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Pharmaceutical Pricing and Reimbursement Information project

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Pharmaceutical Pricing and Reimbursement Information

FINLAND

Pharma Profile

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Executive summary

The Finnish health care system is organised through a National Health Service system covering all 5.3 million Finnish residents and is mainly funded by general taxation. Public funding accounts for more than three quarters of total health expenditure.

The main stakeholders are the 416 independent municipalities (1.1.2007), who are responsible for organising health care and the Social Insurance Institution (Kansaneläkelaitos, Kela), which provides a National Health Insurance (NHI) scheme that covers all permanent residents of Finland for part of the cost of a range of health services.

Municipalities may either provide health care services independently or together with neighbouring municipalities in joint municipal boards, which maintain a joint health care centre. A municipality can also buy in health care services from other municipalities, non-governmental organisations or the private sector. They fund health care through municipal taxation and state subsidies. Public health care is supplemented by private health care, especially in the larger municipalities. Doctors can work in a private surgery outside their regular working hours.

Besides expenses for prescribed pharmaceuticals in out-patient care (cf. 4.2.2 for details) Kela also covers private medical and dental consultations, private diagnostic tests and treatments, patient transportation services, some rehabilitation services and student health services. For all these services the patient pays the provider and can seek reimbursement for part of the cost from NHI, which is funded through a health insurance payment. In principle, the costs of prescribed pharmaceuticals are compensated regardless of whether they arise in connection with the use of public or private sector services.

The Finnish Ministry of Social Affairs and Health (Sosiaali- ja terveysministeriö, STM) is in charge of planning and supervising, e.g. formulation health care targets and guidelines and also decides on health care subsidies to municipalities and the National Health Insurance regulation. Voluntary health insurance is, with the exception of complementary insurance, only of minor relevance.

In general there is free pricing for all pharmaceuticals on manufacturer and wholesale price level in Finland, but in reality prices are indirectly controlled through the reimbursement system. Pharmaceuticals companies wishing to make their pharmaceutical eligible for reimbursement have to apply for approval of a so-called "reasonable" wholesale price at The Pharmaceuticals Pricing Board (Lääkkeiden hintalautakunta, HILA) . So in most cases only OTC - the majority of non-reimbursable pharmaceuticals - are really priced freely, whereas all other pharmaceuticals are subject to indirect price control through the reimbursement system.

The Pharmaceuticals Pricing Board, HILA is an independent body that belongs to STM and is regulated by law. A pre-requisite for the reimbursement eligibility of pharmaceuticals is that HILA has considered that the product is valid for reimbursement and meets the reasonable wholesale price. Reasonable wholesale price refers to the pharmacy purchasing price (PPP). The product can not be reimbursed, if the reimbursement status or the wholesale price can not be agreed on, if the marketing authorisation holder does not apply for reimbursement and an acceptable price as a basis for reimbursement, or if the marketing authorisation holder wants to remove the pharmaceutical product from the reimbursement list. Since 1 January 2006 HILA

has been in charge of all reimbursement decisions, i.e. deciding if a pharmaceutical qualifies for the basic and/or special reimbursement category (cf. 4.2.2). Before 2006 the decisions on restricted basic reimbursement status were made by the government and no decisions on ordinary basic reimbursement status were made. Before 2004 the decisions on special reimbursement status were also made by the government.

Only pharmacies have the right to sell medicines to the public. This provision applies equally to POM and OTC. Only NRT-products are an exception. Licences to run a pharmacy are issued by application by NAM to named individuals with Master degree in Pharmacy. There are about 800 pharmacy branches in Finland. Hospital pharmacies and medicine dispensaries supply medicines for the in-patients of hospitals and health centres.

Pharmacies are required to offer customers a generic alternative with the lowest or close to the lowest price, unless expressly denied by the prescribing doctor. The customer may also deny the substitution. The reimbursement is calculated off the price of the purchased medicine. The generic substitution was introduced in April 2003, resulting in savings of over EUR 88 million in the course of a year.

The pharmacy retail price is regulated by a statutory mark-up scheme. The current pharmacy mark-up scheme (cf. 3.5.2) is valid for all pharmaceuticals (POM and OTC, reimbursable and non-reimbursable, (branded) originals and generics). In addition, pharmacies are paid a fee of € 0.39 (€ 0.42 including VAT) for any prescribed drugs dispensed. Prices of medicines compounded by pharmacies are regulated separately. Their share of pharmacy turnover is less than 0,5 %.

Pharmacies in Finland pay a special tax, known as a pharmacy fee. The pharmacy fee is calculated from the pharmacy's turnover. The average pharmacy fee is approximately 7 % of turnover. Value Added Tax for pharmaceuticals is 8 %.

The wholesale margin is not regulated by the state, but is negotiated freely between wholesalers and the manufacturers or importers of products. The margin is not public, but it is supposed to be in average around 2-4 %.

Neither wholesaler nor the manufacturer is allowed to give rebates to an individual pharmacy or groups of pharmacies, because according to Medicine Act, the wholesale price of a pharmaceutical (PPP) must be the same for each pharmacy in Finland. Also pharmacies are not allowed to give rebates to their customers (with exceptions of war veterans and frequent customer-systems, which are rare). As a result of this, also retail prices are equal for all patients.

The reimbursement is calculated off the retail price. The reimbursement for prescribed medicines is deducted from the price at the pharmacy, provided that the customer presents his or her personal Kela card and that the products are reimbursable in the first place. Pharmacies are authorized to deduct a reimbursement for up to 3 months' worth of medication.

NHI reimburses a portion of the cost of necessary medication prescribed by a doctor or dentist for the treatment of an illness. There are three reimbursement categories:

- Basic reimbursement: 42% of the price
- Lower special reimbursement: 72% of the price

- Higher special reimbursement: 100% of the price after a fixed co-payment of €3 for each medicine purchased at one time.

Basic reimbursement is normally granted. It includes medicines e.g. for gastric ulcers, antibiotics, inflammation analgesics and allergy medicines. The basic reimbursement of certain medicines has been restricted by HILA. These medicines are reimbursable if used for the special indications defined by HILA. Such medicines include the medicines used in the treatment of Alzheimer's disease and multiple sclerosis. In order to receive restricted reimbursement the patient must submit a doctor's certificate to Kela or, in certain cases, the prescription must bear an appropriate marking.

Special reimbursements are available for the medication needed to treat certain severe and chronic illnesses. Eligibility for reimbursement is decided by reference to the illness. In order to receive reimbursement under the special refund category the patient must submit a doctor's certificate to Kela stating the illness, its severity and the medication needed to treat it.

The lower special refund category consists of ten chronic illnesses, where drug treatment is necessary to maintain the patient's health status. The category includes, for example, drugs to treat long-term hypertension, asthma and cardiac insufficiency. The higher special refund category covers 36 illnesses where drug treatment is necessary and effective to maintain the patient's health status and where the drug restores or replaces normal bodily functions. Drugs used to treat diabetes and cancer are examples of drugs belonging to this category.

Some medicines are not eligible for reimbursement. These include most OTC medicines for self-medication, certain medicines of trivial therapeutic value and prescription medicines that the pharmaceutical enterprise does not wish to be included in the class of medicines that are eligible for reimbursement in order to be able to price them without official approval.

An annual maximum has been set to the co-payments a patient is expected to pay of his/her reimbursable medicines, basic topical ointments and clinical nutritional preparations. When the annual ceiling sum (EUR 627 in 2007) is reached the patient is entitled to an additional refund. Subsequent costs of reimbursable products are reimbursed in full after €1.50 fixed co-payment per medicine per purchase. The patients' out-of-pocket medicine expenses are tracked by Kela.

Table of contents

List of tables and figures

List of abbreviations

AFP	Association of Finnish Pharmacies (Suomen Apteekkariliitto)
Apta	Pharmacy Employers' Association
ATC	Anatomic Therapeutic Chemical classification
ATY	Association of Pharmaceutical Distributors (Apteekkitavaratukkukauppiaat ry)
DDD	Defined daily dose
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnostic related groups
EBM	Evidence based medicine
EEA	European Economic Area
EMEA	European Medicines Agency
EU	European Union
FMA	Finnish Medical Association (Suomen Lääkäriliitto)
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HILA	Finnish Pharmaceuticals Pricing Board (Lääkkeiden hintalautakunta)
HOM	Hospital-Only Medicine
INN	International Non-Proprietary Name (Generic or active ingredient name)
Kela	The Social Insurance Institution of Finland (Kansaneläkelaitos)
Mio.	Million
N. a.	Not available
N. app.	Not applicable
NAM	National Agency for Medicines (Lääkelaitos)
NHI	National Health Insurance

NRT	Nicotine replacement therapy
OECD	Organisation for Economic Co-operation and Development
OOP	Out-of-Pocket
OPP	Out-of-Pocket Payment
OSF	Official Statistics of Finland
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
PIC	Pharmaceutical Information Centre
PIF	Pharma Industry Finland (Lääketeollisuus ry)
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
ROHTO	Centre for Pharmacotherapy Development
STAKES	National Research and Development Centre for Welfare and Health
STM	Ministry of Social Affairs and Health (Sosiaali- ja terveysministeriö)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health Organisation

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

The Finnish health care system provides comprehensive coverage to all 5.3 million residents and it is mainly tax-financed. Average life expectancy was 79.3 years in 2006 (females: 82.8 years, males: 75.8 years), and 16.5 % of population was above 64 years of age (cf. Table 1.1).

The responsibility for organising health care lies with the about 416 municipalities[1], who organise and/or purchase most of the health services they need, and they mostly finance this via local taxation. Another important stakeholder is the Social Insurance Institution (Kansaneläkelaitos, Kela), which provides a National Health Insurance (NHI) scheme that covers all permanent residents of Finland for part of the cost of a range of health services.

In 2004, about 40 % of total health care expenditure (THE) was financed by the municipalities, about 20 % by the state, 17 % by the National Health Insurance (NHI) and about 23 % by private sources (mainly households, also other private funding including employers, relief funds and private insurance institutions). NHI revenues come mainly from employers' and employees' payroll contributions, as well as from other minor sources. The government is responsible for ensuring the adequacy of the health insurance funds.

General planning, direction and supervision of specialised medical care is the responsibility of the Ministry of Social Affairs and Health (Sosiaali - ja terveysministeriö, STM) and, at the provincial level, of provincial governments. State financing of health care occurs largely in the form of state subsidies, which are allocated to every municipality to enable them to arrange the obligatory services. In 1993, the resource allocation system to municipalities which channels state subsidies was reformed so that funds were prospectively set and ceased to be earmarked. Municipal allocations are calculated mainly according to the number of inhabitants, age structure and morbidity, under a weighted capitation system. As the Finnish health care system is very decentralised, there are significant variations in health service provision and clinical practice between municipalities. Legislation does, nevertheless, define the main primary health care and specialized medical services which all local authorities have to provide. In 2005, legislation entered into force defining the time frame in which a person must be ensured access to necessary medical care.

Finland is divided into 20 hospital districts and each municipality belongs to one of these. Five of them are university hospital districts. In the municipalities, primary health care services are provided by health centres, and specialised medical care is provided by hospital-district hospitals. A municipality may run its own health centre, or may do so together with several other municipalities. Municipalities may also purchase their health centre services from private providers. One health centre can have several units and wards for inpatient care. Primary health care also covers maternity and child welfare clinics, school health care, medical rehabilitation, and dental care. Most municipalities have switched from a primary health care system to a family-doctor (general practitioner, GP) system. Each GP is responsible for about 2,000 patients.

[1] 416 municipalities in the beginning of 2007 www.kunnat.net/k_perussivu.asp?path=1;29;374;36984;31661;4869

Residents of the municipalities can book appointments in a health centre by themselves and prove their right to benefits by presenting a valid Health Insurance Card. Access to specialised medical care requires a referral from a health centre physician or private practitioner for non-emergency cases.

Alongside municipal health care, there is an occupational health service system, financed by employers and the State, which is responsible for much of the health care for the workforce. There is also a fairly extensive system of private medical services, patients being partly reimbursed by National Health Insurance.

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

Variable	1995	2000	2001	2002	2003	2004	2005	Source
Total population	5,116,826	5,181,115	5,194,901	5,206,295	5,219,732	5,236,611	5,255,580	Statistics Finland
Life expectancy at birth, total	76.5.	77.6	78.1.	78.2	78.5.	78.8.	78.9	
Life expectancy at birth, females	80.2	81.0	81.5	81.5	81.8	82.3	82.3	
Life expectancy at birth, males	72.8	74.1	74.6	74.9	75.1	75.3	75.5	
GDP in Mio. €	95,916	132,272	139,868	143,974	145,938	151,935	157,377	Statistics Finland[1]
GGE in Mio. €	59,039	63,917	66,778	70,226	73,035	76,484	78,903	Statistics Finland, OSF Statistical Summary 2006
THE in Mio. €	7,149	8,703	9,405	10,119	10,677	11,240	11,854	
Public Health Expenditure in Mio. €	5,403	6,538	7,136	7,704	8,131	8,609	9,222	
Private Health Expenditure in Mio. €	1,746	2,165	2,269	2,415	2,546	2,631	2,632	
Total number of hospitals	371	389	n. a.	391	380	371	n. a.	STAKES
No. of acute care beds	20,332	16,535	16,245.	16,024	15,788	15,579	15,300	
Total number of doctors[2]	12,936	14,807	14,854	15,077	15,271	15,469	15,731	FMA
No. of visits to GPs per patient and year	2.0	2.0	1.9	1.8	1.8	1.8	1.8	STAKES

GDP = Gross Domestic Product, GGE = General government expenditure, GP = General Practitioner, THE = Total Health Expenditure, Mio- = Million; FMA = Finnish Medical Association, OSF=Official Statistics of Finland

[1] Current prices

[2] Including practicing doctors under 63 years of age

Hospital physicians and most doctors in municipal health centres are salaried employees. They usually have a basic monthly salary and an additional remuneration for being on call or for certificates of health status. Under the family doctor system, GPs are paid a combination of a basic

salary, fees for service and fees for capitation. The Commission for Local Authority Employers and the trade unions autonomously negotiate the wages, salaries and fees of health personnel. Doctors' earnings depend largely on how much they work out-of-hours, and how many extras and bonuses they receive for experience, level of training, responsibility, etc. Many doctors also work part-time in private practices. In the private sector, physicians are paid fee-for-service.

As a consequence of the reform of the state subsidy system, since 1993 hospitals have received their revenue from the municipalities according to the services used by their inhabitants. Services are defined and prices calculated in very different ways. Municipalities negotiate annually on the provision and prices of services with their hospital district. The agreements may be revised during the year according to the actual amount and type of services provided by hospitals. Hospitals and hospital districts have become increasingly interested in using diagnostic related groups (DRGs) as the basis for billing municipalities.

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

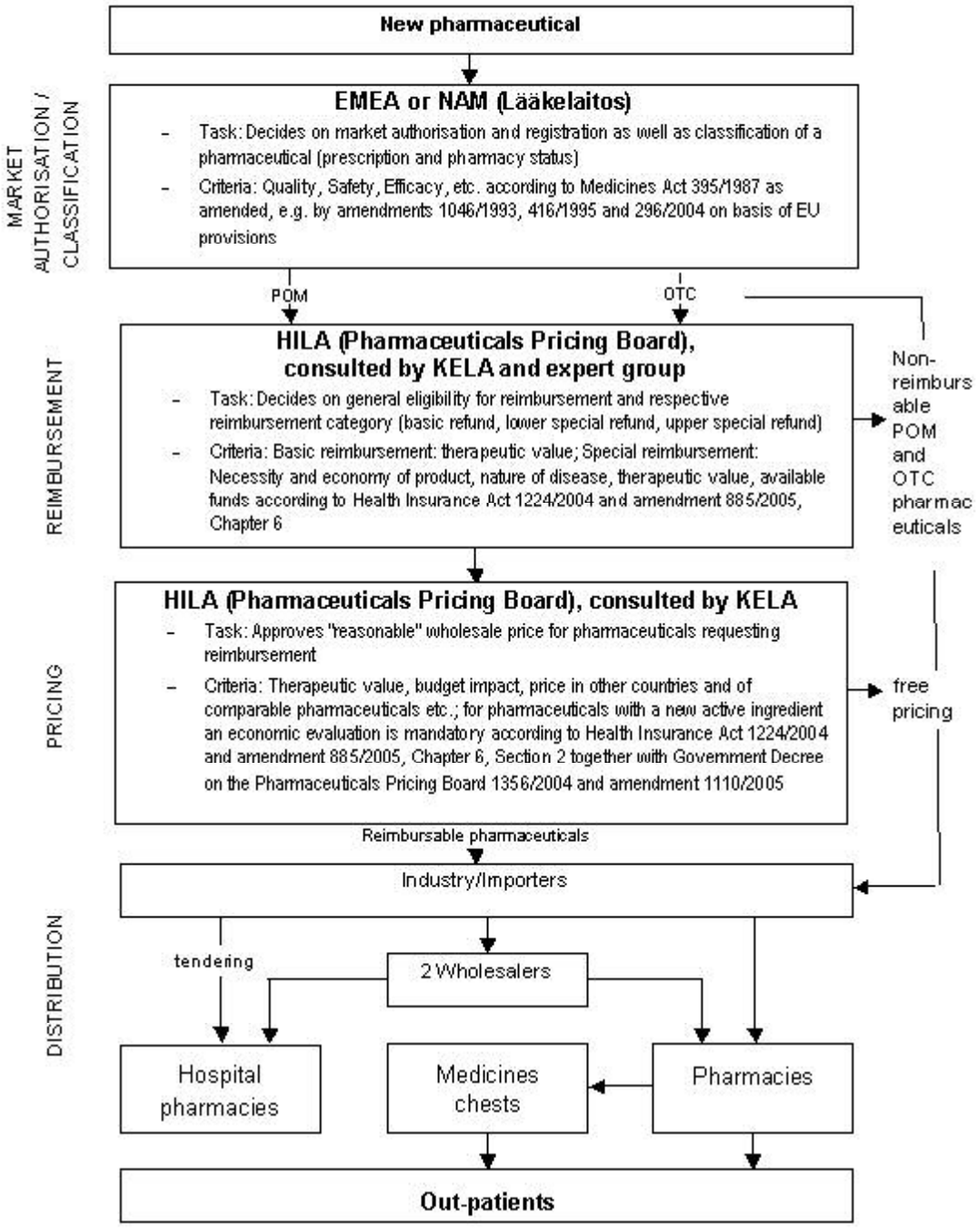
No.	Top 5 diseases with highest morbidity (1 = most common)	ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	ICD-10 code
1	Mental disorders and diseases of the nervous system	F00-F99, G00-G99	1	Diseases of the circulatory system	I00-I99
2	Diseases of the circulatory system	I00-I99	2	Malignant neoplasms	C00-C97
3	Injury, violence, poisoning	V01-Y89	3	Diseases of the respiratory system	J00-J99
4	Malignant neoplasms	C00-C97	4	Diseases of the digestive system	K00-K99
5	Diseases of the respiratory system	J00-J99	5	Other diseases	
Source: National Public Health Institute (Suomalaisten terveys), treatment days, all age groups			Source: Statistics Finland, all age groups		
Year: 2003			Year: 2005 (Updated 22.11.2006)		

2 Pharmaceutical system

2.1 Organisation

In the following section the regulatory framework, the Finnish pharmaceutical system and the pharmaceutical market is described in detail (cf. Figure 2.1 for an overview).

Figure 2.1: Finland - Flowchart of the pharmaceutical system



Source: STM 2006

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.

2.1.1.1 Policy and legislation

The Finnish government has adopted a set of acts that govern the pharmaceutical system, most of the laws mentioned can be found at the STM website[2].

- The Medicines Act (395/1987) covers the legislative framework for the production, registration and distribution of pharmaceuticals as well as the prerequisites of licences for pharmacies, hospital pharmacies, pharmaceutical wholesalers and pharmaceutical industry.
- The Medicines decree (693/1987) gives more detailed instructions for responsibilities and tasks of various actors in the pharmaceutical field.
- The Health Insurance Act (1224/2004) and its amendment (885/2005) gives the overall legal framework for the drug reimbursement system. The pricing of medicines is regulated by the Government Decree on Pharmaceuticals Pricing Board (1356/2004) and its amendment (1110/2005).
- Pharmacies are remunerated via a digressive mark-up scheme, which is regulated by the Government decree on pharmacy margin (1087/2002).
- The Decision of the drug list by the National Agency for Medicines defines the substances, herbs, vitamins and minerals that may be classified as medicines.

2.1.1.2 Authorities

The Finnish Ministry of Social Affairs and Health (Sosiaali - ja terveysministeriö, STM) is in charge of planning and supervising, e.g. formulation health care targets and guidelines and also decides on health care subsidies to municipalities and the National Health Insurance regulation.

The National Agency for Medicines (Lääkelaitos, NAM) promotes health and safety of the citizens by regulatory control of pharmaceuticals, medical devices and blood products. It grants marketing authorisation for products in the mutual recognition procedure as well as permission for the manufacturing, import and wholesale of pharmaceuticals. In addition, NAM takes care of post-licensing monitoring, market surveillance and clinical trials. NAM also classifies pharmaceuticals into Prescription-only (POM) and Over-the-Counter (OTC) medicines and grants sales permits to pharmacies for the sale of pharmaceuticals.

[2] www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx

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

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Sosiaali- ja terveysministeriö (STM)	Ministry of Social Affairs and Health	Regulatory body	Overall planning and legislative authority In charge of the legislation.
Lääkelaitos	National Agency for Medicines (NAM)	Medicines Agency (subordinate to the STM)	In charge of market authorisation, classification, vigilance, pharmacy licences, wholesaler permissions, manufacturer's permissions, control and inspections
Lääkkeiden Hintalautakunta (HILA)	Pharmaceuticals Pricing Board	Independent regulatory body within the STM	Reimbursement and price decisions for reimbursable medicines
Kansaneläkelaitos (Kela)	The Social Insurance Institution	National third party payer under the Finnish Parliament	In charge of executing the reimbursement system of pharmaceuticals used in out- patient care

Source: STM 2007, AFP 2006

The Pharmaceuticals Pricing Board (Lääkkeiden hintalautakunta, HILA), being STM-affiliated, is responsible for reimbursement decisions and approves the requested wholesale price of pharmaceutical companies claiming reimbursement for their products (cf. 3.2). Since 1 January 2006 HILA is in charge of all reimbursement decisions, i.e. deciding if a pharmaceutical qualifies for the basic and/or special reimbursement category (cf. 4.2.2).

HILA consists of seven members and their deputies, who are nominated by the STM. Two members each represent the STM and Kela, in addition to one member each from NAM, the National Research and Development Centre for Welfare and Health (STAKES) and the Ministry of Finance.[3] All board members must have a Masters' degree and at least one member must be a representative of the medical, pharmaceutical, legal and economic discipline. The Chairman convenes the HILA meetings and cases are presented by the Chief Pharmaceutical Officers or the Pharmaceutical Officers of the Secretariat under the supervision of the Secretary General.[4] In the abbreviated procedure the Secretary General may approve a wholesale price or decide on reimbursement category without contacting the Board Members. The members meet once a month except in July and when necessary.

The services covered by the National Health Insurance scheme are administrated by the Social Insurance Institution of Finland (Kansaneläkelaitos, Kela). Among others it is in charge of executing the reimbursement system of pharmaceuticals in out- patient care. It has a central role in giving guidance to HILA concerning reimbursement decisions, i.e. when HILA decides on the

[3] Government Decree on the Pharmaceuticals Pricing Board 1356/2004, section 1

[4] Sirkia/Rajaniemi 2002

"reasonable" wholesale price and the reimbursement status.[5,,6]. Kela operates directly under the parliament.

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

Pharmaceuticals are regulated in general by the Medicines Act (395/1987) and Decree (693/1987), that are being amended from time to time. The latest amendment so far occurred in February 2006, allowing the dispensing of Nicotine Replacement Therapy products outside pharmacies, e.g. in licensed grocery stores or supermarkets, that also sell tobacco.[7]

On 1st January 2006, a total of 7,071 pharmaceuticals had valid marketing authorisations (including all pharmaceutical forms and strengths). The number of trade names was 3,126. Of these, 59 % are POM, and 36,5 % are reimbursable.

Table 2.2: Finland - Number of pharmaceuticals 1995, 2000 – 2006[1, 2]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	3,658	3,653	4,757	4,990	5,309	5,751	6,513	7,071
On the market	n. a.	3,960	4,014	4,072	4,214	4,308	4,457	4,672
POM	n. a.	3,410	3,485	3,546	3,675	3,781	3,944	4,163
Reimbursable	n. a.	2,565	2,552	2,536	2,595	2,603	2,644	2,581
Generics	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.
Parallel traded	-	81	93	94	94	96	110	134
Hospital-only	-	-	-	-	-	-	-	-
Registered trade names	1,910	1,854	2,688	2,804	2,952	3,009	3,157	3,126
Licences for non-registered pharmaceutical products	11,261	11,298	15,050	15,404	16,758	18,783	20,784	21,454

POM = Prescription-Only Medicines

1 as of January 1st

2 Including different pharmaceutical forms and strengths; excluding package sizes. Some pharmaceutical forms (asthma product in combination with an inhalation device / asthma inhalation medicine alone / single device package) differ in various statistics, which explains some inappropriateness in figures, like e.g. in 2000

Sources: Lääkelaitos/Kela 1994-2005, AFP Medicines Database 2006

Lääkelaitos (NAM) is responsible for classifying medicines in the prescription / non-prescription categories as well as to the subgroups according to the Narcotics Act.

[5] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5 and 6
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i209.pdf

[6] Government Decree 1110/2005 amending the Decree on the Pharmaceuticals Pricing Board 1356/2004

[7] http://www.nam.fi/uploads/english/Legislation/Medicines_act_and_decree_041210.pdf

Pharmaceuticals are classified in the following groups:

- Prescription only-medicines (POM)
  - Subgroups for medicines affecting central nervous system and narcotics
- Over-The-Counter pharmaceuticals (OTC)
  - pharmacy only
  - Nicotine Replacement Therapy preparations: general sales in tobacco selling outlets
- Reimbursable and non-reimbursable pharmaceuticals
  - 60,8 % of POM have reimbursement status
  - 8,7 % of OTC have reimbursement status
  - besides pharmaceuticals, also clinical nutrition products, basic ointments and breast milk replacement products may be eligible for reimbursement

Finland has been acting in the European mutual recognition procedure as a reference member state. A consistent number of the generic marketing authorisations have probably been applied for in view of a subsequent European mutual recognition. This is the technique to launch the generics in question more rapidly on to the pharmaceutical markets of other EU countries. This has lead to the situation, where there have been granted marketing authorisations for a high amount of products which have actually never been marketed in Finland. Since 2006, the marketing authorisation procedure has been changed so that the products in the mutual recognition procedure must be brought to the market in Finland. This will reduce the amount of registered pharmaceuticals in Finland.

Switches

There are no specific rules regarding POM to OTC switches in place. Between 1989-1998 altogether 36 active substances were switched. Recently the number of annual switches has been low (2003: 1 active substance, 2004: 4 active substances). Switching decisions are taken by NAM on a case-by-case basis either because requested by the manufacturer of the pharmaceutical or on its own intent.

2.1.2.1 Market data

Table 2.3 presents pharmaceutical market data for Finland between 2000 and 2005. In 2005 the total pharmaceutical sales at consumer price (incl. VAT) level amounted to 2.4 billion Euro, compared to 2.3 billion in 2004. Between 2004 and 2005 total pharmaceutical sales rose by 6,4 %.[8]

In 2005, 72% of the total sales was attributable to POM used in out-patient care, 15% to pharmaceuticals used in in-patient care and 13% to OTC.[9] The sales value of outpatient POM grew by 4,2 %, which may be considered a very modest increase compared with the previous years.

[8] Lääkelaitos/KELA 2006

[9] Out-patient pharmaceutical sales calculated at pharmacy retail prices (incl. VAT and pharmacy tax), in-patient pharmaceutical sales calculated at wholesale prices.

The sales value of inpatient medicines increased by 11 % and that of OTC medicines by 14,5 %.

In 2004, reimbursement payments were provided to 3.3 million individuals for pharmaceuticals used in out-patient care. The cost of these payments was approximately € 1 billion, which corresponds to an increase of 10.6% compared to 2003.

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

In million €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume (in thousands)	30 784	37 934	37 696	38 421	39 972	40 834	42 161
Annual prescriptions by value (Mio. Euro, at pharmacy retail price with VAT)	n.a.	1 188	1 336	1 478	1 565	1 685	1 756
Pharmaceutical sales							
Sales at ex-factory price level	n. a.	n. a.	n. a.-	n. a.	n. a.	n. a.	n. a.
Sales at wholesale price level	n. a.	902	1,008	1,111	1,179	1,271	1,345
Sales at pharmacy retail price level (incl. hospital sales)	n. a.	1,646	1,840	2,025	2,137	2,288	2,435
Sales at hospitals	n. a.	686	781	875	920	1,004	1,060
Sales of generics	n. a.	213	224	232	245	243	258
Sales of parallel traded pharmaceuticals	n. a.	2,6	3,0	4,0	14,3	23,7	26,8
Exports and imports							
Total pharmaceutical exports*	n. a.	285	330	443	451	494	629
Total pharmaceutical imports	n. a.	746	854	1036	1108	1283	1418

* Including finished products and raw material

Sources: IMS Finland, National Board of Customs 2006, Finnish Statistics on Medicines 1995-2005

The share of generics in terms of value (19 %) is relatively high in Finland due to the patent legislation and mandatory generic substitution (cf. 5.5), whereas the share of parallel import is only 2 %. Total pharmaceutical import is remarkable higher than export (incl. drug substances, pharmaceutical preparations and other pharmaceuticals); 86 % of the import originates in the EU.

In 2005, the growth of medicine sales continued to be slower than it was before the introduction of generic substitution in April 2003. The increase in costs was kept under control by price competition between pharmaceutical companies as well as the extensive re evaluation of prices carried out by the Pharmaceuticals Pricing Board HILA during 2004 and 2005.

Consumption in DDD/1,000 inhabitants/year at ATC-2 level was highest in the groups A11 vitamins (150.45 DDD/1,000 inhabitants/year), C09 Agents acting on the rennin-angiotensin system (137.87 DDD/1,000 inhabitants/year) and N05 Psycholeptics (102.96 DDD/1,000 inhabitants/year).

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

Position	Pharmaceutical, by active ingredient and value (at PPP)	Pharmaceutical, by active ingredient and volume
1	Atorvastatin	Ibuprofen
2	Fluticasone	Paracetamol
3	Hydrochlorothiazide	Acetylsalicylic acid
4	Salmeterol	Ascorbic acid
5	Olanzapine	Calcium
6	Ibuprofen	Magnesium
7	Calcium	Pyridoxine
8	Budesonide	Hydrocortisone
9	Paracetamol	Nicotinamide
10	Losartan	Cyanocobalamin

Source: IMS Finland

2.1.2.2 Patents and data protection

In Finland, pharmaceutical preparations may be protected by analogous process patent (i.e., process patent motivated by the novelty of the pharmaceutical substance at the application stage) or by product patent.

The Finnish data protection period was harmonized with EU legislation in the end of 2005 and is eight years. Previously, data protection period was six years.

Before early 1995, it was not possible to apply for a Finnish product patent for a pharmaceutical substance, and therefore the process patent was the only alternative.

The Finnish Parliament adopted an amendment to the Medicines Act in December 2005. According to it, innovative medicines, that are protected in Finland merely by an analogous process patent and also protected by a product patent in at least five EEA countries, are excluded from the generic substitution regime. The Act was implemented as of the beginning of February 2006.

The new Act also allows the elimination of products already included in the generic substitution list, besides the products that do not yet have a marketing authorisation.

2.1.3 Market players

This section describes the key players in the pharmaceutical system except from 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

Most pharmaceutical companies operating in Finland are members of the Pharma Industry Finland, PIF. In 2005 their number was 65 companies.[10]

PIF represents almost all the pharmaceutical companies researching, manufacturing and marketing pharmaceuticals in Finland. The members represent the research-based, generic, OTC and veterinary pharmaceutical industry. PIF is a part of the pharmaceutical corporation, together with the Pharmaceutical Information Centre, the Supervisory Commission for the Marketing of Medicinal Products and the Finnish Cooperative for the Identification of Medicines-Related Injuries.

In 2005 altogether 6,123 persons (compared to 6,648 in 2004 were employed at the Finnish pharmaceutical industry.[11] The three leading companies by market share are Pfizer, Orion Pharma and AstraZeneca. The usual distribution channel of medicines and other medicinal products is via wholesale.

Table 2.5: Finland - Key data on the pharmaceutical industry 1995 - 2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	65
- research-oriented	3	3	3	3	3	3	3
- generic producers	2	1	1	1	1	1	1
- biotech	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	20
Persons employed [2]	4,118	4,379	4,273	4,225	4,043	3,998	3,329

[1] as of 1 January

[2] counted per head, excl. generic producers and biotech companies

Source: PIF 2007

2.1.3.2 Wholesalers

In Finland, pharmaceuticals have been distributed through a single-channel system, based on a fixed-term agreement between the supplier and pharmaceutical wholesale company since the 1970ies. A single-channel distribution system does not require pre-wholesaling stocks, and therefore it is cost-effective for pharmaceutical companies. Two wholesalers, Oriola and Tamro Finland, share the market. Wholesalers are only allowed to deliver to pharmacies, hospitals and community health centres, but not directly to patients.

The wholesale margin is freely negotiated between pharmaceutical companies and wholesalers with the granting of discounts being allowed. Agreements between manufacturers and wholesalers are not public. The wholesale margin is supposed to be in average around 2-4 %.

[10] www.pif.fi/page.php?page_id=117

[11] http://www.laaketeollisuus.fi/tiedostot/PHARMAFACTS040406_(ID_1101).pdf

Wholesalers distribute pharmaceuticals within 24 hours from the order; in most cases even faster. Both companies deliver throughout the whole country. In addition to Oriola and Tamro, there are 81 wholesale companies with licences granted by the National Agency for Medicines in 2006. These companies are importing medicines, medical products or equipments into Finland.

Table 2.5: Finland - Key data on pharmaceutical wholesale 1995 - 2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	2	2	3	3	3	2	2
Total number of outlets	9	8	9	7	7	6	4

[1] as of 1 January

Source: ATY (Association of Pharmaceutical Distributors)

Drug distribution is solely done by Oriola and Tamro. Tamro Finland has distribution centres in Vantaa, Tampere and Oulu. Medicine sales was € 1,026 million in 2005. Also Nicotine Replacement Therapy products, which were liberalised in 2006 are distributed via Tamro. Oriola Oy is a part of Oriola-KD Corporation. Oriola Oy has distribution centres in Espoo and Oulu. Medicine sales was 740 million Euros in 2005.

Parallel trade is not a major feature of the Finnish market.[12] It started in 1996, but its share of the pharmaceutical market is low, accounting for 2 % of pharmaceutical sales by value and 0.5% by volume in 2005. This was a small boost compared to former times where the market share was around 0.2%.[13] The reason is that not only generics but also parallel imported products fall under the obligatory substitution system that was introduced in 2003 (cf. 5.5.1).

Finland, on the other hand, is no significant source of parallel export to other EU Member States. Application for a marketing authorisation of the parallel import of a pharmaceutical can be made, if the original product already has a valid marketing authorisation in Finland.

The prerequisites for the application of a marketing authorisation for a parallel-imported product are laid down in the NAM Administrative Regulation *Parallel Import of Medicinal Products.* In addition, the application must comply with the NAM Administrative Regulations *Applying for and maintaining marketing authorisation for a medicinal product* and *Labelling and package leaflet for medicinal products*.

The marketing authorisation shall be applied for by the parallel importer of the product (a natural person or legal person). The holder of a marketing authorisation for a pharmaceutical to be parallel imported must, at the time of the application, hold an authorisation for wholesale distribution in Finland. A marketing authorisation for parallel-imported products must be renewed on the authorisation holder's initiative in accordance with the same provisions as the marketing au-

[12] PIF 1/2006

[13] Tilson/Barry 2005

thorisation for other medicinal products. There are four major parallel traders acting in Finland 2006.

2.1.3.3 Pharmaceutical outlets / retailers

Dispensing of pharmaceuticals to patients happens mainly through pharmacies, their subsidiary pharmacies and for a limited selection of OTC through so-called medicine chests, that operate under the supervision of a pharmacy. The dispensing of pharmaceuticals through other outlets, such as drugstores or through internet pharmacies, is not allowed in Finland, with the exception of NRT-products, which were liberalised 1.1.2006 to tobacco selling shops .[14]

The number of pharmacies and branch pharmacies in Finland has increased by 7 % since 1990 (53 outlets). In 2005 there were 799 pharmacy outlets, thereof 193 branch pharmacies and two university pharmacies with all together 18 outlets in big cities. In 2006, the corresponding figure was 800 pharmacy outlets.

Pharmacies and hospital pharmacies are allowed to offer their patients a dose dispensing service. This service was enhanced by 1 January 2006 for a three year test period as it is now partly reimbursed by Kela for persons aged 75 or above, who are being prescribed at least six reimbursable pharmaceuticals qualifying for dose dispensing, i.e. tablets, etc.[15]

2.1.3.3.1 Pharmacies

On average a Finnish pharmacy serves about 6,510 inhabitants. Pharmacies are widely spread, and 99 % of citizens are living in communities with at least one pharmacy.

According to the Medicines Act, there must be a sufficient number of pharmacies in Finland to allow the general public, wherever possible, to obtain pharmaceuticals without difficulty. The responsible authority for pharmaceutical services is the National Agency for Medicines, who grants licences to operate a retail pharmacy. A pharmacy licence may be granted to a citizen of any state belonging to the European Economic Area who is a licensed Master of Science (Pharmacy), and who has not been declared bankrupt or incompetent to manage his or her affairs. If there are several applicants for a pharmacy licence, it shall be granted to the applicant who may be considered best qualified to operate the pharmacy. Applicants' qualifications in this field are assessed by considering the competence and aptitude for the business that they have shown in their earlier work in pharmacies and other tasks relating to pharmaceutical services.

A pharmacy licence is granted to a named individual. The pharmacy business may not be rented or transferred to another person. If a licensed pharmacist obtains a new pharmacy licence, the pharmacy licence previously issued to the pharmacist will simultaneously be annulled. The main principle is that a licensed pharmacist must manage the pharmacy personally. A licensed pharmacist may operate a pharmacy business until the age of sixty-eight.

[14] Suomen Apteekkariliitto 2005

[15] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5, Section 10
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i209.pdf

Pharmacy chains are not allowed except of the Helsinki University Pharmacy, which is entitled to maintain one pharmacy in the city of Helsinki and 16 outlets in big cities. The University of Kuopio is allowed to run one pharmacy in the city of Kuopio. Besides selling medicines, the function of these pharmacies is to provide practical training in connection with pharmacy teaching and to conduct research on pharmaceutical services. Nevertheless, 70 % of pharmacy students take their practical training at private pharmacies.

Responsibilities for the pharmacy mentioned at the Medicines Act are the following:

- The stock of pharmaceuticals, the equipment and supplies for administering drugs, and the dressings kept by a pharmacy must correspond to its usual customer needs.
- The opening hours of pharmacies and branch pharmacies must be such as to ensure the availability of pharmaceuticals. Licensed pharmacists must notify the opening hours to the municipality in which the pharmacy is located.
- Pharmacies and their branches must have the necessary number of staff with pharmaceutical qualifications.
- The facilities of pharmacies, branch pharmacies and licensed medicine chests must be appropriate for selling and storing pharmaceuticals. Facilities used for preparation and examination of pharmaceuticals must be appropriate for this purpose and equipped accordingly.
- When supplying pharmaceuticals pharmacies must ensure, through the advice and guidance of pharmaceutical staff, that patients are aware of the correct and safe use of the product. In addition, medicinal product purchasers must be given information about the price of the products and about other factors affecting their choice (for instance if it is a substitutable product).

Table 2.6: Finland - Retailers of pharmaceuticals 1995, 2000 - 2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies[2]	788	796	797	799	800	802	799	800
No. of private pharmacies[2]	771	779	779	781	782	784	781	782
No. of public pharmacies[3]	17	17	18	18	18	18	18	18
Number of hospital pharmacies for outpatients	23	23	24	24	24	24	24	24
Number of other POM dispensaries	0	0	0	0	0	0	0	0
Total number of POM-dispensaries[1]	788	796	797	799	800	802	799	800
No. of internet pharmacies	0	0	0	0	0	0	0	0
No. of medicine chests	348	283	289	283	187	166	160	n.a.

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number

POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

[1] as of 1 January

[2] incl. branch pharmacies and university pharmacy outlets

[3] University Pharmacies (acting as community pharmacies)

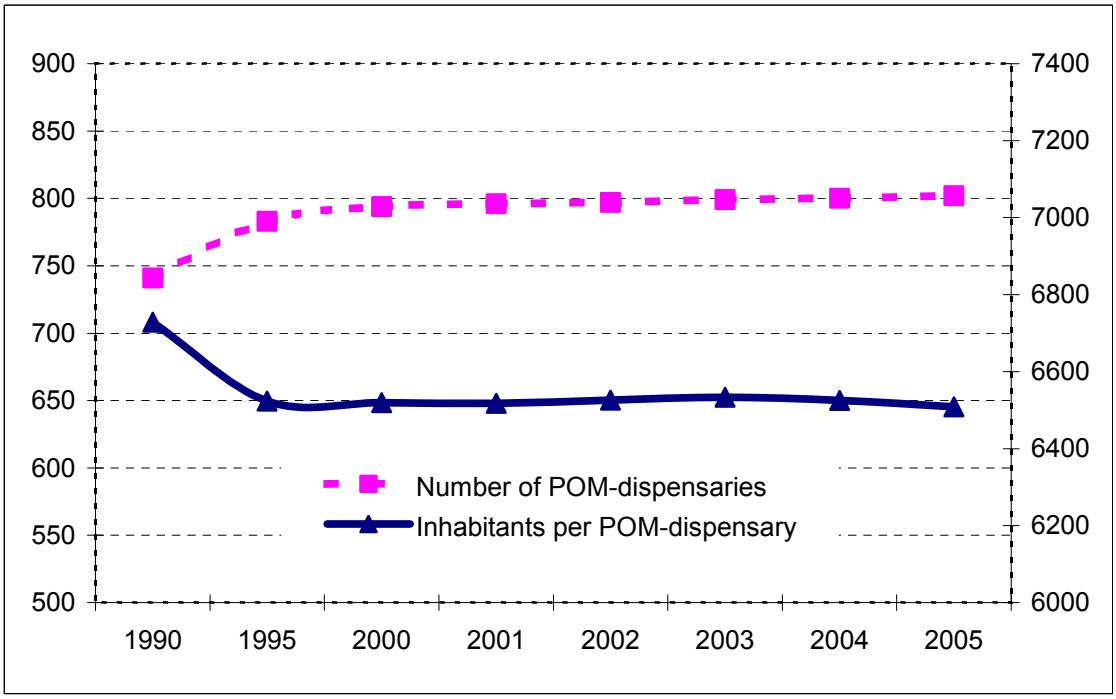
Source: AFP 2006

The Association for Finnish Pharmacies (Suomen Apteekkariliitto, AFP) represents private pharmacy owners in professional and legislation related questions. Membership is voluntary, but all pharmacy owners except of three are members. Members of AFP as well Helsinki University Pharmacy and Kuopio University Pharmacy are members of the Pharmacy Employers' Association (Apta), which is negotiation partner in collective agreements with the Finnish Pharmacist's Association.

Most pharmacists and bachelors of pharmacy are members of the Finnish Pharmacists Association (Suomen Farmasialiitto), which is a professional and employee organisation for the profession. Pharmacists, especially those working at the industry, may be members of the Finnish Pharmacists' Society (Suomen Proviisoriyhdistys).

Pharmacies are remunerated via a statutorily fixed mark-up scheme for all pharmaceuticals (on- and off patented, POM, OTC). Rebates from wholesalers or industry to pharmacies are forbidden by the Medicines Act. Pharmacies are not allowed to give rebates to the patients, except of war veterans, to whom a 10 % rebate is mandatory. Also rebates for frequent customers are allowed.

Figure 2.2: Finland - Number of retail pharmacies and inhabitants per pharmacy 1990, 1995 and 2000 - 2005



Source: AFP 2006

The pharmacy licensing system secures services in the rural areas, because the career of a pharmacy owner often starts with a small pharmacy there. As years go by, the pharmacy owner may apply for a bigger pharmacy and thus get an opportunity to return to city-centres.

A turnover-depended annual tax, the so-called pharmacy fee, is levied on pharmacy owners under the Act on Pharmacy Fees. The amount payable is calculated from the pharmacy's turnover, after VAT and some other deductions, using a specific table. The fees are confirmed annually by the parliament. In 2005, the fee ranged from 0 to 1.18 million Euro per pharmacy. The average fee was 6,6 % of the pharmacy's turnover. Private pharmacies pay pharmacy fee for the state. The University Pharmacies pay it to their owners, the universities. Pharmacies at the Åland Islands pay their fees to the Provincial Government. The aim of the fee is to balance economical outcome of different size pharmacies and thus maintain the equal prices of medicines in the whole country. The pharmacy fee could also be considered as a kind of "claw back-system" for pharmacies.

2.1.3.3.2 Other pharmacy outlets

Apart from branch pharmacies, which provide the same range of pharmaceuticals and services as their main pharmacy, there are medicine chests maintained by the pharmacy in rural areas. These chests are often situated within grocery shop, post office etc. They may include a restricted selection of OTC medicines, but no POM.

2.1.3.3.3 Internet pharmacies

Distance selling, e.g. purchasing of pharmaceuticals via mail orders or internet is not allowed in Finland.

2.1.3.3.4 Dispensing doctors

Doctors are not allowed to dispense in Finland.

2.1.3.4 Hospitals

In 2005, there were five university hospital pharmacies and 19 other hospital pharmacies in Finland. Besides, there are 180 medicine dispensaries, of which 147 were owned by municipals, 3 by the state and 30 by private health care providers. However, hospitals or health centres are neither allowed to run pharmacies for out-patients nor to sell pharmaceuticals directly to the public. Hospital pharmacies and medicine dispensatories issue medicines only to their own wards and other departments. NAM permits hospitals and other health care institutions to operate a hospital pharmacy or a medicine dispensary.

Only on special occasions may patients, who are being discharged or temporarily transferred to out patient care, be issued medicines from the hospital to ensure the continuation of their medication. These medicines are supplied without a charge and normally for one or two days only. However, this is minor, and the share of pharmaceuticals dispensed in pharmacies in outpatient care is therefore roughly 100 %.

In addition, basic vaccinations, medicines for certain dangerous infectious diseases (HIV, veneric diseases, tuberculosis) and buprenofin / methadone therapy for opioid dependant people may be acquired from hospital pharmacies or municipal medicine dispensatories.

Hospitals and health centres operate with restricted number of pharmaceuticals, a so called basic drug list, which is decided autonomously by each outlet. The selection is based on the therapeutic and economic effectiveness of medicines. The public sector has to follow procure-

ment regulations, and usually the cheapest bargain price is selected. Hospital pharmacies and medicine dispensatories are allowed to get rebates from industry. Thus the cheapest pharmaceutical in the in-patient sector is not always the cheapest in the out-patient sector.

2.1.3.5 Doctors

Since 1997, doctors, who prescribe more than 200 reimbursable pharmaceuticals per annum, i.e. the vast majority of doctors, receive a summary of their prescriptions and their respective cost from Kela. The data provided include the number of prescriptions and their distribution by patients' age and gender as well as the average cost per prescription etc. compared to those of other doctors in the same region and are intent to raise the prescribing awareness of doctors.[16]

Between 1998 and 2002 a program for rational prescribing, ROHTO, was implemented. Since 2003 the Centre for Pharmacotherapy Development (Lääkehoidon kehittämiskeskus ROHTO) is in charge of promoting rational use of pharmaceuticals and supporting the implementation of such activities in Finland (cf. 2.3 for details).[17]

2.1.3.6 Patients

Finnish patients have to be fully informed on their medication by the prescribing doctor in the first place and by the dispensing pharmacists in the second place.[18] The latter has to inform the patient on his/her co-payments as patients always have to pay a co-payment for a reimbursable pharmaceutical. Pharmacists are also obliged to inform the patient of the cheap generic alternatives, if their prescribed medicine can be substituted (Medicines Act).

According to STM the changes in the reimbursement system that took place in 1 January 2006 are cost-neutral for patients. Still, there is no necessity for patients to shop around to search for cheap pharmaceuticals, as retail prices of pharmaceuticals are the same throughout the country as the wholesale price must be the same for all pharmacies according to Medicine Act and pharmacy mark-ups are statutorily fixed.

Several patient organisations are actively lobbying authorities and politicians.

2.2 Funding

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

[16] Pekurinen/Häkkinen 2005

[17] http://www.rohto.fi

[18] Act on patient's rights 785/1992

2.2.1 Pharmaceutical expenditure

The total pharmaceutical expenditure amounted to EUR 2,4 billion in 2005, a growth of 6.4% compared to 2004. Since 1995 the total pharmaceutical expenditure has increased by 158 percent.[19]

The growth of medicine sales continued to be slower than it was before the introduction of generic substitution in 2003 (cf. 5.5.1). The cost increase was kept under control by price competition between pharmaceutical companies as well as the extensive re evaluation of prices carried out by the Pharmaceuticals Pricing Board HILA during 2004 and 2005.

In Finland, the share of outpatient pharmaceutical expenditure in total health care expenditure (incl. reimbursements, self-medication and patient's out-of-pocket payments) was 16,3 % in 2004, which is below the European average. In the hospital sector, the pharmaceutical expenditure is included in the costs of inpatient care and therefore not available.

Table 2.7: Finland - Total pharmaceutical expenditure 1995, 2000 – 2005.

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in million €	1,013	1,646	1,840	2,025	2,137	2,288	2,435
TPE in % of THE	14.2	18.9	19.6	20.0	20.0	20.4	20.5
TPE per capita[1] in €	198	317	354	388	409	437	463
Public PE in % of THE	6,4	7,8	8,1	8,4	8,6	9,1	n. a.
Private PE in % of THE	7,8	11,1	12,3	11,4	11,4	11,4	n. a.

GDP = Gross Domestic Product, THE = Total Health Expenditure, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

[1] population data from as basis for calculation

Source: Lääkelaitos/Kela 1995, 2000-2005

Total health expenditure as a share of GDP was 7.4 percent in Finland (2004), well below the OECD average (8.8 % in 2003), cf. Table 1.1. Generally speaking, public health spending is well under control in Finland. Finns also report higher satisfaction with their health system than people in many other OECD countries.

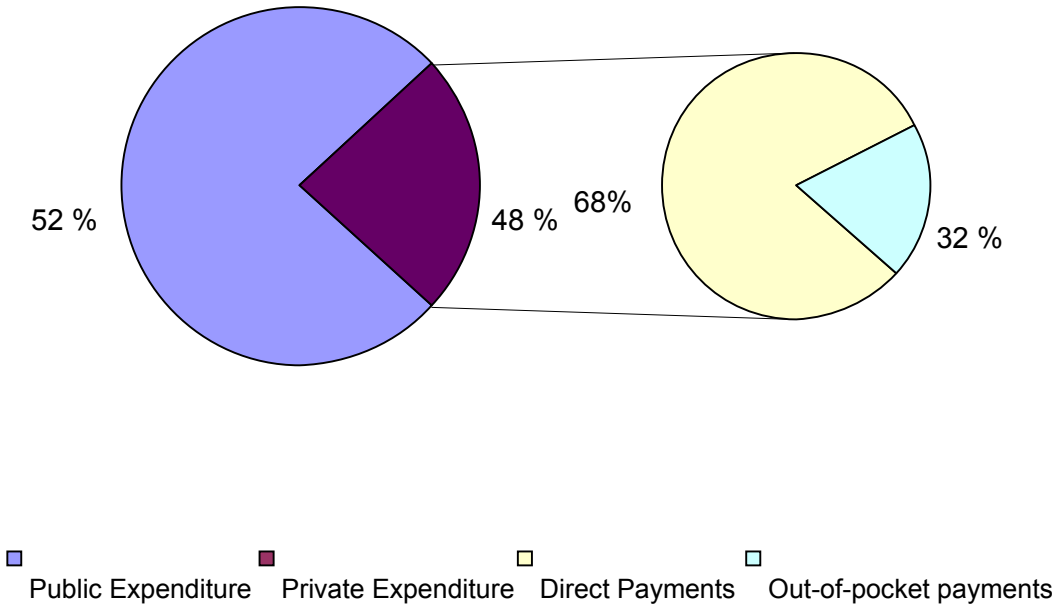
2.2.2 Sources of funds

Health care expenditure is primarily financed by public funds, i. e. the public share amounted to 77.8 % in 2005 (municipalities: 40.4 %, state: 20.8 % and Kela: 16.6 %). In 2004, the private share was 23.4 %: employers paid 2.1 %, sickness funds 0.4 %, private insurance 2.0 % and private persons 18.9 %. In 2005, 22.2 % of total health care expenditure were funded privately.

The share of public pharmaceutical expenditure in the total pharmaceutical expenditure has been quite stable: 44,9 % in 1995; 41,1 % in 2000 and 44,2 % in 2005.

[19] Lääkelaitos/Kela 2006

Figure 2.3: Finland - Share of private and public pharmaceutical expenditure, 2004



Source: Lääkelaitos/Kela 2005

2.3 Evaluation

Between 1998 and 2002 a program for rational prescribing, ROHTO, was implemented (cf. 2.1.3.5)[20]. Since 2003 the Centre for Pharmacotherapy Development (Lääkehoidon kehittämiskeskus ROHTO) is in charge of promoting rational use of pharmaceuticals and supporting the implementation of such activities in Finland.[21] ROHTO is an independent expert unit under the STM collecting and disseminating information to monitor prescribing habits of doctors and proving information to doctors. As of 1 January 2006 ROHTO has the right to request from HILA information on the cost-effectiveness and other details submitted by pharmaceutical companies with their application for pricing and reimbursement.

Although there are no sanctions in place for "over-spending" doctors or those who oppose generic substitution, doctors must act on good medical reasons for refusing and document his/her decision. Already since the year 1997 doctors, who prescribe more than 200 reimbursable pharmaceuticals per annum, i.e. the vast majority of doctors, receive a summary of their prescriptions and their respective cost from Kela. The data provided include the number of prescriptions and their distribution by patients' age and gender as well as the average cost per prescription etc. compared to those of other doctors in the same region and are intent to raise

[20] Pekurinen/Häkkinen 2005

[21] http://www.rohto.fi

scription etc. compared to those of other doctors in the same region and are intent to raise the prescribing awareness of doctors.[22]

Only the most recently published "Current Care" guidelines include a economic component and so far neither the effect of ROHTO program nor "Current Care" guidelines on prescribing behaviour have been thoroughly evaluated.

Since 1983, Lääkelaitos (NAM) and Kela have been publishing the national statistics on medicines, medicines costs and reimbursements annually.[23] The statistics cover medicines consumption expressed by volume (ATC/DDD-system) and sales, reimbursement costs by patients and disease groups, development of co-payment levels per patient category and information on drug control and the Finnish health care system.

[22] Pekurinen/Häkkinen 2005

[23] Lääkelaitos/Kela 1983-2006

3 Pricing

3.1 Organisation

In Finland the main regulations on pricing of pharmaceuticals are enacted in the Medicine Act, the Health Insurance Act and the Government Decree on pharmacy margin (Table 3.1). Supplementary provisions are laid down by decrees of Government and the Ministry of Social Affairs and Health and by a decision of the Pharmaceuticals Pricing Board[24].

The pricing of a non-reimbursable pharmaceutical by the marketing authorisation holder is unregulated. For reimbursable pharmaceuticals, both POM and OTC, the Pharmaceuticals Pricing Board (HILA), being STM-affiliated, approves their maximum wholesale prices. The marketing authorisation holder may set the wholesale price below or equal to the price confirmed by HILA. According to the Medicine Act the wholesale price of a pharmaceutical (= pharmacy purchase price) must be the same for all pharmacies.

The wholesale margin is included in the wholesale price and is not regulated; the pharmacist margin is regressive and is defined by the Government Decree on pharmacy margin (cf. 3.5.1 and 3.5.2).

The reasonableness of the wholesale price is one of the prerequisites of a reimbursement. The decisions on reasonable wholesale price and reimbursement status are made simultaneously by HILA. The Pharmaceuticals Pricing Board (HILA) also confirms increases in confirmed reasonable wholesale prices, cf. 3.2.1 for the criteria taken into consideration.

Before deciding on the matter HILA obtains an opinion on the reasonableness of the proposed wholesale price, or price increase, in terms of the Health Insurance Scheme and the envisaged costs under the scheme from Kela.

HILA must deliver its decision concerning the reasonable wholesale price and reimbursement status of a pharmaceutical to the applicant within 180 days of receiving the application. If a decision concerns only the increase of a previously confirmed wholesale price, the decision must be delivered to the applicant within 90 days of receiving the application. Decisions made by the Pharmaceuticals Pricing Board are valid for a fixed term only (cf. 3.2).

3.2 Pricing policies

The current pricing system in Finland was implemented in 1994. As described in 3.1 the control of a wholesale price applies only reimbursable pharmaceuticals. The marketing authorisation holder may set the wholesale price below or equal to the confirmed wholesale price. Table 3.1 gives an overview on the ways of pricing in Finland.

[24] A detailed overview of legal reimbursement provisions may be found in section 7.3

Decisions made by HILA on the reasonable wholesale price are binding for the marketing authorisation holder and are valid for a maximum of five years. The decisions are valid for a maximum of three years, however, if the issue concerns a product containing a new active substance.

The procedure concerning the price approval is the same for generics, parallel trade products and original products. If the proposed wholesale price for the first generic product is 40 % lower than the price of original product and for the subsequent generic products not higher than for the other generics the Secretary General of the Pharmaceuticals Pricing Board can make the decision on reasonable wholesale price. In such case the procedure is faster than the basic procedure when the decision is made by the Board.

Table 3.1: Finland - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all non-reimbursable pharmaceuticals (POM and OTC) set by marketing authorisation holder (cf. below 'Price Negotiations').		Free pricing for NRT-products sold also outside pharmacies For other pharmaceuticals a statutory regressive pharmacy mark-up scheme is applied
Statutory Pricing	A reasonable wholesale price (maximum PPP) for reimbursable pharmaceuticals (POM and OTC) is confirmed by HILA. Marketing authorization holder may set the wholesale price below or equal to the confirmed wholesale price (cf. below 'Price Negotiations').		A regressive mark-up scheme defined by Government Decree on pharmacy margin
Price Negotiations	Marketing authorization holders and wholesalers negotiate their share of the wholesale price, which is set by the marketing authorisation holder (cf. above 'Free Pricing' and 'Statutory Pricing').		Not applicable
Discounts / rebates	Not applicable	No	Discounts only for veterans, regular customers and business-to-business
Public Procurement	➢ For all pharmaceuticals used in hospitals (not only HOM but also for others) ➢ Not relevant in out-patient sector		
Institution in charge of pricing	➢ HILA for reasonable wholesale price of reimbursable pharmaceuticals ➢ Government for pharmacy mark-up scheme		
Legal Basis	➢ Medicine Act (395/1987) and its amendments ➢ Government Decree on pharmacy margin (1087/2002) and its amendment (1183/2002) ➢ Health Insurance Act (1224/2004) and its amendment (885/2005) ➢ Government Decree on the Pharmaceuticals Pricing Board (1356/2004) and its amendment (1110/2005)		

HILA= Pharmaceuticals Pricing Board, HOM = Hospital-Only Medicines, POM =Prescription-Only Medicines, OTC = Over-The-Counter pharmaceuticals, PPP= pharmacy purchase price, NRT = Nicotine Replacement Treatment

Source: STM 2007, AFP 2007

3.2.1 Statutory pricing

A reasonable wholesale price (= synonymous with the maximum pharmacy purchase price) is one of the prerequisites for reimbursement eligibility of a pharmaceutical. A marketing authorisation holder must apply to HILA for approval of the requested reasonable wholesale price for a reimbursable product. The application must include well-grounded arguments for the price, thereof the following obligatory points:

- a statement on the average daily dose and the cost of the medical treatment on the basis of the proposed wholesale price and the retail price including value added tax;
- a well-grounded estimate of the sales of the medicinal product on the basis of the proposed wholesale price and the retail price including value added tax and an estimate of the number of patients who would be using the product;
- a statement on the cost-effectiveness of the pharmaceutical and a market forecast for it compared with other products used for the treatment of the same disease;
- a statement concerning the pharmaceutical's patent protection and supplementary protection certificate;
- other trade names of the pharmaceutical, with their approved, valid wholesale prices in case of reimbursement eligibility, and the bases of reimbursement for the product in other European Economic Area states (EEA);
- a health economic evaluation if the pharmaceutical contains a new active substance.

The Pharmaceuticals Pricing Board obtains an opinion from Kela on the reasonableness of the proposed wholesale price, or price increase, in terms of the National Health Insurance Scheme (NHI) and the envisaged costs under the Scheme. Criteria for confirmation of the reasonable wholesale price are enacted in the Health Insurance Act. In its evaluation the Board takes furthermore into account:

- treatment cost incurred from the use of the pharmaceutical and the benefits to be gained from its use regarding both, the patient's needs and the total costs of health care and social services
- benefits and costs incurred from other available treatment alternatives
- prices of comparable pharmaceuticals in Finland
- prices of the pharmaceuticals in other EEA countries
- manufacture, research and product development costs of the pharmaceuticals and
- funds available for reimbursement.

These criteria are defined in the Health Insurance Act and have been in effect since 1998. In the original provisions introduced in 1994 the obligatory storage costs of medicinal product were also taken into account. In addition, the prices in other Nordic countries were mentioned separately in the criteria.

A decision of the Pharmaceuticals Pricing Board concerning the reasonable wholesale price and reimbursement status of a pharmaceutical must be delivered to the applicant within 180 days of receiving the application. If a decision concerns only the increase of a previously confirmed wholesale price, the decision must be delivered to the applicant within 90 days of receiving the application. Decisions enter into force as of the beginning of the second calendar month following the issue of the decision.

Applicants may apply for an increase of the reasonable wholesale price with HILA whenever they wishes to do so. Prior to price confirmations or approval of price changes HILA has to consult Kela.[25]

Those companies dissatisfied with a decision of the Pharmaceuticals Pricing Board (HILA) may appeal to the Supreme Administrative Court as laid down in the Administration Judicial Procedure Act (586/1996). Notwithstanding any appeals, the decision of HILA shall apply until final judgement has been made in the matter.

Holders of marketing authorisations must inform the Pharmaceuticals Pricing Board without delay if the sales of a pharmaceutical significantly exceeds the preliminary estimate that was the basis for the decision on reimbursement status and a reasonable wholesale price.

The Pharmaceuticals Pricing Board may, on its own initiative, examine the reasonability of a pharmaceutical's wholesale price and reimbursement status and decide to terminate the confirmed wholesale price and its reimbursement status. A confirmed wholesale price and reimbursement status may be terminated if, while the price is in force,

- the pharmaceutical's patent expires
- a generic product containing the same medicinal substance is approved within the reimbursement system
- the indicated use of the pharmaceutical expands
- the criteria of eligibility for reimbursement cease to exist
- the product sales or the reimbursement expenses for the product significantly exceed the estimate accepted as the basis for the price confirmation decision.

HILA must hear the holder of the marketing authorisation and the Social Insurance Institution before terminating a wholesale price and reimbursement status. In examining the criteria for terminating the wholesale price and reimbursement status, the Pharmaceuticals Pricing Board must assess the therapeutic value of the pharmaceutical or the reasonability of the wholesale price on the basis of the new information it has acquired.

In addition, a statutory pharmacy mark-up applies all pharmaceuticals except nicotine replacement treatment products (cf. 3.5.2).

[25] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Sections 3 and 4

3.2.2 Negotiations

As described in 3.2.1 the procedure concerning a reasonable wholesale price and reimbursement status is based on a written application made by a marketing authorisation holder. During the process, however, the Pharmaceuticals Pricing Board (HILA) or the Secretariat of the Board can at an applicant's request arrange a meeting with a marketing authorisation holder. In the meeting the applicant can bring up specific justifications for the proposed reimbursement status and price. This information is taken into account when the final decision on the matter is made by HILA.

The wholesaler margin is unregulated in Finland and is based on the negotiations between a marketing authorisation holder and a wholesaler (cf. 3.5.1).

3.2.3 Free pricing

After the implementation of EEA agreement at the beginning of 1994, the unreasonableness of the price has no longer prevented the granting of a marketing authorisation. Free pricing is therefore applied for all non-reimbursable pharmaceuticals (POM and OTC).

3.2.4 Public procurement / tendering

Public procurement applies only for pharmaceuticals used in hospitals (HOM and other), cf. 3.4.1 for details.

3.3 Pricing procedures

In principal, manufacturer prices are uncontrolled in Finland. Only for pharmaceuticals, both POM and OTC, applying for reimbursement a reasonable wholesale price must be applied at the Pharmaceuticals Pricing Board HILA (cf. 3.2.1). When assessing the reasonability of a proposed wholesale price the Board takes several criteria, that are listed in detail in 3.2.1 into account.

The current pricing procedures are summarised in Table 3.2.

Table 3.2: Finland - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing	Scope
Internal price referencing	Yes (cf. 3.3.2)	Wholesale price	Reimbursable pharmaceuticals (POM and OTC)
External price referencing	Yes (cf. 3.3.1)	Wholesale price	Reimbursable pharmaceuticals (POM and OTC)
Cost-plus pricing	No (cf. 3.3.3)		
Other: funds available for reimbursements	Yes	Retail price based on reasonable wholesale price	Reimbursable pharmaceuticals (POM and OTC)

Source: Health Insurance Act (1224/2004) and its amendment (885/2005)

3.3.1 External price referencing

The wholesale prices in other EEA countries are taken into account when assessing the reasonableness of the proposed wholesale price of a pharmaceutical in Finland. The individual countries are: Austria, Belgium, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom. Yet, none of the individual countries has a special status in this connection. The Finnish wholesale price is either calculated on the basis of prices in other countries.

The data on wholesale prices in other EEA countries shall be submitted by the applicant. The applicant shall also submit the updated data on prices in subsequent applications for renewal of fixed-term decision. However, the price in other EEA countries is only one criteria among many others that are considered when approving the "reasonable" wholesale price.

3.3.2 Internal price referencing

When assessing the reasonability of a proposed wholesale price, which is the basis for reimbursement eligibility, HILA takes into account benefits and costs incurred from other available treatment alternatives and prices of bio-equivalent products and other pharmaceuticals used for the treatment of the same disease in Finland.[26]

An applicant shall provide a statement on the cost-effectiveness of the medicinal product and a market forecast for it compared with other medicinal products used for the treatment of the same disease.

See also the section on generics (cf. 5.5) for details.

[26] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 3, Art. 2 and 3

3.3.3 Cost-plus pricing

There is no explicit cost-plus pricing applied in Finland. Though, when applying for a reimbursement price pharmaceutical companies are encouraged to proof their R&D expenses and manufacturing costs by delivering the information to HILA.

HILA considers this information especially for complex pharmaceutical forms. Such pharmaceuticals might receive a higher reimbursement price than the same product in a conventional pharmaceutical form. In such cases the cost-plus is maximum + 20 %. On special grounds also higher cost-plus may be approved.

3.3.4 (Indirect) Profit control

Not applicable.

3.4 Exceptions

3.4.1 Hospital-only

The medicine purchases within the public social welfare and health care sector are subject to public tendering in accordance with the respective legislation. Besides the medicine prices, the tendering of medicine purchases must also address safety issues as well as ensured supply of the pharmaceuticals. Hospital districts, joint municipal authorities for primary health care and municipalities collaborate on the practical level for the procedures and organisation of tendering. The aim of the tendering procedure is a purposeful and economical use of medicines, as well as a containment of medicine expenditure at a reasonable level.

3.4.2 Generics

In principle the procedure and the criteria concerning the approval of a reasonable wholesale price is the same for generics, parallel trade products and original products.

If the proposed wholesale price for the first generic follower is 40 % lower than the price of original product and for the subsequent generic products not higher than for the other generics the Secretary General of the Pharmaceuticals Pricing Board (HILA) may approve him/herself the reasonable wholesale price alone. In such cases the approval procedure is faster than the basic procedure when the decision is made by the Board.

3.4.3 Over-The-Counter pharmaceuticals

The wholesale price of a non-reimbursable OTC pharmaceutical can be set freely by a marketing authorisation holder. For reimbursable OTC pharmaceuticals the reasonableness of the wholesale price is assessed by HILA according to the criteria described in section 3.2.1. Furthermore, the wholesale prices as well as the retail prices of nicotine replacement treatment products, which are also allowed to be sold outside the pharmacies, are uncontrolled.

3.4.4 Parallel traded pharmaceuticals

The procedure and the criteria concerning the approval of a reasonable wholesale price is the same for parallel trade products and original products.

3.4.5 Other exceptions

None.

3.5 Margins and taxes

In Finland all pharmaceuticals except certain nicotine replacement treatment (NRT) products (cf. 3.4.3) are regulated via regressive mark-up scheme for pharmacies as shown in Table 3.4

Table 3.3: Finland - Regulation of wholesale and pharmacy mark-ups 2006

Wholesale mark-up			Pharmacy mark-up		
Regulation (yes/no)	**Content**	**Scope**	**Regulatio (yes / no)**	**Content**	**Scope**
No	Not appl.	Not appl.	Yes	Regressive mark-ups	All pharmaceuticals except NRT-products also sold outside the pharmacy

NRT = Nicotine replacement treatment, Not appl. = Not applicable

Source: Government Decree on pharmacy margin

3.5.1 Wholesale remuneration

Wholesalers in general may freely set their prices as wholesaler margins are unregulated in Finland. But as already explained in 3.2, the wholesale price of reimbursable pharmaceuticals is indirectly controlled through the reimbursement system. To be eligible for reimbursement pharmaceuticals need an approved "reasonable" wholesale price.

The profit share, i. e. the wholesale margin that is freely negotiated between marketing authorisation holders and wholesalers (with the granting of discounts being allowed) is included in the wholesale price set by the marketing authorisation holder. However, these agreements between manufacturers and wholesalers are not public. On average the wholesale margin is 4%.[27]

3.5.2 Pharmacy remuneration

Pharmacies are remunerated via a statutory mark-up based on the pharmacy purchase price (PPP).[28] The applicable mark-up scheme is regressive and is defined by Government Decree

[27] Pekurinen/Häkkinen 2005

[28] Government Decree on pharmacy margin 2002/1087

(Table 3.4). The mark-up scheme applies for all pharmaceuticals except certain NRT-products (see 3.4.3). Pharmacies are also paid a fee of € 0.42 for any pharmaceutical dispensed (cf. 3.5.5).

In addition, pharmacies in Finland pay a special tax, known as a pharmacy fee. The pharmacy fee is calculated from the pharmacy's turnover. The average pharmacy fee is approximately 7 % of turnover (cf. 3.5.5). The pharmacy fee has been taken into account when determining the pharmacy mark-up.

Table 3.4: Finland - Pharmacy mark-up scheme 2006

Pharmacy purchase price (PPP) from … to… in €	Pharmacy mark-up coefficient in % of PPP
0 – 9.25 €	1.5 x PPP + 0.50 €
9.26 – 46.25 €	1.4 x PPP + 1.43 €
46.26 – 100.91 €	1.3 x PPP + 6.05 €
100.92 – 420.47 €	1.2 x PPP + 16.15 €
over 420.47 €	1.125 x PPP + 47.68 €

PPP = Pharmacy Purchase Price

Source: Government Decree on pharmacy margin (1087/2002)

3.5.3 Remuneration of other dispensaries

Since February 2006 nicotine replacement therapy products have been available also in non-pharmacy outlets (retail stores, kiosks and gas stations selling cigarettes). The remuneration of these outlets is unregulated.

3.5.4 Value-added tax

Since 1998 value-added tax for pharmaceuticals has been 8 % in Finland.[29]

3.5.5 Other taxes

Pharmacist's dispensing fee per purchase for a POM and a prescribed OTC is € 0.39 excluding VAT. The fee is determined in the Government Decree on pharmacy margin.

Depending on their sales all private proprietary pharmacists have to pay a progressive, tax-like pharmacy fee to the state. The two university pharmacies pay a corresponding fee to their owners.[30] This tax was introduced to secure the country-wide provision of services, also in remote areas.

[29] Act on value-added tax 1501/1993

[30] Pharmacy Fee Act 1946/148

The pharmacy fee for 2005 ranged from zero to 1.18 million Euro. The average pharmacy fee was 6.6 percent (6.7 % in 2004), of the pharmacy's turnover (ca. € 199,220). The pharmacy fee system enables pharmacies of different sizes to sell the medicines at the same prices based on the medicine tariff. The smaller pharmacies get a larger share of the margin than the larger pharmacies. The pharmacy fee system thus ensures the operation of small pharmacies, as well as comprehensive pharmacy services in every part of the country.

In the course of the discussions on reducing the prices of pharmaceuticals in 2005 it was proposed to halve the pharmacy tax, but this proposal was dropped by the end of the year.[31]

3.6 Pricing related cost-containment measures

3.6.1 Discounts / Rebates

Manufacturers and wholesalers may grant discounts to each other, which is because of the exclusive distribution contracts. However, there are no legal provisions in place and agreements between wholesalers and manufacturers are not public, therefore no details are available. Neither wholesalers nor pharmaceutical industry are allowed to give discounts to pharmacies as this is forbidden by law.[32] According to Medicine Act the pharmacy purchase price of a pharmaceutical must be the same for all pharmacies.

Pharmacies may grant discounts to their customers but only if this is the case for all customers in the same way; other discounts are prohibited in Finland. These rules do not apply to the nicotine replacement therapy products, which are also allowed to be sold in non-pharmacy outlets.

In addition, war veterans are entitled to an obligatory 10 % discount. However, the discount doesn't apply to the costs of the medicines for which the special refund or a restricted basic refund is granted nor the costs above the annual ceiling sum [33, 34]

3.6.2 Margin cuts

The pharmacy mark-up scheme as well as the pharmacy tax system have been unchanged for almost a decade. The last margin cut occurred in April 1998 to reflect the gradual shift towards a use of more expensive pharmaceuticals.[35] Since that time there have only been minor adaptations to the scheme, when the Euro was introduced in the year 2002.

[31] PPR 11/2005

[32] Medicines Act 395/1987, amendment 2006/22

[33] ÖBIG 2006

[34] Government Decree on pharmacy margin 2002/1087

[35] Sirkia/Rajaniemi 2002

3.6.3 Price freezes / Price cuts

On 1 January 2006 the Finnish government followed the example of other EU Member States and for the first time statutorily cut the approved reasonable wholesale prices for all reimbursable pharmaceuticals by 5%.[36]

This price cut was based on the Health Insurance Act laid down by the Parliament and happened on top of the changes in the reimbursement system that also become valid on 1 January 2006.[37] . The report on the impacts of the price cut will be available in the first quarter of 2007.

3.6.4 Price reviews

Before the 2006 price cut HILA was evaluating prices of reimbursable pharmaceuticals only on an individual basis and often decided to reduce the reasonable wholesale price if any of the following situations occurred:[38]

- The indications had been significantly expanded.
- The same pharmaceutical product became available for a significantly lower price.[39]
- The price of the pharmaceutical was significantly lower in other EEA-countries.

In 1998 the reasonable wholesale prices of reimbursable pharmaceuticals confirmed by HILA were set for a fixed term only. Between the years 1998 and 1999 and 2004–2005 HILA evaluated the prices of reimbursable pharmaceuticals for selected ATC-Codes, which in some cases led to considerable price reductions.[40]

At the moment the decisions made by HILA are valid for a maximum of five years and in case of a new active substance for a maximum of three years. In connection with the applications for renewal of fixed-term decision the reasonableness of the price will be assessed again by the Board. The reasonableness of the price is assessed according to the criteria described in section 3.2.1. Manufacturers are in principle allowed to change their prices as long as the wholesale price does not exceed the approved reasonable wholesale price. If the marketing authorisation holder wants to price the product above the approved reasonable wholesale price, it must apply for a price increase in order to remain reimbursable or withdraw the product from the reimbursement system.

[36] Health Insurance Act 1224/2004 and amendment 885/2005, Annex

[37] PPR 10/2005 and 2/2006

[38] Martikainen/Rajaniemi 2003

[39] This is especially the case when the product goes off-patent.

[40] Peura 2006

4 Reimbursement

4.1 Organisation

Reimbursement is regulated by the National Health Insurance legislation and is administrated by Kela. The main rules are enacted in the Health Insurance Act and supplementary provisions are laid down by decrees of Government and the Ministry of Social Affairs and Health (STM) and by a decision of the Pharmaceuticals Pricing Board (HILA).[41]

POM which are deemed necessary for the treatment of an illness and prescribed by a physician or a dentist, are reimbursed under the National Health Insurance Scheme by Kela. Some OTC medicines indispensable on medical grounds are also reimbursable when prescribed by a physician. Basic topical ointments used for the treatment of chronic skin ailments are also reimbursable, as are clinical nutritional preparations used for serious illnesses. Reimbursement for a product is made provided that the product has been approved for reimbursement and a reasonable wholesale price has been confirmed by the Pharmaceuticals Pricing Board HILA. Reimbursements are paid for medicines in outpatient care purchased at pharmacies.

In Finland price and reimbursement decisions are made together. There is only one exception, application of price increase, which only concerns the price. First, the requirements for granting a reimbursement status are evaluated and then the reasonableness of a proposed wholesale price is considered. There are several reimbursement categories, basic, lower special and upper special in place (cf. 4.2.2).

The Pharmaceuticals Pricing Board (HILA, cf. 2.1.1.2), being affiliated with the STM,

- decides on the reimbursement status of pharmaceuticals, clinical nutritional preparations and basic ointments,
- confirms their reasonable wholesale prices as described in Chapter 3,
- decides on the discontinuation of reimbursement status of pharmaceuticals, clinical nutritional preparations and basic ointments and
- confirms increases in their confirmed reasonable wholesale prices, and termination during the validity of the wholesale price.

An expert group consisting of a maximum of seven members operates as part of the Pharmaceuticals Pricing Board. This expert group represents medical, pharmacological and health economics, and social insurance expertise. The STM appoints the chairmen, deputy chairmen and other members of the Pharmaceuticals Pricing Board and the expert group and a personal deputy for each member for three years at a time. The Board is quorate when at least three members in addition to the chairman are present.

[41] A detailed overview of legal reimbursement provisions may be found in section 7.3

A marketing authorisation holder must apply to HILA for a confirmation of basic reimbursement status and a reasonable wholesale price as well as special reimbursement status. The applicant must include in an application for confirmation of basic reimbursement status a well-grounded proposal concerning the (basic) reimbursement eligibility of a pharmaceuticals The application, which is the same as for the price approval, must include well-grounded arguments for the price, like a statement on the use of the product, its therapeutic value, and the benefits achieved through reimbursement status compared with other medicinal products used for the treatment of the same disease (cf. 3.2.1 for details).

In an application concerning special reimbursement status (cf. 4.2.2), the holder of the marketing authorisation must present an itemized, well-grounded statement on

- the pharmaceutical's therapeutic value
- the benefits and costs of its special reimbursement status
- the pharmaceutical's replacement or remedial effect or indispensability
- the cost-effectiveness of the medicinal product and
- the medicinal product's market forecast.

Regarding the timeliness of the decision the 180 respectively 90-day rule is applicable, cf. 3.2.1.

After having reimbursement status and an approved wholesale price the product qualifies for reimbursement in the basic refund category.

In selected occasions[42], e.g. if the concerned pharmaceutical

- is already on the positive list and the application is for
  - a new package size within defined limits or
  - a new strength provided that the wholesale price proposed for the new strength is at least 10 % below that of the lower strength as calculated per active substance or combination of substances or
- is a corresponding generic for a pharmaceutical provided that the proposed wholesale price for the first generic product is 40 % lower than the price of original product and for the subsequent generic products not higher than for the other generics
- is a parallel imported pharmaceutical for a pharmaceutical provided that the proposed wholesale price is not higher than the wholesale price approved for a corresponding product

the Secretary General of HILA may approve the wholesale price without consultation of Kela and the Board.

Decisions made by HILA are valid for a maximum of five years. The decisions are valid for a maximum of three years, however, if the issue concerns a product containing a new active sub-

[42] Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm the basic reimbursement status of a medicinal product and a reasonable wholesale price as the basis for reimbursement as well as to approve the special reimbursement status of a medicinal product in virtue of Chapter 6, section 14, as it reads in Act 885/2005, of the Health Insurance Act (1224/2004)

stance. Decisions will enter into force as of the beginning of the second calendar month following the issue of the decision unless otherwise provided in the decision.

HILA also has the power to terminate the reimbursement status and the confirmed wholesale price, if actual sales exceed the estimates the company has delivered with its application.[43]

The Pharmaceuticals Pricing Board may, on its own initiative, examine the reasonability of a medicinal product's wholesale price and reimbursement status and decide to terminate the confirmed wholesale price and reimbursement status. A confirmed wholesale price and reimbursement status may be terminated if, while the price is in force,

- the patent expires
- a generic product containing the same active substance is approved within the reimbursement system
- the indicated use of the pharmaceutical expands
- the criteria of eligibility for reimbursement cease to exist
- the product sales or the reimbursement expenses for the product significantly exceed the estimate accepted as the basis for the price confirmation decision.

HILA must hear the marketing authorisation holder and Kela before terminating reimbursement eligibility. In examining the criteria for terminating the wholesale price and reimbursement status, HILA must assess the therapeutic value of the pharmaceutical or the reasonability of the wholesale price on the basis of the new information it has acquired.

4.2 Reimbursement schemes

The general pharmaceutical reimbursement system was implemented in Finland in 1964 as a part of the overall public health insurance scheme. For reimbursable pharmaceuticals that are prescribed by a doctor or a dentist for the treatment of an illness, reimbursement is granted for a part of the cost (4.2.2). The NHI covers all permanent residents of Finland, regardless of age, wealth or address and is administered by the Social Insurance Institution (Kela). The main regulations concerning the health insurance scheme are enacted in Health Insurance Act (cf. 4.1.).

In Finland there are also other schemes than health insurance that may cover the patient's costs of medicines, e.g. social assistance paid to people with low incomes by the local municipal authorities and support paid to pensioners, children and people with disabilities.

4.2.1 Eligibility criteria

The Finnish reimbursement system consists of three reimbursement categories: basic refund, lower special refund and higher special refund, cf. 4.2.2 for details. The reimbursement categories are graded according to medical criteria, that are defined by law.[44]

[43] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 6, Section 8

Before reaching a decision, the Pharmaceuticals Pricing Board (HILA) requests a statement on the basic and special reimbursement status of a pharmaceutical by Kela. In addition, the Board obtains an opinion from its group of experts when the matter concerns a pharmaceutical containing a new active medicinal substance. In other matters, an opinion is requested when necessary. Criteria for approval of a reimbursement status are enacted in Health Insurance Act.

Basic reimbursement

When deciding on the basic reimbursement status of a pharmaceutical HILA must take into account its therapeutic value. Basic reimbursement status may be confirmed for a OTC product only in the case of a product indispensable on medical grounds.

Basic reimbursement status is not confirmed if

- the pharmaceutical is used for the treatment of a disease of a temporary nature or with mild symptoms;
- a pharmaceutical has minor therapeutic value;
- a pharmaceutical is used for purposes other than treatment of a disease; or
- it concerns a herbal medicinal product, a homeopathic product or an anthroposophic product.

The Board may decide on these non-reimbursable products by pharmaceutical group.

The Pharmaceuticals Pricing Board (HILA) may also restrict the basic reimbursement status of a pharmaceutical to explicit defined indications if the use of and research on a pharmaceutical has shown significant therapeutic value in certain diseases and

- the product is particularly expensive and indispensable in the treatment of a severe disease and its medically justified use would, with basic reimbursement status, entitle the insured to the additional reimbursement or
- extensive use of the product would cause unreasonable costs in relation to the benefit gained.

Pharmaceuticals in this group are reimbursed only if the illness fulfils certain criteria. Examples are Xenical® for patients with pathological obesity or Enbrel® for certain rheumatoid diseases. Kela may further decide on the medical criteria to be met to justify reimbursement of the insured and the documentation required. Doctors have to state medical reasons for the prescription of such pharmaceuticals and document them individually for each patient.

Special Reimbursement

When deciding about the special reimbursement status the following are considered by HILA: type of disease, necessity and cost-effectiveness of the product, proven therapeutic value of the medicinal product, and funds available for special reimbursement products. A decision on special reimbursement status can be restricted to apply only to a specific form or degree of severity

[44] www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i219.pdf

of a disease as defined by Government Decree. Special reimbursement status may be granted to an OTC only if it is indispensable on medical grounds. Kela decides on the medical criteria for a severe and chronic disease that must be met to provide medical justification for special reimbursement for the medicinal products and on the documentation required.

In order to receive reimbursement under the Special Refund Category the patient must submit a doctor's certificate to Kela stating the illness, its severity and the medication needed to treat it.

One of the reasons for the establishment of new reimbursement rules during the last years was that the European Court of Justice had condemned Finland guilty of the breach of the EU Transparency Directive 89/105/EEC on 12 June 2003. It had ruled that the procedural regulations and timelines on ruling upon pharmaceutical reimbursement within the special reimbursement category (the method of approving a drug into special reimbursement category by statute of the Council of State instead of petition proceedings, cf. 4.1.) contravened the Transparency Directive.

Appeal Procedure

Those dissatisfied with a decision of the Pharmaceuticals Pricing Board (HILA) may appeal to the Supreme Administrative Court as laid down in the Administration Judicial Procedure Act (586/1996). Notwithstanding any appeals, the decision of the Pharmaceuticals Pricing Board shall apply until final judgement has been made in the matter.

4.2.2 Reimbursement categories and reimbursement rates

According to the Health Insurance Act reimbursement of pharmaceuticals is divided in three different categories:[45]

- **Basic Refund Category:** 42 % reimbursement of the gross pharmacy retail price of the pharmaceutical.
- **Lower Special Refund Category:** 72 % reimbursement of the gross pharmacy retail price of the pharmaceutical. Here pharmaceuticals for ten chronic conditions (such as hypertension, asthma, coronary heart disease and rheumatoid arthritis) where drug treatment is necessary to maintain the patient's health status are included.
- **Higher Special Refund Category:** 100 % reimbursement of the gross pharmacy retail price of the pharmaceutical above a fixed co-payment of € 3.-. This category covers pharmaceuticals for 34 severe chronic conditions and life-threatening diseases (such as diabetes, glaucoma, breast cancer and epilepsy) where drug treatment is necessary and effective to maintain the patient's health status and where the drug restore or replaces normal bodily functions

[45] Health Insurance Act 1224/2004 and amendment 885/2005, Chapter 5 and Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of medicinal product and on the documentation to be appended to the application (1111/2005)

A pharmaceutical can belong to one or two or in all three reimbursement categories at the same time. HILA decides in which category/categories a pharmaceutical will be included.

Table 4.1: Finland - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
Basic refund	42 % (co-payment 58 %)	HILA may restrict the basic reimbursement status of a medicinal product to specifically defined indications
Lower special refund	72 % (co-payment 28 %)	The lower special refund category includes ten chronic illnesses defined by a Government Decree where drug treatment is necessary to maintain the patient's health status.
Higher special refund	100 % - co-payment € 3.- per medicine per purchase	The higher special refund category covers 34 chronic illnesses defined by a Government Decree where drug treatment is necessary and effective to maintain the patient's health status and where the drug restore or replaces normal bodily functions.
Additional refund	100 % - co-payment € 1.50 per medicine and purchase above the annual out-of pocket maximum	If the co-payments for reimbursable drugs exceed defined annual limit (€ 616.72 year 2006), all cost after a fixed co-payment € 1.50 per medicine and purchase will be reimbursed in full

HILA = Pharmaceuticals Pricing Board (Lääkeiden hintalautakunta)

Source: Health Insurance Act 1224/2004, its amendment 885/2005 and Government Decree 1108/2005

The reimbursement categories are graded according to medical criteria based on the severity of the illness and the necessity of the drug treatment. A Government Decree defines the severe and chronic illnesses[46] that entitle the patients to reimbursement under the special refund categories.

An additional refund is granted if the patients' out-of pocket payments of reimbursable products exceed an annual ceiling sum, the out-of pocket maximum (~ € 617.- in 2006).

4.2.3 Reimbursement lists

All medicines for which the Pharmaceuticals Pricing Board (HILA) has confirmed reimbursement status and a reasonable wholesale price are covered by the reimbursement system. A list of these medicines and their prices ('positive list')[47] is available on the website of HILA. The list is updated once a month.

The Social Insurance Institution (Kela) keeps a list of medicinal products and preparations in the special reimbursement category by disease.

[46] www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i219.pdf

[47] www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/notices.htx

Since 1.1.2006 the HILA has had the power to decide on the medicines to be included in a negative list. At the moment no negative lists are available. The expert group of the Pharmaceuticals Pricing Board is currently evaluating medicines that might be included in such list. The first decisions relating to a negative list are expected to be made in the end of 2007.

The reimbursement system does not apply for pharmaceuticals in in-patient care.

4.3 Reference price system

Currently there is no reference price system in place in Finland. However, the Minister of Social Affairs and Health has set up a working group in June 2006 to evaluate the suitability of a reference price system in Finland. The working group shall report its suggestions in August 2007.

4.4 Private pharmaceutical expenditure

4.4.1 Direct payments

The costs of pharmaceuticals not eligible for reimbursement are paid by a patient. These cost are not included in the annual ceiling sum ("out-of-pocket maximum") concerning the additional refund. However, the social assistance paid to people with low incomes by the local municipal authorities and support paid to pensioners, children and people with disabilities may cover the patient's costs of medicines.

Despite obligatory generic substitution (cf. 5.5.1) the patient is always entitled, if desired, to choose the prescribed original product. Both the prescribing physician and the purchasing individual have the power to forbid the substitution. The percentage co-payment amount is always based on the price of the dispensed product.

4.4.2 Out-of-pocket payments

4.4.2.1 Fixed co-payment

In a higher special refund category and in additional refund a patient pays a fixed co-payment for each pharmaceutical (cf. Table 4.4.2.2).

4.4.2.2 Percentage co-payments

In a basic refund and lower special refund categories the co-payment is calculated as a percentage of the expenses of a pharmaceutical (cf. Table 4.4.2.2).

In each reimbursement category (cf. Table 4.4.2.2) as well as in additional refund the patient always has to cover a part of cost. The co-payment rate depends on:

- the severity of the illness and the necessity of the drug treatment

- the product and it's reimbursement category and
- the consumption of the patient, as there is a out-of-pocket maximum of € 616.72 (in 2006) in place.

Co-payment does not depend on the patient's age or financial standing. However, social assistance by the local municipal authorities covering the cost of medicines is available to people with low incomes, pensioners receiving support, children and people with disabilities.

The co-payment rate per reimbursement categories are summarised in Table 4.2.

Table 4.2: Finland - Reimbursement rates and patient co-payment rates, 2006

Reimbursement category	Co-payment rate	Reimbursement rate
Basic refund	58 %	42 %
Lower special refund	28 %	72 %
Higher special refund	€ 3.- per medicine per purchase	100 % - co-payment € 3.- per medicine per purchase
Additional refund	€ 1.50 per medicine per purchase after annual ceiling sum (= OOP maximum), € 616.72 in 2006	100 % - co-payment € 1.50 per medicine per purchase after annual OOP maximum (€ 616.72 year 2006), all expenses after co-payment € 1.50 per medicine per purchase will be reimbursed in full

Source: Sairausvakuutuslaki (Health Insurance Act) 1224/2004 and its amendment 885/2005

In 2006, the patients' share of total expenditure for reimbursable medicines was 31 %. The figure does not include social assistance paid by the local municipal authorities for pharmaceutical expensed, nor the drug costs taken into account in calculating the level of support paid to pensioners, children and people with disabilities. No figures on these compensations are available.

An annual out-of pocket (OOP) maximum has been set to the co-payments a patient is expected to pay of his/her reimbursable medicines, basic topical ointments and clinical nutritional preparations. When the annual ceiling sum (€ 617.- in 2006) is reached, the patient is entitled to an additional refund. Subsequent expenses for reimbursable products are reimbursed in full with a € 1.50 fixed co-payment per medicine per purchase.

4.4.2.3 Deductibles

No longer relevant to Finland; the former deductibles were abolished in 2006, cf. 4.6.3.

4.5 Reimbursement in hospitals

Health Insurance applies only pharmaceuticals in outpatient care. Hospital pharmacies and medicine dispensaries issue medicines only to their own wards and other departments. They are not allowed to sell pharmaceuticals to patients or directly to the public. Only on special occasions may patients, who are being discharged or temporarily transferred to outpatient care,

be issued pharmaceuticals from the hospital to ensure the continuation of their medication. These pharmaceuticals are supplied without charge and normally for one or two days only.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists[48]

- 1994: Direct price monitoring was abolished. Lääkekorvauslautakunta (now Lääkkeiden hintalautakunta, the Pharmaceuticals Pricing Board) became responsible for setting the wholesale price, on which reimbursement is based.
- 1998: The criteria for new drugs to become eligible for Special Refunds were reviewed.
- 1999: The sub-group of “significant and expensive pharmaceuticals” was introduced.
- 2003: Generic substitution was introduced on 1st April, cf. 5.5. An amendment to the Medicines Act (395/1987) places the dispensing pharmacy under an obligation to substitute the prescribed preparation with the cheapest, or close to the cheapest, interchangeable product, unless the substitution is forbidden either by prescribing physician or the purchasing individual. Interchangeable products include all generic alternatives and parallel import products containing same active substance. The list of substitutable medicinal products is provided by the National Agency for Medicines. The list is reviewed quarterly.
- 2004: In the beginning of 2004 the Pharmaceuticals Pricing Board became responsible for decisions on the special reimbursement status of pharmaceuticals. Until the end of 2003 the Council of State was responsible for deciding which chemical entities were to be given special reimbursement status, and the Social Insurance Institution maintained a list of pharmaceuticals qualifying for a Special Refund.
- 2006: Basic reimbursement status needs to be applied. HILA has the right to restrict the reimbursement; Possibility to create a negative list. Changes to generic substitution.

  Lipitor (atorvastatin) and Crestor (rosuvastatin) are reimbursed only for patients with severe disorders of lipid metabolism when lifestyle changes and cheaper statins have failed to lower cholesterol or when side effects or interactions occur when using cheaper statins. The limitation came into effect on 1st of October 2006.

4.6.2 Introduction / review of reference price system

Not applicable.

[48] Martikainen/Rajaniemi 2002

4.6.3 Introduction of new / other out-of-pocket payments[49]

- 1990: The fixed deductible per purchase for pharmaceuticals in the Basic Refund Category was increased from FIM 30 to FIM 35 (~ € 5.05 to € 5.89).
- 1992: The fixed deductible per purchase for drugs in the Basic Refund Category was increased from FIM 35.- to FIM 45.- (from € 5.89 to € 7.57). The reimbursement percentage for drugs in the Basic Refund Category was reduced from 50 % to 40 %. The reimbursement percentage for the Lower Special Refund Category was reduced from 90 % to 80 %. Some OTC were de-listed from the reimbursement system.
- 1994: A fixed deductible, payable per purchase, was also introduced into the Special Refund Categories. The reimbursement percentage for the Lower Special Refund Category was reduced from 80 % to 75%. The fixed deductible of the Basic Refund Category was increased from FIM 45 to FIM 50 (from € 7.57 to € 8.41) and the reimbursement percentage from 40 % to 50 %. An Additional Refund became payable only after the annual ceiling set to the patient's own payments was exceeded by FIM 100.- (€ 16.82).
- 2003: The fixed deductible, payable per purchase for drugs in the Basic refund Category was increased from € 8.41 to € 10.-. The fixed deductible in the Lower and in the Higher Special Refund Category was increased from € 4.20 to € 5.- per purchase.
- 2006: A cost-neutral change in patient co-payments for reimbursed pharmaceuticals. New reimbursement categories:
  - Basic reimbursement category: 42 % reimbursement
  - Lower special reimbursement category: 72 % reimbursement
  - Higher special reimbursement category: 100 %, the patient pays € 3.- per pharmaceutical and purchase
  - Additional refund: if the costs of reimbursable pharmaceuticals paid by patient exceed the defined annual sum of, all costs after co-payment € 1.50 per pharmaceutical and purchase will be reimbursed in full.

4.6.4 Claw-backs

Not applicable.

4.6.5 Reimbursement reviews

Decisions made by the Pharmaceuticals Pricing Board are valid for a maximum of five years. The decisions are valid for a maximum of three years, however, if the issue concerns a product containing a new active substance. In connection of a renewal it is evaluated if the criteria for reimbursement are fulfilled.

[49] Martikainen/Rajaniemi 2002

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

Not applicable.

5.2 Prescription guidelines

Finland has two systems for national treatment guidelines. Both are produced by Finnish Medical Society Duodecim and are updated regularly:

- **Current Care guidelines**[50]

  These guidelines are intended for national use and are produced in Finnish since 1994. The board of Current Care selects topics from among suggestions made mostly by the specialist societies. The development group consists of relevant clinical experts, always including a general practitioner, and allied health professionals when appropriate. The process begins with literature search done by an experienced medical librarian. Critical appraisal of the literature is based on criteria originally outlined by the Evidence Based Medicine Working Group. The level of the evidence is graded from A to D. The Current care guidelines cover diagnosis and treatment of one illness or medical condition (e.g. high blood pressure). When it is relevant diagnostic limits, dose limits and/or duration limits of pharmaceuticals are given. Over 70 guidelines are produced and as many in progress.

  All Current Care guidelines are freely easily accessible via Internet. These electronic versions are also available on CD-ROM. The significant difference from the printed version is the accessibility of the evidence summaries on which the grading is based. There are direct links to the original Cochrane reviews and in the near future the original articles. The electronic version is the main medium of guideline dissemination. Importantly, this allows linking of guidelines with locally developed implementation programmes or models of shared care. Dissemination of guidelines also includes a wide variety of publications directed to specific audiences.

  Adherence to guidelines is not systematically monitored at the moment. Scientific research has been conducted. For the latest guidelines quality indicators, which allow monitoring of adherence, have been developed.

- **EBM Guidelines**

  Almost 1,000 concise primary care practice guidelines covering a wide range of medical conditions. Both diagnosis and treatment are included. Over 2,500 high-quality evidence summaries supporting the given recommendations – a specific feature of the guidelines is the use of evidence codes (graded from A to D). EBM Guidelines are available online and in print.

[50] www.kaypahoito.fi

Regarding implementation, both national guidelines are effectively disseminated electronically and easily available in physician's offices in online database and/or CD-ROM. The Centre for Pharmacotherapy Development ROHTO is using the guidelines in promoting rational pharmacotherapy but there is no regular clinical audit.

5.3 Information to patients / doctors

In Finland, the marketing of pharmaceuticals is regulated both, by general legislation regarding consumer protection and by the provisions of the Medicines Act and Medicines Degree. Sections 91-93 of the Act and section 25 of the Decree specify in detail the minimum information that must be included, and the restrictions to be observed, when marketing medicinal product. The legality of marketing is monitored by the National Agency for Medicines (NAM).

All statutes regarding the marketing of pharmaceuticals are based on the EU Directive 2001/83/EC relating to products for human use. Only pharmaceuticals with a marketing authorisation may be marketed. The information provided in marketing must be in accordance with the Summary of Product Characteristics approved in conjunction with the marketing authorisation.

Direct advertising of OTC to patients is allowed in all media, also in TV, but the marketing of POM is restricted to those authorised to prescribe and supply medicinal products. The same regulations concern advertising of pharmaceuticals on the internet.

There are no measures implemented in order to restrict or control promotional spending of manufactures.

The National Agency for Medicines does not carry out pre-marketing surveillance. Should any violations to the legislation be noted, a statement will be requested from the company in question to clarify the issue. If necessary, the continuation of marketing may be forbidden, sometimes with an accompanying conditional fine. NAM has to intervene annually in 20-30 cases.

Pharma Industry Finland (PIF) controls on voluntary basis pharmaceutical marketing in accordance with a strict code of conduct (The Code for the Marketing of Medicinal Products), which the member companies have agreed to follow. They have an administrative body (Supervisory Commission for the Marketing of Medicinal Products) for monitoring the compliance with the code of conduct, and two Inspection Boards: one for POM and one for OTC. The control is post marketing except of TV-advertising, where each advertisement has to be approved in advance.

There are no general regulations or restrictions on the activities of representatives of pharmaceutical companies who visit doctors.

Pharmacies (supported by the Association for Finnish Pharmacies) are producing and delivering industry independent information on the rational use of medicines to the patients. There are various materials; booklets, leaflets, printable information on specific medicines, internet database on self care medicines, oral information and counselling (supported by the database for pharmacists and bachelors to be used with dispensing) and media campaigns.

The prices of pharmaceuticals are publicly available, e.g. on the website of the Social Insurance Institution.[51] The list of substitutable pharmaceuticals is available in the internet and is up-dated on a quarterly basis.[52] The Pharmaceutical Information Centre PIC (owned by The Pharma Industry) is producing material on the correct use of medicines. PIC also publish the national drug compendium (Pharmaca Fennica) and its patient version.

In 2005, the National Agency for Medicines launched a media campaign warning about excessive use of medicines. There are no regulations concerning information to patients in the inpatient sector.

5.4 Pharmaco-economics

Since 1999 pharmaceutical companies are obliged to present a pharmaco-economic evaluation of their product to HILA when applying for an "approved" wholesale price of a pharmaceutical with new active ingredient, i.e. claiming reimbursement status. Among other issues, treatment costs and the benefits to be gained from a pharmaceutical as regards both the patient and the total costs of health care and social services are taken into account by HILA.

There is no government body or research organisation that performs pharmaco-economic evaluations so far, but the STM has already published guidelines on the conduct of pharmaco-economic studies in 1999, thus being one of the first European countries to do so. The evaluations have to demonstrate the therapeutic value and cost-effectiveness of the pharmaceutical in question, i.e. they have to contain data on effectiveness and experience of usage in daily life.[53] [54] The comparator should be the product it is designed to replace, the most common practice or the minimum practice.

The guidelines contain detailed explanations on e.g. the quality of acceptable studies (e.g. in terms of sensitivity analysis) and the necessary adoptions to the Finnish health care system (i.e. economic modelling).[55] The guidelines, that sometimes are claimed not to be specific enough, have not been revised since.

Manufacturers conduct research within their own organisations or commission them from sub-contractors. Submitted pharmaco-economic evaluations are then assessed by HILA and utilised in the decision-making process. HOM are not covered by Social Health Insurance, and therefore

[51] http://asiakas.kela.fi/laakekys_app/LaakekysApplication?kieli=en

[52] List of substitutable medicinal products (1.4.-30.6.2006)
http://www.nam.fi/uploads/rinnakkaislaakeluettelo/q22006/Laakevaihtoluettelo_Q2.2006.pdf and
http://www.apteekkariliitto.fi/geneerinen/geneerinen.koti

[53] Decree by STM on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005);
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i212.pdf

[54] Guidelines for Preparing a Health Economic Evaluation (Annex to the Decree 1111/2005);
www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i197.pdf

[55] Guidelines for Preparing a Health Economic Evaluation (Annex to the Decree 1111/2005);
www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx.i197.pdf

need not be applied for reimbursement. However, if reimbursement for such products for some reason is applied, a pharmaco-economic evaluation is required.

Analysis should include all health effects of the patient and all the direct costs irrespective of the payer. If indirect costs are included, the results should also be presented without those. The analysis does not need to be an original study, but can be based on a previous study conducted in Finland or elsewhere. All relevant studies concerning treatment alternatives should be considered in the pharmaco-economic evaluation. All essential research reports and other sources of information used as a basis for the evaluation should be annexed. If the evaluation is based on studies conducted outside Finland, the credibility of that information and its applicability to Finnish conditions should be assessed. Therapy practices and costs should be adjusted to correspond to Finnish treatment practices and cost structure. The maximum willingness to pay (cost per QALY) is not set.

5.5 Generics

In general, the same rules apply to pricing and reimbursement of generics - although a simplified procedure is applied for the reimbursement and price decision if the active substance is already reimbursed. In this case the Secretary General of HILA may approve the reimbursement status and the "reasonable" wholesale price without consultation of Kela and the Board.[56].

Generic substitution is mandatory since 1 April 2003, cf. 5.5.1.

The generic share of the market is estimated to be about 44 percent in terms of volume and 18.4 % in terms of value in 2004 (44 % and18 % in 2006, respectively).

Table 5.1: Finland - Development of the generic market in the out-patient sector, 2000 - 2006

Generic market share	2000	2001	2002	2003	2004	2005	2006
Volume (number of prescriptions per year)	n.a.	n.a	n.a.	n.a.	n.a.	n.a.	n.a.
Value (Mio. Euro, at PPP)	213	224	232	245	243	258	232
Market share of total sale value	24%	22%	21%	21%	19%	19%	18%

Source: IMS Finland (incl. licensed preparations)

[56] Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm the basic reimbursement status of a medicinal product and a reasonable wholesale price as the basis for reimbursement as well as to approve the special reimbursement status of a medicinal product in virtue of Chapter 6, section 14, as it reads in Act 885/2005, of the Health Insurance Act (1224/2004)

5.5.1 Generic substitution

Since mandatory generic substitution was introduced by 1 April 2003 pharmacists are obliged to substitute the prescribed pharmaceutical with its cheapest, or close to the cheapest, generic or parallel imported alternative if the price difference between the prescribed and the cheapest product

- is € 2.- or more if the Pharmacy retail price (PRP) is below € 40.-
- is € 3.- or more if the PRP is € 40.- or above.

Both the prescribing doctor and the patient have the right to refuse the substitution without sanctions. However, the doctor has to document scientific or therapeutic grounds for the refusal.

Refusal of substitution does not reduce the reimbursement level of the originally prescribed pharmaceutical, i.e. patients need not pay the price difference to the more expensive pharmaceutical if they oppose substitution.[57]

The list of the interchangeable ("substitutable ") pharmaceuticals is compiled and administrated by NAM and is up-dated on a quarterly basis.[58] Pharmaceutical companies are obliged to report prices of substitutable products at least 21 days before the first day of each calendar quarter.[59]

The basic criteria for inclusion in the list of substitutable medicinal products are, that the pharmaceuticals[60]

- contain the same active ingredient,
- contain the same quantity of the active ingredient,
- have the same pharmaceutical form, although tablets may be substituted for capsules or capsules for tablets,
- have been reliably shown to be biologically equivalent, and
- belong to an ATC group in which the substitution may be performed safely.

The list of substitutable medicinal products may not include[61]:

- Hospital-only medicines,
- Pharmaceuticals given
  - in medicated plaster form,
  - given parenterally or
  - as an inhalation,

[57] Medicines Act 395/1987 as amended and Decree 210/2003

[58] List of substitutable medicinal products:
www.nam.fi/english/medicines/substitutable_medicinal_products/index.html

[59] www.finlex.fi/fi/laki/alkup/2003/20030210?search%5Btype%5D=pika&search%5Bpika%5D=vaihtokelpo%2A

[60] www.nam.fi/english/medicines/substitutable_medicinal_products/criteria_used/index.html

[61] Medicines Act 395/1987 as amended in 2005

- Pharmaceuticals belonging to ATC groups where substitution by other products is not appropriate for pharmacological or clinical reasons (substitution by a parallel import or parallel distribution product is possible); these include insulins and insulin analogues, haematological medicines, cardiac glycosides, anti-arrhythmics, antiserums, immunoglobulins and vaccinations, anti-epileptics and inhaled pharmaceuticals for obstructive respiratory diseases.
- Pharmaceutical being protected by a process patent in Finland (currently only applicable for six pharmaceuticals: Proscar®, Amaryl®, Cozaar®, Efexor®, *Imigran*® and *Risperdal*®).[62]

The obligatory substitution system is considered as a tremendous success, as e.g. in the first 12 months (April 2003 - April 2004) Kela obtained savings of € 49.1 million and patients paid € 39.2 million less co-payment.[63]

5.5.2 Generic prescription

Generic prescribing (by INN) has been allowed since 1996[64], but not very common especially as by 1 April 2003 generic substitution (cf. 5.5.1) was introduced. The annual number of generic prescriptions is minor. There is no benefits or profits for doctor to encourage generic prescribing.

5.5.3 Generic promotion

When the generic substitution was introduced in 2003, there was a lot of public debate about the use of generics. The authorities, especially the Ministry of Social Affairs and Health (STM), and the Association of Finnish Pharmacies, produced material for the patients to support use of generics.

Pharmacists were provided with discounts in order to choose specific generic products in substitution. This possibility was abolished by 1 January 2006 by changing the Medicines Act. Since then pharmacies are not allowed to receive or accept any discounts from the pharmaceutical industry.

5.6 Consumption

Medicine consumption statistics maintained by the National Agency for Medicines is based on the volume of sales to pharmacies and hospitals by the largest drug wholesalers of Finland. The statistic is based on the Anatomical Therapeutic Chemical (ATC) classification and the Defined Daily Dose (DDD). Consumption is usually expressed as a number of DDDs per 1,000 inhabitants per day. The figure offers an estimation of what proportion of the population theoretically receives a certain pharmaceutical treatment. The consumption statistics is available on the

[62] PPR 2/2006

[63] Tilson/Barry 2005 basing on KELA prescription data

[64] Decree by the Ministry of Social Affairs and Health on the prescribing of medicines 726/2003

internet[65] and in the yearly publication of Finnish Statistics on Medicines, which is published jointly by NAM and Kela.

Drug reimbursement is part of the overall public health insurance scheme covering all permanent residents of Finland. As Kela administers the health insurance scheme it also monitors the purchases of reimbursed medicines and patient's personal contributions. Countrywide prescription register on all medications reimbursed directly at the pharmacy was established in 1994. In 2005 the register comprised about 97 % of all reimbursed prescriptions (28.8 million). The register includes all data derived from the prescription, relating to the patient, the medicine, the prescribing doctor, as well as the cost and reimbursement paid for the medicine. Information is collected monthly from all pharmacies.

The prescription register for example enables to ensure that up to three months' supply of medicines is reimbursed at any transaction and monitor that the medicines reimbursed fully, after patient has reached the annual limit of personal contributions, are necessary (cf. 4.2). The register also enables research on drug utilisation. Statistics on medicine reimbursement is available on internet[66]. No authority monitors the individual consumption of non-reimbursable prescription medicines or OTC-medicines.

[65] www.nam.fi/english/medicines/drug_consumption

[66] www.kela.fi/research

6 Current challenges and future developments

6.1 Current challenges

The main challenge facing the pharmaceutical system in Finland, as in many other countries, is the rising cost of pharmaceutical expenditures. The major reasons for the growing costs are the ageing population and the uptake of new, more expensive pharmaceuticals.

The fast uptake of new, often extremely expensive, active substance is a threat to the rational pharmaco-therapy including good prescribing and patient adherence to the treatment. The new pharmaceuticals are displacing older, less expensive pharmaceuticals with the same indication. There is a clear need for priority setting.

The age structure of the population is changing. The number of children and young people and the working-age population will decrease and the number of older people increases. Elderly people are the heavy-users of pharmaceuticals. One acknowledged challenge is to prevent the possible disadvantages of medical treatment among the elderly.[67]

6.2 Future developments

The Government has set a maximum for the annual growth of pharmaceutical reimbursement expenses during years 2008-2011. The growth should be 5 percent the most.

In 2006, the Ministry of Social Affairs and Health (STM) has set up two working groups relating to pharmaceuticals. The mission of the other group is to evaluate the suitability of a reference pricing system in Finland. The other group evaluates the possibility to increase the effectiveness of retail distribution of pharmaceuticals by abolishing the pharmacy fee system and improving the accessibility of the OTC products in the areas, where neither pharmacy nor subsidiary pharmacy is located. Both working groups will give their report in summer 2007.

The functioning of the electronic prescription has been tested in Finland during 2004-2005. The purpose of the electronic prescription is to rationalise the processes related to the prescription and dispensing of the prescription, as well as the payment of reimbursements. The legislation came into force April 1st 2007. It sets out the conditions that have to be observed in the use of e-prescriptions as well as the schedule for the country-wide spreading of the new concept. E-prescription should be in use latest by the end of 2011 at all pharmacies and health care organisations (both public and private).

[67] Kivelä 2006

7 Appendixes

7.1 References

AFP (Association of Finnish Pharmacies) Medicines Database 2006.

ATY (Association of Pharmaceutical Distributors) statistics.

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Tilson, L.; Barry, M. 2005
European Pharmaceutical Pricing and Reimbursement Strategies. National Centre for Pharmacoeconomics, Dublin 2005

7.2 Further reading

7.3 Web links

The following documents may be retrieved at:
http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htx

Legal Background Pricing

- Medicine Act (395/1987) and its amendments
- Government Decree on pharmacy margin (1087/2002)
- Health Insurance Act (1224/2004)
- Changes (885/2005) to the Health Insurance Act (1224/2004)
- Government Decree on the Pharmaceuticals Pricing Board (1356/2004)
- Government Decree amending the Government decree on the Pharmaceuticals Pricing Board (1110/2005)
- Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005)
- Guidelines for Preparing a Health Economic Evaluation (Annex to the Decree 1111/2005)
- Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm the basic reimbursement status of a medicinal product and a reasonable wholesale price as the basis for reimbursement as well as to approve the special reimbursement status of a medicinal product (1st of July 2006)legislation on pricing of a medicine in 2006

Legal background Reimbursement

- Health Insurance Act (1224/2004)
- Changes (885/2005) to the Health Insurance Act (1224/2004)
- Government Decree on the Pharmaceuticals Pricing Board (1356/2004)
- Government Decree amending the Government decree on the Pharmaceuticals Pricing Board (1110/2005)
- Government Decree on the diseases regarded as severe and chronic on medical grounds, and the medicinal costs for which a 72 or 100 per cent reimbursement is made under chapter 5, section 6(2) of the Health Insurance Act (1108/2005)

- Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application (1111/2005)
- Guidelines for Preparing a Health Economic Evaluation (Annex to the Decree 1111/2005)
- Decree by the Ministry of Social Affairs and Health on the priced services of the Pharmaceuticals Pricing Board (1241/2005)
- Government Decree on diseases regarded as severe on medical grounds for which a 72 or 42 per cent reimbursement of the costs of clinical nutritional preparations used for their treatment is made under the Health Insurance Act (1107/2005)
- Decision of the Pharmaceuticals Pricing Board on authorizing the Secretary General of the Board to confirm the basic reimbursement status of a medicinal product and a reasonable wholesale price as the basis for reimbursement as well as to approve the special reimbursement status of a medicinal product (1st of July 2006)

www.stm.fi (Ministry of Social Affairs and Health)

www.hila.fi (Pharmaceuticals Pricing Board)

www.kela.fi (The Social Insurance Institution)

www.nam.fi (National Agency for Medicines)

www.apteekkariliitto.fi (The Association of Finnish Pharmacies)

www.pif.fi (Pharma Industry Finland)

www.stakes.fi (National Research and Development Centre for Welfare and Health)

www.laakariliitto.fi (Finnish Medical Association)

7.4 Detailed description of authors and editors

7.4.1 Authors

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7.4.2 Editorial Board

The Finnish Pharma Profile was reviewed in spring 2007 by Health Economists Ms. Claudia Habl and Ms. Danielle Arts, both of GÖG/ÖBIG. Ms. Trine Lyager Thomsen, editor-in-chief of WHO Euro and Ms. Christine Leopold of GÖG/ÖBIG assisted in the editing process.

The main authors were assisted by Ms. Taina Mäntyranta, Director of the Centre for Pharmacotherapy Development (ROHTO), Ms. Jaana Martikainen, Senior Researcher, Social Insurance Institution (Kela), Mr. Akseli Kivioja, Chief Pharmaceutical Officer of the Pharmaceuticals Pricing Board and Ms. Mareena Paldán, Chief Pharmaceutical Officer of the Pharmaceuticals Pricing Board and Mr. Ari Jansen and Ms Johanna Salimäki, Advisory Pharmacists at the Association of Finnish Pharmacies.

The final editing was performed by Ms. Habl of GÖG/ÖBIG.