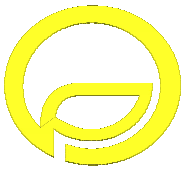

ÖBIG

Pharmaceutical Pricing and Reimbursement Information

ESTONIA

June 2007

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Pharmaceutical Pricing and Reimbursement Information

ESTONIA

Pharma Profile

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Executive summary

Estonia is the smallest of the three Baltic countries on the east coast of the Baltic Sea, bordered by the Russian Federation to the east and Latvia to the south. It covers an area of 43,432.3 km^2, and has a population of 1,344,684 inhabitants at the time of writing. Estonia is a parliamentary republic. The Parliament (Riigikogu) consists of one chamber with 101 members, elected for a period of four years. In May 2004 Estonia joined the European Union (EU).

Estonia embarked on as series of significant economic reforms at the beginning of the 1990s, and by 1993 the country had succeeded in reversing the declining trend in its gross domestic product (GDP).

The main causes of death are cardiovascular diseases and different types of cancer. Alcohol consumption plays a major role as well. It is important to note that the Estonian mortality rate has gone decreased considerably again, after a peak between 1993 and 1995.

Since regaining independence in 1991, the Estonian health system has undergone two major shifts: first, from a centralised, state-controlled system to a decentralised one, and second, from a system funded by the state budget to one funded through social health insurance (SHI) contributions. At the same time, there has been a growing emphasis on primary care and public health.

The main bodies responsible for health care planning, administration, regulation and financing in Estonia are the Ministry of Social Affairs (Sotsiaalministeerium, SM), the Health Care Board, the State Agency of Medicines (Ravimiamet, SAM), the Health Protection Inspectorate and the Estonian Health Insurance Fund (Haigekassa, EHIF).

Health care in Estonia is largely publicly financed. Since 1992, earmarked payroll taxes have been the main source of heath care financing, accounting for approximately 76% of total expenditure on health care in recent years. Specific groups are covered by contributions from the state budget, including individuals on parental leave with small children, registered unemployed people (eligible for cover for up to nine months) and those caring for disabled people. Other groups, including children, retired people, those receiving a disability pension and students, are eligible for cover without any contribution, from either themselves or the State.

Out-patient care is organised as the first level of contact with the health system and is provided by independent family doctors contracted by the Estonian Health Insurance Fund (EHIF).

All hospitals operate under private law as joint-stock companies or non-profit-making foundations and must be licensed by the Health Care Board. Hospitals have service-related and diagnosis-related group (DRG)-based contracts with the Estonian Health Insurance Fund (EHIF), which are being reviewed on an annual basis.

The most relevant players in the Estonian pharmaceutical system are the Ministry of Social Affairs (SM) (responsible for the strategic planning in terms of pharmaceuticals, as well as pricing and reimbursement decisions), the State Agency of Medicines (SAM) (the supervising body under the Ministry of Social Affairs (SM), responsible for the issuing of marketing authorisations,

as well as classification of pharmaceuticals and pharmacovigilance. The State Agency of Medicines (SAM) also acts as a supervising body in the pharmaceutical field and advises the Ministry of Social Affairs (SM) on the process of reimbursement) and the Estonian Health Insurance Fund (EHIF) (responsible for the reimbursement of pharmaceuticals in practice. The sickness fund EHIF also acts as an advisory body to the SM on the process of reimbursement).

Expenditure for the reimbursement of pharmaceuticals in out-patient care is part of the overall health care expenditure within the budget of the Estonian Health Insurance Fund (EHIF) and may not exceed 20% of health care expenditure according to the present Health Insurance Act (since October, 2002). Pharmaceuticals for in-patient care are fully reimbursed for patients, through the health care services.

The expenditure for tuberculosis (TBC), Anti-Retrovirus (ARV) treatment and certain vaccinations is covered separately, through the common state budget. These pharmaceuticals are procured by the Ministry of Social Affairs (SM) and reach the patients through the hospitals or family doctors. Since 2006, a system of partial reimbursement of the pharmaceutical costs of artificial insemination is in place, covered by the state budget.

There is no research-oriented pharmaceutical industry located in Estonia, but rather representative offices of approximately 18 international innovative producers, as well the representative companies of generics producers. Regarding the distribution of pharmaceuticals at the wholesale level there is a multi-channel system, with 43 companies with a wholesale licence in place. Pharmaceuticals are solely dispensed to the public through privately-owned community pharmacies in Estonia. A total of 80% of the community pharmacies are linked into different pharmacy chains (of which there are four of five altogether). Hospital pharmacies only provide pharmaceuticals for hospital use (in-patient care). The wholesalers and community pharmacies are remunerated via statutory maximum mark ups (cf. 3.5.1 and 3.5.2), and a discounted value-added tax (VAT) of 5% is applied for all pharmaceuticals (standard VAT 18%).

Several measures have been applied for the control of out-patient pharmaceutical expenditure (PE) in Estonia. First, a diagnosis-based reimbursement system of pharmaceuticals (with the current reimbursment categories 100% and 75% (or 90% for “exemption”) (cf. 4.2.2 and Table 4.1) was introduced at the beginning of the 1990s (with minor changes in the year 2002). The “exemption” reimbursement category of 90% is valid for most vulnerable people (patients up to 16 years, disabled and retired patients).

The out-of-pocket payment (OPP) system is rather intricate and combines fixed co-payments, percentage co-payments and deductibles. The fixed co-payments are, e.g., prescription fees of EEK 20 / € 1.28 at the 100% and 75/90% reimbursement levels and EEK 50.- / € 3.20 at the 50% reimbursement level. These prescription fees have not been changed since the mid-1990s and there have been minor changes in the overall percentage out-of-pocket payments (OPP) (90% reimbursement level divided into 75/90% in 2002), cf. 4.4.2.

An important characteristic of the Estonian reimbursement system is that pharmaceuticals are reimbursed on the basis of the positive reimbursement list. The criteria for inclusion of pharmaceuticals in this list also take into account the cost-effectiveness of the product and rational expenditure is a binding rule. The pharmacoeconomic aspects of reimbursement are

constantly assessed according to the Baltic Guidelines on Economic Evaluation of Pharmaceuticals, which were approved by Estonia, Latvia and Lithuania in September 2002.

In Estonia, there is statutory pricing (after the negotiations) for reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals at manufacturer level. The decision on the manufacturer price should be made after the decision on reimbursement, but in reality the process of pricing is incorporated into the procedure of reimbursement. During the price negotiations both external and internal price referencing mechanisms are used.

Estonia established a reference price system in January 2003. The refence price is based on internal price referencing, where the pharmaceuticals are grouped on the basis of different active ingredients (Anatomic Therapeutic Chemical classification ATC-5 level), administration methods and pharmaceutical forms. Parallel traded pharmaceuticals have been incorporated into the reference price system as well.

Although there is no explicit regulation on the (mandatory) use of generics in Estonia (i.e. generic substitution), there are some regulative measures in place, directing doctors and patients towards the use of more generics rather than innovative pharmaceuticals, e.g. doctors are obliged to write the prescriptions generically by using the International Nonproprietary Name (INN) and, in addition to any fixed co-payment or percentage co-payment rates, patients have to pay the difference between the reimbursed amount (calculated from the reference price) and the actual pharmacy retail price (PRP) of the pharmaceutical in question.

Pharmaceutical budgets for doctors have not been applied in Estonia. Treatment guidelines have been created for doctors in many specialities. Following these guidelines is voluntary in most cases.

Advertising and industry behaviour towards health professionals is regulated by the Medicinal Product Act, which is in line with European Commission Directive 2001/83/EC. The State Agency of Medicines (SAM) is the competent institution in charge of supervising pharmaceutical advertising activities.

Advertising of prescription-only medicine(s) (POM) is allowed only to health professionals (i.e. medical practitioners, pharmacists and pharmaceutical assistants). The advertising of over-the-counter (OTC) pharmaceuticals is allowed to the public as well.

The the consumption of reimbursed pharmaceuticals is monitored by the Estonian Health Insurance Fund (EHIF) on a quarterly basis and overall consuption is assessed by the Agency (SAM), also on a quarterly basis.

The current challenges in Estonia are connected with the application of E-prescription, which would make the life of doctors, pharmacists and patients easier and improve the monitoring of overall pharmaceutical consumption.

Estonia has planned to compile a comprehensive Pharmaceutical Policy document during 2007, which would appear as part of the overall health policy document. Changes in the reimbursement system are part of the future challenges.

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List of Tables and Figures

Abbreviations

ARV	Anti-Retrovirus
ADD	Average Daily Dose
ATC	Anatomic Therapeutic Chemical (classification)
DDD	Defined Daily Dose
DG SANCO	(European Commission) Health and Consumer Protection Directorate General
DRG	Diagnosis-Related Group(s)
EC	European Commission
EEK	Estonian Kroons
EGRAL	Estonian Generic Medicines Association
EHIF	Estonian Health Insurance Fund (Haigekassa)
EHRL	Estonian Association of Pharmaceutical Wholesalers
EU	European Union
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health Systems in Transition
HOM	Hospital-Only Medicine(s)
INN	International Nonproprietary Name
IVF	In Vitro Fertilisation
MAH	Marketing authorisation Holder
Mio.	Million
MRP	Mutual Recogniton Procedure
GÖG/ÖBIG	Gesundheit Österreich Gmbh, Geschäftsbereich ÖBIG / Austrian Health Institute

OPP	Out-of-Pocket Payment
OTC	Over-The-Counter (pharmaceuticals)
PC	Pharmaceutical Committee (of the Ministry of Social Affairs)
PE	Pharmaceutical Expenditure
PIL	Patient Information Leaflet
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
RRLE	Association of International Pharmaceutical Manufacturers in Estonia
SAM	State Agency of Medicines (Ravimiamet)
SHI	Social Health Insurance
SM	Ministry of Social Affairs (Sotsiaalministeerium)
SPC	Summary of Product Characteristics
TBC	Tuberculosis
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
TRIPS	Trade-Related Aspects of Intellectual Property Rights
VAT	Value-Added Tax
WHO	World Health Organisation
XEU	European Curreny Unit

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

Estonia is the smallest of the three Baltic countries on the east coast of the Baltic Sea, bordered by the Russian Federation to the east and Latvia to the south. It covers the area of 43,432.31 km[1].

1.1 Demography

Estonia has a current population of 1,344,684 inhabitants (2006)[2], of whom approximately two thirds live in urban areas (69% in 2000). As in the other Baltic countries there is a large Russian minority (28%). Unlike to other former Soviet Union republics, many of the Russian inhabitants came to Estonia after the Second World War. The Russian population is concentrated near the Russian border, especially in the city of Narva. Since 1989, the population of Estonia has decreased by approximately 100,000 people, mostly because of the migration of Russians to the Russian Federation[1].

Table 1.1: Estonia - Demographic indicators 1995, 2000-2006

Variable	1995	2000	2001	2002	2003	2004	2005	2006
Total population	1,448,075	1,372,071	1,366,959	1,361,242	1,356,045	1,351,069	1,347,510	1,344,684
Population density per km^2	33.3	31.6	31.5	31.3	31.2	31.1	31.0	31.0
Population aged 0-14 (as a % of total)	20.9	18.3	17.7	17.2	16.6	16.0	15.4	15.1
Population aged 15-64 (as a % of total)	65.8	66.8	67.0	67.3	67.5	67.8	68.0	68.2
Population aged > 64 (ias a % of total)	13.3	15.0	15.2	15.5	15.9	16.2	16.5	16.7
Life expectancy at birth, total	67.6	70.6	70.4	71.0	71.6	72.0	72.8	n.a.
Life expectancy at birth, females	74.1	76.0	76.2	76.9	76.9	77.8	78.1	n.a.
Life expectancy at birth, males	61.3	65.1	64.6	65.1	66.0	66.3	67.2	n.a.

n.a. = not available

Source: Statistics Estonia 2007

The average current population density is 31.0 inhabitants per km^2, and is higher in urban and lower in rural areas. Administratively Estonia is divided into 15 counties. The counties mostly

[1] HiT Profile Estonia 2004

[2] Statistics Estonia 2007

have a population of 40,000-50,000 people, but one – Harju county, which includes Tallinn – has 521,313 inhabitants (in 2006)[2]. A trend towards the concentration of younger sections of population to the urban areas can currently be observed, mainly because of better professional career possibilities. The population in rural areas is significantly older than in urban areas.

Trends in the life expectancy at birth have mirrored those in the other Baltic republics and the Russian Federation. As in the other Baltic states of the Russian Federation, life expectancy began to improve in 1994. The main causes of death are cardiovascular diseases and various cancers. Alcohol consumption has played a major role as well. Fluctuations have occurred on top of an underlying high prevalence of many chronic diseases, including many cancers and cardiovascular and cerebrovascular disease[1].

1.2 Economic background

Estonia embarked on as series of significant economic reforms at the beginning of the 1990s, and by 1993 the country had succeeded in reversing the declining trend in its gross domestic product (GDP).

The present aim of the economic policy of Estonia is to achieve sustainable, socially and regionally balanced economical growth. The economic policy should support an increase in productivity, with the purpose of decreasing the differences in the levels of development in Estonia compared to other Member States of European Union (EU).

These aims are being fulfilled on the basis of the following economic policy principles:

1. guarantee of the persistence of the system of currency stability
2. following the principle of a balanced budget in the governmental sector;
3. proceeding with liberal commercial policy and providing an advantageous climate for investment[3].

Table 1.2 shows an overview of main economic indicators for Estonia. As can be seen from the data, the economy of Estonia has a tendency towards continuous growth.

[3] Rahandusministeerium 2007

Table 1.2: Estonia - Macroeconomic indicators 1995, 2000-2005

Variable (in EEK or %)	1995	2000	2001	2002	2003	2004	2005
GDP in EEK, Mio.	43,061	95,491	108,218	121,372	132,904	146,694	173,062
GDP in €, Mio.	2,835	6,103	6,916	7,757	8,494	9,375	11,061
GDP per capita in EEK	29,736.7	69,596.3	79,167.0	89,162.7	98,008.6	108,576.3	128,431.0
GDP per capita in PPPa	n.a.	7,798	8,879	9,992	10,992	12,177	14,404
Growth rate from 1995-2000[1]	n.a.	10.8	n.a.	n.a.	n.a.	n.a.	n.a.
Growth rate from 2001-2005[1]	n.a.	n. a.	7.7	8.0	7.1	8.1	10.5
GGE, Mio.	n.a.	35,555	38,786	43,007	46,745	51,512	n.a.
GGE as a % of GDP	n.a.	37.2	35.8	35.4	35.2	35.1	n.a.
Exchange rate (EEK per €), annual rate	15.1888 (XEU)	15.6466	15.6466	15.6466	15.6466	15.6466	15.6466

EEK = Estonian Kroons = National currency unit, GDP = gross domestic product, GGE = general government expenditure, PPPa = purchasing power parity, n.a. = not available, XEU = European Currency Unit

[1] Growth of GDP in %

Sources: Statistics Estonia 2007, Eurostat 2007

1.3 Political context

Estonia is a parliamentary republic. It first gained independence in 1918. In 1940, at the beginning of the Second World War, the country was occupied by the Union of Soviet Socialist Republics (USSR). Independence was restored on 20 August 1991.

The Parliament (*Riigikogu*) consists of one chamber with 101 members. It is elected for a period of four years. Since 1992, when the first elections in independent Estonia were held, all governments have been coalition governments of two or three political parties. Although none of the coalitions has governed for a full term, they have been stable enough to launch and implement economic and social reforms.

Estonian political parties tend to be at the centre or to the extreme right of the political spectrum. To date, governments have been on the right, although social-democratic values and ideology have become more visible in recent years[1]. The latest parliamentary elections were held in March 2007, resulting again in a three-party coalition.

The second political layer in Estonia consists of numerous municipalities, ranging in size from approximately 100 to 100,000 people. The capital city, Tallinn, with its 396,193 inhabitants (as of 1 January 2006), is one of the the largest municipalities. Municipal elections are held every three years. Each county is run by a Governor and an administrative structure known as county government. Both the Governor and the county government staff members are civil servants of the

central administration. However, many state agencies, including those engaged in health care administration and finance, operate not on a county basis but through regional departments that cover two to four counties.

At the beginning of the 1990s, Estonia signed around 30 of the most important United Nations conventions. When joining the World Trade Organisation in 1999, Estonia signed up to the General Agreement on Trade in Services, making commitments relating to trade in medical and dental services as well as health and social services. While no limitations have been put on consumption abroad, cross-border supply and foreign commercial presence come under specific Estonian regulations. In May 2004, after a successful period of negotiations, Estonia joined the European Union (EU)[1].

1.4 Health care system

Since regaining independence in 1991, the Estonian health system has undergone two major shifts: first, from a centralised, state-controlled system to a decentralised one, and second, from a system funded by the state budget to one funded through social health insurance (SHI) contributions. At the same time, there has been a growing emphasis on primary care and public health[1].

1.4.1 Organisation

The restructuring of the health system has taken place in several phases. The beginning of 1990s saw the introduction of a social health insurance (SHI) system operated through the Central Sickness Fund and 22 regional sickness funds. In 1994, responsibility for planning health services was partially decentralised to the county level through the 15 county Governors and the county doctors. The current organisational and management principles were established between 1999 and 2002 by acts of the Parliament intended to re-centralise some health system functions.

The main bodies responsible for planning, administration, regulation and financing in Estonia are the Ministry of Social Affairs (Sotsiaalministeerium, SM), the Health Care Board, the State Agency of Medicines (Ravimiamet, SAM), the Health Protection Inspectorate and the Estonian Health Insurance Fund (Haigekasse, EHIF).

Towards the end of 1990s, some main trends in decentralisation could be seen. First, the responsibility for overall health care planning was firmly re-established at the national level under the control of Ministry of Social Affairs (SM). County- and municipal-level responsibilities for planning and administering health services were reduced. Second, organisations such as the Estonian Health Insurance Fund (EHIF) and the Health Protection Inspectorate, which used to have representation in each county, centralised these offices so that they now cover several counties. These changes aimed to improve efficiency in the use of qualified personnel and the level of administration costs. In the case of the Estonian Health Insurance Fund (EHIF), increased centralisation has strengthened its purchasing function, optimised its administrative capacity and enabled the employment of full-time health economists and lawyers in the new regional offices, which was not possible previously. Third, increased rights and obligations have

been delegated to managers at the Estonian Health Insurance Fund (EHIF) and at the provider level. Health care providers now have legal status as private entities operating under private law, which means direct responsibility for provider performance has been delegated by the Ministry of Social Affairs (SM) and the municipalities to the hospital supervisory boards. In the case of primary care, the process of privatisation began in 1998 and was completed in 2002.

Since 2001 the Estonian Health Insurance Fund (EHIF) is the public independent legal body responsible for health insurance. It operates through four regional branches, each covering two to six counties and its main responsibilities include pooling funds and paying for health care (including pharmaceuticals) and for some sick leave and maternity benefits. Entitlement to Estonian Health Insurance Fund (EHIF) coverage is based on residence in Estonia and membership of specific groups, defined by law. Those covered by the Estonian Health Insurance Fund (EHIF) fall into four main categories: those who make their own contributions, those who are covered by contributions from the State, those who are eligible for coverage without contributing and those who are covered on the basis of international agreements. There is no possibility of opting out. The only group excluded from coverage is the prison population, whose health care is organised and paid for by the Ministry of Justice. Since the end of 2002, some groups who were not previously covered have been able to obtain coverage on a voluntary basis[1].

Employees and self-employed people make contributions to the Estonian Health Insurance Fund (EHIF) via an earmarked payroll tax collected by the Taxation Agency. This tax is known as the social tax and covers both health and pension contributions (equal to 13% and 20% of employee wages and of self-employed individuals' earnings, respectively). In practice, employers actually make contributions on behalf of employees. The Taxation Agency transfers the health part of the social tax to the Estonian Health Insurance Fund (EHIF).

Specific groups are covered by contributions from the state budget, including individuals on parental leave with small children, registered unemployed people (eligible for cover for up to nine months) and those caring for disabled people. Other groups, including children, retired people, those receiving a disability pension and students, are eligible for cover without any contribution, from either themselves or the State.

People are covered regionally, on the basis of where they live and use health services[1].

1.4.2 Funding

Health care in Estonia is largely publicly financed. Since 1992, earmarked payroll tax has been the main source of health care financing, accounting for approximately 76% of total expenditure on health care in recent years. Other public sources of health care financing include state and municipal budgets, accounting for approximately 8% and 2% of the total health expenditure (THE), respectively. The public share of health care spending has declined since 1998.

In Estonia, approximately 95% of the 1.34 Mio. inhabitants are covered by statutory health insurance. Only a small part of the population (approximately 3%) is covered by private health insurance.

Out-of-pocket payments (OPP) (not including private health insurance) have grown steadily since the mid-1990s and are mostly spent on pharmaceuticals and dental care. Private health insurance mainly consists of travel insurance. External sources of health care financing play a minor role in Estonia[1].

The changes applied have been set out in the following laws:

- Law of Obligations Act (2001)[4]
- Health Services Organisation Act (2001)[5]
- Health Insurance Act (2002)[6]
- Medicinal Product Act (2005)[7].

As can be seen from the data presented in Table 1.3, total health expenditure (THE) has grown steadily since 2000, and even the percentage of THE in terms of gross domestic product (GDP) has remained the same. Total health expenditure (THE) per capita has grown as well. Public health expenditure (HE) equals approximately three quarters of the total health expenditure (THE), with one third for private health expenditure (HE).

Table 1.3: Estonia - Health expenditure (HE) 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE in EEK, Mio.	n.a.	5,145.5	5,353.8	5,958.8	6,812.2	7,782.7	n.a.
THE in €, Mio.	n.a.	328.86	342.17	380.84	435.38	497.41	n.a.
THE as a % of GDP	n.a.	5.4	5.0	4.9	5.1	4.5	n.a.
THE per capita in EEK	n.a.	3,750	3,917	4,378	5,024	5,760	n.a.
THE per capita in €	n.a.	240	250	280	321	368	n.a.
Public HE as a % of THE	n.a.	76.4	77.8	76.3	77.0	75.5	n.a.
Private HE as a % of THE	n.a.	23.3	22.2	23.7	22.9	24.0	n.a.

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, EEK = national currency unit (NCU) (Estonian Kroons)

Source: Estonian Health Statistics Yearbook 2004

1.4.3 Access to health care

The 1995 Public Health Act introduced the reform of the sanitary-epidemiological public health system from the Soviet era and established the current framework for the financing and provision of public health services in Estonia.

[4] www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X30085K2&keel=en&pg=1&ptyyp=AT&tyyp=X&query=08

[5] https://www.riigiteataja.ee/ert/act.jsp?id=12766722

[6] http://www.legaltext.ee/failid/findfile.asp?filename=X60043

[7] http://www.sam.ee/orb.aw/class=file/action=preview/id=5118/EstonianAct-10May2005.doc

1.4.3.1 Out-patient care

The Health Services Organisation Act from 2002 sets out the regulatory framework for out-patient care. Out-patient care is organised as the first level of contact with the health care system. It is provided by independent family doctors contracted by the Estonian Health Insurance Fund (EHIF). Although family doctors are allowed to work without a contract, there are few reasons for them to operate on a purely private basis: most patients have rapid access to Estonian Health Insurance Fund (EHIF)-contracted family doctors and few patients are willing to pay for out-patient care. The abbreviation of GP (general practitioner) has not been used to refer to the family doctor, as there are also registered general practitioners (GPs) in Estonia, not acting as family doctors (cf. Table 1.4).

Each family doctor has a list of registered patients. These lists cannot contain less than 1,200 or more than 2,000 patients (except some specific cases, e.g. occuring in some rural areas or on some islands). The average size of a patient list is 1,600. Patients can change their family doctor at any time, if they can find a new family doctor to list them.

Family doctors usually operate in rented premises (sometimes in facilities which used to be polyclinics), although some doctors have taken out loans to build new facilities[1].

The main services provided by family doctors include diagnostic procedures, treatment of general illnesses, health counselling, health promotion and disease prevention. Family doctors control most access to specialist care. Patients need a family doctor's referral in order to see most specialists and to be admitted as a non-emergency patient. Patients have to pay out of pocket for any visits to specialists made without referral from their family doctor. However, patients are able to access the following specialists directly, without a family doctor's referral: ophthalmologist, dermatoveneorologist, gynaecologist, psychiatrist, dentist and, in case of trauma, traumatologist and surgeon.

As of 2003, every family doctor has a contract with the Estonian Health Insurance Fund (EHIF). The contents of the basic contract are agreed by the Estonian Health Insurance Fund (EHIF) and the Estonian Association of Family Doctors. The contracts with family doctors are concluded on an individual or group basis for every calendar year. The financial part of the contract is revised twice a year based on changes in the patient list.

The model of out-patient care organised around out-patient pharmaceuticals is supported by the way in which family doctors are paid: a combination of a basic monthly allowance, a capitation fee per registered patient per month, some fee-for-service payments and additional payments based on distance to the nearest hospital, etc. The system of payment is designed to provide family doctors with incentives to take more responsibility for diagnostic services and treatment, as well as to compensate them for the financial risks associated with caring for older patients and working in remote areas.

The out-of-pocket payment (OPP) of up to EEK 50 / € 3.20 for home visits and direct payments for certificates and documentation for driving licences have been applied in the field of out-patient care. In out-patient specialist care, with a family doctor's referral the out-of-pocket payment (OPP) for one visit is up to EEK 50 / € 3.20. Children under two years and pregnant women from the 12th week of pregnancy are exempt from all out-of-pocket payments (OPP)[1].

*Table 1.4: Estonia - Out-patient care 1995, 2000, 2002, 2004 and 2005**

Variable	1995	2000	2002	2004	2005
Total no. of doctors[1]	4,832	4,233	4,268	4,312	n.a.
No. of doctors per 1,000 inhabitants[1]	3.34	3.09	3.14	3.19	n.a.
Total no. of out-patient doctors[2]	2,922	2,187	2,131	2,138	n.a.
of which GPs	104	448	701	818	n.a.
No. of out-patient doctors per 1,000 inhabitants[2]	2.02	1.59	1.57	1.58	n.a.
No. of out-patient clinic departments ("ambulatories")[3]	300	540	625	715	n.a.
Total no. of dentists	929	1,041	1,078	1,166	n.a.
Dental care institutions[4]	181	364	384	443	n.a.

[1] Dentists are not included

[2] Including GPs not acting as family doctors as well

[3] No. of general and special care departments

[4] No. of independent dental care institutions

* = all by the end of the year, n.a. = not available, GP = general practitioner

Source: Estonian Health Statistics Yearbook 2004

1.4.3.2 In-patient care

All hospitals operate under private law as joint-stock companies or non-profit-making foundations and must be licensed by the Health Care Board. The licences are being issued by Health Care Board on the basis of minimum standards for hospitals and are valid for five years (cf. Table 1.5).

The following types of hospital provide acute care:

- two regional hospitals (secondary and tertiary care), each serving an area with approximately 500,000 people;
- four central hospitals (some tertiary but mainly secondary care), each serving an area with approximately 200,000 people;
- general or local hospitals in almost every other remaining county – based on population size, these are either general hospitals, offering services in internal medicine, surgery, paediatrics and obstetrics, or local hospitals offering only treatment services for internal diseases.

In addition, there are few hospitals offering specific specialities. The hospital network was planned according to certain criteria including population size and distance[1].

Most hospitals are owned by municipal governments, although regional hospitals have been founded by the State. Private hospitals exist, providing only services in specifc fields, e.g. gynaecology, obstetrics and cardiology, with one exception, providing internal medicine and general surgery services.

Hospitals have considerable autonomy in making decisions about renovation, employment, staff salaries and obtaining loans from financial institutions. Hospitals can generate income by renting out space to private enterprises. Liability in the event of payment default follows the general regulations of commercial law and the law governing foundations.

*Table 1.5: Estonia - In-patient care 1995, 2000, 2002, 2004 and 2005**

Variable	1995	2000	2002	2004	2005
No. of in-patient doctors	1,910	2,046	2,137	2,174	n.a.
No. of in-patient doctors per 1,000 inhabitants	1.32	1.49	1.57	1.61	n.a.
No. of hospitals	83	68	51	51	n.a.
Total no. of hospital beds[1]	11,994	9,828	8,248	7,850	n.a.
of which in private sector	219	954	876	794	n.a.
No. of acute care beds	9,528	7,600	6,118	5,750	n.a.
No. of hospital beds per 1,000 inhabitants[1]	8.28	7.16	6.06	5.81	n.a.
Acute care beds per 1,000 inhabitants	6.58	5.54	4.49	4.26	n.a.
Average length of stay in hospital[2]	12.7	9.2	8.5	6.9[3]	n.a.

* = all by the end of the year, n.a. = not available

[1] Acute and long term care, respectively

[2] For all hospital beds

[3] Owing to a change in the calculation formula, 2004 is not comparable with previous years

Source: Estonian Health Statistics Yearbook 2004

The out-of-pocket payment (OPP) for in-patient care is approximately up to EEK 25 / € 1.60 per hospital day, for up to a maximum 10 days per episode of illness. Special payments have been established by providers for above-standard accommodation (private rooms, television, etc). There are also some set out-of-pocket payments (OPP) for specific services, on the basis of a price list:

- voluntary termination of pregnancy: 30%
- rehabilitation (per day): 20%
- medical devices: 10%
- in vitro fertilisation (IVF) treatment: 0-30%.

The hospitals have service- and diagnosis-related group (DRG)-based contracts with the Estonian Health Insurance Fund (EHIF), which are being reviewed on an annual basis. The hospitals are paid by the Estonian Health Insurance Fund (EHIF) on the basis of services provided. Doctors are essentially the employees of the hospitals[1].

2 Pharmaceutical system

The most relevant players in the Estonian pharmaceutical system are listed here.

- The Ministry of Social Affairs (SM), responsible for strategic planning in terms of pharmaceuticals and also in charge of pricing and reimbursement decisions and public procurement of Anti-Retrovirus (ARV) and tuberculosis (TBC) pharmaceuticals and vaccines.
- The State Agency of Medicines (SAM), under the Ministry of Social Affairs (SM), responsible for issuing market authorisations as well as classification of pharmaceuticals and pharmacovigilance. The State Agency of Medicines (SAM) also acts as a supervising body in the pharmaceutical field in Estonia and advises Ministry of Social Affairs (SM) on the process of reimbursement.
- The Estonian Health Insurance Fund (EHIF), responsible for the reimbursement of pharmaceuticals in practice and supervising in the field of reimbursement. The Estonian Health Insurance Fund (EHIF) also acts as an advisory body to Ministry of Social Affairs (SM) on the process of reimbursement[8].

The procedures of granting market authorisations and reimbursement/pricing decisions of pharmaceuticals in Estonia are in line with the relevant European Union (EU) regulations.

Pharmaceutical companies need to include certain information in their applications for market authorisations, to prove the quality, safety and efficacy of their pharmaceuticals. If all requirements for market authorisations are fulfilled, the State Agency of Medicines (SAM) issues the marketing authorisation, deciding the classification of the pharmaceuticals as either prescription-only medicine(s) (POM) or over-the-counter (OTC) products at the same time[7].

After the granting of the marketing authorisation, pharmaceutical companies have the possibility to apply to the SM for reimbursement of the new products. In this process the companies need to prove the cost-effictiveness of the pharmaceutical. The Agency (SAM) and the Estonian Health Insurance Fund (EHIF) will give their expert opinions to the Ministry of Social Affairs (SM) about the application for reimbursement of the pharmaceutical. The Pharmaceutical Committee (PC), working within the SM, will then make its advisory decision about the reimbursement and pricing of the pharmaceutical, whereby the final decision on reimbursement eligibility is then taken by the SM.[9]

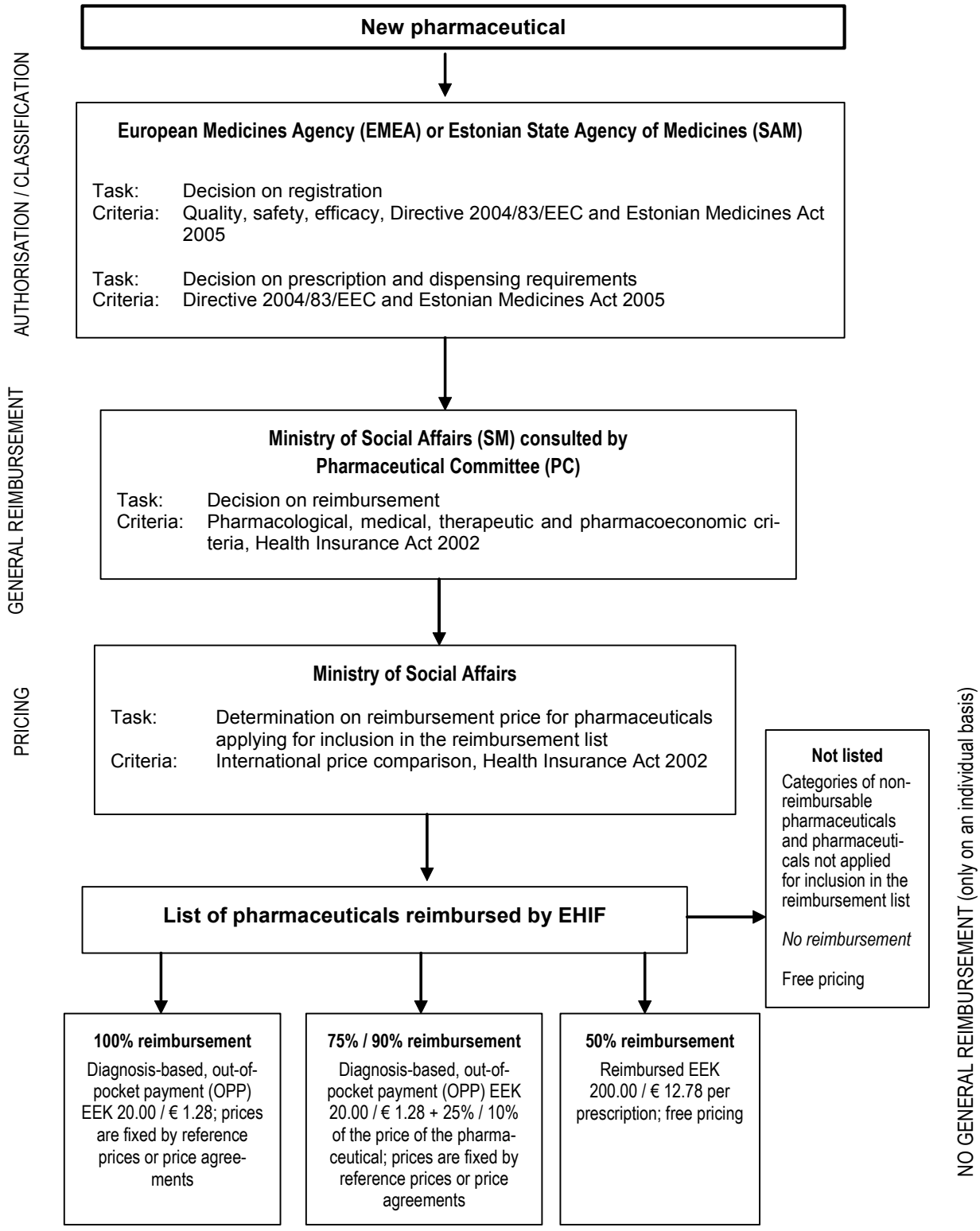
2.1 Organisation

Figure 2.1 shows the basis of the organisation of the pharmaceutical system in Estonia.

[8] www.sm.ee → Tervishoid → Ravimid

[9] www.sm.ee/eng/HtmlPages/HaigekassaravimiteloeteluEN_ok_ED_C1/$file/Haigekassa%20ravimite%20loetelu%20EN_ok_ED_C1.doc

Figure 2.1: Estonia - Flowchart of the pharmaceutical system



Source: www.sm.ee → Tervishoid → Ravimid

2.1.1 Regulatory framework

The regulatory framework in the pharmaceutical sector is based on the Medicinal Product Act (last amended in 2005)[7] and the Health Insurance Act of 2002[6], with the main stakeholders being the Ministry of Social Affairs (SM), the State Agency of Medicines (SAM) and the Estonian Health Insurance Fund (EHIF).

2.1.1.1 Policy and legislation

The main laws in the pharmaceutical sector are listed here.

1. Medicinal Product Act 2005[7]

Several enactments and regulations (more than 40) according to the Medicinal Product Act, regulating different practical fields on the quality and safety of pharmaceuticals.

2. Health Insurance Act 2002[6]

Several enactments and regulations (eight) according to the Medicinal Product Act, regulating different practical fields on the reimbursement and pricing of pharmaceuticals.

At the time of writing, Estonia is elaborating a comprehensive policy document in the health field. This includes a section on pharmaceutical policy (the ensurance of quality, efficay, safety, availability and rational use of pharmaceuticals).

In 2002 a draft pharmaceutical policy document was created, containing the basic principles of overall pharmaceutical policy – ensuring the quality, efficacy, safety, availability and rational use of pharmaceuticals. Estonia plans to complete this draft during 2007 and create the finalised Pharmaceutical Policy Document.

2.1.1.2 Authorities

The procedure on the application for market authorisations of pharmaceuticals is based on the Medicinal Product Act[7] and according ministerial regulations (the main authorities in the pharmaceutical system are described in Table 2.1).

Dealing with market authorisations is the duty of the State Agency of Medicines (SAM) and basicly only the SAM and the marketing authorisation holders (MAH) are involved in this process. A Committee on the issue of marketing authorisations of pharmaceuticals in SAM has been created as an advisory body for the Agency's (SAM) Director General. The Committee consists of university professors in the medical field and some SAM employees.

The quality, efficacy and safety of the pharmaceutical are evaluated during the process of the issue of marketing authorisationby the State Agency of Medicines (SAM), according to the application and accompanying documentation presented. The product of this work is evaluated by the advisory committee mentioned above and the decision is made. The Agency's Director General makes the final decision, based on the decision of the Committee. During the process of marketing authorisation the classification of the product as a Prescription (POM) or non-prescription medicine (OTC) is also evaluated and decided on. Alongside these duties the post-

marketing surveillance of the safety of pharmaceuticals also falls within the tasks of the State Agency of Medicines (SAM).

The duration of the process for the decisions on marketing authorisations by the Agency (SAM) corresponds to the time frame set by the relevant EU legislation: 210 days for the national procedure; 120 days for the decentralised procedure; 90 days for MRP (Mutual Recognition Procedure) applications; and 1-3 months for changes to marketing authorisations (Note: this does not include the time necessary for applicants to respond to potential SAM questions, i.e. clock-stop procedure). There is no possibility to shorten these periods.

There is no decision or negotiation on the price of the pharmaceuticals involved in the marketing authorisationprocess, nor does reimbursement of the pharmaceuticals automatically follow after the receiving market authorisation.

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

Estonian Name	Name in English (Abbreviation)	Description	Responsibility
Sotsiaalministeerium	Ministry of Social Affairs (SM)	Regulatory body	Overall planning and legislative authority In charge of the reimbursement legislation/decision, price decision and public procurement of certain pharmaceuticals
Ravimiamet	State Agency of Medicines (SAM)	Medicines agency (subordinate to the SM)	In charge of market authorisation; classification, vigilance and supervision in the fields of distribution; licensing of manufacturers, wholesale companies and pharmacies; and supervising the pharmaceutical market in Estonia
Eesti Haigekassa	Estonian Health Insurance Fund (EHIF)	Public independent body	Basic financing of the health care system, reimbursement, supervising reimbursement issues in Estonia
Tervishoiuamet	Health Care Board	Supervisory body (subordinate to the SM)	Supervising the quality of health services in Estonia, licensing of hospitals, registering of doctors and pharmacists
Tervisekaitseinspektsioon	Health Protection Inspectorate	Supervisory body (subordinate to the SM)	Sanitary-epidemiological supervision in Estonia

Source: SM 2007

Since November 2002 companies have to apply for reimbursement to the Ministry of Social Affairs (SM) (explicitly the Pharmaceutical Policy Unit, created in August 2002 as a Department of Pharmaceutical Policy – a new entity in the Ministry of Social Affairs (SM)).

Applicants have to provide information on the efficacy and safety of the product, price information and prognosis, and pharmacoeconomic analysis. The State Agency of Medicines (SAM) and the Estonian Health Insurance Fund (EHIF) give their expert opinions on the pharmaceutical; the SAM from the point of view of efficacy and safety and the EHIF from a pharmacoeconomic point of view. Once the expert opinions have been collected, the Pharmaceutical Commitee (PC), advisory body for the SM, working under the auspices of the

Ministry, discusses the application and gives an advisory positive or negative decision on the reimbursement and, in the case of positive decisions, an acceptable price level of the pharmaceutical (as a basis for the price negotiations). After this, the SM makes the decision on the solution of application, and starts the price negotiations with the company representatives. The PC, as mentioned above, consists of representatives of the SAM, the EHIF, specialists, family doctors and two patient organisations. The Head of the Pharmaceutical Policy Unit is in charge, leading the Pharmaceutical Commitee (PC).

This process takes around 180 days for applications for the reimbursement of innovative molecules. For generics, following innovative pharmaceuticals, the procedure has been simplified and shortened to 90 days and does not usually need the decision of the PC. Similarly to the marketing authorisationprocedure, these time scales do not include the period necessary for the applicant to answer questions or supplement the documentation. The period of 180 days for the solution of reimbursement applications for new molecules has been set according to the European Commisson (EC) Transparency Directive[9]. There is no possibility to shorten these periods in Estonia.

With the purpose of achieving better transparency, a full database on the applications and their solutions has been generated on the web site of Ministry of Social Affairs (SM), and is being renewed on a regular basis[10]. All the agendas and protocols about the meetings of the Pharmaceutical Commitee (PC) are also available on the web site of Ministry of Social Affairs (SM).[11]

2.1.2 Pharmaceutical market

This section describes the availability of pharmaceuticals in Estonia and the main players in the pharmaceutical market.

2.1.2.1 Availability of pharmaceuticals

The basic difference between the pharmaceutical market structure in 1995 and at the time of writing is that nowadays there are a low number of “inexpensive” pharmaceuticals being imported from the Russian Federation and other Eastern countries. These pharmaceuticals received their market authorisations during a transitional phase in the 1990s, when the Agency (SAM) was still elaborating their procedures for marketing authorisationand specifying the requirements. Most of these market authorisations have ended and have not been renewed or have been stopped due to of absence of necessary documentation. The number of Russian and other Eastern countries pharmaceuticals has been decreasing continuously since 1995.

It is common that some pharmaceuticals, despite having market authorisations, are not available on the market. This is usually caused by the marketing strategy of the international pharmaceutical company concerned.

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10 www.sm.ee/est/HtmlPages/Menetletavadtaotlusedseisuga1/$file/Menetletavad%20taotlused%20seisuga%204.5.2007.xls

11 www.sm.ee/est/pages/goproweb1644

The classification of pharmaceuticals as prescription-only medicine(s) (POM) or over-the-counter (OTC) products is decided by State Agency of Medicines (SAM), on the basis of the safety data of the pharmaceutical. The decision is made during the issue of market authorisation. The classification may be changed by SAM during the time that the marketing authorisationis valid, if new data on the safety of the pharmaceutical become available.

There is no official classification on out-patient and hospital-only medicine(s) (HOM). The product is commonly regarded as a hospital-only medicine(s) (HOM) if the patient is not able to administer it by her/himself and/or if the pharmaceutical is mainly used in in-patient care.

*Table 2.2: Estonia - Number of pharmaceuticals 1995, 2000-2006**

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006[1]
Authorised[2]	n.a.	2,565	2,744	2,906	2,978	2,768	2,907	2,925
On the market[3]	n.a.	4,902	4,301	4,239	4,366	4,303	4,078	n.a.
POM[2]	n.a.	2,305	2,440	2,533	2,488	2,275	2,441	2,465
Reimbursable[3]	n.a.	n.a.	n.a.	2,993	2,972	2,972	2,769	2,289
Generics[4]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	886
Parallel traded[5]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only[5]	n. app.	n. app.	n. app.	n. app.	n. app.	n. app.	n. app.	n. app.

POM = prescription-only medicine(s), * = by 31 December, n.app. = not applicable, n.a. = not available

[1] as of September 2006

[2] including different active substances, strengths and pharmaceutical forms, excluding different pack sizes; includes all valid market authorisations for human pharmaceuticals

[3] including different active substances, strengths, pharmaceutical forms and pack sizes

[4] have not been differentiated in the lists officially during 1995-2005, only estimated values could be given

[5] have not been differentiated from the other pharmaceuticals

Sources: SAM 2007; State Gazette 2007

In Estonia, pharmaceutical products are reimbursed on the basis of the positive list for reimbursement. This list contains all the pharmaceuticals, pharmaceutical forms, dosages and pack sizes reimbursed. The list is amended and supplemented on the basis of applications for reimbursement from the representatives of marketing authorisation holders (MAH)[9].

Some pharmaceuticals, though there are no official criteria for these selection published, will under no ciircumstance qualify for the positive list; examples are hospital-only medicine(s) (HOM) and some lifestyle pharmaceuticals.

2.1.2.2 Market data

According to the data in Table 2.3 the pharmaceutical market has grown remarkably during recent years. In 2005 sales at pharmacy retail level amounted to EEK 2,314 Mio. / € 148 Mio. The number of prescriptions of reimbursable pharmaceuticals (5 Mio.) reached is peak in the year 2005.

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

Pharmaceutical industry in Mio. EEK / €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume in 1,000[1]	n.a.	3,454	3,933	2,092	4,013	4,775	5,000
No. of annual prescriptions by value, Mio. EEK	n.a.	763	929	1,033	1,186	1,471	1,536
Number of annual prescriptions by value, Mio. €	n. a.	48.8	59.4	66.0	75.8	94.0	98.2
Pharmaceutical sales							
Sales at ex-factory price level in Mio. EEK	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at wholesale price level in Mio. EEK	n.a.	1,126	1,297	1,473	1,595	1,920	2,012
Sales at wholesale price level in Mio. €	n.a.	72.0	82.9	94.1	101.9	122.7	128.6
Sales at PRP level in Mio. EEK	410	1,350	1,450	1,581	1,819	2,172	2,314
Sales at PRP level in Mio. €	27.0	86.3	92.7	101.0	116.3	138.8	148.0
Sales to hospitals in Mio. EEK	n.a.	187	215	248	280	346	365
Sales to hospitals in Mio. €	n.a.	12.0	13.7	15.9	17.9	22.1	23.3
Sales of generics[2] in Mio. EEK	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals in Mio. EEK[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports							
Total pharmaceutical exports[3]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical imports[3]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

EEK = national currency unit (NCU) (Estonian Kroons), PRP = pharmacy retail price, n.a. = not available

[1] number of reimbursed prescriptions

[2] have not been differentiated

[3] the sales statistics available describe the sales in Estonia only

Source: www.sam.ee/www.haigekassa.ee/Sisukord/Statistika

Table 2.4 shows the 10 most sold pharmaceuticals by active ingredient in Estonia.

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

Position	Pharmaceutical, by active ingredient
1	Metoprololum/Acetylsalicylic acid
2	Fosinoprilum/Ramiprilum
3	Ramiprilum/Gestodenum+ethinyloestradiolum
4	Amlodipinum/Ascorbic acid
5	Enalaprilum+hydrochlorothiazidum/Amlodipinum
6	Isosorbidi mononitras/Enalaprilum+hydrochlorothiazidum
7	Lacidipinum/Enalaprilum
8	Testosteronum/Ibuprofenum
9	Citalopramum/Metoprololum
10	Insulinum aspart/Isosorbidi mononitras

* Data given according to value/defined daily dose (DDD)/1,000 inhabitants per day)

Source: IMS Datawiew 2006

2.1.2.3 Patents and data protection

The issues regarding patents and data protection are regulated according to the Patent Act[12] in Estonia, valid from 1999.

Patent protection legislation in Estonia is harmonised according to the European Patent Convention and ensures market protection for the original pharmaceutical for 20 years. Under European Union (EU) legislation there is the possibility of an extension for five more years under a Supplementary Protection Certificate.

Under the recently adopted EU legislation, the authorities are also obliged to provide data protection for an 8+2+1-year period. This provides for an additional protection period for patented pharmaceuticals. Only after eight years can the State Agency of Medicines (SAM) process applications for generic pharmaceuticals under the EC Bolar amendment, which can then the marketed when the 10-year data protection ends (provided that by that time the patent has also expired). The authorities may provide for an additional year of data protection (and therewith delay generic market entry) for additional innovative indications (e.g. for paediatric indications)[7].

No explicit provisions for parallel import and “government use” of patented products have been applied within the national legislation. There is a valid regulation about compulsory licencing in the Estonian Patent Act, according to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

At the time of writing there are some pending court cases in relation to pharmaceutical patent protection, the most recent ones being Fosamax® and generic alendronate. The cases of “ever greening” of patents in Estonia are notable, e.g. Rispolept Consta injection®, the sustained-

[12] https://www.riigiteataja.ee/ert/act.jsp?id=12791328

released injectable form of risperidon, and Fosavance®, the alendronate in combination with vitamin D.

2.1.3 Market players

The main market players, which also influence pharmaceutical policy-making in Estonia are the representatives of international pharmaceutical companies and their associations; wholesalers and their associations; pharmacists and their associations; and prescribers and their associations.

2.1.3.1 Industry

During the Soviet era there was one manufacturing pharmaceutical plant in Estonia – Tallinn Pharmaceutical Factory – producing different generic tablet forms, injections and ointments (the most famous are Viprosal and Viprosal B ointments from the venom of vipers, used against rheumatic pain). This is no longer an independent enterprise – it merged with Latvian company Grindex in the early 2000s. The production of tablets and injections has been transferred to Latvia and now only the ointments are being prepared in Estonia.

Besides the Tallinn Pharmaceutical Factory there are some generics companies dealing with the packing operations of tablet forms (Nycomed SEFA AS, etc.). Most of these are not of Estonian origin. There is also one company in Estonia producing some galenic pharmaceutical forms (Galenos OÜ).

So there is no direct research-oriented industry presence in Estonia. There are only the representative offices of many international innovative producers of pharmaceuticals. These producers have formed their own interest association in Estonia as well (Association of International Pharmaceutical Manufacturers in Estonia, RRLE). There are also some representatives of foreign companies in terms of generics producers. The producers of generics have formed their own interest association as well (Estonian Generic Medicines Association, EGRAL). The field of biotechnology is continuously growing in Estonia; there are no exact data on the number of existing factories, but there may be approximately 10-15 small producing units working alongside different departments of hospitals, depending on the need for the specific products they produce. There are no producers of raw materials of pharmaceuticals in Estonia.

The manufacturers usually distribute their pharmaceuticals through the bigger wholesalers in Estonia, but some of them have created their own wholesale outlet as a separate company from their representative office or manufacturing plant, in some cases with the possibility of distribution directly to the pharmacies as well.

As there are very few manufacturing companies in Estonia, it should be mentioned that the presence of industry on the economy, on production and when considering the pharamceutical industry as an employer in Estonia is minor, having a only a local effect. The relevance of local manufacturers versus international pharmaceutical companies is very low.

The industry is not directly involved in the process of pricing and reimbursement of pharmaceuticals, but they have, of course, the possibility to influence the policy-makers, basicly through lobbying.

Table 2.5: Estonia - Key data on the pharmaceutical industry 1995-200

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	8	8	8	6	6	6	6
- research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generics producers	8	8	8	6	6	6	6
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of persons employed	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Source: SAM 2007

2.1.3.2 Wholesalers

In terms of pharmaceutical wholesale in Estonia there is a multi-channel system in place with 54 companies with a wholesale licence. The largest wholesaler is Magnum Medical AS, covering more than 25% of the market. Other important wholesale companies in Estonia are Tamro Eesti OÜ, TopMed AS, Oriola AS, Pharmac MS AS and Nordic Pharma Eesti OÜ (cf. Table 2.6 for details). They are organised in the Estonian Association of Pharmaceutical Wholesalers (EHRL). Through the association the wholesalers are continuously trying to influence the activities of policy-makers in Estonia, mainly dealing with proposals about changes to legislative acts.

Most of the wholesale companies are under non-Estonian ownership (Magnum Medical AS - Sweden, Tamro Eesti OÜ and Oriola AS - Finland). The number of staff employed varies, depending on the size of the companies; smaller companies may have couple of employees, while bigger companies may have more than a hundred.

Regarding information on the logistics of pharmaceutical wholesale in Estonia: all the wholesalers mentioned above are “full” wholesalers, with most having (almost) the full necessary assortment of pharmaceuticals in stock. Deliveries are mostly organised during the day the pharmaceuticals are ordered, or at least during the next day. There are also some companies with a wholesale licence that have no stock or distribution rights to the pharmacies.

Table 2.6: Estonia - Key data on pharmaceutical wholesale 1995-2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	46	43	44	45	45	46	54
Total no. of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] as of 1 January

Source: SAM 2007

2.1.3.3 Pharmaceutical outlets / retailers

The dispensing of pharmaceuticals to patients is allowed through the community pharmacies, veterinary pharmacies and their branches only. A branch pharmacy is a structural unit of a pharmacy. One pharmacy may have up to three branch pharmacies, where both prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals may be dispensed.

There may also be a couple of OTC dispensaries (as a specific type of community branch pharmacy), left over from the period of previous legislation before Estonia joined the European Union. During the renewal of their pharmacy activity licence, they must be reorganised into normal branch pharmacies or otherwise stop their activity.

Only pharmaceuticals with a valid marketing authorisationmay be dispensed by a pharmacy, or those for which an authorisation for the import and use has been granted by the State Agency of Medicines (SAM), and the pharmaceuticals have been prepared as magistral formulae or officinal formulae and divided up into packs by the same pharmacy.

A pharmacy is permitted to sell, in addition to pharmaceuticals, further products for medicinal purposes, as well as toiletries, if this does not interfere with the sale of pharmaceuticals[7].

2.1.3.3.1 Pharmacies

The activities of pharmacies are governed by the Medicinal Product Act[7] and according to governmental and ministerial regulations. Most of the community pharmacies are privately owned; only few of them are under public ownership (two pharmacies). If the owner of the pharmacy is a legal entity, there are no valid restrictions regarding the number of pharmacies owned. Approximately 80% of pharmacies have been collected into different chains (4-5 chains altogether), as pharmacies of one chain working under same legal entity (cf. Table 2.7).

A wholesaler cannot act as a pharmacy, but its subsidiary company can: e.g., Tamro, as a wholesaler, cannot also be a pharmacy licence holder, but Tamro owns pharmacy shares and may open other subsidiary companies (under other names) working in the pharmacy field and holding general pharmacy licences. In Estonia, pharmacy licences are issued to pharmacy keepers, not to pharmacists themselves. It is therefore impossible to know who the shareholders are (shareholder companies can also be registered abroad, everywhere in the world).

So, the pharmacies of Magnum Medical AS, Tamro Eesti OÜ, etc. do exist, even though the companies and owners registered according to the public are different. In reality more than 80% of pharmacies are under the influence of wholesaling companies. Vertical integration of wholesalers and pharmacies is present in reality, even this is not strictly allowed according to the valid legal acts.

The biggest share of pharmaceuticals consumed are dispensed in pharmacies, as the other kinds of dispensing, i.e. through dispensing doctors, hospital pharmacies acting as community pharmacies and distance selling (via mail order or Internet) are not allowed and the other possibility for receiving the necessary medication is through hospitals.

Table 2.7: Estonia - Retailers of pharmaceuticals 1995, 2000-2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies	239[2]	265[2]	274[2]	292[2]	419[3]	475[3]	480[3]	524[3]
No. of private pharmacies	n.a.	n.a.	n.a.	n.a.	417[3]	473[3]	478[3]	522[3]
No. of public pharmacies	n.a.	n.a.	n.a.	n.a.	2	2	2	2
No. of hospital pharmacies for out-patients[4]	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of other POM dispensaries[5]:	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total no. of POM dispensaries	239[2]	265[2]	274[2]	292[2]	419[3]	475[3]	480[3]	524[3]
No. of Internet pharmacies[6]	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries, such as drugstores[7]:	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s); n.a. = not available, n.app. = not applicable

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

[1] as of 1 January

[2] without branch pharmacies

[3] including branch pharmacies

[4] no hospital pharmacies for out-patients allowed

[5] no POM dispensaries other than community pharmacies allowed

[6] no Internet pharmacies allowed

[7] no OTC dispensaries other than pharmacies allowed

Source: SAM 2007

Discounts and rebates between the industry and wholesalers and the pharmacies are a reality in Estonia. This works through discounts, rebates, free goods and a “two-for-one” system. These mechanisms have been abused in the past by the wholesaler chains, in that the discounts were in reality only available for the pharmacies that belonged to chains.

Pharmaceutical organisations in Estonia are organised on a voluntary basis. There is no obligation to be a member of one of the following major organisations:

- Estonian Pharmacists Association covers approximately 350 community pharmacists (44% of all community pharmacists) (June 2006);
- Estonian Pharmacies Association represents Apotheka pharmacies (pharmacy chain of wholesaler Magnum Medical) and it is mainly business oriented;
- Society of Hospital Pharmacists unites pharmacists and pharmacist assistants working in hospital pharmacies (< 100 members).

In addition, there are couple of small specialised organisations: the Estonian Academic Pharmaceutical Association (academic pharmacists), the Union of Pharmacists Assistants, etc.

Some of the pharmacy associations have a strong influence over the policy-making at Ministry of Social Affairs (SM) and Parliament levels. The Estonian Pharmacists Association and Estonian Pharmacies Association are the most active in this respect, the latter having strong business interests, connecting pharmacies of Magnum Medical AS, with more than half of the Estonian pharmacy market. The profit of the pharmacies is based on the mark ups (cf. 3.5.2).

Regarding the sale of the reimbursed pharmaceuticals, the patient receives the discount directly at the pharmacy and the EHIF reimburses the difference afterwards, according to the pharmacy invoice and prescriptions. The pharmacists' salary is a combination of the monthly flat fee, (maybe) accompanied by an extra fee, according to the profit margin.

Until 2006, the opening of new pharmacies was not restricted by geographical or demographic criteria. As of 1 January 2006, a restriction came into force, according to which no new activity licences can be issued to pharmacies and branch pharmacies in towns, nor they can change their place of operation, where there are less than 3,000 inhabitants per pharmacy unit. The restriction described is not applied to a change of location, if the new place of operation is not more than 500 metres from the old one[7], cf. Figure 2.2.

Outside of towns, a new pharmacy or branch pharmacy may not be opened closer than 1 km from an existing pharmacy unit. The same restriction also applies to a change of the place of operation of a pharmacy or a branch pharmacy. If the number of inhabitants increases or if a local government has submitted to the State Agency of Medicines (SAM) a written suggestion for opening a new pharmacy unit, with grounds to support the suggestion, it is announced on the web site of State Agency of Medicines (SAM).

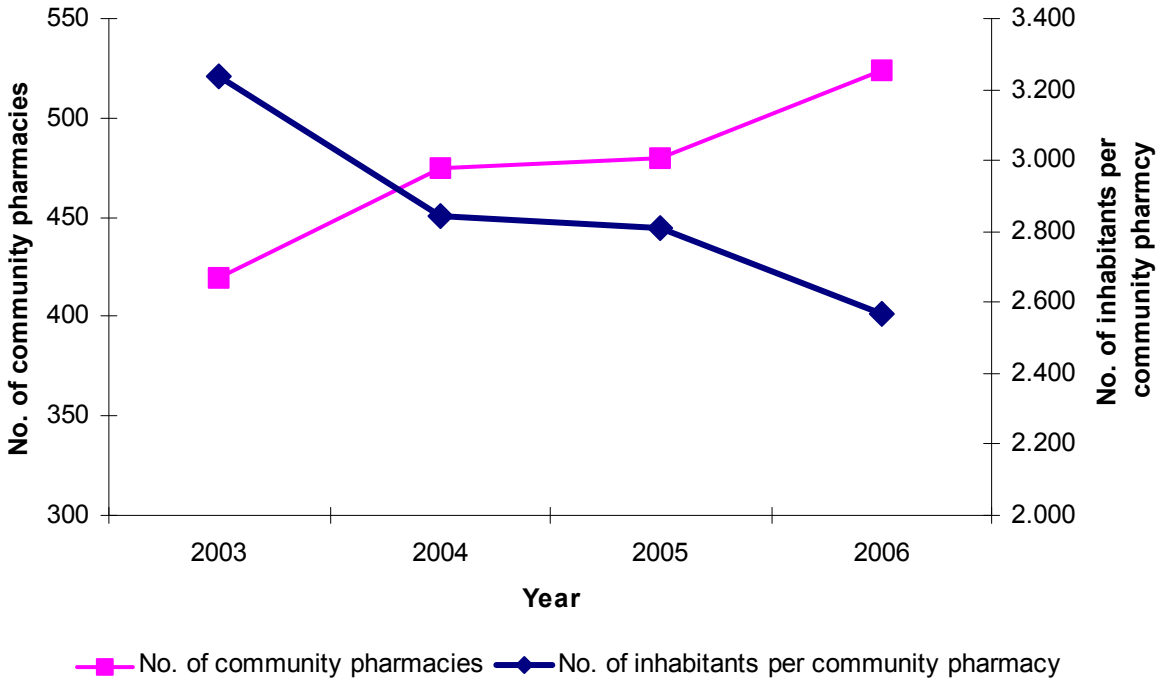
If more than one application is submitted, a person applying for the right to open a retail pharmacy is favoured. In case more than one application for opening a retail pharmacy is submitted, lots are drawn by the applicants. The results drawing lots are announced on the homepage of the State Agency of Medicines (SAM) within three working days.

The person who has been granted the right to open a pharmacy unit must apply for an activity licence within no longer than 180 days[7].

In the situation of critical shortage of pharmaceutical personnel (more than 100 workplaces available, one fifth of personnel have reached retirement age), restrictions on opening new pharmacies in towns were planned with the purpose of holding back the closing of rural pharmacies.

The opening of new pharmacies is considered as an entrepreneur's activity. There is no remuneration, lost compensation or other supporting system for rural pharmacies. Pharmacy business is considered as an ordinary business enterprise and neither public nor private pharmacies are subsidised by the state.

Figure 2.2: Estonia - Number community pharmacies and number of inhabitants per pharmacy 2003-2006



Source: SAM 2007

Pharmacy services are to be provided only by pharmacies holding a corresponding activity licence and structural units thereof, taking account of the restrictions established for different categories of pharmacy.

2.1.3.3.2 Other pharmacy outlets

The dispensing of pharmaceuticals to the public through pharmacy outlets other than community pharmacies or their branches, e.g. hospital pharmacies, is forbidden by law in Estonia[7]. Only community pharmacists working in a community pharmacy are allowed to dispense pharmaceuticals to the public.

2.1.3.3.3 Internet pharmacies

The dispensing of pharmaceuticals through Internet pharmacies ior via mail order is not allowed in Estonia[7].

2.1.3.3.4 Dispensing doctors

The dispensing of the pharmaceuticals through family doctors, general practitioners (GPs), specialists, etc. in the out-patient care setting is not allowed in Estonia[7].

2.1.3.4 Hospitals

The hospital pharmacies in Estonia are only for hospital use (in-patient care) and are not allowed to dispense pharmaceuticals to out-patients. Only Anti-Retrovirus (ARV) and tuberculosis (TBC)

pharmaceuticals and vaccines are dispensed through the hospitals and family doctors, but these are bought by the Ministry (SM) through public procurement and are free of charge for the patients.

The hospitals working with the list of pharmaceuticals belonging to the medical formularies of the relevant hospitals. In reality the formularies are based on the pharmaceuticals of the medical services of the EHIF. These pharmaceuticals do not belong in the national positive list for reimbursement.

The hospitals are private entities, contracting with the Estonian Health Insurance Fund (EHIF) for certain amounts of predetermined medical services. The amount and structure of medical services bought by the EHIF from the hospital are determined by the ability of the hospital to offer the services (rooms, presence of equipment and personnel). The EHIF pays the hospitals according to their invoices detailing the medical services provided.

The hospitals buy necessary pharmaceuticals themselves, using the purchasing and procurement mechanisms as necessary. For the inclusion of a new pharmaceutical to the hospital list the relevant association of medical specialty has to apply to the EHIF. This cannot enhance pharmaceutical prescribing in the primary care setting, as the pharmaceuticals in out-patient and in-patient care are regarded separately. The hospital pharmacies are owned, run and paid for by the hospitals themselves[5,7].

2.1.3.5 Doctors

There are many associations of doctors in Estonia. The most important of these are the Estonian Doctors Association and the Estonian Family Practitioners Associations. These associations are the most actively involved in pharmaceutical policy-making; they have representatives in the Pharmaceutical Commitee (PC), and give advisory decisions about the reimbursement and pricing of the pharmaceuticals. There are no official contracts in place between doctors or their associations and the government.

Best practice, in terms of prescribing, is described in several guidelines. These guidelines are usually created by the associations of the relevant specialty and following the guidelines is essentially voluntary for the doctors, i.e. there are no sanctions for non-compliance.

2.1.3.6 Patients

Patients have many different societies in Estonia, which are not equally involved in pharmaceutical policy-making. The most important patient organisations with regard to pharmaceuticals are the Estonian Chamber of Disabled People and the Estonian Patients Advisory Chamber. The representatives of these organisations are involved in the Pharmaceutical Commitee (PC), advisory body for the Ministry of Social Affairs (SM), regarding the decisions on the reimbursement of pharmaceuticals. The Estonian Patient Advocacy Association is one of the most active patient organisations as well, but is no longer involved in the work of the PC. Some other patient organisations, e.g. the Estonian Diabetes Association, the Estonian Rheumatism Association, etc., have explored the possibility of lobbying within the Ministry of Social Affairs (SM), with the aim of achieving the key changes to the legal acts and reimbursement of pharmaceuticals.

There are no specific mechanisms to enable patients to decide on the pharmaceuticals prescribed. In any case, the mechanism of prescribing on the basis of active substances is applied, and according to such prescription practices the pharmacist is obliged to offer different possibilities to the patient and the patient has the right to choose the most suitable pharmaceutical for her/himself. If the trade name has been prescribed and “not to substitute” has been noted on the prescription, the pharmacist has no possibility to provide any other pharmaceuticals than those precribed[13].

The prices of the pharmaceuticals are not actually the same in every pharmacy. For this reason some patients find it useful to “shop around” for pharmaceuticals.

2.2 Funding

Expenditure for pharmaceuticals is funded from the budget of the Estonian Health Insurance Fund (EHIF) through the mechanisms of reimbursement (all hospital and ambulatory treatment) and also from the state budget through the mechanisms of public procurement (tuberculosis (TBC), HIV treatment and vaccines).

2.2.1 Pharmaceutical expenditure

Pharmaceutical expenditure (PE) in Estonia amounted to EEK 2.3 billion / € 149.9 Mio. in 2005 (cf. Table 2.8 for more data on pharmaceutical expenditure in Estonia).

Table 2.8: Estonia - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE	1995	2000	2001	2002	2003	2004	2005
TPE in EEK[1], Mio.	n.a.	1,351	1,459	1,591	1,831	2,184	2,345
TPE as a % of THE	n.a.	26.3	27.2	26.7	26.9	28.1	n.a.
TPE per capita in EEK	n.a.	984.64	1,067.33	1,168.79	1,350.25	1,616.50	1,740.25
Public PE as a % of THE	n.a.	12.5	14.3	16.6	13.7	14.9	n.a.
Private PE as a % of THE	n.a.	13.8	12.9	16.0	17.3	16.6	n.a.

EEK = national currency unit (NCU) (Estonian Kroons), GDP = gross domestic product, TPE = total pharmaceutical expenditure (public), PE = pharmaceutical expenditure, THE = total health expenditure

[1] excluding veterinary pharmaceutical expenditure

Source: Estonian Health Statistics Yearbook 2004, www.sam.ee

[13] https://www.riigiteataja.ee/ert/act.jsp?id=1019211

2.2.2 Sources of funds

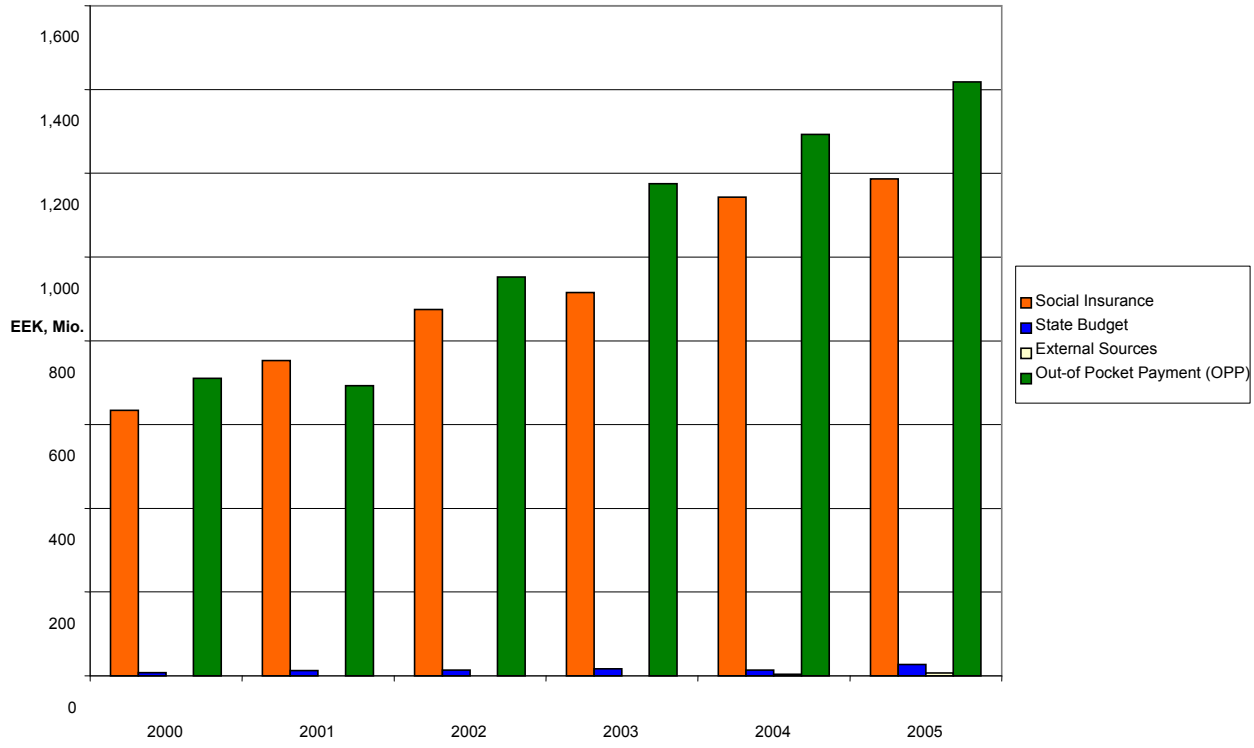
The main funding source for public pharmaceutical expenditure (PE) comes from the social tax, paid by the employees on the basis of the salaries of their employers. This money becomes part of the budget of the Estonian Health Insurance Fund (EHIF) and is divided up according to the relevant legal mechanisms.

The expenditures for tuberculosis (TBC), Anti-Retrovirus (ARV) treatment and vaccinations are covered through the common state budget. Since 2006, a special additional reimbursement scheme for the pharmaceuticals used in in vitro fertilisation (IVF) has been in place. This scheme is financed by the state budget through the Estonian Health Insurance Fund (EHIF).

Private pharmaceutical expenses consist of:

- expenses for self-medication
- expenses for private voluntary supplementary health insurance
- out-of-pocket payments (OPP) (prescription fees, percentage co-payments, etc.)
- expenses for non-reimbursed prescription pharmaceuticals
- informal payments[1].

Figure 2.3: Estonia – Share of the funding of total pharmaceutical expenditure (TPE) 2000-2005



Source: SAM 2007

Figure 2.3 illustrates the shares of social health insurance (SHI), state budget, external sources (foreign investment, Global Fund) and out-of-pocket payments (OPP) in the total pharmaceutical expenditure (TPE). It is evident that the expenditure for out-of-pocket payments (OPP) has increased continuously along with the costs of social health insurance for the pharmaceuticals. One of the reasons for the increase in the out-of-pocket payment (OPP) share might be the current active “drug tourism” from Finland, taking place with the purpose of acquiring basicly psychotropic and some narcotic (Subutex) pills from Estonia (these are purchased at full price and therefore increase the OPP share of pharmaceutical expenditure (PE)). However, this is clearly not the only reason for the increase in overall out-of-pocket payment (OPP) for pharmaceuticals in Estonia – this is caused by the reimbursement system on the one hand and non-rational use of pharmaceuticals on the other (use of expensive original pharmaceuticals instead of cheaper generics).

2.3 Evaluation

As yet, there are no common programmes or specific methods used for the evaluation of pharmaceutical policy, the pharmaceutical system (in general and its impact on health), access to the pharmaceuticals, or cost-containment.

The State Agency of Medicines (SAM) monitors yearly trends in the consumption of pharmaceuticals, broken down by groups of pharmaceuticals, and the price trends of the pharmaceuticals are monitored both by the commercial medicines statistic company IMS (routinely) and the Ministry of Social Affairs (SM). The Estonian Health Insurance Fund (EHIF) provides information on the yearly co-payment levels. Regulatory action on the quality and safety of the pharmaceuticals is routine and based on the valid relevant legal acts.

The Agency (SAM) and the Sickness fund EHIF make data available in their reports, and data are also available on their web sites. There are no written official policies in the field of pharmaceuticals.

3 Pricing

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

3.1 Organisation

The pricing of pharmaceuticals in Estonia is based on the Health Insurance Act (2002)[6] and Regulation of the Ministry of Social Affairs (SM) on the conclusion of price–volume agreements[14]. The Ministry of Social Affairs (SM) acts as the main authority in the negotiation and conclusion of the price–volume agreements and the Estonian Health Insurance Fund (EHIF) acts as an expert in this process. The pricing criteria of the pharmaceuticals have been determined by the law and regulation mentioned above, consisting mainly of a comparison of the prices in the reference countries. The prices of pharmaceuticals of similar effect are compared as well, if applicable.

The process for the conclusion of price agreements starts with a proposal from the representative company to the Ministry of Social Affairs (SM). Besides the proposed price and the volume of the pharmaceutical, the proposal should contain the prices of the pharmaceutical in certain reference countries (native country of the manufacturer, Latvia, Lithuania and Hungary) and an explanation about the price and the volume proposed. The Ministry (SM) asks the expert opinion of the Estonian Health Insurance Fund (EHIF) if necessary and publishes information about the conclusion on the price agreement on the web page. After receiving the expert opinion and successful negotiations, the price agreement is concluded and information about the wholesale and retail prices and validity of the price agreement are published accordingly, on the SM web site, before the agreement is considered valid and the public are informed.

The price-volume agreement based payback system (cf. PPRI glossary) is not applied in such cases when the manufacturer has acted in good faith, i.e. could not foresee the over-spending); however, if the sales volume set before is likely to be exceeded, negotiations with the aim of increasing the volume of the price agreement will be started by the representative of the pharmaceutical company.

There has been no separate price committee created. Besides giving its advisory decision on the reimbursement of the pharmaceutical, the Pharmaceutical Committee (PC), working alongside the Ministry of Social Affairs (SM), proposes the preliminary price level for the negotiations as well. So the same institution, the Ministry (SM), is responsible both for pricing and reimbursement decisions of the pharmaceuticals.

14

www.sm.ee/eng/HtmlPages/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C/$file/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C.doc

The length of the process of price agreement depends on the success of the negotiations, but does not usually take longer than 90 days. The preliminary decision on the acceptable price of the pharmaceutical is made by the PC together with the decision about reimbursement.

There have been no major changes or developments in the legal framework and organisation of the pricing process since the procedure was first applied in 2003.

3.2 Pricing policies

In Estonia, there is statutory pricing (after price negotiations between companies and the the SM have taken place) for reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals (only statutory mark ups are applied). The decision on the manufacturer price should be made after the decision on reimbursement, but in reality the process of pricing is incorporated into the procedure of reimbursement.

Public procurement of pharmaceuticals is applied by the Ministry of Social Affairs (SM) for the buying of HIV and tuberculosis (TBC) pharmaceuticals and vaccines for the relevant patient groups, and by the hospitals. An overview of the different methods of pharmaceutical pricing in Estonia is presented in Table 3.1.

The current price negotiation system was implemented from 2003 and it is applicable only for reimbursable pharmaceuticals. The statutory margin schemes for wholesalers and pharmacies were last updated in 2002 and are applicable for both reimbursable and non-reimbursable pharmaceuticals.

Table 3.1: Estonia - Ways of pricing pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free pricing	Non-reimbursed pharmaceuticals	No	No
Statutory pricing	Reimbursed pharmaceuticals	Statutory maximum mark ups applicable for all pharmaceuticals	Statutory maximum mark ups applicable for all pharmaceuticals
Price negotiations	Reimbursed pharmaceuticals	No	No
Discounts / rebates	Likely	Possible	Possible
Public procurement	➢ Relevant for products used in hospitals ➢ Relevant to TBC, HIV pharmaceuticals and vaccines		
Institution in charge of pricing	➢ SM		
Legal basis	➢ Health Insurance Act 2002, Regulation of SM No. 121, 3.12.2004 “Procedure for entry into price agreement”		

SM = Ministry of Social Affairs, TBC = tuberculosis

Source: www.sm.ee → Tervishoid → Ravimid

The procedures for setting manufacturer prices differ depending on whether the pharmaceutical is innovative or generic. There are specific criteria for reimbursement of parallel traded pharmaceuticals: the price for these has to be 10% lower than the price of original product on the market.

Price changes are possible; these are usually decreases. Price changes are decided by the Ministry of Social Affairs (SM) according to the change in the price agreement. Usually the manufacturer applies for the price change or any other changes in the price agreement, but the Ministry of Social Affairs (SM) itself may also start the process of a change.

There is no specific pricing system for hospital-only medicine(s) (HOM). The hospitals buy the pharmaceuticals through their own hospital pharmacies, and different discounts and rebates are applied by the manufacturers and wholesalers, so low-price pharmaceuticals can be acquired. Public procurement is the mostly used buying mechanism, very often used by the hospitals as well.

3.2.1 Statutory pricing

Statutory pricing – in combination with negotiations – is applied for the innovative and in-patent reimbursable pharmaceticals in Estonia. The statutory price levels are set according to the prices of the product in the reference countries (Latvia, Lithuania, Hungary, Portugal, France and native country) – the prices in Latvia, Lithuania and Hungary are used for comparison more often. If applicable, and similarity is proved, the prices of pharmaceuticals of similar effect are also compared.

The Ministry of Social Affairs (SM) is the main authority involved in the pricing decisions and the Pharmaceutical Commitee (PC), setting the advisory decisions on pharmaceutical reimbursement, decides the price of the pharmaceutical at the same time as well. External price referencing is used in the pricing procedure and the criteria have been described above.

The process to conclude the price agreement starts with the proposal of the representative company to the Ministry (SM). In 15 days, starting from when the application is received, this would be sent to the Estonian Health Insurance Fund (EHIF) for evaluation; within 45 days the sickness fund EHIF should give its expert opinion on the proposal. The information on processing the price agreement is published on the SM web site. The contract is created and negotiated by the Ministry of Social Affairs (SM) and the representative company.[14]

This stage may take the longest period of time, because the thoughts of the SM, the EHIF and the manufacturer about reasonable prices and the appropriate volume of the pharmaceutical may differ. As the price agreement has been signed by both sides, the SM publishes the information about the maximum wholesale and retail prices on the web site and informs all bodies of interest about that via a mailing list.

3.2.2 Negotiations

Negotiations are one part of the price agreement procedure, starting after the preliminary statutory pricing decision of the Ministry (SM), if the manufacturer is not able to justify the price of the

pharmaceutical according to the the decision made on the basis of advice of the Pharmaceutical Commitee (PC). Negotiations are possible for the same pharmaceuticals and on the basis of the same legal framework/procedure as statutory pricing. This has been applied since 2003[14].

Usually negotiations start after the decision on reimbursement of the pharmaceutical (containing the decision on the acceptable price) by the Ministry of Social Affairs (SM). Sometimes the price negotiations also start before the decision of the PC, because the preliminary information on the acceptable price level of the pharmaceutical is usually available in the expert opinion of the sickness fund (EHIF), enabling the preliminary negotiations to take place. In the event of disagreement, negotiations continue, being concluded with a compromise in some particular cases, if that is found to be a relevant solution. If negotiations fail completely, the pharmaceutical will not be reimbursed.

3.2.3 Free pricing

Before 2003 most pharmaceuticals were free; only maximum mark ups for wholesalers and pharmacies were applied, and manufacturer prices were not controlled. The Estonian Health Insurance Fund (EHIF) made an attempt to conclude price agreements for certain pharmaceuticals (some cardiovascular pharmaceuticals and pain-killers) in 2002, but there were only around seven agreements concluded. These agreements were used as the starting points for the conclusion of new price agreements according to the valid legislation in 2003.

Since 2003, the free pricing applies only for the non-reimbursed pharmaceuticals. As price freezing was found impossible to apply in 2003, the prices of pharmaceuticals subject to the price agreements, have been essentially free until the conclusion of the price agreement. At the time of writing all necessary price agreements have been concluded.

3.2.4 Public procurement / tendering

Public procurement is used for provision of pharmaceuticals in hospitals, both through the official structures and directly.

The Ministry of Social Affairs (SM) provides certain hospitals with HIV and tuberculosis (TBC) pharmaceuticals and vaccines, being bought from the manufacurers according to the valid public procurement procedures. The same procedures are usually being applied by the hospitals to supply themselves with the in-patient pharmaceuticals.

There are special programmes set out for HIV and TBC treatment and vaccination, according to which the pharmaceuticals are distributed to the patients.

3.3 Pricing procedures

Two basic procedures for pharmaceuticals pricing are being used in Estonia: external and internal methods of pricing. The first of these is most likely to be used and the letter is used where appropriate and necessary (cf. Table 3.2).

Table 3.2: Estonia - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing	Scope
Internal price referencing	Yes	Manufacturer price level	Reimbursable pharmaceuticals
External price referencing	Yes	Manufacturer price level	Reimbursable pharmaceuticals
Cost-plus pricing	No	No	No
Other, e.g. indirect profit control	No	No	No

Source:
www.sm.ee/eng/HtmlPages/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C/$file/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C.doc

3.3.1 External price referencing

External price referencing is applied for the reimbursed innovative pharmaceuticals, which are the subject of the price agreements. The comparison is carried out at manufacturer price level.

The procedure for external price referencing is interlinked both with the process of reimbursement and with the conclusion of price agreements according to the valid Regulations of the Ministry of Social Affairs (SM) and based on the Health Insurance Act 2002. The selection of countries (Latvia, Lithuania, Hungary and the country of origin) is also set out in the legislation.[15] Latvia and Lithuania were chosen for the price referencing comparison because these are the closest neighbouring countries to Estonia and have essentially similar economic situations as Estonia. They are also of similar structure of population and epidemiological status. The price of the pharmaceutical in the country of origin is just the natural choice for the referencing. Sometimes some other European Union (EU) countries have been used as alternatives for the referencing, if the data have been available. If the product is rather new and not on the market in any of the countries noted above, the situation just has to be accepted as there is no possibility for external price referencing.

In many cases the price comparison influences the prices of the pharmaceuticals, especially the comparisons with Latvian and Lithuanian prices, by making the manufacurers lower the prices. It is more complicated to get the manufacturers to offer the same prices for Estonia as they do for, e. g. Hungary.

The comparisons are made directly on the calculated manufacturer prices, and no adjustments are made according to purchasing power parity (PPPa). For the calculations, valid fixed exchange rates are usually used.

15 www.sm.ee/eng/HtmlPages/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C/$file/hinnakokkulepetekordtõlkimiseksEN_ok_ED_C.doc

The country price information is provided with the manufacturer prices by the representative of the manufacturer in the reimbursement applications and in the proposals for the price agreement. The validity of the information can be checked on the basis of the information presented on the homepages of the other authorities (the information on the prices of reimbursed products is available on the homepages of the relevant authorities in Latvia, Lithuania and Hungary)[14].

If the price of a reimbursed pharmaceutical is lowered in one of the reference countries and the Ministry of Social Affairs (SM) has valid information about that, then the representative company is forced to reduce its price for Estonia according to the lower reference price.

3.3.2 Internal price referencing

Internal price referencing is one of the criteria applied in the procedure concluding price agreements, used in setting the statutory price, if appropriate and necessary. The pharmaceuticals are comparable, if there is evidence about their similar effects and efficacy[14].

3.3.3 Cost-plus pricing

Cost-plus pricing is not applied in Estonia.

3.3.4 (Indirect) Profit control

Profit control is not applied in Estonia.

3.4 Exceptions

The aforementioned pricing control measures do not apply to non-reimbursable pharmaceuticals, e.g. most over-the-counter (OTC) pharmaceuticals, hospital-only medicine(s) (HOM), etc.

3.4.1 Hospitals-only

The hospitals carry out by themselves their own procurement of pharmaceuticals (except HIV and tuberculosis (TBC) pharmaceuticals and vaccines, which are procured by the Ministry of Social Affairs (SM)). In practice, the hospitals are able to achieve the lower prices for pharmacyeuticals than those that are available for the out-patient sector. The price changes of the pharmaceuticals in the hospitals have not been monitored or evaluated and there is no public information available about the prices of these pharmaceuticals.

3.4.2 Generics

If a generic of current active substance in the current form of administration first applies for reimbursement, the same pricing procedure is applied as for the original pharmaceutical. If the original product joins the list after the generic, then it has to be at least a little bit cheaper than the

previously added generic. If the original pharmaceutical is first in the reimbursement list, the generic product has to be at least 30% cheaper than the original.

The next pharmaceutical to join the list has to be 10% cheaper than the valid reference price and the next two pharmaceuticals 5% below the reference price. All the following pharmaceuticals added have to be cheaper than the last generic or reference price. All these rules only apply for the reimbursed pharmaceuticals and are set out in the Regulation of Ministry of Social Affairs (SM) on the Procedure for drawing up and amending the list of pharmaceuticals of the Estonian Health Insurance Fund (EHIF), the contents of the criteria for establishment of the list of pharmaceuticals, and the persons to assess compliance with criteria[9].

3.4.3 Over-the-counter pharmaceuticals

Some of the over-the-counter (OTC) pharmaceuticals that are reimbursed are dealt with similarly to other reimbursed pharmaceuticals. For the others, free pricing applies, except where there are maximum mark ups for wholesalers and pharmacies.

3.4.4 Parallel traded pharmaceuticals

Parallel traded pharmaceuticals have to be 10% cheaper than the price for the original marketing authorisationholder (MAH) of the pharmaceutical[9].

3.4.5 Other exceptions

Some artificial nutritional mixtures for allergic children and people with phenylketonuria are reimbursed similarly to other pharmaceuticals in Estonia. Similar procedures for the fixing of manufacturer prices apply as well, but the statutory pharmacy and wholesale mark ups (cf. 3.5) are not legally applicable for these products. The wholesalers and pharmacies could therefore apply whatever mark ups they chose for these products, but fortunately there is a silent agreement that the same mark ups as for pharmaceuticals will also apply for these products.

3.5 Margins and taxes

Maximum mark ups are applied for wholesalers and pharmacies by a Governmental Regulation[16] that was last changed in 2002 (cf. Table 3.3 for an overview of the current regulation; cf. 3.5.1 and 3.5.2 for detailed mark ups applied in wholesaling and in retail; and 3.5.4 for information on value-added tax (VAT)).

The Estonian mark-up schemes regulate the maximum profit value that wholesalers and pharmacies are allowed to add to their pharmacy purchasing price (PPP). In practice, the applied mark up may be lower than this maximum, which is especially true for over-the-counter (OTC)

16 www.sm.ee/eng/HtmlPages/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C/$file/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C.doc

pharmaceuticals. This is one of commercial possibilities for wholesalers and pharmacies to attract clients.

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

Wholesale mark up			Pharmacy mark up		
Regulation (yes / no)	**Content**	**Scope***	**Regulatio (yes / no)**	**Content**	**Scope**
Yes	Regressive mark ups	All pharmaceuticals	Yes	Regressive mark ups	All pharmaceuticals

Source: http://www.sam.ee/orb.aw/class=file/action=preview/id=5118/EstonianAct-10May2005.doc

3.5.1 Wholesale remuneration

Wholesalers are mainly remunerated via mark ups (percentage of the wholesale purchase price), but there are contractual relations between manufacturers and wholesalers as well. The wholesale mark ups are regulated by the aforementioned Regulation of the Government, last updated in 2002. The regulations cover all pharmaceuticals (prescription-only medicine(s) (POM), over-the-counter (OTC) products, etc.). The system of mark ups has been built up in the regressive scheme[15]. There have been not planned any changes in the mark-up system for wholesalers.

Table 3.4: Estonia - Wholesale mark-up scheme 2006

Ex-factory price in EEK / €	Maximum mark up (% of ex-factory price)
Up to EEK 25.00 / € 1.60	20
EEK 25.01-45.00 / € 1.60-2.88	15
EEK 45.01-100.00 / € 2.88-6.39	10
EEK 100.01-200.00 / € 6.39-12.78	5
Over EEK 200.00 / € 12.78	3%, but not more than EEK 100 / € 6.39 per pack

EEK = national currency unit (NCU) (Estonian Kroons)

Source:
www.sm.ee/eng/HtmlPages/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C/$file/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C.doc

3.5.2 Pharmacy remuneration

The pharmacies are also remunerated through mark ups (percentage of pharmacy purchasing price (PPP), cf. Table 3.5). Most of the pharmacies enter into contractual relations with wholesalers as well (chain pharmacies). The pharmacy mark ups are regulated by the same Regulation of the Government as the wholesale mark ups, last updated in 2002. Similarly to the wholesale mark ups, the regulations cover all pharmaceuticals with no difference between prescription-only medicine(s) (POM) or over-the-counter (OTC) products[15].

Table 3.5: Estonia - Pharmacy mark-up scheme 2006

Estonia		
Pharmacy purchasing price (PPP) from … to … in EEK / €	**Pharmacy mark up coefficient (% of PPP)**	**Fixed pharmacy mark up in NCU / €**
Up to EEK 10.00 / € 0.64	0	EEK 6 / € 0.38
EEK 10.01-20.00 / € 0.64-1.28	40	EEK 6 /€ 0.38
EEK 20.01-30.00 / € 1.28-1.92	35	0
EEK 30.01-40.00 / € 1.92-2.56	30	0
EEK 40.01-50.00 / € 2.56-3.19	25	0
EEK 50.01-100.00 / € 3.19-6.39	20	0
EEK 100.01-700.00 / €6.38-44.74	15	0
Over EEK 700.00 / € 44.74	0	EEK 80 / € 5.11

NCU = national currency unit (EEK), PPP = pharmacy purchasing price

Source:
www.sm.ee/eng/HtmlPages/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C/$file/ravimitejuurdehindlusedtõlkimiseksEN_ok_ED_C.doc

3.5.3 Remuneration of other dispensaries

There are no other dispensaries of pharmaceuticals than pharmacies allowed in Estonia.

3.5.4 Value-added tax

A value-added tax (VAT) of 5% is applied for all pharmaceuticals and nutritional mixtures used for medicinal purposes. A standard value-added tax (VAT) of 18% is applied for other goods in Estonia[17]. The value-added tax (VAT) for pharmaceuticals has not been changed in the last few years and there are no planned any changes in the value-added tax (VAT) for pharmaceuticals in near future.

3.5.5 Other taxes

No other taxes than value-added tax (VAT) are applied for pharmaceuticals in Estonia.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

No statutory discounts are applied in the pharmaceutical sector in Estonia. All types of discounts are essentially acceptable, but no legal basis for this has been created, so these are rather commercially driven discounts.

[17] https://www.riigiteataja.ee/ert/act.jsp?id=12796909

There is no official information available about the discounts that hospitals receive from wholesalers and manufacturers.

3.6.2 Margin cuts

There are statutory maximum mark ups in place in Estonia (cf. 3.5). Major changes in the statutory mark-up scheme were applied in November 2002, justifying the mark ups between price groups of pharmaceuticals. This involved dividing the mark ups for pharmaceuticals of cheaper price groups, with the aim of making the sale of cheaper pharmaceuticals more profitable.

3.6.3 Price freezes / Price cuts

Neither statutory price freezes nor price cuts have been applied in Estonia over the last decade (since the mid-1990s).

3.6.4 Price reviews

The methods of pricing and pricing procedures in Estonia have not yet been reviewed nor evaluated at the time of writing.

4 Reimbursement

This chapter characterises the reimbursement procedures and regulations in Estonia.

4.1 Organisation

The policy of reimbursement of pharmaceuticals in Estonia is based on the Health Insurance Act and on the Regulation of Ministry of Social Affairs (SM) No. 123, 8.12.2004 “Procedure for drawing up and amending the list of pharmaceuticals of the Estonian Health Insurance Fund (EHIF), the contents of the criteria for establishment of the list of pharmaceuticals, and the persons to assess compliance with criteria”[9].

Since 2003 the reimbursment system is characterised by a reference price system. Generally speaking, all pharmaceuticals used in out-patient care have been included within the reimbursement scheme, whereas most of the over-the-counter (OTC) pharmaceuticals intended for use in the in-patient care setting and some lifestyle pharmaceuticals (like drugs against erectile dysfunction, obesity, nicotine and alcohol substitution therapy) have been excluded and will never be included within the scope of the purposes mentioned above. OTC included in the list of reimbursement are OTC products for children with severe illnesses, pharmaceuticals containing iron and calcium and some artificial food preparations for allergic and premature children and for patients with phenylketonuria. The common policy covers the whole country and all institutions.

The Ministry of Social Affairs (SM) is responsible for the reimbursement decision. The reimbursement process is linked to the pricing – the preliminary decision on the acceptable price of the pharmaceutical is made along with the decision on the reimbursement. The SM is advised by the experts of the State Agency of Medicines (SAM) and the Estonian Health Insurance Fund (EHIF) during the reimbursement procedure, and by the independent Drug Committee for the final decision.

The reimbursement status of the pharmaceutical can change on the basis of a positive application. Most of the positive decisions on the reimbursement of different pharmaceuticals are closely connected with certain recommended price levels of interest; the realisation of the reimbursement is very much connected with the ability of the manufacturer to accept the price levels asked.

The content of the application for reimbursement differs, depending on whether a pharmaceutical with the same active ingredient in the same pharmaceutical form has already been listed. The general and simplified reimbursement procedures are explained in more detail in the list below.

- **General procedure – reimbursement of the pharmaceutical for which the active ingredient in the pharmaceutical form is not yet listed[9]**
  - Manufacturers have to submit an application in Estonian to the Ministry of Social Affairs (SM). The application should contain information on the target group of patients, clinical efficacy and safety, and pharmacoeconomic analysis according to the Baltic Guidelines on

Economic Evaluation of Pharmaceuticals. The price information of the pharmaceutical in all other EU Member States, where the product is marketed, also has to be provided.

- The Ministry of Social Affairs (SM) examines the application for conformity with the legal requirements before the forwarding this to the State Agency of Medicines (SAM) and the EHIF. SAM has to prepare its expert opinion within 45 days; the expert opinion of the EHIF has to be ready within the next 45 days after the expert opinion of the SAM. Among other factors, the State Agency of Medicines takes into account the financial justification for the use of the pharmaceutical compared to other available pharmaceuticals/treatment alternatives. The EHIF considers the financial and budgetary impact of the application.
- Taking into account the written opinions by the State Agency of Medicines (SAM) and the Estonian Health Insurance Fund (EHIF), the Ministry of Social Affairs (SM), advised by the Pharmaceutical Commitee (PC), announces the final decision on the reimbursement within 180 days of the start of the application process9.

- **Simplified procedure – reimbursement of the pharmaceutical for which the active ingredient and pharmaceutical form are already listed**
  - Applications in Estonian are also submitted to the Ministry of Social Affairs (SM). Commonly, no additional information will be required. The main criteria considered in the simplified procedure are the financial justification for use, patient need for the pharmaceutical, proven medical effectiveness, availability of alternatives and their prices, and budgetary considerations. The SM may also ask for the opinion of the EHIF, the State Agency of Medicines (SAM) and the Pharmaceutical Commitee (PC), but this is not mandatory. The SM announces the final decision on the reimbursement within 90 days of the start of the application process[9].

4.2 Reimbursement schemes

The reimbursement of many pharmaceuticals in Estonia is based on the diagnoses for which they are applied (diagnosis-based reimbursement). Criteria for the classification of diagnoses have been described in the Health Insurance Act (based on the severity of illness or suffering as a result of the illness) and the list of diagnoses is based on the Regulation of the Government No. 308 of 26.09.2002 “List of diseases in the case of which a pharmaceutical intended for the treatment or alleviation of the disease is, upon the existence of a valid reference price or price agreement, subject to entry in the list of pharmaceuticals with a 100% or 75% discount rate”.

According to the law, additional reimbursement on the basis of one part of list of diagnoses is available for certain social groups (children below the age of 16, disabled and retired people). On the basis of the same law, children below four years old receive 100% reimbursement for all pharmaceuticals listed for the reimbursement in any rate[6].

In September 2006 an additional pharmaceutical reimbursement scheme was applied – reimbursement of pharmaceutical expenses incurred during artificial insemination procedures. This change was initiated by the Ministry of National Affairs with the aim of achieving additional births and the scheme is therefore being funded from the state budget. For 2006 10 million EEK / € 639,116.5 were foreseend and the patients are being reimbursed through the Estonian

Health Insurance Fund (EHIF). The role of the EHIF here is technical (receive the application, control the rights for reimbursement and carry out the payments to the patients).

The legal basis of the scheme described above has been added to the Artificial Fertilisation and Embryo Preservation Act of 1997. The detailed procedure has been described in the Regulation of the Ministry of Social Affairs (SM) on the procedure of according additional pharmaceutical reimbursement.[18]

In general, the pharmaceuticals with active ingredient and pharmaceutical form already listed will receive the decision on reimbursement within 90 days, starting from the day of application. The reimbursement actually will enter into force with the next change in the positive list and reference prices, usually within 1-2 months after the decision. The Ministry of Social Affairs (SM) has the right to supplement the positive list up to seven months following the positive decision.

The pharmaceuticals with active ingredient and pharmaceutical form not listed usually receive the reimbursement decision within 180 days of the day of application. The actual change in reimbursement depends not only on the next change of the positive list, but also (mainly) on the agreement of the company with the conditions, set out on the basis of the Pharmaceutical Commitee's (PC) decision. Sometimes the associated negotiations will take a long time and some products will never be reimbursed, even if the decision was positive.

Indivdual reimbursement

In exceptional circumstances, patients may apply for reimbursment of pharmaceuticals without a valid Estonian marketing authorisationand/or without the pharmaceutical being included in the positive list of the Estonian Health Insurance Fund (EHIF), if there are no alternative therapies available in Estonia. The patient has to apply to the Estonian Health Insurance Fund (EHIF) to receive exceptional reimbursement for such a pharmaceutical, and the application should be accompanied by an explanation from the doctor. The Estonian Health Insurance Fund (EHIF) has in place an internal procedure to manage such exceptional reimbursement[19].

4.2.1 Eligibility criteria

The criteria for reimbursement egligibility are:

- medical and therapeutic value and safety of the pharmaceutical; lack of alternative therapies;
- price and cost-effectiveness of the pharmaceutical; price comparison with prices in the reference countries; conformation with reference price criteria; budget impact;
- severity of illness; special medical needs.

[18] https://www.riigiteataja.ee/ert/act.jsp?id=1048155

[19] www.sm.ee/eng/HtmlPages/HAIGUSTELOETELUtõlkimiseksEN_ok_ED_C/$file/HAIGUSTE%20LOETELU%20tõlkimiseks%20EN_ok_ED_C.doc

The suitable reimbursement category is noted by the applicant in the application of reimbursement and this is based on the indication of the pharmaceutical – if one of the indications belongs to a group of diseases reimbursed for a higher rate, it is possible to apply for a higher rate of reimbursement. If not, a lower reimbursement rate will be applied or the relevant list of diagnoses will be supplemented, if appropriate.

If the pharmaceutical is denied reimbursement, the company has the right to appeal the decision of the Pharmaceutical Commitee (PC) with the Ministry of Social Affairs (SM) and then to appeal the decision of the SM within one month after the decision is announced. The application may be reissued six months after the negative decision.

4.2.2 Reimbursement categories and reimbursement rates

In general, there is a disease-specific reimbursement system in place in Estonia. There are two groups of diagnoses, classified on the basis of the severity of illness. The criteria of division of the diseases into two groups has been determined by the Health Insurance Act. The diagnoses are determined according to the aforementioned Regulation of Goverment on the list of diagnoses. The pharmaceuticals listed for the most severe diseases (26) receive the full (100%) rate of reimbursement and the pharmaceuticals for less severe (mostly chronic) diseases (42) are reimbursed on a 75% basis. In the latter case a higher reimbursement level of 90% for certain social groups (children under age 16, disabled and retired people) is applied. Children below four years of age receive 100% reimbursement for all pharmaceuticals listed for reimbursement in any case. Other pharmaceuticals in the positive list of reimbursed pharmaceuticals are reimbursed at the rate of 50% (cf. Table 4.1 and Table 4.2, along with 4.4.2).

The pharmaceuticals reimbursed at a 100% and/or 75% (or 90%) rate are subject to:

- the reference price system, provided that more than one pharmaceutical with the same active ingredient (Anatomic Therapeutic Chemical classification ATC-5 level) and pharmaceutical form is included in the positve list and available on the market; or
- price–volume agreements, if only one pharmaceutical with this active ingredient and pharmaceutical form is in the positive list and available on the market.

A pharmaceutical cannot be reimbursed at the 100% or 75% (90%) rate without having an established reference price or a valid price agreement.

Table 4.1: Estonia - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate (%)	Characteristic of category
Serious or epidemic diseases	100	Pharmaceuticals for the treatment of choice of serious, life-threatening or epidemic diseases
Chronic diseases	75 / 90	Pharmaceuticals for the treatment of choice of chronic diseases, threatening the quality of life
General	50	All pharmaceuticals in the positive list

Source: http://www.legaltext.ee/failid/findfile.asp?filename=X60043

4.2.3 Reimbursement lists

Estonia has a positive list of reimbursable pharmaceuticals, with the list being set according to a Regulation of the Ministry of Social Affairs (SM).

There is no official negative list of pharmaceuticals, but there are some groups of pharmaceuticals which never will be added to the positive list (hospital pharmaceuticals, nicotine and alcohol replacement therapy pharmaceuticals, pharmaceuticals for the treatment of obesity and sexual disorders, and sedatives).

The SM is responsible for amending the positive list of reimbursed pharmaceuticals, on a quarterly basis. The amendments are communicated to doctors, pharmacists and patients via web sites, group mailings and the media.

The list consists of:

- code of the pharmaceutical
- name of the active ingredient
- Anatomic Therapeutic Chemical (ATC) code
- trade name of the pharmaceutical, strength, pharmaceutical form and pack size
- name of the marketing authorisation holder (MAH)
- reimbursement details (reimbursement rates, diagnoses, restrictions for prescribing)[6].

The specialists in the Pharmaceutical Policy Unit of the Health Care Department of the Ministry of Social Affairs (SM) are responsible for the changes to the positive list for reimbursement and the communication of these changes to the public.

The criteria for the inclusion of pharmaceuticals into the positive list are as follows:

1. need of the insured patient for the treatment regarding the indicated medicinal service;
2. proved medicinal efficacy of the pharmaceutical and need of the insured person for the other pharmaceuticals during the treatment;

3. economic reasonability of the use of the pharmaceutical;
4. presence of the alternate pharmaceuticals or modes of treatment;
5. correspondance to the budgetary possibilities, including the wholesale purchase prices of the pharmaceutical in Latvia, Lithuania, France, Portugal and Hungary.

(In the case of generic pharmaceuticals the requirement is that the price be 30% lower than the original pharmaceutical of the same active ingredient in the list of reimbursed pharmaceuticals, or, in the presence of a reference price, the requirement is for the next generic to be 10% below the reference price, for the next two to be 5% below the reference price and all the rest joining the pharmaceuticals to be just below the reference price; in the case of parallel imported pharmaceuticals, their price should be 10% below the price for the original marketing authorisation holder (MAH) on the market.)

The criteria for the simplified exclusion of the pharmaceutical from the positive list are as follows:

1. marketing authorisation of the pharmaceutical has finished or stopped
2. price agreement of the pharmaceutical has finished or stopped
3. the pharmaceutical has been (re-)classified as an over-the-counter (OTC) pharmaceutical;
4. the pharmaceutical is not marketed.

If the pharmaceutical does not fulfil the inclusion criteria, all the conditions will be negotiated with the marketing authorisation holder (MAH) and if there is no agreement between both parties, the application will be denied.

Hospitals have a service- and diagnosis-related group (DRG)-based financing system through the Estonian Health Insurance Fund (EHIF). The prices of pharmaceuticals have been bound to the reference price of hospital day in most cases. The reference prices of some pharmaceuticals, handled like services, have been presented in Regulation of the Government No. 327, 22.12.2005 “List of the medicinal services of the Estonian Health Insurance Fund (EHIF)”.

The hospitals are paid by the Estonian Health Insurance Fund (EHIF) on the basis of invoices presented to the Estonian Health Insurance Fund (EHIF). Payment to the hospitals for the pharmaceuticals is arranged in two ways:

- according to the reference price of hospital day;
- according to the separate service price in the list of medicinal services – used for the most expensive and rarely used pharmaceuticals[9].

These are the prices, determined by the Estonian Health Insurance Fund (EHIF). The hospitals may buy the pharmaceuticals at the prices according to the contracts with suppliers. In other cases the prices of pharmaceuticals have been bound to the price of hospital day and are not available to the public[20]. There are no longer any specific reimbursement conditions/systems in place for pharmaceuticals used in hospitals and nursing homes.

[20] https://www.riigiteataja.ee/ert/act.jsp?id=12795127

4.3 Reference price system

Estonia has applied a reference price system since January 2003. Pharmaceuticals are grouped on the basis of different active ingredients (i.e. Anatomic Therapeutic Chemical ATC-5 level) if pharmaceuticals of the same active ingredient and route of administration from more than one marketing authorisation holder (MAH) are available on the market. Parallel traded pharmaceuticals are included into the reference price system as well.

The basis for settling reference prices of pharmaceuticals is set out in the Health Insurance Act[6]. According to this, the Ministry of Social Affairs (SM) is responsible for establishing the calculation methodology for reference prices and for the actual calculation of reference prices. The methodology for the calculation of reference prices has been set out in a Regulation of the Ministry of Social Affairs[21], along with the reference prices, which are changed (re-calculated, if applicable) quarterly, along with the changes to the positive list of reimbursed pharmaceuticals. The specialists in the Pharmaceutical Policy Unit of the Health Care Department of the SM are responsible for the calculation of the reference prices.

The pharmaceuticals are compared at pharmacy retail price (PRP) level, calculated according to the average daily dose (ADD). The ADD is mainly based on the defined daily dose (DDD) of the active ingredient within the noted route of administration, but it may differ sometimes, if the different average dosage of pharmaceutical enables the treatment of completely different diagnoses. Then the pharmaceuticals with the same route of administration, containing the same active ingredient are subgrouped according to the different dosage possibilities.

The pharmaceuticals are grouped for the calculation of reference prices according to their pharmaceutical form, as follows:

1. oral solid pharmaceutical form
2. oral liquid pharmaceutical forms
3. sublingual pharmaceutical forms
4. parenteral pharmaceutical forms
5. inhaled pharmaceutical forms
6. nasal pharmaceutical forms
7. transdermal pharmaceutical forms
8. rectal pharmaceutical forms
9. vaginal pharmaceutical forms
10. local pharmaceutical forms.

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www.sm.ee/eng/HtmlPages/RavimitepiirhindadearvutaminetõlkimiseksEN_ok_ED_C/$file/RavimitepiirhindadearvutaminetõlkimiseksEN_ok_ED_C.doc

Inhaled pharmaceutical forms are subgrouped to include inhaled aerosols, powders and solutions.

The subgroups may also be formed in the calculation of the reference prices of the following types of pharmaceutical:

1. pharmaceuticals taking effect over a prolonged period”?;
2. pharmaceuticals, containing an administration tool, which enables different dosages;
3. pharmaceuticals of local administration, having different pharmaceutical forms depending on the type of administration;
4. combined pharmaceuticals.

If the content of the active ingredient in a single dose of the pharmaceutical differs by more than 100% from the size of average daily dose (ADD), then a new subgroup is established[20].

The reference groups of pharmaceuticals have to contain at least two pharmaceuticals of the same pharmaceutical form and duration of effect from the different marketing authorisation holders (MAH) – then the average daily dose (ADD) price of the cheaper product is used as a reference. If more than two pharmaceuticals of the same pharmaceutical form and duration of effect from different marketing authorisation holders (MAH) are available in the reference price group, the next chepest average daily dose (ADD) price of the pharmaceutical is taken for the reference price. According to the average daily dose (ADD) in pharmacy retail prices (PRP) by pack the final reference prices of pharmaceuticals are calculated for the retail level. This measure ensures better availability of the pharmaceuticals on the market at the reference price level. In addition, with the purpose of ensuring the availability of pharmaceuticals at the reference price level, the Ministry of Social Affairs (SM) concludes the relevant contracts with the pharmaceutical marketing authorisation holders (MAH) at the reference price level or below, agreeing the related wholesale purchase prices and availability of the pharmaceuticals. If the pharmaceutical will not be available on the market after the reference price comes into force, a penalty for the marketing authorisation holder (MAH) will follow.

Reference price groups are reviewed and evaluated during the quarterly changes to the reference prices, if applicable. If there are no matching pharmaceuticals on the market, the reference price is not calculated.[20]

There is no generic substitution system in Estonia. According to Regulation of Ministry of Social Affairs (SM) No. 30, 18.02.2005, on the prescription and delivery of pharmaceuticals, doctors are obliged to prescribe preferably by using the International Nonproprietary Name (INN) of the pharmaceutical. If the trade name of pharmaceutical has been used in prescribing, the doctor has to note “not to substitute” on the prescription and explain the need for that particular pharmaceutical in the patient’s medical record.

If the pharmaceutical, prescribed by the trade name, has a pharmacy retail price (PRP) above the related reference price in the group, the patient has to pay the difference at the pharmacy. If the pharmaceutical has been prescribed by International Nonproprietary Name (INN) and the patient chooses a more expensive one, the same system applies. The Estonian Health Insur-

ance Fund (EHIF) only reimburses the pharmaceuticals with reference prices up to their reference price levels[13].

4.4 Private pharmaceutical expenses

In Estonia, all pharmaceuticals included in the positive list for reimbursement are reimbursed at the 100%, 75%/90% or 50% levels, depending on the diagnoses. The exception of 90% for diagnoses reimbursed at a 75% level is valid for patients up to 16 years old, disabled and retired patients (i.e. more vulnerable people). Prescription fees applied ((national currency unit (NCU) EEK 20 at the 100% and 75%/90% reimbursement levels and EEK 50 / € 3.20 at the 50% reimbursement level) do not provide incentives for patients to opt for cheaper pharmaceuticals or treatment alternatives[6].

The price sensitivity of the patient occurs in the group of pharmaceuticals reimbursed at the 75%/90% (25%/10% of the price of the pharmaceutical paid by the patient) and 50% levels (50% of the price of the pharmaceutical above EEK 50 / € 3.20 for a total maximum EEK 200 / € 12.78 per prescription paid by the Estonian Health Insurance Fund (EHIF) and all remaining parts paid by the patient) and especially in the case of pharmaceuticals with reference prices (the Estonian Health Insurance Fund (EHIF) reimburses up to the level of the reference price). All these mechanisms have been applied in order to promote rational consumption of pharmaceuticals and encourage the responsibility of the customers[6].

The current system was applied in 2002. The system may be changed to some extent during the next years, but the plans are not clearly set out as yet.

4.4.1 Direct payments

The patients have to pay directly for pharmaceuticals not belonging to the positive list of reimbursed pharmaceuticals, as well as for the over-the-counter (OTC) products.

However, patients may apply to the Estonian Health Insurance Fund (EHIF) for individual reimbursement under special circumstances. This is mainly used in the case of pharmaceuticals with no valid marketing authorisation in Estonia, but still necessary for the individual patients and therefore imported on the basis of a one-time marketing authorisation.

If a pharmaceutical does not qualify for reimbursement on a general or individual basis (e.g. because a medicinal-therapeutically equal but cheaper treatment alternative is available, which the patient refuses), doctors may still prescribe it and patients may purchase it at their own expense[6].

4.4.2 Out-of-pocket payments

The system of out-of-pocket payments (OPP) in Estonia consists of a combination of fixed and percentage co-payments as well as deductibles, depending on the disease, the type of patient (children, adult, old age pensioner) and the reimbursement status of the pharmaceutical, as shown in Table 4.2.

In addition to any fixed co-payment or percentage co-payment rates, patients have to pay the difference between the reimbursed amount (that is calculated from the reference price) and the actual pharmacy retail price (PRP) of the pharmaceutical in question.

If the pharmaceutical expenses of a patient exceed EEK 6,000 / € 383.47, s/he has the right to request an additional pharmaceutical reimbursement from the Estonian Health Insurance Fund (EHIF). The patient has to apply for this once and the Estonian Health Insurance Fund (EHIF) calculates quarterly the sum of money that the patient should get back from the Estonian Health Insurance Fund (EHIF). This additional reimbursement scheme has been applied according to the Health Insurance Act and the Regulation of the Ministry of Social Affairs (SM) on additional pharmaceutical reimbursement[6].

This right to additional reimbursement applies until pharmaceutical expenses of EEK 20,000 /€ 1,278.23 are reached. Above this threshold no reimbursment is possible, meaning that, in contrast to many other countries, there is no out-of-pocket maximum (cost ceiling), i.e. a maximum payable annual amount for pharmaceuticals to be paid by the patients in Estonia.

Table 4.2: Estonia - Reimbursement rates and patient co-payment rates 2006

Reimbursement groups of pharmaceuticals	Co-payment rate	Reimbursement rate (%)
All insured persons		
Pharmaceuticals used in the treatment of diagnoses in the 100% reimbursement list	Fixed co-payment EEK 20.00 / € 1.28[1]	100
Children under 4 years old		
All pharmaceuticals in the positive list for reimbursement	Fixed co-payment EEK 20.00 / € 1.28	100
All insured persons		
Pharmaceuticals, used in the treatment of diagnoses in the 75% reimbursement list	Fixed co-payment EEK 20.00 / € 1.28 plus 25% of the price of the pharmaceutical per prescription[1]	75
Children up to 16 years old, disabled and retired people		
Pharmaceuticals used in the treatment of diagnoses in the 75% reimbursement list	Fixed co-payment EEK 20.00 / € 1.28 plus 10% of the price of the pharmaceutical per prescription[1]	90
All insured people		
All other pharmaceuticals in the positive list for reimbursement	Fixed co-payment EEK 50.00 / € 3.20 plus 50% of the price of the pharmaceutical above EEK 50.00 / € 3.20 plus all remaining cost above EEK 200.00 / € 12.78 per prescription[1]	50% of the price of the pharmaceutical above EEK 50.00 / € 3.20 (maximum EEK 200.00 / € 12.78 per prescription)

[1] If the pharmaceutical has a reference price or price agreement, the part of the price of pharmaceutical above the reference or agreed price is paid by patient as well

Source: http://www.legaltext.ee/failid/findfile.asp?filename=X60043

4.4.2.1 Fixed co-payments

The fixed co-payment (prescription fee) is EEK 20 / € 1.28 in the 100% and 75%/90% reimbursement scheme and EEK 50 / € 3.20 in the 50% reimbursement scheme[6].

4.4.2.2 Percentage co-payments

In Estonia, all pharmaceuticals on the positive list for reimbursement are being reimbursed at different levels, based on diagnoses – 100%, 75%/90% and 50% reimbursement. In the group of pharmaceuticals reimbursed at 75%/90%, 25%/10% of the price of the pharmaceutical is paid by the patient and in the 50% category, 50% of the price of the pharmaceutical above EEK 50 / € 3.20 (in total a maximum of EEK 200 / € 12.78 per prescription) is paid by the Estonian Health Insurance Fund (EHIF) and the remaining part by the patient[6].

4.4.2.3 Deductibles

The patients, with private pharmaceutical expenditure (PE) for the pharmaceuticals in the positive list for reimbursement between EEK 6,000 / € 383.47 and EEK 20,000 / € 1,278.23 per year, have the right to supplementary benefits from the Estonian Health Insurance Fund (EHIF). The patients have to apply for the benefit once in their lifetime and from then on the Estonian Health Insurance Fund (EHIF) calculates them on a quarterly basis and pays the benefits. The private pharmaceutical expenditure (PE) concerned does not include the fixed co-payment sus and the sums paid over and above the reference price or agreed price of the pharmaceuticals.

If the overall sum of private pharmaceutical expenditure (PE) described above falls between EEK 6,000 / € 383.47 and EEK 10,000 / € 639.12 per year, the Estonian Health Insurance Fund (EHIF) reimburses patients 50% of the sum over EEK 6,000 / € 383.47. If the expenditure is between EEK 10,000 / € 639.12 and EEK 20,000 / € 1,278.23 per year, the Estonian Health Insurance Fund (EHIF) reimburses patients 75% of the sum above EEK 10,000 / € 639.12. If the pharmaceutical expenditure (PE) is over EEK 20,000 / € 1,278.23, the maximum additional benefit is EEK 9,500 / € 607.16 per year[6].

In September 2006 a new additional reimbursement scheme was introduced for the partial reimbursement of expenses incurred for the pharmaceuticals used during in vitro fertilisation (IVF). This scheme is in fully financed through the state budget to an overall sum of EEK 10 Mio. / € 639,116 for 2006 and the legal basis for the procedure was set out in the Artificial Fertilisation and Embryo Preservation Act of 1997. The detailed procedure for the reimbursement is described in the related Regulation of Ministry of Social Affairs (SM) No. 50, 14.08.2006. According to this, female insured patients have the right to receive additional reimbursement for the pharmaceuticals used in their in vitro fertilisation (IVF) procedure, up to the sum of EEK 10,000 / € 639.12 per in vitro fertilisation (IVF) procedure and for a maximum three procedures. The Estonian Health Insurance Fund (EHIF) is responsible for the calculation and payment of the sums reimbursed, as all the necessary data are kept in their database[17].

4.5 Reimbursement in the hospital sector

The reimbursement process for pharmaceuticals in the in-patient sector differs completely from that of the out-patient sector. The pharmaceuticals are fully reimbursed in in-patient care through the diagnosis-related group (DRG)-based medicinal services[6].

The related society of the doctors has to apply to the EHIF for the inclusion of a new pharmaceutical into the list of medicinal services of the Estonian Health Insurance Fund (EHIF) or for a change of the price of the service. The EHIF manages the reimbursement procedure and it's Board makes the final decision about inclusion. The criteria for the inclusion of pharmaceuticals are essentially the same as in the out-patient care sector and this is regulated by Regulation of the Government No. 301, 24.09.2002, on the creation of the list of medicinal services of the EHIF[22].

4.6 Reimbursement-related cost-containment measures

The costs and efficacy related to the use of pharmaceuticals are estimated during the reimbursement procedure and this is a crucial part of the decision on reimbursement. In the autumn of 2002 Estonia, Latvia and Lithuania agreed in the unified Baltic Guidelines on Economic Evaluation of Pharmaceuticals. Since this time the pharmacoeconomic estimation of pharmaceuticals applying for reimbursement in Estonia is carried out according to these guidelines[23].

4.6.1 Major changes in reimbursement lists

The major change introduced in 2002 involved the positive list of reimbursed pharmaceuticals – before 2002 all the pharmaceuticals with marketing authorisation were reimbursed by the Estonian Health Insurance Fund (EHIF) at least on the lowest level, without any separate application being submitted.

4.6.2 Review of reference price system

The reference price system was introduced in January 2003 in Estonia. During the first two years, the mean average daily dose (ADD) price of the second and third cheapest pharmaceutical was taken as a reference for the ADD price, for the calculation of the reference prices of packs according the number of average daily doses (ADD) per pack. Since January 2005 the average daily dose (ADD) price of the second cheapest one is being taken for the average daily dose (ADD) reference price. There have also been some minor changes in the subgrouping techniques of pharmaceuticals.

Parallel traded pharmaceuticals are being included in the reference price system. At the time of writing, no parallel traded pharmaceuticals are reimbursed in Estonia.

[22] https://www.riigiteataja.ee/ert/act.jsp?id=12817970

[23] http://www.sm.ee/eng/HtmlPages/balticguideline/$file/balticguideline.pdf

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

Since the mid-1990s some changes have occured in the field of out-of-pocket payments (OPP). The prescription fee has been raised by EEK 10 / € 0.64 since 1997. The level of reimbursement of the pharmaceuticals listed for the treatment of certain chronic illnesses has been reduced from 90% to 75% in 2002, but this was not particularly meaningful, because reimbursement of 90% has remained for certain social groups, which are in fact the majority of the users of these pharmaceuticals.

The major change introduced in 2002 involved the positive list of reimbursed pharmaceuticals – before 2002 all the pharmaceuticals with marketing authorisation were reimbursed by the Estonian Health Insurance Fund (EHIF) at least on the lowest level. Since 2002, the patient has to pay full price for the pharmaceuticals that are not part of the positive list of reimbursed pharmaceuticals. The reference price system was the major change introduced in 2003. Since then, the EHIF only reimburses these pharmaceuticals up to their reference prices, and the remaining part has to be paid by the patient at the pharmacy[6].

4.6.4 Claw-backs

Neither claw-backs nor a pay-back scheme are used as cost-containment tools in Estonia. Even the standard text of price–volume agreements contains reference to the possibility for the EHIF to claim for the proportion of the volume of pharmaceutical superseded. However, this possibility is only a reality if the manufacturer has not acted in a good faith in her/his marketing procedures.

It is therefore clear that the option of a pay-back scheme would not work in reality.

4.6.5 Reimbursement reviews

As yet, there are no official or unofficial reviews of reimbursement decisions in Estonia. The earlier decisions of the Ministry of Social Affairs (SM) are being continuously reviewed within the changes to the positive list of reimbursed pharmaceuticals, where this is relevant and applicable.

The pharmaceutical companies, patients, third party payer, etc., have the option to ask the Pricing Committee (PC) and the Ministry of Social Affairs (SM) to review the certain reimbursement decisions. They then have the possibility to appeal to various levels of court(s) regarding the review of reimbursement decisions[24].

[24] https://www.riigiteataja.ee/ert/act.jsp?id=12793353

5 Rational use of pharmaceuticals

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

5.1 Impact of pharmaceutical budgets

There are no pharmaceutical budgets for doctors applied in Estonia.

5.2 Prescription guidelines

There are clinical guidelines for the doctors in many specialities in Estonia. Following the guidelines is voluntary in most cases.

Clinical guidelines are mainly elaborated by the relevant societies of doctors, in close collaboration with the Estonian Health Insurance Fund (EHIF). The Ministry of Social Affairs (SM) is sometimes involved as well.

If the pharmaceuticals to be reimbursed are expensive and planned restrictions for reimbursed prescription are too complicated to describe in the legal act, the option of referencing to the relevant clinical guideline is used. In these cases, the Ministry of Social Affairs (SM) also takes part in the elaboration of the relevant treatment guidelines and this makes the following of clinical guidelines obligatory where prescribing of reimbursed pharmaceuticals is concerned. EHIF has the right to monitor this and does so every year retrospectively, using a system of random sampling. If any serious violations are discovered in the reimbursed prescriptions, the Estonian Health Insurance Fund (EHIF) may demand that the doctors pay back the reimbursement amount spent on unnecessary prescriptions.There are no other official or unofficial clinical audits of doctors other than those EHIF carries out.

The content of the clinical guidelines is available on the web sites of the doctors' organisations and of the Estonian Health Insurance Fund (EHIF) (and sometimes in printed form as well). This information is provided by the doctors that elaborated the guidelines and the EHIF. The guidelines are updated, if this is found to be necessary by the doctors (e.g. when new treatment options become available, if there is a change in international clinical opinions, etc.). Clinical guidelines also contain information about diagnostic limits, dosage and duration of treatment for pharmaceuticals.

Prescription of smaller size packs pharmaceuticals is not a problem in Estonia. The EHIF database is suitable for the analysis of prescribing habits of doctors and delivery habits of pharmacists. This database contains information on the reimbursed prescriptions; information on non-reimbursed prescriptions now stays in pharmacies. The most recent study, in collaboration with the EHIF, conceerned prescribing and delivery habits (i.e. how often the doctors precribe by International Nonproprietary Name (INN) or trade name and how the pharmaceuticals are being delivered).

5.3 Information to patients / doctors

Advertising and industry behaviour towards health professionals is regulated by the Medicinal Product Act 2005[7], which is in line with European Commission (EC) Directive 2001/83/EC. The State Agency of Medicines (SAM) is the competent institution in charge of supervising pharmaceutical advertising activities.

The advertising of pharmaceuticals without prevailing marketing authorisation is prohibited. The advertising of prescription-only medicine(s) (POM) to the public is also not allowed in Estonia. The patient information leaflet (PIL), summary of product characteristics (SPC) and the articles in referenced medicinal or pharmaceutical journals in their unchanged form are not regarded as advertisements.

The advertising of prescription-only medicine(s) (POM) is allowed only to health professionals (i.e. medical practitioners, pharmacists and pharmaceutical assistants).

There are many resctrictions regarding the advertising of pharmaceuticals to the health professionals, listed here.

1. Scientific literature used in the advertisements to the health professionals has to be cited without any changes.

2. The use of reimbursement rates and information in the advertisement is prohibited.

3. One health professional may receive up to five samples of pharmaceuticals (the smallest possible pack, with the label “not for sale”) per year. In total 300 samples per pharmaceutical may be provided annually.

4. The provision of samples of narcotic or psychotropic pharmaceuticals is prohibited.

5. The samples may only be provided to the prescribing medical doctors according to their written applications. The delivery of samples has to be appropriately documented.

6. Advertisements have to contain summary of product characteristics (SPC) information or information necessary for prescribing.

7. Advertising of the pharmaceuticals on the Internet is allowed only in cases where access to the information is restricted to health professionals.

Marketing authorisation holders (MAH) are prohibited to give gifts to health professionals of a value above EEK 100 / € 6.39. Higher financial support is only acceptable in supporting participation in the scientific conferences. This support cannot be broadened for people other than health professionals. The arrangement of pharmaceutical “lotteries” is prohibited[7].

Advertising of over-the-counter (OTC) pharmaceuticals is also allowed to the public, but prescription-only medicine(s) (POM), homoepathic products and contraceptives may not be advertised to the public in Estonia. Public advertisement may not contain any references to tuberculo-

sis (TBC); sexually transmitted infections or any other serious infectious disease; cancer; chronic insomnia; diabetes; or any other serious metabolic disease.

Public advertisement of the pharmaceuticals through the medium of video cassettes, CDs, books, journals or newspapers (on their top or back side), printed material directed towards children or youths, outdoor advertisements, and advertising by Internet and mail are prohibited. The marketing authorisation holder (MAH) has to report to the State Agency of Medicines (SAM) every year the amount spent on supporting health professionals, patient information stalls/stands, free samples and discounts (rebates). There is no other regulation about informing patients in the in-patient care setting[7].

5.4 Pharmacoeconomics

The Baltic Guidelines on Economic Evaluation of Pharmaceuticals have been elaborated by experts from all three Baltic states and were accepted officially by the relevant ministers of Estonia, Latvia and Lithuania in September 2002. Since then, the Guidelines have been applied in the evaluation of reimbursement applications.

These Guidelines contain the characteristics of the studies necessary for the analysis and their quality indicators, as well as the choice of analysis methods and their description. There are also some recommendations on the experts performing the analysis, but this is not restricted (i.e. any expert in the field would be acceptable)[22].

The pharmacoeconomic analysis is required within the reimbursement applications for the pharmaceuticals of new active substances for 75% or 100% reimbursement.

The same rules are also applied in the addition of any pharmaceutical to the list of medicinal services (in-patient care)[21]. As yet, there is no “willingness to pay” limit, expressed in quality-adjusted life years (QALY) or any similar criteria, set in Estonia. The pharmacoeconomic guidelines available have not been evaluated since 2002.

5.5 Generics

There is no explicit regulation (e.g. mandatory substitution) on the use of generics in place in Estonia. However, there are some regulative measures established directing the patients to the use of generics over the innovative pharmaceuticals, especially through the reference price system (cf. 4.3).

Generics are mainly seen as cost-containment tool in the out-patient care setting. There are no data available about the use of generics in the in-patient sector.

Table 5.1: Estonia - Development of the generics market in the out-patient sector 2000-2005

Generics market share	2000	2001	2002	2003	2004	2005
Volume (no. of prescriptions per year)[1]	73.4	72.0	71.0	70.0	68.4	67.7
Value in Mio. EEK	542.9	627.4	715.1	777.6	937.2	n.a.
Value in Mio. €	34.7	40.1	45.7	49.7	59.9	n.a.

[1] generics market share by packs as a % of total market

EEK = national currency unit (NCU) (Estonian Kroons)

Sources: IMS Dataview 2005; IMS Dataview 2006

As shown from the IMS data the sales of innovative and generic pharmaceuticals are almost equal by value in Estonia and have had similar growth patterns (cf. 2.1.2.2 for information on the market penetration of pharmaceuticals).

5.5.1 Generic substitution

There is no mandatory generic substitution in Estonia. However, doctors have to prescribe pharmaceuticals by their International Nonproprietary Name (INN) in the first instance; if prescribing by trade name, they have to document this in the medical record of the patient and mark "not to substitute" on the prescription.

If the pharmaceutical has been prescribed by International Nonproprietary Name (INN), the pharmacist has to offer different pharmaceuticals to the patient. In discussion with the patient the most appropriate pharmaceutical is to be chosen[13].

The prevailing reference price system, establishing the reference price of a pharmaceutical as the basis for the reimbursed amount, is a strong incentive to accept substitution, as patients would have to pay the price difference between the reference price and the reimbursed amout on top of their "normal" out-of-pocket payments (OPP) (cf. 4.4.2).

5.5.2 Generic prescription

Cf. 5.5.1.

5.5.3 Generic promotion

As mentioned earlier, the use of generics or off-patent pharmaceuticals is promoted through the reference price system among the patients and health professionals. Patients are being encouraged to ask health professionals for the cheaper alternatives; doctors are obliged to prescribe by International Nonproprietary Name (INN), if there is no medical reason for prescribing the specific trade name; and pharmacists are obliged to recommend different possibilities to the patients, if the pharmaceutical has been prescribed by International Nonproprietary Name (INN)[13].

The promotion of generic pharmaceuticals is related to the improvement of patient access to a greater variety of pharmaceuticals and cost-containment methods.

5.6 Consumption

All wholesalers report on their sales of pharmaceutical products quarterly to the State Agency of Medicines (SAM). The statistical analysis of the data is carried out regularly since 1994 and published on the State Agency of Medicines (SAM) web site (www.sam.ee). The consumption of each pack is calculated in volumes (DDD/1,000 inhabitants per year), in units and according to the amount of money spent. Reporting on sales is mandatory for wholesalers according to the Medicinal Product Act and Decree of the Ministry of Social Affairs (SM).

Information on the consumption of reimbursed pharmaceuticals in Estonia, updated quarterly, is available on the web site of the Estonian Health Insurance Fund (EHIF).

Compliance data are sometimes used in the decisions regarding reimbursement, but not on an individual basis.

The list of authorised pharmaceuticals is also published on the State Agency of Medicines (SAM) web site. This list covers most of the essential pharmaceuticals as defined by WHO, which are all freely available in the market. There are few essential pharmaceuticals not being approved by the State Agency of Medicines (SAM) because of the low interest of manufactures in the Estonian market. These pharmaceuticals can be imported according to a request of the doctors' association or specific applications from doctors on behalf of patients.

There is no separate Essential Drug Policy in place - this is one part of overall policy that requires attention, regarding the country's readiness for critical situations. However, there is an emergency stock of the choice of essential pharmaceuticals in the hospital at the University of Tartu.

6 Current challenges and future developments

This chapter covers the most relevant pharmaceutical challenges for the health care system and the future plans to meet these challenges in Estonia.

6.1 Current challenges

The current challenge in Estonia relates to the overall application of a digital prescription and retail delivery system of pharmaceuticals (so-called “E-prescription”). This project is in the process of being developed at the time of writing and the changes are planned for the year 2008.

The project mentioned above is being carried out in close cooperation with the other important initiatives, including digital enrolment, digital medical records and digital results of observation (“digital picture”).

The digital prescription system simplifies the situation both for the health care workers and the patients: the doctors will have a lot of information (e.g. the reimbursement possibilities) already specified in digital format, with all the reimbursement possibilities that are actually available for that specific patient, which makes prescribing much easier and helps to avoid any mistakes; the pharmacists have the prescription in digital form already, along with the digital controls; and patients no longer have to bring paper prescriptions with them.

6.2 Future developments

Estonia has planned to compile a comprehensive Pharmaceutical Policy document during 2007, which would appear as part of the overall health policy document.

There are also plans to increase the maximum reimbursable amount of EEK 200 / € 12.78 per prescription within the 50% reimbursement scheme and to apply reference prices and price agreements to this group of pharmaceuticals as well. These changes should decrease the out-of-pocket payment (OPP) on the part of the patients, simplify the system of reimbursement and ensure price controls are in place for all pharmaceuticals reimbursed. These changes are to be negotiated during 2007.

7 Appendixes

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State Gazette 2007
https://www.riigiteataja.ee/ert/intr/en.htm

7.3 Web links

www.sam.ee → Human medicines

www.sm.ee → Public Health → Medicines

Information on Estonian legal regulations may be retrieved from:
http://www.sm.ee/eng/pages/goproweb1274

www.haigekassa.ee → Legislation

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7.5 Editorial board

The first draft of the Estonian PPRI Pharma Profile was reviewed in December 2006 by Health Economist Ms. Claudia Habl of GÖG/ÖBIG and by Regional Adviser Mr. Kees de Joncheere of WHO Regional Office for Europe in March 2007. The second draft was reviewed by Editor-in-Chief Ms. Trine Lyager Thomsen of WHO Regional Office for Europe and again by country editor Ms. Claudia Habl in June 2007.

The final version was edited as well as layouted by Ms. Habl and copy-edited by Ms. Nicole Satterley.