

GENERAL (in 2001)

Population – **1,36 million**

GDP - **6 221,26 million EUR**

Health expenditure – **342,17 million EUR**

Health expenditure as proportion of GDP – **5,5%**

Size of pharmaceutical market – **95,86 million EUR**

Proportion of GDP spent on pharmaceuticals – **1,5%**

Pharmaceutical market growth rate – **10% a year**

Local currency – **Estonian crown (EEK)**

SUMMARY

Before 1992, Estonian health care was centrally planned and financed.

Health care reforms in early nineties introduced statutory health insurance funded by employers. Estonian health insurance is a social insurance and it relies on the principle of solidarity. Health insurance spending has been increasing at about 10% a year.

Estonia is suffering from high rates of pharmaceutical growth and stretched budgets.

How is the healthcare system structured?

The general organisation of health care and health policy in Estonia has been the responsibility of the **Ministry of Social Affairs**.

State Agency of Medicines is responsible for import and export authorization, marketing authorisation and quality control of medicinal products, inspection of pharmaceuticals and supervision over medical devices.

Estonian Health Insurance Fund covers the cost of health services required by the person in case of illness regardless of the amount of social tax paid for the person concerned. The Fund uses the social tax paid for the working population also for covering the cost of health services provided to persons who have no income with regard to work activities. 94% of the population is covered by health insurance.

The health care system and the organization of its associated bodies underwent a radical overhaul as part of the democratisation of the country.

The government has been pursuing a process of decentralisation through privatisation. Estonian Health Insurance fund makes contracts with providers for services. Their expenditure has to be equal to their revenue.

What size is the pharmaceutical market?

Sale of pharmaceuticals in Estonian retail and hospital pharmacies has continuously increased. Pharmaceutical expenditure in 2001 totalled 95,86 million EUR at public prices, an increase of 10% compared to 2000.

Total pharmaceutical expenditure as % of total health expenditure has been around 20-25% during the last years. As widely known, in most of the EU countries the total pharmaceutical expenditure as % of total health expenditure has been between 10-20%. At the same time % paid by public sector is higher in EU countries.

Approximately 98-99% of the total public pharmaceutical expenditure is covered by the health insurance budget and only 1-2% is financed by other sources.

Table 1
Expenditure for pharmaceuticals as absolute amount (in EUR) and as percentage of total health expenditure

	1999	2000	2001
Expenditure for pharmaceuticals as absolute amount (in EUR)	72 660 000	86 280 000	95 860 000
Total pharmaceutical expenditure as % of total health expenditure	19,4	22,3	25,2
Public pharmaceutical expenditure as % of total pharmaceutical expenditure	40,1	43,6	51,1

Are pharmaceuticals taxed?

Since January, 1 2001 all medicines – prescription and OTC – are subject to VAT. The standard rate of tax for all medicines is 5%.

How are prices for reimbursed drugs set?

Since 01. October 2002 an applicant must present a fair amount of information to give a cause for the proposed prices including estimated volume of retail sale in three next years and comparison prices from reference countries. The final decision on prices is made by the minister.

How are drugs reimbursed?

Pharmaceuticals are paid for according to the Estonian Health Insurance Fund's list of medicinal products (positive list for reimbursement) including 3163 different pharmaceuticals used in ambulatory system. The Ministry of Social Affairs is responsible for reimbursement listing.

The majority of drugs covered by the reimbursement system are provided on a prescription-only basis. A limited number of over-the-counter medicines (OTC) are also covered.

Pharmaceuticals are reimbursed on the basis of diagnosis. In case of some diagnoses, reimbursement may be limited to certain age groups or prescribing by certain medical specialists. Reimbursement is provided for most severe and chronic illnesses.

The reimbursement rate for pharmaceuticals is either 100%, 75% or 50%.

There are 26 different diagnoses altogether in case of which reimbursement rate of 100% is applied. Reimbursement rate of 75% applies to 40 different diagnoses.

The basic refund is 50%.

Besides the diagnoses there are also some social aspects taken into consideration. As an exception, a reimbursement rate of 90 % applies to pharmaceuticals with a reimbursement rate of 75 % in case of the following patient groups:

- ◆ children up to 10 years of age,
- ◆ persons receiving pension for incapacity for work
- ◆ insured persons over 63 years of age.

Table 2
Reimbursement rates for pharmaceuticals in Estonia

Reimbursement rate (%)	Part paid by patient	Part paid by Estonian Health Insurance Fund (EHIF)
100	co payment 20 kroons (ca 1,3 EUR)	anything above 20 kroons (ca 1,3 EUR)
90	co payment 20 kroons (ca 1,3 EUR) and 10% of anything in excess	90% of the amount exceeding 20 kroons (ca 1,3 EUR)
75	co payment 20 kroons (ca 1,3 EUR) and 25% of anything in excess	75% of the amount exceeding 20 kroons (ca 1,3 EUR)
50	co payment 50 kroons (ca 3,2 EUR) and 50% of anything in excess	50% of the amount exceeding 50 kroons (ca 3,2 EUR) but not more than 200 kroons (ca 12,7 EUR) per prescription.

Insured person has to pay his/her own co payment to pharmacy and EHIF pays the discount part to pharmacy after receiving the relevant prescriptions electronically.

Since 2003 patients who have paid more than 6,000 kroons (ca 383 EUR) a year for the necessary pharmaceuticals under the general discount system, have been offered supplementary benefit for pharmaceuticals by Estonian Health Insurance Fund. All in all, the additional compensation for pharmaceuticals may be up to 9,500 kroons (ca 607 EUR) a year.

Criteria for reimbursement

The main criteria to be considered when deciding on the inclusion of new pharmaceuticals in positive list for reimbursement were settled in the Health Insurance Act introduced on October 1st, 2002.

The criteria are:

- 1) insured person's need to get pharmaceuticals;
- 2) economic reason for the use of pharmaceuticals;
- 3) the existence of alternative pharmaceuticals or treatments;
- 4) being in proportion with the finances of health insurance, including the principle of the Health Insurance Act according to which: "In the yearly budget of the Estonian Health Insurance Fund the cost of subsidised pharmaceuticals must not exceed 20% of the cost of health care services".

From 1 November 2002 it became mandatory for applicant companies to provide pharmaco-economic information with reimbursement application.

The annexes to the application for reimbursement must among other things include a pharmacoeconomic analysis of the use of given pharmaceutical in accordance with the Baltic Guideline for Economic Evaluation of Pharmaceuticals.

The guideline governing the evaluation of new products has been in effect since September 2002.

Companies are expected to demonstrate the social, economic and health benefits of new treatments.

In assessment process State Agency of Medicines evaluates efficacy and safety when treating a specific disease and compares it with alternative treatments. Health Insurance Fund evaluates cost-effectiveness, necessity and possibility to include new drug into the positive list for reimbursement.

Two expert opinions are sent to the members of the Commission of Subsidised Pharmaceuticals, which is part of the Ministry of Social Affairs. The decision whether to include new drug into the positive list for reimbursement or not is made by the Commission of Subsidised Pharmaceuticals. Their decision is based on the opinions of State Agency of Medicines and Health Insurance Fund and financial possibilities. The decision also has to be improved by the minister of social affairs.

Is there a payback arrangement?

As the first price-volume agreements were signed in March 2003, no cases are known yet because the first agreement end up in March 2003.

Are hospital sales controlled?

Hospitals are supplied by wholesalers. The prices of drugs supplied to hospitals are controlled by the government by mean of maximum markups for wholesalers and pharmacy.

No special control over hospital's drug prices exist.

Are OTC prices regulated?

Maximum mark-ups allowed for OTCs do not differ from mark-ups valid for prescription-only-pharmaceuticals.

Generally patients have to pay in full for all OTCs. A few non-prescription medicines can be reimbursed if prescribed. OTCs make up about 30% of pharmaceutical sales in Estonia.

Pharmacies have got monopoly in OTC sales. Since all OTC's have considered to be pharmaceuticals only pharmacies are allowed to sell it.

Products paid by patient can be advertised to the public if requirements set by the Advertising Act have been followed.

How are pharmaceutical costs controlled?

According to Health Insurance Act the expenses incurred by the health insurance fund to provide benefits for medicinal products shall not exceed 20 per cent of the expenses prescribed for health service benefits in the annual health insurance budget.

Summary of pharmaceutical cost-containment measures:

Prescribing budgets

Prescribers do not have budgets in Estonia

Prescribing limitations

In order to control costs physicians can write only 1 drug per prescription and up to 6 months' supply can be prescribed and dispensed at one time.

Patient co-payment

Patients must pay the difference between the reimbursed rate and the actual price.

Patient co-payment is of combined nature consisting of both a flat fee and certain percentage. The sum of patient co-payment may vary according to different reimbursement rates for pharmaceuticals.

Price agreements

100% or 75% reimbursed drugs, which are not subject to reference pricing are covered with price agreements. Price agreement is negotiated and signed by ministry of social affairs and the manufacturer. In addition to price also sales volume is agreed in price agreements. So, we actually speak of price-volume agreements.

Reference pricing

In Estonia a reference price system has been in force since January 1st, 2003. Estonian reference price system is based on same active ingredients which are in positive list.

Other prescribing controls

Estonian Health Insurance Fund collects prescribing data from which individual doctors' behaviour can be assessed. This information is sent out to doctors showing their prescribing costs and prescribing behaviour compared to local average. However, there are no penalties or incentives for cost-effective prescribing.

Generic substitution

Estonian reimbursement system did not actively promote the use of generics until the beginning of year 2003. On January 1st, 2003 the reference price system introduced financially promoted the use of less expensive generics.

On January 1st, 2003 also a regulation was introduced that obliges doctors to prescribe pharmaceuticals according to their INN names and pharmacists to offer the cheapest available pharmaceuticals first. The doctors still also have a possibility, in case of medical reasons, to prescribe by trade name adding a note that substitution is not allowed.

Generics account for approximately 35% of pharmaceuticals available in Estonia. Still only 15% of total pharmaceutical expenditure is spent on generics.

Generic substitution is encouraged. There are, though no direct financial pressures on doctors to prescribe generically. The only reason for doctors and pharmacies to prefer generics is patient's price sensitivity.

What are wholesale/pharmacy margins?

A regressive cost plus system is in use for wholesalers and pharmacies. The maximum mark-ups allowed to wholesalers and pharmacies are specified by Minister of Social Affairs.

In the case of the importer being different from that of the wholesale dealer, they would have to share the “profit margin” and the total cost-plus percentage added should not exceed the maximum allowed. Dealings between local wholesalers must follow the same rule.

Table 3

Maximum mark-ups allowed for wholesale dealers

Price of package in EEK (EUR)	Maximum mark-up % allowed
Up to 25.00 (1,6)	20
25.01–45.00 (1,6-2,8)	15
45.01–100.00 (2,8-6,4)	10
100.01–200.00 (6,4-12,8)	5
More than 200.00 (12,8)	3

The maximum wholesale mark up for prescription medicine must not exceed 100 kronas (6,4 EUR) per package.

Retail margins are same for reimbursed drugs and for not reimbursed drugs.

Table 4

Maximum mark-ups allowed for pharmacies

Price of package in EEK (EUR)	Maximum mark-up % allowed	
	Proportional mark-up (%)	Fixed mark-up in EEK (EUR)
Up to 10.00 (0,6)	0	6 (0,4)
10.01–20.00 (0,6-1,3)	40	6
20.01–30.00 (1,3-1,9)	35	0
30.01–40.00 (1,9-2,5)	30	0
40.01–50.00 (2,5-3,2)	25	0
50.01–100.00 (3,2-6,4)	20	0
100.01–700.00 (6,4-44,7)	15	0
More than 700.00 (44,7)	0	80 (5,1)