given of bodies carrying out these types of evaluations and in which areas they are active.

In a report the LFN has studied how prices of generic medicines have developed since the introduction of generic substitution in October 2002 (cf. 5.5.1).

The National Board of Health and Welfare analyses on a continual basis the causes driving the development of medicine sales and accounts for an estimation of the future cost trends for the Pharmaceutical Benefits Scheme. The reports shed light on and analyse in particular the reasons for the differences in pharmaceutical usage between different county councils and between women and men.

National register facilitates analyses of medicine use

In July 2005 a national register on prescribed pharmaceuticals was established at the Centre for Epidemiology at the National Board (Epidemiologiskt Centrum) of Health and Welfare. This register provides complete national data on the number of individuals exposed to dispensed prescribed pharmaceuticals in the Swedish population. The register thus provides good opportunities for exploring pharmaceutical and disease associations and the risks, benefits, effectiveness and health economic effects of pharmaceutical use.

The county councils utilise various initiatives to evaluate pharmaceutical policy. An example of this is the county council in Stockholm which together with Apoteket has founded the Centre for Pharmacoepidemiology (Läkemedelsepidemiologiskt Centrum). This is an organ formed for collaborations regarding follow-up and evaluation of pharmaceutical usage in Stockholm County. In the short term this collaboration is aimed at producing standard reports for feedback regarding prescription patterns to healthcare units and at analysing the pharmaceutical usage in the county. The objective is to in the long term increase knowledge and thereby contributes to improved medical treatments as well as has the ability to forecast developments in the years to come.

Follow up on diabetes and breast cancer care

Furthermore, national quality registries are run with the county councils as main sponsor and with financial support from the state. Quality registries exist for approximately 60 conditions, such as diabetes, breast cancer and prostate cancer. These registries make it possible to monitor the effects of treatment on the individual patients and, above all, the data can be aggregated

to show the effects of a certain type of treatment on the entire group of patients. This enables individual hospital departments to measure their treatment results with respect to certain types of patients and treatments and then compare them with the national average and with corresponding results of other departments.

Apoteket collates statistics regarding pharmaceutical sales in the country on a continual basis.

Various aspects of pharmaceutical policy are evaluated at both universities and research institutes. An example of this is the thesis “Swedish Pharmaceutical Benefit Reforms - Analyses of implementation, pharmaceutical sales patterns and expenditures”, which was presented in autumn 2006 at the Sahlgrenska Academy (Sahlgrenska akademi) at Gothenburg University.

Another example is the Centre for the evaluation of medical technology (Centrum för utvärdering av medicinsk teknologi, CMT) at Linköping University which is a research centre. Its mission is method development, knowledge sharing and evaluations of methods and procedures within healthcare with an eye towards medical, social, economic and ethical consequences.

Report on decentralised pharmaceutical budgets

The Swedish Institute for Health Economics (Institutet för hälso- och sjukvårdsekonomi, IHE) is a non-profit research institute and is a wholly-owned subsidiary of Apoteket. IHE aims to contribute to well-founded decision-making in the healthcare sector by providing health economic assessments and policy analyses for public discussion. Among its recent publications one can mention two studies: 1) The impact of decentralised pharmaceutical budgets in Sweden - A survey of physicians’ attitudes towards costs and cost-effectiveness, 2) Reimbursement and clinical guidance for pharmaceuticals in Sweden - Do health economic evaluations support decision-making?

The Network for Pharmaceutical Epidemiology (Nätverk för läkemedelepidemiologi, NEPI) is a foundation formed by the Swedish Parliament and it works for an improved usage of medicines. The aim of the NEPI is to promote a medical and economically better usage of medicines through a combination of research, studies, analyses, training and information. Their main emphasis is on the evaluation of the effectiveness of pharmaceutical treatments in routine healthcare.

A comprehensive description of different university research units and their involvement in policy evaluation can be found in a report with an evaluation of Swedish health economics research conducted by the Swedish Council for Working Life and Social Research (Forskningsrådet för arbetsliv och socialvetenskap, FAS)[9].

[9] www.fas.se/upload/dokument/evaluations/evalswehealtheco.pdf

3 Pricing

This chapter gives an overview of the pricing system in Sweden by describing the process and the regulation of the pricing of pharmaceuticals.

3.1 Organisation

Pricing and reimbursement processes are combined

Since October 2002 it is the LFN which decides whether a pharmaceutical shall be included in the Pharmaceutical Benefits Scheme or not. The LFN decides on both reimbursement and price of a medicine. Reimbursement and pricing processes are combined and an application from a pharmaceutical company results in a joint reimbursement and pricing decision by the LFN.

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

- *The human value principle*; which underlines the respect for equality of all human beings and the integrity of every individual. It is not allowed to discriminate against people because of sex, race, age etc. when making reimbursement decisions.
- *The need and solidarity principle*; which says that those in greatest need take precedence when it comes to reimbursing pharmaceuticals. In other words, people with more severe diseases are prioritised over people with less severe conditions.
- *The cost-effectiveness principle;* which states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective. (cf. 5.4)

The above mentioned criteria for reimbursement eligibility should all be considered and weighed together by the LFN when making its decision on reimbursement.

A product-oriented, not indication-based, system

If the assessment of an application from a pharmaceutical company concludes that the criteria are fulfilled, the LFN decides that the pharmaceutical should be reimbursed at the preferred price (cf. 4.1). The reimbursement system is mainly product-oriented. This means that usually pharmaceuticals are granted reimbursement status for the whole of their approved area of use. In exceptional cases the LFN can circumvent this and choose to limit the reimbursement of a pharmaceutical to a limited area of use or to a particular patient group.

Acting on the initiative of a sponsor or manufacturer of a specific medicinal product included in the scheme, the LFN can rule on a price increase and price decrease respectively (cf. 3.2). This is in addition to deciding whether a pharmaceutical is to be included in the benefit scheme.

Furthermore, acting on its own initiative, the LFN can remove a medicinal product from the benefits scheme.

Decisions may be appealed. An appeal against the LFN's decisions can be made in a administrative court.

The Board makes decisions on reimbursement…

The LFN is headed by a Director-General. In the LFN's executive office work mainly pharmacists, health economists and lawyers who review applications regarding pricing and reimbursement. The LFN has a Board which makes decisions on pricing and reimbursement of medicines and other medical products covered by the Pharmaceutical Benefits Scheme (cf. 2.1.1.2).

…and the Director-General decides on price changes

In contrast to decisions on reimbursement, decisions regarding price increases or decreases are made by the Director-General and not by the Board.

In accordance with the EU's Transparency Directive the Board is to announce its decisions on pricing and reimbursement within 180 days after receiving a fully completed application. However, the Swedish government has set a tighter target when it comes to the time-limit for decisions on pricing and reimbursement in Sweden. The LFN has to announce decisions within 120 days.

A decision whether or not to approve an increase of a previous sale price is to be announced within 90 days after the LFN has received an application. If many applications for a price increase are submitted, the processing time can be extended for a single 60-day period. If a decision is not made within that timeframe then the requested price is accepted.

3.2 Pricing policies

The LFN decides whether a pharmaceutical should be included in the reimbursement system after reviewing an application from the pharmaceutical company. Reimbursement and pricing processes are combined and an application results in a joint reimbursement and price decision by the LFN.

Prices are not negotiated

The LFN does not negotiate prices (cf. 4.2.1). Prices are looked upon as an integral part of the cost-effectiveness analysis (cf. 5.4). If the price is too high there will be no cost-effectiveness. Then the Board will reject the application in question. And the company will have to decide if they should apply again and suggest a lower price.

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 plus mark-up, which is decided by the LFN (cf. 3.5.2).

In general, all pharmaceuticals - including OTC medicines - may be reimbursed, provided that the conditions stipulated in the Act on Pharmaceutical Benefits, etc., (cf. 4.2.1) are fulfilled. However, the following groups of OTC pharmaceuticals are explicitly excluded from reimbursement:

- Pharmaceuticals for antidotal smoking treatment
- Natural remedies

Certain pharmaceuticals for external use approved by the MPA

Table 3.1: Sweden - Ways of pricing pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Statutory Pricing		Statutory pricing for reimbursed pharmaceuticals. Decision is taken by the LFN after reviewing application from manufacturer Manufacturers and wholesalers negotiate their share of the price[10]	Wholesale price plus mark-up, that is enacted by the LFN
Free Pricing	Free pricing for pharmaceuticals not included in the benefits scheme i.e. non-reimbursed prescription-only medicines and most OTC medicines. The manufacturer reports price to Apoteket AB.[11]	Not applied	Not applied
Price Negotiations	Manufacturers and wholesalers negotiate the wholesale margin[12]		Not applied
Discounts / rebates	Relevant for pharmaceuticals used in hospitals (see public procurement)	No	No
Public Procurement	➢ Relevant for pharmaceuticals used in hospitals (performed by the county councils)		
Institution in charge of pricing	➢ LFN (decides price of reimbursed pharmaceuticals and the pharmacy margin)		
Legal Basis	➢ Act on Pharmaceutical Benefits etc. (Lagen om läkemedelsförmåner m.m.) ➢ LFN decision on Pharmacy Mark-ups from 1 January 2006		

Source: LFN 2007

[10] Wholesalers are free to negotiate their margin directly with the manufacturer. There are two wholesalers in the Swedish market, Tamro and Kronans Droghandel (KD), with a roughly equal market share.

[11] The pricing of non-reimbursed prescription-only and OTC pharmaceuticals is free but are limited to distribution from the state-owned Apoteket at equal prices around the country.

[12] Wholesalers are free to negogiate their margin directly with the manufacturer. There are two wholesalers in the Swedish market, Tamro and Kronans Droghandel, with a roughly equal market share.

Most OTC medicines are not reimbursed

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 system are subject to free pricing. Thus, the LFN is not in charge of pricing of not reimbursed pharmaceuticals (like most of OTC as well as prescription pharmaceuticals not included in the benefits scheme). The companies are obliged to inform Apoteket of the price of not reimbursed medicines for inclusion in the official pharmacy sales list.

For medicines used in hospitals public procurement is performed by the county councils, usually by several counties together (cf. 3.4.1).

3.2.1 Statutory pricing

An application shall illustrate a medicine's cost-effectiveness

The LFN decides, after receiving an application from the pharmaceutical company, whether a medicinal product is to be included in the Pharmaceutical Benefits Scheme. An application regarding pricing and reimbursement for a new (original) pharmaceutical is considered complete if the following documents are submitted:

- The price requested and reasons for the price on the application
- Proof of authorisation to market
- Summary of product characteristics
- Commodity number certificate issued by Läkemedelsstatistik AB (LSAB) or the Nordic Number Office
- The authorising agency's overall assessment of the scientific basis of fact
- Information on the patient groups for which the pharmaceutical is intended
- Information on the pharmaceuticals already included on the Pharmaceutical Benefits Scheme within the relevant areas of indication
- Information on the estimated number of patients who might be considered for treatment with the pharmaceutical
- Information on the estimated average cost of treatment per day
- Information on the estimated average duration of treatment

The documentation shall illustrate the clinical effects of the pharmaceutical, the cost/benefit ratio of the pharmaceutical and the total expected costs to society. Comparisons shall be made with the best generally accepted treatment in order to illustrate the marginal benefit and marginal cost of the pharmaceutical.

Besides making decisions on prices in conjunction with inclusion in the reimbursement system, the LFN decides on price changes of pharmaceuticals that are already reimbursed.

In Sweden generic substitution is mandatory between medically equivalent pharmaceuticals. The pharmacy dispenses the least expensive generic pharmaceutical or parallel-imported pharmaceutical available regardless of what the doctor has written on the prescription. The companies have to apply to the LFN if they want to increase or decrease a price on a pharmaceutical which is subject to generic substitution. (cf. 5.5.1)

Competition between suppliers of generic medicines

To boost competition between the pharmaceutical companies the LFN has introduced a simplified process for price decisions concerning substitutable pharmaceuticals. If the new price, which a company applies for, is lower or the same as the highest price within a group of substitutable medicines (maximum price), the LFN allows both price cuts and price rises without further investigation. The LFN made over 9,000 decisions during 2006. About 70 percent of these were price cuts

The LFN makes decisions on price changes once a month and a company does not know which price its competitors have applied for. The application form is sent to the LFN 6 weeks before the month the transition to the new price should be in effect. Because of generic substitution the company which can offer the lowest price will get the vast majority of sales during the following month.

Strict rules for price increases on original medicines

Companies can also apply for price increases of non-substitutable pharmaceuticals, but such increases are only accepted under exceptional conditions. In order for the LFN to approve a price increase for medicines not included in the system of generic substitution two criteria need to be fulfilled (LFN 2006a):

- The pharmaceutical is an urgent treatment alternative because it is used to treat serious conditions which threaten the patient's life and health. There are patients who risk being without similar alternative treatments if the medicine disappears from the Swedish market.
- There is a big risk tha the medicine will disappear from the Swedish market (or that supply will decrease sharply), if the price increase is not approved.

It is only when both of these conditions are fulfilled that a price increase can be approved.

If the conditions for price increases described are not fulfilled but the company still wants a higher price, then the company must first request the medicine to be removed from the pharmaceutical benefits system in order to apply for reimbursement again. To apply once more for inclusion in the reimbursement system means a wholly new decision based on new supporting documentation. Therefore, there is no guarantee that reimbursement will be granted at the new, higher price, nor even at the old price.

3.2.2 Negotiations

The LFN does not negotiate prices. It looks upon the price as an integral part of the cost-effectiveness analysis. If the price is too high there will be no cost-effectiveness. Then the Board

will reject the application in question. The manufacturer will have to decide if they should apply again and suggest a lower price. (cf. 4.2.1)

The wholesale margin is not regulated by the state but based on free agreements between manufacturers and wholesalers. These agreements are not public.

3.2.3 Free pricing

Manufacturers may freely set the price for pharmaceuticals not included in the reimbursement scheme i.e. most OTC products, as well as prescription pharmaceuticals not included in the benefits scheme.

Manufacturers are obliged to inform Apoteket of the price so that it can be included in the official pharmacy sales list. An obligatory pharmacy mark-up is applied also regarding freely priced medicines (cf. 3.5.2).

3.2.4 Public procurement / tendering

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

3.3 Pricing procedures

Table 3.2: Sweden - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing	Scope
Internal price referencing	No (However, within the system for generic substitution substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation.)	-	-
External price referencing	No	-	-
Cost-plus pricing	No	-	-
Other, e. g. indirect profit control	No	-	-

Source: LFN 2007

3.3.1 External price referencing

External price referencing is not used as basis for price and reimbursement decisions in Sweden.

3.3.2 Internal price referencing

There is no reference price system in place in Sweden. However, within the system for generic substitution substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation (cf. 5.5.1)

3.3.3 Cost-plus pricing

Cost-plus pricing procedures are not used in Sweden.

3.3.4 (Indirect) Profit control

In Sweden, no indirect profit control procedures are in place.

3.4 Exceptions

3.4.1 Hospitals-only

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

3.4.2 Generics

In Sweden generic substitution is mandatory between medically equivalent pharmaceuticals. The companies have to apply to the LFN if they want to increase or decrease a price on a pharmaceutical which is subject to generic substitution. To boost competition between the pharmaceutical companies the LFN has introduced a simplified process for price-decisions concerning substitutable pharmaceuticals. If the new price, which the company in question is applying for, is lower or the same as the highest price within a group of substitutable medicines, the LFN allows both price cuts and price rises without further investigation.

3.4.3 Over-The-Counter pharmaceuticals

For OTC products, as well as prescription-only pharmaceuticals not included in the benefit scheme, companies may freely set the price.

3.4.4 Parallel traded pharmaceuticals

The pricing of parallel traded pharmaceuticals is identical to the pricing of generics (section 3.4.2).

3.4.5 Other exceptions

No other exceptions are in place.

3.5 Margins and taxes

Table 3.3: Sweden - Regulation of wholesale and pharmacy mark-ups 2005

Wholesale mark-up			Pharmacy mark-up		
Regulation (yes/no)	**Content**	**Scope**	**Regulation (yes / no)**	**Content**	**Scope**
No	Manufacturers and wholesalers negotiate the wholesale margin	All pharma-ceuticals	Yes	Different mark-ups for POM and OTC medicines	All pharma-ceuticals

Source: LFN 2007

3.5.1 Wholesale remuneration

In Sweden there are two wholesalers, Kronans Droghandel (Oriola KD) and Tamro (Phoenix group), with a roughly equal market share. 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.

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.

3.5.2 Pharmacy remuneration

Two different pharmacy mark-up schemes are in place in Sweden, one for prescription-only medicines (table 3.4) and one for OTC pharmaceuticals (table 3.5).

The mark-up scheme for prescription-only medicines is decided by the LFN and has been valid since 1 January 2006. Apoteket decides about the mark-up scheme for OTC pharmaceuticals and this has been valid since 1 July 2002.

Table 3.4 Sweden - Pharmacy Mark-up Scheme for prescription-only medicines, 2006

PPP from ... to ... in SEK / €	Gross PRP in SEK / €
until SEK 75.00 / € 8.08	PPP x 1.20 + SEK 31.25 / € 3.37
SEK 75.01 - 300.00 / € 8.08 - 32.32	PPP x 1.03 + SEK 44.00 / € 4.74
SEK 300.01 - 6,000.00 / € 32.32 - 646.40	PPP x 1.02 + SEK 47.00 / € 5.06
> SEK 6,000.01 / € 646.40	PPP + SEK 167.00 / € 17.99

PPP = Pharmacy purchase price, SEK = Swedish Crowns, PRP = Pharmacy Retail Price

Source: LFN 2007

Table 3.5 Sweden - Pharmacy Mark-up Scheme for OTC Pharmaceuticals, 2006

PPP from ... to ... in SEK / €	Gross PRP in SEK / €
until SEK 20.00 / € 2.15	(PPP x 1.42 + SEK 4.10 / € 0.44) x 1.25
SEK 20.01 - 50.00 / € 2.15 - 5.39	(PPP x 1.40 + SEK 4.50 / € 0.48) x 1.25
SEK 50.01 - 100.00 / € 5.39 - 10.77	(PPP x 1.12 + SEK 18.50 / € 1.99) x 1.25
100.01 - 1,000.00 / € 10.77 - 107.73	(PPP x 1.11+ SEK 19.50 / € 2.10) x 1.25
> SEK 1,000.01 / € 107.73	(PPP x 1.10 + SEK 29.50 / € 3.18) x 1.25

PPP = Pharmacy purchase price, PRP = Pharmacy retail price
Note: Multiplication with 1.25 attributes to VAT rate.

Source: Apoteket 2006

3.5.3 Remuneration of other dispensaries

Apoteket employs about 875 representatives who stock a small amount of non-prescription pharmaceuticals available for customers. Those representatives, for example grocer's stores, are mostly located in rural areas where there are long distances to community pharmacies. The same pharmacy mark-up schemes are valid as for community pharmacies.

3.5.4 Value-added tax

The standard value-added tax (VAT) rate is 25 percent for products in Sweden. However, with the exception of OTC products, pharmaceuticals are exempt from VAT.

3.5.5 Other taxes

Besides VAT there are no further taxes/fees on pharmaceuticals applicable.

3.6 Pricing related cost-containment measures

This section contains a description of the price control mechanisms currently used in Sweden

3.6.1 Discounts / Rebates

Reimbursed medicines are priced according to the Act on Pharmaceutical Benefits and no further negotiations of the price take place. However, it is common that county councils are given discounts on medicines used in hospitals.

3.6.2 Margin cuts

The LFN changed the pharmacy mark-up scheme the last time in 1 January 2006, but this change meant an increase, rather than a decrease. The latest decrease of the pharmacy margins took place in 1 January 2005, when the compensation (service fee) for multi-dose packaging was removed from the mark-up regulations.

3.6.3 Price freezes / Price cuts

Not applicable.

3.6.4 Price reviews

The ways of pricing and pricing procedures are not reviewed and evaluated on a regular basis. However, companies can appeal against the LFN's decisions in a public administrative court. Companies can only appeal decisions regarding their own applications. Thereafter, the court will judge if the LFN has conformed to the Act on Pharmaceutical Benefits etc.

However, by order of the government the LFN is currently conducting a review of the entire list of pharmaceuticals that were eligible for reimbursement when the new Pharmaceutical Benefits Scheme came into force in October 2002. At this time, it was impossible to confirm overnight that all pharmaceuticals conformed to the new regulations. The pharmaceuticals which had been reimbursed in the old system were allowed to keep their reimbursement status until a review of these products had been carried out (cf. 4.6.5).

4 Reimbursement

This chapter gives an overview of the reimbursement system, the reimbursement procedure and the regulation of reimbursement of out-patient medicines.

Sweden made some major changes to its reimbursement system in 2002. Earlier almost all prescription medicines were automatically approved for reimbursement. Today applications are thoroughly scrutinized and cost-effectiveness is a crucial decision-making criteria.

In October, 2002, a new Pharmaceutical Reimbursement System took effect in Sweden and the LFN was consequently appointed by the government to decide whether or not a medicine should be reimbursed.

4.1 Organisation

In general, all pharmaceuticals - including OTC pharmaceuticals - may be reimbursed, provided that the conditions stipulated in the Act on Pharmaceutical Benefits, etc., (cf. 4.2.1) are fulfilled. Nonetheless, the following groups of OTC pharmaceuticals are explicitly excluded from reimbursement (LFN 2003a):

- Pharmaceuticals for antidotal smoking treatment,
- Natural remedies
- Certain pharmaceuticals for external use approved by the MPA

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 system are subject to free pricing.

A medicines reimbursement status is the same all over Sweden

The reimbursement system is a national scheme and covers the whole country. In other words, all reimbursed pharmaceuticals are reimbursed in every county council. 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.

Costs of medicines used in hospitals are not covered by the national reimbursement scheme. The responsibility for in-patient pharmaceutical expenditure lies solely on the county councils (cf. 4.5).

The LFN determines whether a medicine should be reimbursed and sets its price (cf. 2.1.1.2). Reimbursement and pricing processes are combined and an application from a pharmaceutical company results in a joint reimbursement and price decision by the LFN.

Draft decisions are sent to companies and county councils for comments

Prior to the Board making a decision a memorandum with a draft decision is communicated for comments to the company concerned. County councils also have the opportunity of submitting comments.

Furthermore, the company as well as the county councils has the possibility of deliberations with the Board before it makes its decision. The 21 county councils have delegated their right to deliberations to the so-called Pharmaceutical Benefits Group for County Councils. This group consists of members from a few of the county councils and from the SALAR, which is an interest organization for all Swedish county councils and municipalities.

An application shall illustrate a medicine's cost-effectiveness

The LFN requires that an application for a new medicine to be included in the Pharmaceutical Benefits Scheme contains the following information (LFN 2003b:

- The price requested and reasons for the price on the application
- Proof of authorisation to market
- Summary of product characteristics
- Commodity number certificate issued by Läkemedelsstatistik AB (LSAB) or the Nordic Number Office.
- The authorising agency's overall assessment of the scientific basis of fact
- Information on the patient groups for which the pharmaceutical is intended
- Information on the pharmaceuticals already included on the Pharmaceutical Benefits Scheme within the relevant areas of indication
- Information on the estimated number of patients who might be considered for treatment with the pharmaceutical
- Information on the estimated average cost of treatment per day
- Information on the estimated average duration of treatment

The documentation shall illustrate the clinical effects of the pharmaceutical, the cost/benefit ratio of the pharmaceutical and the total expected costs to society. Comparisons shall be made with the best generally accepted treatment in order to illustrate the marginal benefit and marginal cost of the product.

The pharmaceutical company shall prove a medicine's cost-effectiveness by submitting a pharmaco-economic analysis to the LFN. The Board has published general guidelines for economic evaluations submitted with applications for the inclusion of a medicine in the Pharmaceutical Benefits Scheme (cf. 5.4).

Requirements regarding applications for generic medicines and parallel imported medicines are less extensive than for new medicines.

New circumstances might lead to de-listing

The LFN may decide to exclude (de-list) a pharmaceutical from the Pharmaceutical Benefits Scheme (cf. 4.6.5). It is not specified under which conditions the Board can take such an initiative. However, if the circumstances under which the Board made its original decision have changed considerably, due to a patent expiry, new pharmaco-economic data etc., the Board may decide to de-list a specific medicine.

LFN is obliged to inform the manufacturer when it initiates an investigation that might lead to the de-listing of a pharmaceutical. Prior to the Board making a decision a memorandum with a draft decision is communicated to the company concerned for comments. Also, county councils, represented by the Pharmaceutical Benefits Group for County Councils, have the opportunity of submitting comments. The company as well as the Pharmaceutical Benefit Group for County Councils has furthermore the possibility of deliberations with the Board before it makes its decision.

4.2 Reimbursement schemes

The name of the current scheme, that covers the entire Swedish population, is the Pharmaceutical Benefits Scheme (läkemedelsförmånerna). It was introduced on the 1st of October 2002. At the same time a new independent government agency, the LFN, was set up.

The aim of the system: rational and cost-effective use of medicines

There were mainly three more specific reasons for abandoning the old scheme:

- As in most of the rest of Europe, the cost of reimbursed pharmaceuticals had increased rapidly during the 1990s.
- Sweden ran a very generous reimbursement system. For instance, practically all prescription medicines which had been granted market authorisation and had received a fixed sales price were automatically approved for reimbursement.
- The society did not know if it got value for the money it spent on reimbursed medicines. There were uncertainties regarding if the increase in costs was balanced by, for example, added therapeutic value.

The overall aim of changing the system was that a new reimbursement scheme and a new agency would lead to a more rational and cost-effective public use of medicines.

Table 4.1 Sweden - The situation before the new law (then) and after (now

Then	Now
Almost all medicines accepted	All medicines subject to 3 main criteria and carefully scrutinized
Civil servants decided on reimbursement	LFN expert Board decides based on recommendations from civil servants
Costs sky-rocketing on an annual basis	Cost development stabilized on a low level
Negotiation major part of work	Cost-effectiveness central criterion and no negotiations
Many blockbuster pharmaceuticals on market	Many patents expired, generics take their place
Pharmacies dispensed brand name pharmaceuticals	Generic substitution mandatory; if an identical generic exists, it must be dispensed

Source: LFN 2007

The legal framework for the scheme consists mainly of the following documents:

- Act (2002:160) on Pharmaceutical Benefits, etc.
- Ordinance (2002:687) on Pharmaceutical Benefits, etc.
- Pharmaceutical Benefits Board Regulation (LFNFS 2003:1) on Applications to and Decisions by the Pharmaceutical Benefits Board Pursuant to the Act (2002:160) on Pharmaceutical Benefits, etc.
- Pharmaceutical Benefits Board Regulation (LFNFS 2003:2) on Non-prescription Drugs Pursuant to the Act (2002:160) on Pharmaceutical Benefits, etc.
- General guidelines for economic evaluations from the Pharmaceutical Benefits Board (LFNAR 2003:2)
- General guidelines concerning price increases of pharmaceuticals from the Pharmaceutical Benefits Board (LFNAR 2006:1)

The Pharmaceutical Benefits Scheme is the only scheme available and it covers the entire Swedish population.

Tighter target for reimbursement decisions applies in Sweden

In accordance with the EU's Transparency Directive the Board is obliged to announce its decisions on pricing and reimbursement within 180 days after receiving a fully completed application. However, the Swedish government has set a tighter target when it comes to the time-limit for decisions on pricing and reimbursement in Sweden. The LFN has to announce decisions within 120 days.

In 2006 it took on average 91 days for a new pharmaceutical to obtain reimbursement. In 2005 the average processing time was 90 days and in 2004 it was 79 days. Since the LFN was set up in October 2002 all decisions have been made within 180 days, i.e. in accordance with the Transparency Directive.

4.2.1 Eligibility criteria

Three criteria are weighed together

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

- *The human value principle*; which underlines the respect for equality of all human beings and the integrity of every individual. It is not allowed to discriminate against people because of sex, race, age etc. when making reimbursement decisions.
- *The need and solidarity principle*; which says that those in greatest need take precedence when it comes to reimbursing pharmaceuticals. In other words, people with more severe diseases are prioritised over people with less severe conditions.
- *The cost-effectiveness principle;* which states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective. (cf. 5.4)

The above mentioned criteria for reimbursement eligibility should all be considered and weighed together by the LFN when making its decision on reimbursement.

Need and solidarity vs. cost-effectiveness

One example of how the LFN has put the need and solidarity principle into practice is its decision to withdraw the reimbursement for the group of medicines called H2 antagonist within its review of pharmaceuticals against diseases caused by stomach acid (cf. 4.6.5).

The LFN concluded that H2 antagonists could be a cost-effective choice for some milder symptoms like heartburn, but that these diseases give so small losses in quality of life that the treatment should not be reimbursed by the society. Instead, the patients should bear the full cost of using these pharmaceuticals. In this case the LFN, when weighing together the different eligibility criteria, let the need and solidarity principle take precedence over the cost-effectiveness principle.

A number of companies have appealed the LFN's decision. This means that many H2 antagonists may retain their reimbursement status until the courts have ruled on the matter.

Cost-effectiveness from a societal perspective: a different approach

In the Swedish reimbursement system cost-effectiveness is analysed from a societal perspective. This means that all relevant costs and revenues for treatment and ill health should be considered, regardless of who pays or benefits – be they state, county council, municipality or patient. This broad societal approach to cost-effectiveness analysis differs from some other national systems which also use pharmaco-economics in decision-making. In these systems a narrower approach is applied, taking into account e.g. only cost and revenues which occur in the healthcare sector.

When the LFN evaluates the cost-effectiveness of a pharmaceutical it first pools all of the costs associated with using the pharmaceutical; such as costs for the pharmaceutical, costs related to

visits to the doctor, costs for possible further healthcare measures, and costs due to the side-effects of the pharmaceutical.

Then the LFN balances total costs against the benefits from using the pharmaceutical. The benefits come in two forms: effects on health and cost savings. The beneficial effects on health show up either as a longer life expectancy or as a higher health-related quality of life.
To get a full societal perspective the LFN also takes into account if the pharmaceutical means that the patient can work and support himself or herself instead of being sick-listed or perhaps being forced into early retirement. Here the benefits go to the individual, the employer and to the state which avoids the costs for sick-listing or early retirement. If the patient is older perhaps the treatment means that he or she can manage better without as much help from the municipality's elderly care services or relatives.

This kind of analysis is done to show whether or not the use of a pharmaceutical costs citizens a reasonable amount of money in relation to the health gains it offers the patients. The actual size of the health bill is not a good measure of whether we are using the right amount of pharmaceuticals or even the right kind of pharmaceuticals. The crucial aspect here is instead that the pharmaceutical is cost-effective, and not just for the healthcare sector, but for society as a whole.

As much value as possible for the money spent on medicines

That is why Sweden has chosen to consider cost-effectiveness rather than cost-containment as an instrument to get as much value for tax-money as possible, when reimbursing pharmaceuticals.

Sometimes the good effects of a medicine are so great that they easily compensate for all costs. Then the treatment is considered as cost saving. But such high demands are not made in order to consider if the use of a medicine is cost-effective. That people get well, do not experience pain and can live a more normal life through using a medicine is important enough for society to be willing to pay for it.

Another important aspect of the Swedish reimbursement system is that the LFN does not negotiate prices. It looks upon the price as an integral part of the cost-effectiveness analysis. If the price is too high the pharmaceutical will not be cost-effective. Then the Board will reject the application in question. And the company will have to decide if they should apply again and suggest a lower price.

Why does the LFN not negotiate prices?

Why is the LFN not eager to force the price down as much as possible? There are mainly three reasons:

Firstly, the LFN does not believe that it really is possible for a government agency to efficiently set prices as the pharmaceutical companies will soon learn to adjust their prices accordingly.

For example, if the reimbursement agency always tries to get a 30 percent lower price, the companies will learn to start the negotiation with a price 30 percent higher than they actually want.

Secondly, the pharmaceutical market is much regulated. But the LFN do not want to regulate it more than necessary. The LFN wants to allow the market to work as freely as possible by letting the companies set the price and then decide whether or not we as taxpayers and patients are willing to buy that particular pharmaceutical.
And thirdly, a reimbursement system which uses cost-effectiveness from a societal perspective can play an important role when it comes to stimulating innovations. If the pharmaceutical industry can rely on the public being ready to pay a high price for pharmaceuticals which are beneficial to society, then they will probably deliver more new pharmaceuticals for urgent treatments.

Decisions can be appealed to administrative courts

If the LFN has rejected an application for reimbursement the market authorisation holder may lodge an appeal against the decision to an administrative court. The administrative court system consists of three instances: County Administrative Courts (länsrätter), Administrative Courts of Appeal (kammarrätter) and the Supreme Administrative Court (Regeringsrätten).

4.2.2 Reimbursement categories and reimbursement rates

A product-oriented, not indication based, system

In Sweden pharmaceuticals are not grouped together into certain reimbursement categories. The reimbursement system is mainly product-oriented.

This means that pharmaceuticals are either granted reimbursement status for the whole of its approved area of use or not at all. In exceptional cases the LFN can circumvent this and choose to restrict the reimbursement of a medicine to a limited area of use or to a particular patient group.

An example of this is the weight reduction medicine Xenical (orlistat) which is reimbursed only for particular groups of patients. Patients with diabetes type 2 must have a Body Mass Index (BMI) of at least 28. For other patients the BMI must be at least 35.

Another example is Crestor (rosuvastatin) against high cholesterol. It is approved for reimbursement only for patients who do not achieve the desired result with the use of generic simvastatin. This is because Crestor is not deemed cost-effective compared with generic simvastatin on a general basis. Crestor is, in other words, only reimbursed if it is used as a second-line pharmaceutical.

Reimbursement can be limited in time

Moreover, the LFN can make a decision dependent on certain conditions. So far, the Board has used four different types of conditions. Here are two examples:

- The reimbursement is limited in time to make it possible for the company to provide the LFN with more clinical and/or pharmaco-economic data, for example on long-term effects on morbidity and mortality and/or with a follow up report on the product to see if it is used according to the restrictions for reimbursement.
- The pharmaceutical company has to specify the restrictions set by the Board in their marketing of the product.

The reimbursement rate is calculated based on the pharmacy retail price of each pharmaceutical and out-of pocket payments depend on the consumption of each patient and not on the product. The reimbursement rate ranges from 0% (for patients with expenses below a threshold of SEK 900 / € 96.96) to 100% (for patients who have reached a 12-month co-payment ceiling of SEK 1, 800 / € 193.91). All children under 18 years of age within a family unit are considered as one beneficiary and their costs are pooled together. (cf. 4.4.2)

4.2.3 Reimbursement lists

Positive list with three exceptions

Sweden has a system with a positive list indicating which medicines that are reimbursed for outpatient use. There is currently no negative list in place. However, according to the LFN's regulations three groups of non-prescription medicines are exempt from the possibility of being assessed against the criteria for reimbursement (LFN 2003a). These three groups are:

- Pharmaceuticals for antidotal smoking treatment
- Natural remedies
- Certain pharmaceuticals for external use approved by the MPA.

Information on reimbursement status is available on the web

Decisions to grant a medicine reimbursement or withdraw a medicine's reimbursement status made by the LFN are publicly announced on the Board's web site, www.lfn.se. The positive list with reimbursed medicines is updated continuously on a monthly basis.

Besides on the LFN's website, doctors and patients can find information about products included on the positive list in Fass, www.fass.se. Fass is published by the LIF and contains useful information on for example recommended dosages, contraindications, side effects and is well-known to most doctors and many patients.

Doctors also receive information regarding the LFN's reimbursement decisions through the MPA's paper, which is distributed to all prescribers of medicine about seven times a year.

4.3 Reference price system

In Sweden there is currently no reference price system in place. There was a reference price system previously in operation between 1993 and 2002 (cf. 4.6.2). The reference price system

was abolished when the system for generic substitution was introduced on the 1st of October 2002 (cf. 5.5.1)

However, within the system for generic substitution substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation.

4.4 Private pharmaceutical expenses

The Swedish Parliament is the body responsible for making decisions regarding private pharmaceutical expenses.

In 2004 the private pharmaceutical expenditure's share of the total expenditure on pharmaceuticals was slightly above 30 percent. This share has been quite stable the last couple of years. (cf. 2.2.2).

4.4.1 Direct payments

Besides payments for most OTC medicines (cf. 4.1), patients are faced with direct payments for medicines which are not reimbursed. This is regardless whether the medicine is outside the reimbursement system because the manufacturer has not applied for reimbursement, because the LFN has rejected an application for reimbursement or because the LFN has decided to discontinue reimbursement in its review of all medicines (cf. 4.6.5).

An example of a medicine for which patients bear the full cost is the proton pump inhibitor Pariet (rabeprazol). In the review of medicines against diseases caused by stomach acid the LFN found it not cost-effective and therefore withdrew its reimbursement status.

Furthermore, a patient has to pay the difference between a price set for a prescribed pharmaceutical and the corresponding price for the least expensive substitutable medicine if he or she refuses generic substitution at the pharmacy (cf. 5.5.1).

4.4.2 Out-of-pocket payments

4.4.2.1 Fixed co-payments

No fixed co-payments, for example prescription fees, are used within the Swedish reimbursement system.

4.4.2.2 Percentage co-payments

Patients pay a maximum of SEK 1,800 per year

The Swedish reimbursement system contains no social clauses, e.g. for old age pensioners or unemployed persons, covering private pharmaceutical expenses. However, individuals who use large amounts of medicines are protected from high costs. The patient pays the full price for re-

imbursed medicines up to a certain level (cost ceiling), after which they obtain different amounts of reductions in the additional cost. The maximum amount payable by the patient during a 12 month period is SEK 1,800 /€ 193.91. All children under 18 years of age within a family unit are considered as one beneficiary and their costs are pooled together

Table 4.2 displays in more detail the different co-payment rates and reimbursement rates which apply in certain situations.

Table 4.2 Sweden - Reimbursement rates and patient co-payment rates, 2006

Annual expenses for patients in terms of reimbursement price in SEK / €	Co-payment rate in %	Reimbursement rate in %
SEK 0-900 / € 0-96.96	100%	0%
SEK 901-1,700 / € 96.97-183.15	50%	50%
SEK 1,701-3,300 / € 183.16-355.52	25%	75%
SEK 3,301-4,300/ € 355.52-463.25	10%	90%
SEK 4,301 / € 463.26	0%	100%

Source: Act on Pharmaceutical Benefits etc.

According to an agreement between the state and the county councils the county councils cover the patients' co-payment for insulin. Insulin is the only pharmaceutical which is completely free of charge for the patients.

Patients bear full cost of not reimbursed medicines

For not reimbursed medicines the patient bears the full cost. This is regardless whether the medicine is outside the reimbursement system because the manufacturer has not applied for reimbursement, because the LFN has rejected an application for reimbursement or because the LFN in its review of all medicines has decided to discontinue reimbursement (cf. 4.6.5).

In addition to the above-mentioned co-payments, patients have to pay the difference between a price set for a prescribed pharmaceutical and the corresponding price for the least expensive substitutable medicine if he or she refuses generic substitution at the pharmacy (cf. 5.5.1). Neither these co-payments, nor payments for not reimbursed medicines or out-of-pocket payments for OTC medicines are included when calculating the 12-month co-payment ceiling of SEK 1,800 / € 193.91.

4.4.2.3 Deductibles

In Sweden, there are no deductibles.

4.5 Reimbursement in the hospital sector

Costs for medicines for in-patient care are not covered by the Pharmaceutical Benefits Scheme (cf. 4.2).

County councils pay for hospital medicines

Instead, the county councils are solely responsible for costs for pharmaceuticals used for in-patient care. This is a part of their overall responsibility for providing healthcare and they have the right to levy taxes to finance these duties.

Patients pay a fee of SEK 80 / € 8.62 for every day in hospital care and this fee covers costs for pharmaceuticals as well as all other treatments.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

In spring 2001 the government decided to exclude pharmaceuticals against erectile dysfunction and obesity from the positive list. When the new system for reimbursement of medicines was introduced in October 2002 the specific exemption regarding these medicines was abolished and the pharmaceutical companies concerned were allowed to apply for re-entry into the Pharmaceutical Benefits Scheme.

Review leads to de-listing

The LFN is currently conducting a review of the entire list of medicines that were eligible for reimbursement when the abovementioned scheme came into force (cf. 4.6.5).

As a result of the ongoing review the LFN has decided to de-list several medicines against diseases caused by stomach acid. This is the case for some proton pump inhibitors (PPI) and all H2 antagonists. A number of companies have however appealed the LFN's decision regarding discontinued reimbursement. Therefore a number of medicines, despite the LFN's decision, may retain their reimbursement status until the courts have ruled on the matter.

4.6.2 Introduction / review of reference price system

In Sweden there is currently no reference price system in place. There was a reference price system previously in operation between 1993 and 2002. The reference price system was abolished when the system for generic substitution was introduced on the 1st of October 2002 (cf. 5.5.1)

However, within the system for generic substitution substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a group of substitutable pharmaceuticals is accepted without further investigation.

4.6.3 Introduction of new / other out-of-pocket payments

In June 1999 the latest change in the system for out-of pocket payments was made. At that time the Swedish Parliament raised the maximum amount payable by the patient during a 12 month period from SEK 1,300 / € 140.05 to SEK 1,800 / € 193.91. The reasons for this increase were

that the society's costs for medicines had continued to increase since the current system of out-of pocket payments was introduced in 1997 (cf. 4.4.2.2) and that the average co-payment paid by patients had decreased (Government bill 2001).

Earlier several medicines were cost-free for patients

Before the reform in 1997 the cost of the medicine with the highest price on a prescription was maximized to SEK 170 / € 18.31 and to SEK 70 / € 7.54 for each and every additional medicine prescribed at the same time. Some medicines for lingering and serious diseases were cost-free for patients and in addition to that a high cost ceiling applied which limited out-of pocket payments for medicines and other healthcare measures for a patient during a 12 month period to SEK 2,200 / € 237.01.

With the new regulations for out-of pocket payments the government wanted to create a system which targeted high costs of medicine for individual patients, instead of reimbursing every purchase of medicines over a certain sum. Another reason for implementing a new system was to curb the rapid increase in society's cost of medicines (Government bill 1996).

4.6.4 Claw-backs

Claw-backs are not used in Sweden.

4.6.5 Reimbursement reviews

By order of the government the LFN is currently conducting a review of the entire list of medicines that were eligible for reimbursement when the new Pharmaceutical Benefits Scheme came into force on the 1st of October 2002 (cf. 4.2). At the time of the transition to the new system it was impossible to confirm overnight that all medicines conformed to the new regulations. Therefore, pharmaceuticals which had been reimbursed in the old system were allowed to keep their reimbursement status until a review of these products had been carried out.

All medicines are reviewed for reimbursement

The LFN has started an overall review of the entire list of medicines in order to say if they fulfil the new criteria for reimbursement or not (cf. 4.2.1). Each and every medicine will be reviewed according to the new regulations.

The pharmaceutical benefits review is a once-off event with the aim of including in the new reimbursement system medicines that were tested against the old rules for reimbursement. However, the LFN always has the possibility of initiating a new review of a therapeutic group or an individual product if the conditions have changed (SFS 2002).

No other party than the LFN, such as a pharmaceutical company, a county council or a patient organisation, has the formal right to initiate a review of a therapeutic group or an individual medicine.

Sales value steers the order

All reimbursed medicines have been divided by the LFN into 49 therapeutic groups and the Board will review one therapeutic area after the other. The LFN will go through these therapeutic groups in the order biggest first, based on the size of the sales value for each group in 2003. The two first groups though, pharmaceuticals against migraine and against diseases caused by stomach acid, were pilot groups and were chosen based on other criteria. Results of the reviews which have been completed so far may be found on the LFN Website. [13]

The organisation of the work with the review is flexible. Many of the therapeutic groups to be reviewed are however of the type demanding a project structure. Normally a pharmacist/pharmacologist, a health economist and a lawyer from the LFN's executive office take part in the projects.

The main aim of each project is to provide the decision-making board within the LFN with as complete and comprehensive information as possible on a certain group of medicines, and individual medicines in that group. This is in order to make the best decision possible.

External medical experts are brought in

In order to produce this, information is needed on the special medical needs of a patient group receiving treatment with a certain medicine and how the medicine is applied by clinics in everyday use. This knowledge and the necessary experience are normally provided through the external sourcing of experts. Doctors specialised in General Practice as well as doctors specialised in the relevant therapeutic area are primarily brought in.

The review of pharmaceutical products is divided into a mapping phase and a decision-making phase.

In connection with the LFN informing the pharmaceutical companies concerned of the commencement of the review of a certain pharmaceutical at the beginning of the mapping phase, it requests that the company in question should submit information on, amongst other things, the clinical use and cost-effectiveness of the medicine which they market.

Medical and pharmaco-economic literature is scrutinized

As a part of the mapping phase the project group reviews the existing medical and pharmaco-economic literature on the therapeutic group which is the object of the review.

The project group creates a memorandum summarising the level of knowledge regarding the group in question. The objective of the memorandum is that the Board should receive enough information to be able to take a stance on the continuation or conclusion of the review.

[13] www.lfn.se/LFNTemplates/Page____709.aspx

If the opinion of the Board is that the memorandum gives sufficient information to justify the continued inclusion of all pharmaceuticals in the group in the pharmaceutical benefits system then the Board decides to conclude the review at this stage.

If the opinion of the Board is however that there is uncertainty regarding an element of or the entire reviewed therapeutic group's eligibility for continued reimbursement, then the review continues into the next decision-making stage. This means that the project group goes on to carry out a more comprehensive investigation and analysis regarding the pharmaceutical or pharmaceuticals brought into question.

In cases where the project group after further investigation and analysis concludes that a pharmaceutical should continue to be included in the Pharmaceutical Benefits Scheme, then a suggested course of action is submitted to the Board to the effect that the review of this particular pharmaceutical should be concluded. The Board will then take a position on the suggested course of action.

If the project group on the other hand concludes that a pharmaceutical should not in continuation be included in the pharmaceutical benefits system then a proposal to that effect is submitted to the Board. It will then accordingly take a decision on the inclusion or not of the pharmaceutical in question.

Final report includes decisions on changes in reimbursement status

Each and every review of therapeutic groups is concluded with the publication of a final report. This report contains a description of how the review has been conducted and an account of the present level of knowledge regarding the group in question. The LFN's analysis of this level of knowledge is presented along with its conclusions regarding which medicines that should no longer be included in the pharmaceutical reimbursement system. Where there is a difference regarding cost-effectiveness of different medicines which are to get continued reimbursement, then the LFN also accounts for our estimation of the cost-effectiveness of each medicine relative to the others.

The working guidelines for the pharmaceutical reimbursement review which the LFN has issued may be retrieved from its website.[14]

[14] www.lfn.se/upload/Genomgangen/GLS_060815_guidelines_english.pdf

5 Rational use of pharmaceuticals

This chapter gives an overview of the current methods used to promote an equitable and efficient use of pharmaceuticals.

5.1 Impact of pharmaceutical budgets

Government grant covers costs for out-patient medicines

In Sweden the county councils are responsible for financing pharmaceuticals for in-patient as well as for out-patient care. However, there is a State subsidy to cover expenses for out-patient medicines. The government and the SALAR have reached an agreement concerning the subsidy for the years 2005 to 2007. If the actual costs substantially exceed the fixed subsidy the government and the SALAR together will decide whether the agreement should be renegotiated or not. Unlike the 2002-2004 agreement, the current agreement includes no formal risk-sharing model setting out responsibility for covering excess spending. But in practice, if expenditure do not substantially exceed the subsidy then they are covered by the county councils and if the costs, like in 2005 and 2006, are below the subsidy the remaining means can be used by the county councils for other purposes. (cf. 2.2.2)

County councils decentralise responsibility of costs

According to a study carried out by the IHE (IHE 2006) the responsibility for out-patient pharmaceutical expenditure has been pushed further out in the organisation by more and more county councils. Only 3 out of 21 county councils have a centralised responsibility for costs. Others have either decentralised the cost responsibility to a middle level (for example to primary care areas within the county) or to primary care centres or hospital clinics. Most county councils which retain the responsibility at a middle level have however the ambition to push the responsibility all the way out to the primary care centres and hospital clinics.

By responsibility for medicine costs the IHE means that a unit either has a fixed pharmaceutical budget (the unit may keep at least part of a surplus and to some extent take responsibility for going over budget) or an integrated healthcare budget (the unit has the same responsibility to cover surplus and deficits for pharmaceuticals as for the other healthcare costs).

Most county councils intend to integrate out-patient care with the rest of healthcare, meaning that pharmaceuticals should be prioritised within the same budget as the rest of healthcare. However, there are not many county councils which have an integrated budget, and in general pharmaceuticals are placed in a budget all of their own.

Increased awareness of costs

Representatives from the county councils which have been asked by the IHE say that decentralised responsibility for costs has contributed towards an increased awareness of costs.

Prescription of medicines is monitored in the various county councils at the level of primary care centres and hospital clinics. This is made possible by the fact that in order for a patient to get a

medicine reimbursed the doctor is obliged to indicate a so-called ”workplace code” on the prescription.

Doctors can see prescription patterns

Individual doctors can choose if they want to have access to statistics of their individual prescription patterns. This is however voluntary and assumes that each doctor chooses to indicate a so-called “prescribing code” on the prescription.

5.2 Prescription guidelines

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.

The MPA publishes national guidelines for prescribing medicines for various diagnoses. In the agency’s treatment recommendations the pharmaceutical treatment options are considered in regard to other measures such as for example lifestyle changes or surgery.

Committees point out first choice medicines

At a regional level there is at least one pharmaceutical committee in each county council. The committees support doctors in their choice of medicines thorough publishing an annual list of medicines recommended as the first choice treatment for a range of common diseases.

As a complement to the recommendation lists, and as a way to further promote effective pharmaceutical prescribing, many Pharmaceutical Committees produce various forms of prescription targets. According to a study by the IHE the committees in 15 of 21 county councils have produced such targets for 5-10 pharmaceutical groups.

For instance in Stockholm, which is Sweden’s most densely populated county, the pharmaceutical committee has produced targets for prescriptions at a county level, such as that generic simvastatin should make up 80 percent of statin prescriptions and that the recommended proton pump inhibitors (PPI) should comprise 65 percent of PPI prescriptions.

County councils use incentive agreements

Ten county councils have also designed, to a varying degree, extensive incentive agreements. More than half of these agreements are based solely on adherence to the prescription targets. Some county councils have incentive agreements where both adherence to the budget and prescription targets result in a reward. These agreements are directed in 9 out of 10 cases from county councils towards the primary care centres and hospital clinics.

In Stockholm the incentives agreement consist of three main parts:

- Bonus in the form of rewards for adherence to the recommendations list.
- Possibility to get a part of the surplus in relation to the stated pharmaceutical budget.

- Possibility for rewards for development projects aimed at improving the use of pharmaceuticals.

5.3 Information to patients / doctors

EC directives, like the Marketing Directive 2002/83/EC, are transposed into acts and ordinances by the Swedish Parliament and government and into provisions by the MPA.

Direct-to consumer advertising of OTC pharmaceuticals, but not prescription-only medicines, is allowed. The same regulations apply regardless of the type of media e.g. television or Internet.

In Sweden no measures are implemented in order to restrict or control promotional spending of manufacturers and a code of marketing practice for pharmaceutical companies is laid down by the LIF.[15]

Agreement limits cooperation between companies and doctors

In June 2004, the SALAR and the LIF reached an agreement[16] concerning forms of cooperation between pharmaceutical companies and employees of public healthcare. The agreement covers the areas of consultation, product information, training and scientific conferences, refreshments, expenses and remuneration and sponsorships. It covers all employees of the public healthcare and medical service in contact with pharmaceutical companies and Swedish marketing companies in the industry or their agents.

There are restrictions on sending pharmaceutical samples to doctors: 1) only products authorised in Sweden are allowed as samples 2) in general only one package per prescription is allowed 3) no samples with narcotics are allowed 4) the samples may not be intended for treatment of humans or animals.

Information to patients available on the web

Information to patients on the rational use of pharmaceuticals is available for example on the MPA's web site, www.lakemedelsverket.se. The information is produced by doctors and pharmacists at the MPA. Furthermore, patient information on all medicines marketed in Sweden is available on www.fass.se. Fass is published by the LIF and contains, besides from prices, useful information on for example recommended dosages, contraindications, side-effects and is well-known to many patients. Apoteket also produces information for patients that is available on Internet, www.apoteket.se, or supplied as handouts at the pharmacies.

There are no specific regulations for information to patients in the in-patient sector.

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15 www.lif.se/cs/Publik%20webb/Sidinnehall/Publik_Dokument/Documents%20in%20English/Rules_drug_information.pdf

16 www.lif.se/cs/default.asp?id=6899

5.4 Pharmaco-economics

The cost-effectiveness principle is one of three eligibility criteria for reimbursement laid out in the Act on Pharmaceutical Benefits, etc (cf. 4.2.1). This principle states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective.

Applications shall contain pharmaco-economic analyses

A pharmaceutical company shall prove a medicine's cost-effectiveness by submitting a pharmaco-economic analysis to the LFN together with the application for reimbursement. The pharmaceutical companies perform the pharmaco-economic analyses and the LFN reviews and evaluates them. A pharmaco-economic analysis is not required for market authorisation.

When reviewing the reimbursement status of all reimbursed products (cf. 4.6.5), the LFN sometimes performs pharmaco-economic analyses in addition to those provided by the industry or available in the literature.

Guidelines for pharmaco-economic evaluations

Since pharmaco-economic analysis can be done in a number of ways the LFN has published general guidelines for economic evaluations submitted with applications for the inclusion of a medicine in the pharmaceutical reimbursement scheme (LFN 2003c). The LFN recommends that:

- The analysis should be done from a societal perspective (cf. 4.2.1). All relevant costs and revenues, regardless of who pays or benefits (county council, municipality, patient, relative) should be considered. The information must describe the situation in Sweden.
- The treatment in question should be compared with the most appropriate alternative treatment in Sweden. This could be a pharmaceutical treatment, another treatment or no treatment at all. In making calculations, the reference point should be practice applicable in Swedish medical treatment.
- The analysis should include the whole patient population to which the reimbursement application refers. Separate calculations should be made for different patient groups where the treatment is expected to differ in cost-effectiveness (e.g. separately for different degrees of severity of the illness or for groups with different risk levels).
- Cost-effectiveness analysis is recommended, with quality-adjusted life years (QALYs) as outcome-measure. For treatments that mostly affect survival, both QALYs and life years gained should be shown. If surrogate end-points are used, the account should also include modelling from these end-points to illustrate the effects on morbidity and mortality, i.e. QALYs gained. If it is difficult to use QALYs (e.g. with severe pain for a short time in connection with treatment), then a cost-benefit analysis with willingness to pay may be used as a measure of effect. If there is supporting evidence that the pharmaceutical in question has the same health effect as the best comparable treatment, a cost comparison may suffice.
- All relevant costs associated with treatment and illness should be identified, quantified and evaluated. Production losses due to illness should also be included. If the treatment affects

survival, then the costs for increased survival – total consumption less total production during gained life years – should be included.

- QALY-weights should be based on methods such as Standard Gamble (SG) or Time-Trade-Off (TTO). QALY-weights based on appraisals of persons in the health condition in question is preferred over weights calculated from an average of a population estimating a condition depicted for it (e.g. the social tariff for EQ-5D).
- The time-frame for the study shall cover the period when the main health-effects and costs arise. For treatments affecting survival, a life-long perspective must be used to adequately calculate life years gained. This means that extrapolation must be carried out for the period beyond the data from clinical trials. This should be done via modelling.
- Sensitivity analysis of central assumptions and parameters is important in health economic analysis.

The LFN has not published a maximum willingness to pay for a QALY.

5.5 Generics

The market share of generic pharmaceuticals has increased significantly in terms of volume since the introduction of generic substitution in Sweden in October 2002. However, mandatory generic substitution has only induced a moderate increase in the market share in terms of value. This is due to the fact that generic substitution of out-patient pharmaceuticals has led to a dramatic drop in prices of off-patent medicines. (cf 5.5.1)

The pricing procedure for generics is explained in more detail in section 3.4.2.

Table 5.1: Sweden - Development of the generic market as a share of the total pharmaceutical market, 2000 - 2006

Generic market share	2000	2001	2002	2003	2004	2005	2006
Volume (number of packs per year)	34%	34%	35%	37%	40%	41%	44%
Value	11%	11%	12%	12%	12%	13%	14%

Source: The Swedish Generic Medicines Association (Föreningen för generiska läkemedel, FGL) 2006

5.5.1 Generic substitution

Generic substitution is mandatory in Sweden since October 2002 according to the Act on Pharmaceutical Benefits, etc. The generic substitution system includes generic as well as parallel imported pharmaceuticals.

Competition between suppliers of generic medicines

Pharmaceutical companies have to apply to the LFN if they want to increase or decrease a price on a pharmaceutical which is subject to generic substitution. To boost competition between the

companies the LFN has introduced a simplified process for price-decisions concerning substitutable medicines. If the new price, which a company applies for, is lower or the same as the highest price within a group of substitutable medicines, the LFN allows both price cuts and price rises without further investigation. The LFN made over 9,000 decisions during 2006. About 70 percent of these were price cuts.

The LFN makes decisions on price changes once a month and a company does not know which price its competitors have applied for. Because of generic substitution the company which can offer the lowest price will get the vast majority of sales during the following month. This procedure creates robust price competition.

Swedish doctors are obliged to prescribe products by their brand name, regardless of whether the medicine is an original or generic product (cf 5.5.2).

The pharmacy shall substitute with cheapest available copy

If a pharmaceutical included on the positive list (i.e. in the Pharmaceutical Benefits Scheme) has been prescribed and there is one or more less expensive, substitutable medicine available at the pharmacy – be it a generic, parallel import or even the original brand – the pharmaceutical shall be substituted with the least expensive pharmaceutical available of the same package type (i.e. jar, bottle, combination pack, etc.). Substitution of a certain pack size by another pack size is only possible, if it is nearly the same (e.g. 28 tab-pack by 30 tab-pack).

In order to be substitutable the pharmaceutical has to be approved as such by the MPA. A pharmaceutical is not substitutable if it differs from the prescribed pharmaceutical to such an extent that it cannot be considered equivalent. A list of substitutable pharmaceuticals is published on the MPA's website and is updated on a regular basis.

When ordering products, Apoteket's internal policy obliges local pharmacies to always stock the cheapest possible pharmaceutical within a group of substitutable pharmaceuticals. When generic substitution was introduced Apoteket designed a special IT solution to help local pharmacies to comply with this policy.

Doctors do not object to substitution

A pharmaceutical shall not be substituted if the doctor has objected substitution on medical grounds. The doctor objects to substitution by ticking a designated box on the prescription. It is not very common that the prescribing doctor objects to substitution. During 2006 substitution was objected by the doctor on medical grounds in 2.5 percent of all cases.

Nor shall a pharmaceutical be substituted if the patient pays the difference between the price set for the prescribed pharmaceutical and the corresponding price for the least expensive substitutable pharmaceutical available out-of pocket. However, in only 6.5 percent of all cases the patients used this option during 2006.This additional out-of pocket payment is not taken into account for the calculation of the 12-month co-payment ceiling and is also to be paid even if the patient's co-payment rate at the time is 0 percent (cf. 4.4.2.2).

When relevant the pharmacy shall inform the patient about the system for generic substitution and of the patient's right to obtain the originally prescribed pharmaceutical if he or she pays the difference in price. If a substitution has been made, the pharmacy shall inform the prescriber in writing.

A number of county councils have introduced policies to encourage the use of generics, involving for example financial rewards if certain targets are met. (cf. 5.1, 5.5.3)

In Sweden analogous substitution is not allowed, i.e. pharmacies cannot choose to dispense a pharmaceutical with a different active ingredient but with the same therapeutic effect.

According to an evaluation carried out by the LFN pharmaceutical prices in Sweden have decreased by about 15 percent between October 2002, when generic substitution was introduced, and December 2005. (LFN 2006b)

This means that patients and taxpayers get access to the same amount of pharmaceuticals today for a price on average 15 percent lower than at the end of 2002. This drop in prices is due entirely to the decrease in prices for off-patent pharmaceuticals.

Sharp drop in prices after the introduction of generic substitution

Market prices for generic pharmaceuticals have fallen by approximately 40 percent. The accumulated savings in the pharmaceutical budget have been almost SEK 7 billion / approximately € 760 million.

For some groups of pharmaceuticals the price decreases have had a substantial effect on the cost of treatment. The biggest fall in prices has been for statins. For these the average price has fallen by 71 percent.

The average price for antidepressants (SSRI) fell by about 66 percent. For pharmaceuticals against ulcer and heartburn (proton pump inhibitors) it fell by 41 percent and for calcium antagonists (used in treating hypertension) the price fell by 35 percent.

The main cause for the lower average prices for these groups of pharmaceuticals is that one or more of the pharmaceuticals in the respective therapeutic area has lost its patent and prices have fallen, as was the case for the statin Zocor (simvastatin) and the proton pump inhibitor Losec/Prilosec (omeprazole).

Patented medicines lose market share to generics

Another reason is that the use of other more expensive, and still patented pharmaceuticals, decreases in favour of the pharmaceutical which has lost its patent. The LFN estimates that the average price for proton pump inhibitors would have decreased by only 28 percent rather than 41 percent, if the still patented Lanzo (lanzoprazole) had not lost market share to generic omeprazole.

The effects of generic substitution is thus not limited to the generics market, it also affects the competitive situation in an entire therapeutic area.

Here are some examples of sharp drops in prices for individual pharmaceuticals losing their patents:

Table 5.2 Sweden – Effect of pharmaceuticals losing their patent

Substance	Brand name	Therapeutic area	Price reduction in %
Simvastatin	Zocor	High cholesterol	- 92
Citalopram	Cipramil	Depression	- 83
Omeprazole	Losec/ Prilosec	Ulcer	- 65
Sertraline	Zoloft	Depression	- 62
Felodipine	Plendil	High blood pressure	- 61

Source: LFN 2006

For generic substitution to work efficiently it requires an efficient market where companies can quickly change their prices and react to their competitors. The LFN has developed such a market place to stimulate price competition between generic pharmaceuticals.

5.5.2 Generic prescription

Doctors are currently not permitted to prescribe using the generic name/International Non-proprietary Name (INN). Instead, they must indicate a brand name, regardless of whether that is the name of an original or a generic product.

However, a couple of years ago the government commissioned the MPA to look into the pros and cons of the introduction of a system with generic prescription. The MPA submitted its report at the beginning of 2006 and it is currently being considered by the government. (MPA 2006)

No further economic gains with generic prescription

In the report the MPA concludes that the introduction of generic prescription cannot be assumed to lead to any economic gains from a societal point of view. These gains have already been reached by the introduction of generic substitution. Furthermore, due to lack of evidence-based facts patient safety concerns cannot be used as a scientific reason either for nor against generic prescription. In the MPA's opinion the benefit of generic prescription – simplification for the doctors – has to be weighed against the initial cost of introducing generic prescription. However, this judgement is more of a political than a medical nature.

A pilot generic prescription project took place in the county of Västra Götaland in 2004.

5.5.3 Generic promotion

Promotion towards patients, doctors and pharmacists, with the purpose of encouraging them to choose generic out-patient pharmaceuticals instead of the equivalent branded medicines, is not particularly established in Sweden. The design of the system for generic substitution in pharmacies makes the need for such promotional activities almost unnecessary (cf 5.5.1). Regardless of which brand name a doctor has prescribed, the pharmacy dispenses the cheapest product

within a group of substitutable pharmaceuticals and the pharmaceutical which is least expensive might change from one month to another (cf. 3.2).

Targets set for simvastatin prescribing

On the other hand, many county councils' Pharmaceutical Committees set up targets for the prescription rate of off-patent pharmaceuticals within some classes of medicines. For example, in the county of Stockholm the medicine committee's target for 2006 was that generic simvastatin should amount to 80 percent of the total prescribing of statins (cf. 5.1).

Existing market activities from the generic industry are mainly focused on the use of generic OTC products and the use of generics in hospitals.

5.6 Consumption

Since the October 2005 a patient's all purchases of prescription pharmaceuticals are documented in the so-called pharmaceutical register at Apoteket. (SFS 2005)

The information in this register is to be used by patients, prescribing doctors and pharmacists at the pharmacies. Access to the registered information is however dependent on the explicit consent of the patient.

New register tool for safer prescribing

One purpose of the pharmaceutical register is to create better opportunities for doctors to attain a safe future prescribing of medicines for their patients. When the doctor sees the overall picture of a patient's total purchase of medicines it will reduce the risk of over or under-prescribing and other types of incorrect prescribing of medicines.

Due to data security reasons the register is not yet available to more than a few doctors. Pilot projects are being carried out in three county councils to find technical solutions which comply with data protection regulations.

Individual patients' tendency to comply with a specific treatment regime can be taken into consideration by the LFN when making reimbursement decisions. The LFN can grant for example a new way of administrating an already reimbursed medicine a higher price, if the pharmaceutical company can present a study which shows that it leads to better compliance and the value of this.

There is no explicit Essential Drug Policy document in place in Sweden. It is, however, important to note that community pharmacies have to supply all pharmaceuticals that have been approved for sale in all parts of the country at the same price (cf. 2.1.3.3).

6 Current challenges and future developments

This chapter covers, from the LFN's point of view, the most oppressing challenges facing the pharmaceutical system, with a focus on pricing and reimbursement issues.

6.1 Current challenges

One current challenge is to inform the public about and try to make it to accept the increasing co-payment rates following the reimbursement reform of 2002. With the ongoing review of all reimbursed pharmaceuticals by the LFN, chances are high that patients will have to pay more out-of pocket for their pharmaceuticals. With the reimbursement system in place before 2002 practically all prescription medicines used in out-patient care were reimbursed by society.

Cost-containment vs. cost-effectiveness

Another challenge is the potential conflict between the county councils' limited budgets and the societal objectives of the reimbursement system. The system of financing medicines for out-patients is constructed to encourage the county councils to take various cost-containment measures aimed at keeping the costs for medicine within the limits of the grant paid by the state (cf. 2.2.2). The reimbursement system is structured so as to allow the reimbursement of medicines which are cost-effective from a holistic, societal perspective. In certain situations it can be a challenge to ensure both systems can work side-by-side. Here is a case in point: suppose that the LFN approves reimbursement for a new, very expensive medicine. The medicine is cost-effective but the profits from the use of the medicine are not reflected in the healthcare system. These are instead reflected in another sector of society, for example in the municipal elderly care sector as the patients are better able to take care of themselves and need less care. If extensive use of the medicine threatens to propel the county council over budget the county council may be forced to limit usage, despite the fact that the medicine has been judged to be cost-effective for society as a whole.

A third challenge is the lack of evaluations of the use of medicines in daily clinical practice. This causes problems for example since it limits the LFN's ability to follow up on its decisions. A situation of uncertainty regarding the cost-effectiveness of a medicine often arises when a medicine is new and the Board is to decide on reimbursement. If the Board rules that the analysis presented by the pharmaceutical company support the potential of a cost-effective pharmaceutical usage, then there is a need to follow up and ensure that this is actually the case once the medicine is in daily clinical use. If the LFN decides to limit the reimbursement to a certain patient group or for certain indications, there is a need to follow up so that the medicine is only used by these patients or for the correct indications.

Difficult to prioritise

A forth challenge is to manage the increasing number of applications for orphan drugs. More and more medicines for rare and serious diseases (orphan drugs) are entering the market. This was also the idea behind creating exclusive rules for marketing authorisation for these medicines and giving them longer exclusive rights than other medicines. In contrary to the rules for

marketing authorisation, there are no specific rules for orphan drugs in place when it comes to reimbursement. Many orphan drugs have proven to have a high treatment cost and furthermore a relatively high cost per QALY gained. So far all applications for reimbursement for orphan drugs have been approved. However, the more very expensive orphan drugs that are approved for sale, the clearer the difficulty surrounding making decisions become. How should a society with finite resources prioritise between orphan drugs and other urgent treatments which in many cases are more cost-effective?

6.2 Future developments

Competition in the pharmacy market

The Swedish pharmacy system is facing enormous change. The new government which took office after the election in autumn 2006 has stated in its first budget that Sweden is the only country in the OECD which has a monopoly on pharmacies. The government aims to deregulate the pharmacy market by abolishing the state pharmacy monopoly. The objectives are to guarantee a safe and secure supply of medicines, increase accessibility and the degree of service as well as to increase price pressure. It will become possible for each and every one who is granted a license by the MPA to retail both OTC medicines and prescription-only medicines. The government has appointed a special investigator to propose how a new pharmacy system can be created. The investigator shall submit his proposal before the end of 2007.

The current agreement regarding the state's grant to the county councils for pharmaceutical expenditure (cf. 2.2.2) expires the 1st of January 2008. This means that the government and the SALAR will have to negotiate a new agreement during 2007 to decide what grant the state will pay to the county councils for prescription medicines used in out-patient care.

In 2005, the erstwhile government struck a deal regarding the strategic programme, "Medicines, biotechnology and medical technology – a part of innovative Sweden". This was in collaboration with representatives for the pharmaceutical, bio-technical and medical technology industry as well as representatives for the research community, authorities and unions.

Quality work has an effect on competitiveness

One of the aspects agreed upon was to intensify work on quality in the healthcare system. This concept of "quality in healthcare" encompasses, among other things, the idea that healthcare shall be evidence-based. Evidence-based means structured in accordance with the best available scientific evidence at hand. To ensure that healthcare creates the best possible benefit for both individuals and society it is important that treatment results are followed up systematically on an individual, group and whole society level. In the strategy programme the stakeholders state that it is of great importance that the healthcare system has adequate resources to carry out these kinds of follow-ups for their activities.

It is also stated that increased focus on quality constitutes an important stimulus for the production of new and innovative medicines. Work on quality has through this a direct influence on the pharmaceutical industry's development and competitiveness. A competitive pharmaceutical in-

dustry is also on the other hand of importance for quality work in healthcare (Government report 2005).

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7.2 Web links

See sections 2.3, 4.6.5, 5.3 and 7.1

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7.4 Editorial Board

The first draft of the Swedish Pharma Profile was reviewed in December 2006 by Health Economist Ms. Claudia Habl and Ms. Danielle Arts, both of GÖG/ÖBIG. The second draft was reviewed by the Editor-in-Chief Ms. Trine Lyager Thomsen from World Health Organization(WHO) Regional Office for Europe and again by the country editor Ms. Habl.