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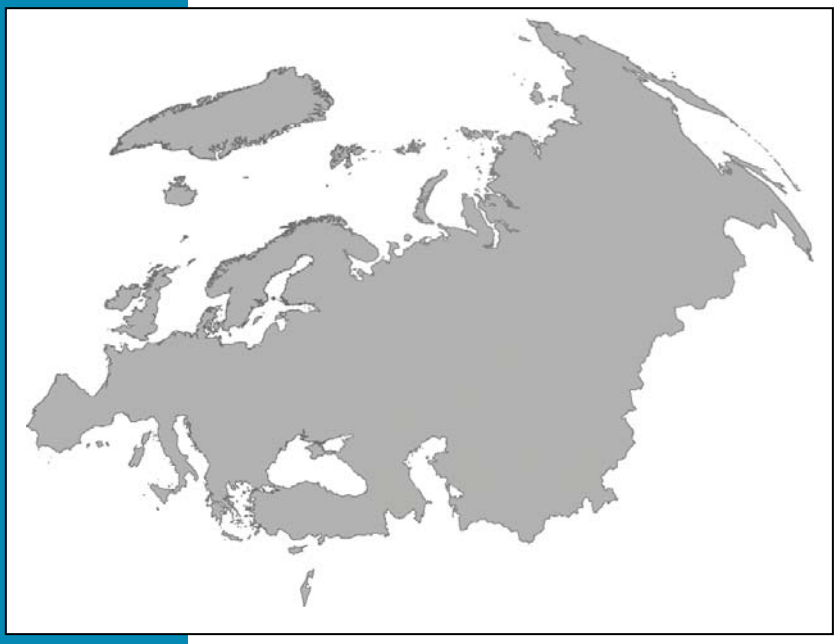

Review of the Estonian Pharmaceutical Sector: Towards the development of a National Medicines Policy

By: Panos Kanavos
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Final Report

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ABSTRACT

This report argues that it is important that a comprehensive medicines policy be developed in Estonia, with clear objectives to address issues of financing, equity in access, protection of vulnerable segments of the population, improvements in rational drug use, macroeconomic efficiency and allocative efficiency. This could be done under the stewardship of the competent authorities, the Ministry of Social Affairs in particular, and involve all relevant stakeholders in consultations to provide input. The areas identified in this report for improvement were: (a) The concerns over increasing and significant out-of-pocket expenses for prescription medicines; (b) Streamlining of the process for drug selection for positive list inclusion and subsequent reimbursement; (c) Stimulate the prescribing and dispensing of generics; (d) Facilitate generic substitution; (e) Market incentives for pharmacies to dispense generics; (f) Simplifying and reducing co-payments for patients; (g) Implementing a national program/system to improve prescribing and use of medicines; (h) Monitoring the availability of medicines at pharmacy level; (i) Ensuring adequate and timely distribution of prescription medicines (both wholesale and retail); (j) Reducing VAT on prescription medicines; and (k) Developing a comprehensive medicines policy to include all important areas.

Keywords

HEALTH SERVICES – organization and administration
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Tables and figures

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Abbreviations

ALOS	average length of stay
ARV	anti-retroviral [drugs]
ATC	Anatomic Therapeutic Chemical [Classification]
CIF	carriage insurance freight (prices)
CNS	central nervous system
CPI	consumer price index
DDD	defined daily dose
DRG	diagnosis-related group
EEK	Estonian Kroon
EHIF	Estonian Health Insurance Fund
EU	European Union
FD	family doctor
GDP	gross domestic product
GP	general practitioner
HCB	health care board
HiT	Health in Transition
HOM	hospital-only medicine
HPI	Health Protection Inspectorate
IPSL	in-patient services list
INN	international nonproprietary name
IVF	in vitro fertilization
MA	marketing authorization
MAH	marketing authorization holder
MoSA	Ministry of Social Affairs
NIHD	National Institute for Health Development
NordDRG	Nordic Diagnosis Related Group
OOP	out of pocket
OTC	over the counter [medicine]
PA	prior authorization
PC	Pharmaceutical Committee
PHC	primary health care
PL	pharmaceuticals list
POM	prescription-only medicine
PPP	purchasing power parity
PrHE	private health expenditure
PuHe	public health expenditure
SAM	State Agency of Medicines
SHI	social health insurance
TB	tuberculosis
THE	total health expenditure
VAT	value-added tax

Executive summary

Current state of the art

General trends

Pharmaceutical expenditure is increasing faster than economic growth and other health care components, such as hospital care, or ambulatory care. As a result, containing costs and spending existing resources wisely poses a continuous challenge for Estonia. Over the period between 1997 and 2008, the total expenditure on prescription only medicines (POMs) consumed in out-patient settings increased nearly six-fold, with an average annual growth rate exceeding 25% and increased from Estonia Kroon (EEK) 391 million (€25.2 million) in 1997, to EEK 2281 million (€147 million) in 2008. Of the prescription medicines that are reimbursed by health insurance, the total contribution by patients (effective co-payment) exceeded 37% in 2008 and has increased continuously from 1997, when it accounted for 25% of the total reimbursed out-patient prescription drug spending. If one takes into account the non-reimbursed component of out-patient prescription medicines, then the total effective co-payment has ranged between 36.3% (2002) and 43% (2008). This could imply increased difficulties in access, mainly for lower-income groups.

Pricing and reimbursement

A well-established system of pharmaceutical pricing and reimbursement is currently in operation in Estonia. It resembles the policies and practices followed in other EU member states. Despite that, three broad issues arise from the way the Pharmaceutical Committee (PC) operates. First, the manner in which the Pharmaceutical Committee operates has in recent years generated some tension among its constituent members, particularly the governmental agencies represented on it as it is often felt that some decisions are taken in a non-transparent manner. Second, based on local consultations with stakeholders, it is also possible that not all members of the Pharmaceutical Committee make adequate use of their voice in the decision-making process, particularly patients and medical experts (physicians). Third, the existence of In Patients Services List (IPSL) weakens the Pharmaceutical Committee, lessens its credibility, and creates further tensions among its constituent members.

Availability and affordability

There are three policy elements related to affordability problems in Estonia: the first is the extent and the structure of patient co-payments; the second relates to the determination of the reference price which is not based on the capacity of the manufacturer to supply the (entire) market; and, third, there exist differential co-payments for the same diagnosis and course of treatment based on the type of provider visited.

Dispensing and utilization of certain medicines for chronic illnesses post-patent expiry have revealed a number of interesting issues which relate to the availability of medicines in Estonia: first, generic substitution is not allowed; second, generic prescribing is in principle, compulsory, but in practice it is not enforced vigorously; third, in many cases, the originator drug continues to maintain a significant market share, and, indeed, is the market leader, despite generic alternatives being in principle

available; fourth, in many cases, the more expensive generics –priced above the reference price – seem to be "preferred" by patients, or patients are dispensed with more expensive generic alternatives, which in most cases results in them paying a significant amount out-of-pocket; fifth, cheaper generics, whose prices are closer to the reference prices in almost all cases, have very small market shares and may not be available; sixth, several thousand applications are made by individual patients each year to import medicines for which the Marketing Authorization (MA) has expired and, therefore, they are not allowed to be placed on the market.

Rational drug use

It appears that little is done to monitor and evaluate prescribing as well as promote rational drug use. Only a small sample of practices are surveyed or audited each year and this occurs ex-post. The ability to exercise policy in this way is somewhat compromised in the absence of incentives or disincentives. Any data on dispensing collected by Estonian Health Insurance Fund (EHIF) from community pharmacists are probably underutilized.

Distribution system

The total number of wholesalers in Estonia is 48, which is a high number, and the market concentration ratio for the leading six wholesalers is 92%. The leading two wholesalers represent 58% of the market. An interesting feature of distribution channel remuneration in Estonia is that markups seem to be guaranteed by law. Estonian law foresees a 7–10% margin for wholesalers and 21–25% for pharmacists and amount to an implicit guarantee of the income of the respective distributor(s). Most pharmacies are concentrated in urban areas and that there is a disincentive to maintain pharmacies in rural or remote areas. The regressive nature of margins in Estonia can often give rise to perverse incentives among retailers so that more expensive drugs can be dispensed and cheaper ones not being available. In practice more expensive drugs could offer higher discounts to (retail) distributors and there are no reasons to suggest that discounting does not occur in Estonia.

Taxation

VAT (value added tax) on medicines in Estonia (9%) is higher than many EU countries. For example, in the United Kingdom, Sweden and Cyprus, the VAT applicable to prescription medicines is 0%, whereas in France, it is a reduced 2%; Hungary, Latvia and Lithuania apply a reduced 5%. Given the high rate of out-of-pocket payments for prescription medicines in Estonia, it is likely that the lower socioeconomic groups (poorer households and elderly people) will be most adversely affected.

Recommendations

A medicines policy

It is important that a comprehensive medicines policy be developed, with clear objectives to address issues of financing, equity in access, protection of vulnerable segments of the population, improvements in rational drug use, macroeconomic efficiency and allocative efficiency. This could be done under the stewardship of the competent authorities, the Ministry of Social Affairs (MoSA) in particular, and involve all relevant stakeholders in consultations to provide input. The areas identified for improvement were: (a) The concerns over increasing and significant out-of-pocket expenses for prescription medicines; (b) Streamlining of the process for drug selection for positive list inclusion and subsequent reimbursement; (c) Stimulate the prescribing and dispensing of generics; (d) Facilitate generic substitution; (e) Market incentives for pharmacies to dispense generics; (f) Simplifying and reducing co-payments for patients; (g) Implementing a national program/system to improve prescribing and use of medicines; (h) Monitoring the availability of medicines at pharmacy level; (i) Ensuring adequate and timely distribution of prescription medicines (both wholesale and retail); (j) Reducing VAT on prescription medicines; and (k) Developing a comprehensive medicines policy to include all important areas.

Pricing

In the area of pricing, generics and health technology assessment (HTA) can be the key foci of improvement. Although Estonia does have an active generics policy, there are inconsistencies, and awareness campaigns are needed to create an atmosphere of unconditional acceptance for generic medicines among patients as well as health care providers.

As HTA is used explicitly in the Estonian decision-making process, it would be beneficial to develop a national competence centre, which will evaluate not only pharmaceuticals but also other health care technologies. Taking into account the structure of institutions it still needs to be agreed who steers the process, who involved, the processes and other details. Estonia has the expertise to develop this further building on the Baltic pharmacoeconomic guidelines under the auspices of MoSA and EHIF. An important aspect would be to involve academic expertise in such an initiative as well as expand the knowledge and skills base in Estonia. The establishment of such a competence centre would require thinking around organizational structure, involvement and direction among others.

Reimbursement

It is likely that the reimbursement list caters for the vast majority of the Estonian population, although certain aspects emerged pointing at gaps particularly in newer treatments and some of the rare conditions.

Action is required on three fronts to improve operation of the Pharmaceutical Committee and strengthen its negotiating capacity, notably, (a) transparency of decisions, (b) voice of stakeholders and (c) antagonism with the in-patient services list (IPSL). The Pharmaceutical Committee should be the only channel that recommends new pharmaceutical products to the Minister of Social Affairs and that its constituent members are seen to contribute to this goal robustly and in a team spirit.

Overall, the structure and composition of the Pharmaceutical Committee would remain the same with its representative basis, but additional evidence and perspective could be added, and, as a result, the Pharmaceutical Committee could be strengthened procedurally. Physicians and patient representatives can submit their views and perspectives on new medicines considered by the Pharmaceutical Committee in writing for the benefit of informed and evidence-based discussion. Guidelines could be drafted on what such statements might contain.

The way decisions are reached for the inclusion of expensive pharmaceuticals in the IPSL, has created certain concerns and tensions among some of the constituent parties of pharmaceutical decision-making as the process is deemed to be non-transparent, not governed by a competent committee empowered with pharmaceutical assessments and can be perceived by many as a back-door entrance to achieving reimbursement with questionable motives and antagonizing the Pharmaceutical Committee. Despite the fact that key stakeholders such as the MoSA and EHIF have the ability to participate in, comment on and validate applications made for inclusion in the IPSL, this occurs in a fragmented manner and at different stages for each stakeholder.

It may be necessary that the process through which some specialty and expensive prescription pharmaceuticals are included in the IPSL be phased out gradually and the decisions currently taken under its auspices, be transferred fully to the Pharmaceutical Committee. This will improve both the process through which new applications are assessed as well as the flow of information across the relevant stakeholders. The process according to which the PC operates needs to be clearly defined and organized, in terms of criteria and principles for drug selection, application process, as well as functioning of the PC.

A common process that decides what is included in the Reimbursement (positive) List and the IPSL is of key importance. The Pharmaceutical Committee or hospitals need to have a uniform procedure to allow for new drugs to be included the national reimbursement list.

Availability and affordability

Co-payments must be universal for patients suffering from the same disease, regardless of the doctor they visit (specialist or family doctor). If EHIF tries to discourage family practitioners from prescribing certain medications, then it should remove this right from them and enable only specialists to do so. At the same time, access to specialists should be improved and waiting times reduced so that patients can visit the right practitioner for their needs.

Co-payments should converge downwards rather than upwards and any prescribing and cost-sharing inconsistencies arising due to problems with the referral system will need to be ironed out. Such reductions in cost-sharing would not necessarily be achieved via a further injection of financial resources in the system, but could materialise through (a) rational drug use, (b) more cost-effective prescribing by physicians and (c) raising awareness on the cost of generic drugs.

Pharmacists should have (greater) generic substitution rights and the rights of physicians to prescribe brands curbed. If physicians wish to prescribe an originator

brand when generics are available this could be done if medically necessary and by seeking prior authorization from EHIF.

The problem of unauthorized medicinal products can be addressed either by EU legislation or by national action with the collaboration of the relevant competent authorities whereby reimbursement occurs on the basis of medical need, irrespective of a valid MA certificate, particularly, if the same product has a valid MA certificate in another Member State.

Exempting low turnover products from annual fees and having favourable provisions or/and practices for re-labelling of out-patient drugs or not having national language labelling in case of hospital products or, even, exempting manufacturers from marketing authorization application fees, could help maintain such products on the local market.

Rational drug use

Although there does seem to be a (clear) regulatory framework in place regarding rational drug use enabling monitoring to take place, its enforcement seems to be lacking and needs to be practiced by the competent authorities. If issues or problems arise with the division of labour and the allocation of supervisory tasks between the agencies involved (SAM, HCB, EHIF), then a new balance should be identified and agreed upon.

An integrated and enforceable system of monitoring and evaluation would provide accurate information on prescribing patterns and dispensing and would guarantee continuous flow of information between prescribers, dispensers and health insurance in real time rather than on an ex-post basis.

While it is important to understand the principles of (cost-) effective prescribing, these principles must be reinforced through adequate training schemes for prescribers as well as timely information on new technologies and rational prescribing. This role could be played by the body responsible for cost-effective prescribing and may be resource intensive.

This body's additional remit would be to facilitate and support the promotion of high quality, cost-effective prescribing through a coordinated programme of activities for health authorities, medical and pharmaceutical advisers, and GPs. Its objectives would be to develop a coordinated programme of activities covering the following five main areas of work, notably, to deliver training and education services to health care professionals and patients; to provide and help coordinate the provision of effective information, particularly to doctors; to ensure health authorities, GPs, and advisers have accurate and correct information on clinical effectiveness and evidence based care; to help design and develop a prescribing information system, including timely monitoring and feedback on prescription patterns; and to help inform national research and development initiatives on prescribing.

Changes in the reimbursement system should aim to protect certain individuals (people with chronic conditions, low-income individuals, for example) against high financial risk and access difficulties. In addition, there is room to improve rational use of pharmaceuticals. In this respect, certain strategies are being considered, including introducing supply-side measures (such as prescription budgets, active feedback to

doctors), encouraging rational prescribing (such as use of cheaper generics instead of expensive originator pharmaceuticals or prescribing well established INN-s instead of more expensive "me-too" drugs, where this is clinically justified), introducing training programmes and promoting rational use of pharmaceuticals by patients. The implementation of e-prescribing should also aid in the direction of rational prescribing.

Distribution system

In order to maintain access, both community pharmacies and internet pharmacies could deliver to the patient's door. Alternatively, as pharmacy chains own a large number of pharmacies, a requirement could be that for every certain number of pharmacies maintained by the same ownership in urban areas, a pharmacy in a remote rural area should be opened. The 30km rule should also be re-visited.

The fact that multiple wholesalers operate in Estonia may be inefficient and would require a market correction over time. While consolidation could work particularly well in wholesaling, where there appears to be some excess capacity with a large number of players, the situation is most certainly different in retailing, where over-concentration in urban centres, while justified by market forces, may leave rural areas underserved. This could be a case of tit-for-tat negotiation between the competent authorities and retail chains, for instance, to require adequate service provisions for rural areas in return for a guaranteed margin and could be laid down in existing regulation(s).

There is no officially guaranteed income for either wholesalers or pharmacists from an international experience, particularly in wholesaling and especially in situations where the market is allowed to operate and adjust the prevailing market structure to the effective market size. The Estonian government should address this by changing the law in the longer term, or/and implement minimum service requirements across the country in the short-term, both in terms of drug distribution, but also drug importation and storage, where the need arises. Where (horizontal and/or vertical) integration is allowed, consolidation may be the most notable outcome to take account of falling margins. This applies most pertinently to wholesaling, where it is probably unrealistic to sustain the current number of players in the market.

The fact that there are extensive vertical links between wholesalers and retailers, particularly in urban areas, renders the statutory margins redundant in many respects, as both sides of the distribution chain can potentially achieve economies of scale and reduced fixed cost structures through these links and the efficiency savings that usually arise. Paying the same markups to structures benefiting from vertical links and to structures that do not, places the latter at a disadvantage compared with the former in terms of financial remuneration.

Potential discounts could be addressed by enabling a clawback policy, which would allow a co-share of discounts between distributors and EHIF. The precise split of revenues would be subject to investigation and further consultation between the parties involved. The alternative would be for EHIF to adopt a preference-type policy, whereby one or two generics are purchased per product.

Pharmacies do not receive additional service fees from Health Insurance for disease management activities, e.g. blood pressure monitoring, although this may be something

that Health Insurance may wish to contemplate over the medium-term, particularly in rural areas. Patients could pay a small fee for that, whether it will be covered by insurance or not.

Taxation

There is no theoretical or empirical justification of imposing VAT on medicines, other than this being a levy by the Treasury on the health care budget and the contributions paid for by employers and employees. It is therefore recommended that the government maintains a low- or, even a zero-VAT rate for prescription medicines and, in general, for all medicines and medicinal preparations reimbursed by EHIF and for prescription medicines that are not reimbursed by EHIF. This is in line with policies in most other European countries.

1. Background and objectives

1.1 Background

Over the past 15 years major changes have been implemented in the pharmaceutical sector in Estonia, in concordance with political reforms, the development of a market economy and the EU membership. Prior to the EU membership, a national medicines policy was drafted in 2002 in close consultation with stakeholders, but this was never adopted at any level. Nevertheless, taking into account the developments in the past five years there is need to gain better understanding of developments in the pharmaceutical sector and update the policy.

In 2002 the Ministry of Social Affairs (MoSA) established a Pharmaceutical Policy Department with the aim to develop overall policy in the sector, and coordinate both within the health sector, as well as with other sectors. The department has had active role in coordinating/steering developments in the sector.

Over time, the work of the State Agency of Medicines (SAM) has been significantly expanded. Legislation has been adopted in line with EU regulations, and SAM is fully involved in the EU regulatory system and networks.

The Estonian Health Insurance Fund (EHIF) covers the costs of health services provided to insured citizens, develops policies to prevent and cure diseases, and finances the purchase of medicinal products and medical technical aids. The Fund covers the vast majority of the population, some 1.3 million inhabitants.[1] The Fund is a mandatory health insurance fund and relies on the principle of social solidarity: it covers the cost of health services required by the insured 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. Among health care services, prescription medicines are also covered by EHIF.

The EHIF's expenditure on prescription medicines included in the positive list has grown steadily in Estonia over the past 15 years, to over €82 million (approximately €60 per capita) in 2008. Overall expenditure on prescription medicines, however, is significantly higher, given the current cost-sharing arrangements and the out-of-pocket requirements for a number of prescription medicines. This is discussed at length in section 5. The reimbursement system functions on the basis of a positive list and differential reimbursement levels (100%, 90%, 75% and 50% reimbursement) and also

[1] Entitlement to EHIF coverage is based on residence in Estonia and membership in specific groups defined by law and with no possibility for opting out (European Observatory, 2008). The only group excluded from coverage is the prison population, whose health care is organized and paid for by the Ministry of Justice. Specific groups are covered by contributions from the state budget, including individuals on parental leave with small children, those who have been registered as unemployed and those catering for disabled people. Other groups, including children, pensioners, those receiving a disability pension and students, are eligible for coverage without any contribution from either themselves or the state. Since the end of 2002, voluntary EHIF coverage has been extended to those who might otherwise remain uninsured, e.g. Estonian citizens receiving a pension from overseas, and those who are not currently eligible for membership but who have been members for at least 12 months in the 2 years prior to applying for voluntary membership, as well as their dependents.

has reimbursement arrangements for special circumstances (e.g. for medicines without MA in Estonia).

Estonia, together with the other two Baltic States, has adopted guidelines on economic evaluation of medicines for their positive list decisions. The increase in pharmaceutical spending in recent years has led to the introduction of several cost containment measures already from 2002/2003, in the form of reference pricing, pricing agreements, and updated rules to introduce new medicines into the positive list, among others. Although there was an observable impact of these policies for a short period of time, public pharmaceutical expenditure has continued to grow significantly in recent years. Additionally, a rapid increase in out-of-pocket payments for medicines has been observed.

In addition to the policy initiatives outlined above, the Pharmaceutical Policy Department at the MoSA is responsible for the implementation of medicines pricing and reimbursement policy, and the composition of a positive list and nomenclature on HIV/AIDS, tuberculosis and security reserves of medicines. It also manages central procurement to cover the country's needs in communicable diseases (HIV/AIDS, tuberculosis) covered by the state budget. Similarly, the vaccines in the Estonian vaccination calendar are purchased centrally. HIV/AIDS presents a particular issue, given its prevalence of more than 1% and the high prices of anti-retroviral (ARV) drugs, which consume a considerable and growing proportion of the pharmaceutical budget.

1.2 Objectives

In light of the above developments, the MoSA requested the support of the WHO Regional Office for Europe in reviewing the current policy on pharmaceuticals and the operational arrangements in the pharmaceutical sector, with a view to supporting the development of a comprehensive policy that reaffirms the aim of equitable access to medicines within an affordable and sustainable health care system, and balances this goal with the various interests in the pharmaceutical sector. This should lead to providing support to the MoSA in policy formulating process and content development.

2. Methodology

In order to address the above objectives, and understand the determinants of access, availability and affordability of pharmaceuticals in the Estonian context, this report has relied on both secondary as well as primary data sources. Secondary sources comprised available publications on health and pharmaceutical policies in Estonia, a significant proportion of which was unpublished. Materials were acquired online or with the assistance of officials at the MoSA and the local WHO Country Office in Estonia. The bulk of the data used in this study was collected at the end of 2008 and the cut-off point for any additional information and data to be used in the report was March 2009. Therefore, the report reflects the information available at that time.

In particular, primary data were collected in the course of two missions in Estonia, the first in September 2008 and the second in November 2008. During these missions a series of meetings were organized with local stakeholders. The objective of the meetings was to canvass the views of all stakeholders operating in the context of Estonian pharmaceutical production, distribution, consumption, regulation and reimbursement, and discuss with them current pharmaceutical policies and ways of improving them. Stakeholders were also asked to highlight the key areas of concern to them. The discussions were based on open-ended questions and focused on current policies and practices. During the meetings in both missions the issues arising from the operation of the current reimbursement system were explored and discussed with stakeholders. In particular, during the visits, meetings with the following stakeholders were held:

- the Ministry of Social Affairs
- the Estonian State Agency of Medicines (SAM)
- the Estonian Health Insurance Fund (EHIF)
- physicians, both general practitioners and specialists
- wholesalers
- pharmacists
- patient associations
- pharmaceutical industry
- Estonian Patent Office.

The draft report that was prepared with the evidence collected above was presented at a seminar on May 22 in Tallinn, which brought together over 30 experts and stakeholders related to the pharmaceutical sector and medicines policy in Estonia, from the MoSA, health sector agencies, representatives of the pharmaceutical industry, pharmacies, doctors, patients, wholesalers and other experts. The seminar provided a unique opportunity to discuss the review of the medicines sector which had not been assessed comprehensively in previous years and enabled to share the draft report with all stakeholders and launch a longer process for Estonian drug policy starting in 2009 and coordinated by the MoSA to develop an updated medicines policy in Estonia. The report and the subsequent debate highlighted a number of problem areas and resulted in

putting together several proposals for improvement with the valuable contribution of all stakeholders.

The areas of medicines policy that were examined and, subsequently discussed, related to expenditures, costs and out-of-pocket payments on pharmaceuticals, pricing of pharmaceuticals, reimbursement and selection of medicines for reimbursement, distribution, taxation, the proxy-demand-side, particularly in relation to prescribing, and the impact that these have on inequalities, access, availability, affordability and rational drug use, dispensing and distribution of pharmaceuticals, also following the WHO guidelines on developing a National Drug Policy (WHO, 2001).

The points raised in the discussions are summarized in the sections that follow. Section 3 outlines the basic principles in the organization, financing and delivery of health care services in Estonia; section 4 provides an overview of pharmaceutical policies in the country and trends in pharmaceutical expenditure and consumption. Section 5, discusses the framework for reimbursement and the process for reimbursement decision-making together with the role of the key stakeholders in this process. Section 6 investigates the issues that arise in connection with access to medicines in Estonia, focusing specifically on inequalities in health care financing, affordability and availability of medicines. Section 7 examines policies aiming at rational drug use, whereas section 8 critically appraises medicines' distribution policies in Estonia. Section 9 presents medicine taxation in a comparative context and the implications for Estonia. Finally, section 10 provides an overview of the problems identified and the recommendations that arise from this process.

3. Organization, Finance and Delivery of health services

3.1 Stakeholders

Since regaining independence in 1991, the Estonian health system has undergone two major shifts: first, from a centralized, state-controlled system to a decentralized 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 planning, administration, regulation, financing and supervision of health care policy in Estonia are the Ministry of Social Affairs (*Sotsiaalministeerium*), the Health Care Board (*Tervishoiuamet*), the State Agency of Medicines (*Ravimiamet*), the Health Protection Inspectorate (*Tervisekaitseinspektsioon*), the National Institute for Health Development (*Tervise Arengu Instituut*) and the Estonian Health Insurance Fund (*Eesti Haigekassa*). In addition, the Ministry of Finance (*Rahandusministeerium*), the Ministry of Justice (*Justiitsministeerium*), the Ministry of Economy and Communication (*Majandus- ja Kommunikatsiooniministeerium*), the Ministry of Internal Affairs (*Siseministeerium*) and the Ministry of Defence (*Kaitseministeerium*), are either involved in a strategic role (e.g. managing health care finances through the state budget – Ministry of Finance), or in implementing policy within areas of their jurisdiction (Ministry of Justice, Ministry of Defence, Ministry of Economy and Communication, and Ministry of Internal Affairs).[2]

3.2 Funding health services

Health care in Estonia is largely publicly financed. Since 1992, earmarked social payroll tax has been the main source of health care financing, accounting for approximately 63% of total expenditure on health care in recent years (Võrk et al, 2009). 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. By contrast, out-of-pocket expenditures have increased as a proportion of total health care spend from 19.7% in 2000 to 23.8% in 2006 (Table 3.1).

At the end of 2006, 95.2% of the population was covered by mandatory health insurance offered by the EHIF. Entitlement to coverage is based on residence in Estonia and entitlement rules of specific groups are defined by law (Koppel et al, 2008). There is no possibility of opting out of this insurance. The only group excluded from coverage is the prison population, whose health care is organized 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. Those covered by mandatory health insurance 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

[2] For a detailed description of the role of each stakeholder in Estonian health policy-making, see Estonia: Health System Review, 2008, European Observatory.

without contributing; and those who are covered on the basis of international agreements.

As health insurance coverage is extended to all children and retired people, the uninsured population are among the working-age population (usually between the ages of 20 and 60 years). On average, the lack of insurance is twice as common among men as among women. The distribution of people with no sufficient coverage varies among household expenditure quintiles, as it is four times higher among people in the lowest quintile compared to the highest quintile, in which every 10th person reports not having (sufficient) insurance coverage. The geographical distribution of coverage shows that the rate of uninsured people is highest in the north-eastern part of Estonia (Ida-Virumaa), with 6.4% compared to a 4.5% national average in 2004 (Võrk et al, 2009). The new Government, which came into power in early 2007, has committed itself in the coalition agreement to extending the benefits package to include the currently uninsured population with regard to PHC services. However, the debate was ongoing in 2008 regarding the details of the financing arrangements and whether these might include prevention, pharmaceuticals or other elective hospital services, but this has currently been placed on hold due to the adverse economic situation.

Table 3.1 Sources of Health care financing, 2000–2006 by tax item (%)

	2000	2001	2002	2003	2004	2005	2006
Social tax	66%	67%	65.6%	65.4%	65.7%	66.2%	62.5%
Personal income tax	3.5%	3.9%	3.8%	3.2%	2.6%	2.1%	2.8%
Value added tax	4.6%	4.4%	4.3%	5.2%	4.1%	5.0%	5.2%
Out-of-pocket payments	19.7%	18.8%	19.9%	20.3%	21.3%	20.4%	23.8%
Excise taxes	1.6%	1.7%	1.7%	1.9%	1.9%	2.2%	2%
Other (foreign sector, other private sector)	4.6%	4.1%	4.7%	4.0%	4.3%	4.1%	3.7%
Total	100%	100%	100%	100%	100%	100%	100%

Source: Võrk et al, 2009.

Total health expenditure has grown steadily since 2000, but as a percentage gross domestic product (GDP) it has remained the same. Total health expenditure per capita has grown as well. Public health expenditure (PuHE) equals approximately three quarters of the total health expenditure, with one third for private health expenditure (PrHE).

3.3 Organization of and access to health care

3.3.1 Primary care

The Health Services Organization Act from 2002 sets out the regulatory framework for primary care. Out-patient care is organized as the first level of contact with the health care system. It is provided by independent family doctors (FD) contracted by 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 EHIF-contracted family doctors and few patients are willing to pay for out-patient care.

In primary care, family doctors and nurses contracted by the EHIF are paid via a combination of capitation payments (on average accounting for 73% of total payment over the past few years) and other remuneration types that together make up the budget for each practice, notably (fee for service, 15%; basic allowance, 10%; and other, 2%). Practices receive monthly prepayments, which are recalculated four times a year to reflect changes in the patient list. In January 2006 a new payment policy for family doctors was launched based on performance indicators. As a result, a family doctor's income depends not only on the size of her/his practice list but also on performance, so that any money spent on unnecessary analyses and procedures will diminish her/his income. The main objective of this initiative was to increase the quality and effectiveness of preventive services, as well as improve monitoring of chronic diseases.

All family doctors are required to work with at least one family nurse, even though there is a shortage of trained family nurses. Since 2008, in order to motivate compliance with this requirement, the EHIF applies a coefficient of 0.8 when paying the capitation fee to family doctors working without a nurse. Regulations specify in detail which services and investigations should be provided by the family physicians according to their contract with the EHIF. These regulations define the services covered by the per capita payment as well as those that are awarded with a fee-for-service payment, that is, beyond the per capita payment.

The Health Services Organization Act set out the legal form for practicing as a family doctor. Family doctors are private owners and may practice as private entrepreneurs, or found companies to provide primary health care (PHC) services. The latter may merge only with other companies providing PHC, and may not be partners or shareholders of companies providing specialized medical care. As a result of a 2007 amendment of the Health Services Organization Act (which entered into force in 2008), the local government can act as a partner and shareholder of a company providing PHC. Most family doctors with a practice list are contracted by the EHIF. The consolidation of family physicians' practices towards the establishment of group practices (from 87% in 2000 to 61% in 2008) is in line with other countries, where the scope and scale of family medicine extends beyond gatekeeping, in order to increasingly manage and coordinate patient care (Atun 2008).

The maximum and minimum number of individuals on a practice list is defined by a regulation of the Minister of Social Affairs and cannot exceed 2000, or be less than 1200. Once the limit of 2000 patients is reached, the practice can be divided into two lists by the county governor. However, lists exist with more than 2000 enrollees (mainly due to historical reasons) and less than 1200 (in specific cases, such as some rural areas or on some islands), which are accepted by the EHIF and the county governor. The average practice list comprises approximately 1800 individuals (EHIF 2008). Patients have the right to change their family doctor at any time after submitting a written application to a new family doctor. A written application is also required in the event that a patient wishes to leave the list. In some cases the family doctor can refuse to register a person – first, when the maximum number enrolled exceeds 2000 people; and second, when the place of residence of the patient is not in the service area of the family doctor concerned.

Family doctors in Estonia exercise a partial gate-keeping function and 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 inpatient. However, patients are free to access the following specialists directly, that is, without a family doctor's referral: ophthalmologists, dermato-venereologists, gynaecologists, psychiatrists, dentists, pulmonologists (in case of TB) and all needed specialist care in case of trauma. Although the chronically ill have access to specialists without referral, analysis of the effectiveness of PHC demonstrates strong evidence for a shift from secondary to primary care. Chronic illnesses are increasingly managed in the PHC setting, with an increased number of primary care consultations and reduced referrals and hospital admissions. Furthermore, management of these chronic illnesses has improved in the PHC setting, as evidenced by changing prescribing patterns pointing to increased uptake of best practices, as well as cost-effective and novel medicines, more sophisticated prescribing patterns and a concomitant decline in medicines with low or questionable therapeutic benefit (Atun et al. 2008).

Currently, patients have to pay the full cost, out of pocket, for any specialist consultation without referral from their family doctor (with the exception of certain specialists mentioned earlier). Prescribing costs in PHC settings may be subject to differential co-payment by patients depending on who actually prescribes. For conditions where the primary prescriber should be a specialist, but in lieu of that a family doctor prescribes, patients will be required to pay out-of-pocket 50% of the cost rather than 25% in the opposite case. This is further explored in section 6.3.4.

Specialist training of family doctors and the EHIF contract significantly broadened the scope of services delivered in PHC settings. Evidence-based guidelines for management of acute and chronic conditions introduced in the late 1990s, commonly encountered in PHC, encouraged family doctors to manage these conditions and reduce referrals to specialists. These changes have had a positive impact on the quality of service delivery.

Access and quality of primary care are monitored by the MoSA and the EHIF. Based on the contractual agreement between the family doctors and the EHIF, a patient with an acute condition must be provided with an appointment with a family doctor on the same day, and a patient with a chronic disease within three working days. According to information gathered from providers, in 2007, in cases of acute conditions, 99% of the patients were given an appointment with the family doctor on the same day. In the case of chronic diseases, an average of 99% of patients were given an appointment with the family doctor within the established limit of three working days. Patients in large practice lists (of over 2000 people) have to wait more than three working days to receive an appointment with their family doctor (EHIF 2007). One of the reasons for this problem is shortage of qualified family doctors and family nurses, which impedes the establishment of new family practices and more effective organization of work.

3.3.2 Secondary care

Hospitals in Estonia are owned by the public sector (the state or municipalities), but operate under private law. They contract with EHIF for a certain amount of pre-determined medical services. The amount and structure of medical services purchased by EHIF from individual hospitals is determined by the ability of the hospital to offer

the relevant services (rooms, presence of equipment and personnel) as well as the type of hospital concerned (whether general, regional, etc). The standards of services are defined in regulations and EHIF reimburses hospitals according to invoices detailing the medical services provided.

The actual payment methods, service prices and benefits package are all included and regulated in a single government-approved health service list that includes in-patient services, out-patient services, primary care and dental services. Service prices are not determined during the contract negotiation process. The management of the price list has remained the responsibility of the EHIF, even though the formal coordination mechanisms have changed. All providers are paid the same prices and there is no adjustment for hospital characteristics, such as teaching status. In addition, EHIF-contracted providers can charge patients for specialist ambulatory visits, a limited number of inpatient days and above-standard inpatient accommodation. Providers who do not have contracts with the EHIF are free to charge patients "reasonable" fees up to a defined maximum. The price list contains more than 2000 different items in total, including the whole range of different payment methods. For outpatient specialist care this includes mainly fee-for-service, per diem and diagnosis-related group (DRG)-based payment methods (Koppel et al, 2008).

The main method in out-patient care is fee-for-service (laboratory tests, radiology etc.) payment, whereas for inpatient care, a mix of fee-for-service, per diem and DRG-related payment methods is used. Fee-for-service payment involves per diem and individual units. The per diem unit includes the costs of basic examination, diagnosis and treatment planning, nursing, meals, simple medical procedures, laboratory tests and pharmaceuticals. It varies according to specialty and length of stay. If an admission lasts for longer than the set duration, additional days are reimbursed at a lower rate (the price of a long-term bed-day). This has encouraged a reduction in the average length of stay (ALOS), which fell from 11.4 days in 1994 to 6.0 days in 2005 (for acute beds). However, during recent years the reduction of the ALOS has been slowing down. Additional procedures, including operations and laboratory tests, are paid per individual item.

During the late 1990s, there was a move away from a detailed fee-for-service payment system to a case-based payment system, in order to tackle some of the perverse incentives created by the former system, particularly over-treatment, but also under-treatment and patient selection. Complex prices were introduced in 1998 for several well-defined surgical diagnoses, such as appendectomies, hip and knee replacements and normal deliveries.

The EHIF decided to introduce a DRG-based payment system for inpatient services in 2001, and in 2004 a new era in provider payment began with the introduction of that system. Due to the former fee-for-service payment system and well-developed electronic data transmission systems, Estonia already had a relatively transparent overview of hospitals' output. Therefore, the main motivation was rather financial, bearing in mind the particularly strict financial constraints of the EHIF budget. The DRG system was mainly seen as a tool to increase productivity and efficiency. Another motivation for introducing a case-based payment system was that the previously employed fee-for-service and per diem payment systems had led to inflation in the

average cost per case: inflation reached approximately 30% between January 2000 and September 2002, whereas the official price increase was only 13%. The use of a DRG system has been facilitated by the high level of detailed diagnostic data available to the EHIF through the invoicing system in place. In 2003 all primary classifications were implemented, and from 2004 the Nordic DRG classification system (NordDRG) system was implemented as a payment method (Koppel et al, 2008).

In terms of reimbursement, the DRG system is used in combination with other payment methods already in place, so the price of a case will be calculated based on the price list and NordDRG groups and reimbursed proportionally. The proportion of DRG payment for each case was initially set at a low 10%, to minimize any financial risk of the new system. In 2005 it was raised to 50% and has been at that level since. The DRG outliers system (rules to detect cases that will not come under the DRG-based reimbursement system) can be divided into two types. Firstly, cases with certain characteristics are treated as DRG outliers and are reimbursed fully through fee for service payment. Secondly, cases that are too low or high cost are reimbursed through fee-for-service payment. All inpatient care cases, as well as outpatient care cases involving surgical procedures, come under DRGs. However, some types of care, such as psychiatry, rehabilitation, long-term care and follow-up cases are not reimbursed using DRGs. There are some exemptions according to the principal diagnosis (e.g. chemotherapy) and referred cases (for example, the higher level hospital is reimbursed according to DRGs and the lower level hospital is reimbursed through fee-for-service payment).

The EHIF's strategy is to eventually increase the DRG share, without a specified numeric target for this. Full implementation will come at a later stage, specifically when the existing fee-for-service lists have been replaced by alternative classifications of health care services, as otherwise the detailed information on provider activities will be lost. How best to balance the new payment mechanism with existing mechanisms remains a major challenge for the years ahead. In principle, health service prices should cover all costs related to providing services except those related to scientific and teaching activities, which are funded separately.

With regards to pharmaceuticals consumed in hospitals, hospitals buy the necessary pharmaceuticals themselves, using the purchasing and procurement mechanisms as appropriate. For the inclusion of a new health service (including pharmaceutical) to the health care services list (HSL) the relevant association of medical specialty has to apply to the EHIF. This cannot enhance pharmaceutical prescribing in primary care settings, as the pharmaceuticals in out-patient care are considered separately from those in in-patient care that are usually attached to additional services (e.g. intravenously administered medicines, injectables, etc). The hospital pharmacies are owned, run and paid for by the hospitals themselves (PPRI, 2007).

Hospital pharmacies in Estonia only serve the needs of medicines for hospital use (in-patient care) and are not allowed to dispense pharmaceuticals to out-patients. Only ARV and tuberculosis (TB) pharmaceuticals and vaccines are dispensed through the hospitals and family doctors, but these are bought by MoSA through public procurement and are free of charge for patients. The hospitals are working with the list of pharmaceuticals belonging to the medical formulary in each hospital.

4. Overview of pharmaceutical policies

4.1 Background and stakeholders

The pharmaceutical sector in Estonia was reformed during the 1990s, with the aim of establishing pharmaceutical regulatory authorities, creating a legislative framework, introducing a system for reimbursing pharmaceuticals and privatizing pharmaceutical services. All this was achieved during a relatively short period of time and with limited human resources. During the 1990s, monitoring of pharmaceutical utilization using Anatomic Therapeutic Chemical (ATC)/defined daily dose (DDD) guidelines were initiated nationally and the Drug Information Bulletin as well as the annual data sheet compendium Pharmaca Estica were launched. The Medicinal Products Act, covering all medicinal products entering the market in Estonia, was prepared during 1993–1994 and presented to the Estonian Government and Parliament. It was not approved in its amended form, however, until December 1995.

The pharmaceutical market was regulated by regulations of the MoSA. Since 1993 a reimbursement system with compulsory patient co-payments for pharmaceuticals purchased in pharmacies was introduced. The reimbursement category, and thus the level of co-payment, is determined according to the severity of the disease, efficacy of medication and the social status (ability to pay) of the patient. Whereas a lack of effective medication was the main issue until 1992, the increase in pharmaceutical costs has become a major problem since the end of 1990s. Pharmaceutical costs increased faster than other components of the EHIF budget and exceeded the consumer price index (CPI) in the health care sector considerably (Koppel et al, 2008). Despite the cost-containment measures implemented in line with the new Health Insurance Act (2002), pharmaceutical costs have continued to increase each year, with the exception of 2003.

The regulatory framework in the pharmaceutical sector is based on the Medicinal Products Act and the Health Insurance Act. The main stakeholders in the pharmaceutical sector are the MoSA, the SAM and the EHIF. Since August 2002, following the introduction of the new Health Insurance Act, a Pharmaceutical Policy Unit was established within the structure of the MoSA. The MoSA is responsible for strategic planning in terms of pharmaceuticals, as well as pricing and reimbursement decisions, alongside a multitude of technical and operational tasks, while the SAM is responsible for control of all pharmaceutical activities (for example, the issuing of marketing authorizations, classification of pharmaceuticals and pharmacovigilance), including medical devices and veterinary products. The SAM also acts as a supervising body in the pharmaceutical field and advises the MoSA on the process of reimbursement. The EHIF is responsible for the reimbursement of pharmaceuticals and acts as an advisory body to the MoSA on the process of reimbursement.

4.2 Trends in pharmaceutical expenditure and consumption

Total pharmaceutical spending as a proportion of total health care spending (THE) in Estonia has increased over time from 17% of THE in 1997 to 27.2% in 2006 and is

comparable with other countries in the region (Poland and the Czech Republic), but higher than other countries, e.g. Spain, Denmark, Sweden or Finland (Table 4.1).[3]

Table 4.1 Total pharmaceutical expenditure as % of total health expenditure, 1997–2006

	1997	2000	2003	2006
Czech Republic	24.9	23.4	24.2	23.4
Denmark	9	8.8	9.1	8.5
Estonia	**17**	**26.4**	**26.6**	**27.2**
Finland	13.9	15.2	15.6	14.6
France	16.4	18.2	16.7	16.4
Germany	13.1	13.6	14.5	14.8
Italy	21.2	22	21.8	20
Poland	n/a	n/a	30.3	27.3
Spain	20.8	21.3	23.2	21.7
Sweden	12.4	13.8	13.7	13.3
United Kingdom	15.8	n/a	n/a	n/a

Source: Health for All Database (HFA-DB), the WHO Regional Office for Europe, 2008.

Per capita pharmaceutical expenditure in Estonia has increased four-fold between 1997 and 2006 (Table 4.2), although Estonia's pharmaceutical spending in absolute terms is lower than that in many other European countries, including some of the countries in the region. Nevertheless, the increase in per capita terms over the 1997–2006 period outpaces by a great margin countries such as Denmark, Sweden, Finland, the Czech Republic and Poland (Table 4.2).

Table 4.2 Total per capita pharmaceutical expenditure, 1997–2006, in $PPPs

	1997	2000	2003	2006
Czech Republic	230	299	324	349
Denmark	185	209	257	286
Estonia	**33.4**	**69.2**	**86.9**	**125**
Finland	218	273	345	389
France	345	441	499	564
Germany	317	363	447	500
Italy	366	452	495	524
Poland	n/a	n/a	208	236
Spain	270	327	469	533
Sweden	234	316	389	426
United Kingdom	237	n/a	n/a	n/a

Source: European Health for All database (HFA-DB), the WHO Regional Office for Europe, 2008; for Estonia, the source is EHIF, 2008.

Tables 4.3–4.7 display some key figures relating to Estonian outpatient drug consumption and expenditure up to 2007. [4] Table 4.3 shows the growth in volume of medicines consumed and the increase in expenditure over time. If the volume effect, in terms of packs, is taken out of the expenditure data, it appears that the combination of the price effect and the switch towards newer products accounts for the majority of

[3] Total pharmaceutical spending is significantly higher than pharmaceutical spending by EHIF.
[4] On average, pharmaceuticals consumed in hospitals account for approximately 18% of out-patient prescription-only medicines (POMs). This is discussed further in section 5.4.

expenditure growth over 2002–2007, assuming that pack sizes have remained the same between 2002 and 2007.

Table 4.3 Sales and consumption of pharmaceuticals, 2002–2007, including OTC medicines

Year	Consumption in packages	Growth,%	Turnover in million EEK	growth,%	Growth caused by structural appreciation (relatively more drugs have sold in more expensive price-classes),%
2007	25 926 272	4	2666	18	14
2006	25 004 665	3	2261	12	9
2005	24 278 789	1	2012	5	4
2004	24 012 172	7	1920	20	13
2003	22 406 285	1	1595	8	7
2002	22 261 982		1473	13	

Source: Ministry of Social Affairs, 2008.

Table 4.4 presents trends in the consumption of medicines by ATC category between 2003 and 2007. The leading category is drugs for the cardiovascular system, followed by drugs for the central nervous system (CNS), alimentary tract and anti-neoplastic agents. Over time the relative weight of drugs for the cardiovascular system, CNS and alimentary tract declines, whereas the biggest increase is that for anti-neoplastic drugs (from 5.6% of the total in 2003, to 11.1% in 2007). All other areas remain unaffected.

Table 4.4 Sales of medicines by ATC category (%), 2003–2007

	ATC main group	2003	2004	2005	2006	2007
C	Cardiovascular System	21.8%	21.8%	20.1%	18.1%	18.0%
N	Central Nervous System	13.6%	13.1%	13.4%	13.2%	12.9%
A	Alimentary Tract and Metabolism	13.6%	13.4%	12.9%	12.6%	11.8%
L	Anti-neoplastic and Immunomodulating Agents	5.6%	7.1%	8.1%	8.8%	11.1%
J	Anti-infectives for Systemic Use	9.3%	8.9%	9.1%	9.5%	10.1%
R	Respiratory System	7.9%	7.5%	7.8%	7.9%	7.7%
G	Genito-urinary System and Sex Hormones	6.5%	6.5%	6.8%	6.8%	6.7%
M	Musculo-skeletal System	6.7%	6.8%	6.9%	7.0%	6.3%
B	Blood and Blood Forming Organs	5.8%	5.6%	5.2%	5.5%	5.3%
D	Dermatological Products	3.8%	3.8%	4.1%	3.9%	3.5%
S	Sensory Organs	2.2%	2.2%	2.4%	2.7%	2.6%
V	Various	1.8%	2.0%	1.6%	1.8%	2.0%
H	Systemic Hormonal preparations, excl Sex Hormones and Insulins	1.1%	1.1%	1.1%	1.0%	0.9%
P	Anti-parasitic products, Insecticides and Repellents	0.4%	0.4%	0.4%	0.4%	0.4%

Source: State Agency of Medicines (SAM), 2008.

Table 4.5 summarizes the 20 most commonly used molecules in 2007, by DDD per 1000 population per day; cardiovascular drugs account for 40% of these molecules.

Table 4.6 uses health insurance data to show the level of expenditure by each of the four health insurance reimbursement categories (a co-insurance of 0%, 10%, 25%, and 50%). In 2007, 43% of all expenses reimbursed concerned prescription drugs covered 100% by health insurance; 29% concerned drugs reimbursed at 90%; 7% of all expenses related to reimbursement at 75%; and 21% of expenditure by EHIF related to medicines reimbursed at 50%. Pharmaceutical expenditure by the Estonian Health Insurance Fund rose by 16% in 2007 over 2006.

Table 4.5 Twenty most used active substances in 2007

	Active substance	DDD/1000/day
1	Ramipril	49.78
2	Amlodipine	33.68
3	Acetylsalic acid + Magnesium hudroxide	33.31
4	Enalapril	22.40
5	Metoprolol	20.97
6	Ibuprofen	20.22
7	Xylometazoline	18.93
8	Enalapril + Hydrochlorothiazide	17.89
9	Fosinopril	16.43
10	Diclofenac	14.81
11	Ascorbic acid	14.51
12	Isosorbide mononitrate	14.42
13	Acetylsalicylic acid	12.22
14	Ergocalciferol	11.68
15	Omeprazole	10.29
16	Zopiclone	9.34
17	Simvastatin	9.19
18	Metformin	9.00
19	Felodipine	8.76
20	Digoxine	8.58

Source: State Agency of Medicines (SAM), 2008.

Table 4.6 Medicinal Products reimbursed for the insured (in EEK thousand)

	2006 actual	2007 budget	2007 actual	Budget implementation %	Medicinal products reimbursed for the insured 2006	2007
Medicinal products reimbursed 100%	406 654	449 100	480 988	107%	42%	43%
Medicinal products reimbursed 90%	289 957	314 152	327 324	104%	30%	29%
Medicinal products reimbursed 75%	71 239	77 183	76 584	99%	7%	7%
Medicinal products reimbursed 50%	194 876	219 900	235 377	107%	20%	21%
Medicinal products reimbursed under special conditions	4 070	4 200	286	7%	1%	0%
TOTAL	966 796	1 064 535	1 120 559	105%	100%	100%

Source: Estonian Health Insurance Fund, 2008.

As Table 4.7 suggests, the increase in pharmaceutical spending was due to both a price and a volume effect. The number of prescriptions increased by 11% in 2007 over 2006 and the average cost per prescription rose by 4%. The total number of prescriptions in the 50% reimbursement category accounted for just under half of the total number of prescriptions wholly or partly reimbursed by EHIF and their number rose by 14% in 2007 compared with 2006. Significant increases in the number of prescriptions were also observed in the 100% reimbursement level, with number of prescriptions rising 10% and the average cost per prescription rising faster than any other category (7%).

Table 4.7 Number and average cost of reimbursement prescriptions

	2006 actual		2007 actual		Change compared to 2006%	
	Number of CP	Average cost of CP for the EHIF in EEK	Number of CP	Average cost of CP for the EHIF in EEK	Number of CP	Average cost of CP for the EHIF in EEK
Reimbursed at 100%	563 593	722	620 426	775	10%	7%
Reimbursed at 90%	1 750 253	166	1 901 540	172	9%	4%
Reimbursed at 75%	433 489	164	462 618	166	7%	1%
Reimbursed at 50%	2 645 767	74	3 012 001	78	14%	6%
TOTAL	5 393 102	179	5 996 585	187	11%	4%

Source: Estonian Health Insurance Fund, 2008.

Overall, there are three main reasons for the continuous increase of pharmaceutical costs. First, the volume of medicines consumed in Estonia has increased (volume effect); second, older pharmaceuticals were replaced by more effective and more expensive medicines (price effect); and third, new pharmaceuticals have been introduced for treatment of diseases for which there was previously no medical treatment available or the existing treatment was not available in Estonia (substitution or switch effect).

4.3 Pharmaceutical pricing

4.3.1 Overview

The pricing of prescription pharmaceuticals in Estonia is based on the Health Insurance Act and Regulations of the MoSA on the conclusion of price–volume agreements and the methodology of calculation of reference prices.

The pricing criteria for new in-patent pharmaceuticals have been determined by the law and regulation mentioned above, consisting mainly of a comparison with the prices of alternative pharmaceuticals in the same therapeutic class and reimbursed already and a comparison with the prices in other EU Member States. Other arrangements apply in the case of generic drugs as discussed in section 4.3.8.

The MoSA acts as the main authority in the negotiation and conclusion of the price–volume agreements, also forms groups of pharmaceuticals with the same active substance and administration route and calculates reference prices to them. EHIF and SAM act as experts in this process. Reimbursement rates are set at 50%, 75%, 90% and 100%. Prices of pharmaceuticals reimbursed 50%, are free. Prices of pharmaceuticals reimbursed at higher level than 50%, are regulated by concluding price-volume agreements and setting marginal prices. These pharmaceuticals that have no alternatives with the same active substance and administration route, or are the cheapest or the second cheapest among alternatives with the same active substance and administration route, are subject to conclude price-volume agreement.

The process for the conclusion of price negotiations commences with a proposal from the manufacturer to the MoSA or vice versa. Besides the proposed price and the volume of the product concerned, the proposal by the manufacturer should contain the prices of the product in other EU Member States where it is available and an explanation about the price and the volume proposed. MoSA asks the opinion of the EHIF as to whether the budget impact from the introduction of a new technology is justified and allowable.[5] Following the conclusion of the process, MoSA publishes the relevant information concerning the wholesale and retail prices on its web site.

The price-volume-based system is not applied in such cases when the manufacturer has acted “in good faith”, i.e. does not foresee any increase in pharmaceutical spending. If the sales volume set *ex ante* 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

[5] As described in http://www.haigekassa.ee/files/eng_legislation/hinnakokkuleppe_maarus_2003-02–10_eng.pdf, which provides the legal basis for this type of interaction.

manufacturer concerned. During that process MoSA clarifies the reason of exceeding and the need to change prescribing conditions. Price-volume agreements are concluded with a one year perspective, and these extended automatically every year if either partner does not wish to initiate changes (price or volume). In every extension MoSA checks the prices in other main reference countries and initiate price reduction if appropriate.

There has been no separate price committee created. Besides giving its advisory decision on the reimbursement of the pharmaceutical, the Pharmaceutical Committee (PC) (see section 5.2), working alongside the MoSA, proposes the preliminary price level for the negotiations as well. So the same institution, the MoSA, is responsible both for pricing and reimbursement decisions of the pharmaceuticals.

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.

4.3.2 Pricing policies

The current price negotiation system was implemented from 2003 and it is applicable only for specified 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.

In Estonia, there is statutory pricing, after price negotiations between manufacturers and the MoSA have taken place, for specified reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals, where only statutory mark ups are applied. The decision on the manufacturer price should be made at the same time as the decision on reimbursement, suggesting that the process of pricing is incorporated into the procedure of reimbursement.

Public procurement of pharmaceuticals is applied by the MoSA for the purchasing of HIV and tuberculosis (TB) pharmaceuticals and vaccines for the relevant patient groups, opioid dependence pharmaceuticals by the National Institute for Health Development, and by hospitals.

Price changes are possible, but are usually price decreases. These are decided by the MoSA according to the change in the price agreement. Usually manufacturers apply for a price change or any other changes in the price agreement, but MoSA may also start the process, in the context of extending a valid price-volume agreement with the manufacturer or establishing or changing an existing reimbursement.

4.3.3 Statutory pricing

Statutory pricing – in combination with negotiations – is applied for the innovative and off-patent reimbursable pharmaceuticals in Estonia. The statutory price levels are set according to the prices of the product in other EU Member States; in this context, prices in Latvia, Lithuania and Hungary are used for comparison most frequently and the lowest or average of these prices is subsequently considered by the PC. If applicable,

and similarity is proved, the prices of pharmaceutical products with similar effect are also included in the comparison.

The process to conclude the price agreement commences with an application/prising proposal from the manufacturer company to MoSA or vice versa. If considerable budget impact is foreseen, EHIF gives an opinion on the proposal within 10 days. If the EHIF opinion is positive, a contract is created and negotiated by MoSA and the respective manufacturer.[6] This stage may take a long time to conclude, because the views of the MoSA, the EHIF and the manufacturer about reasonable prices and the appropriate volume of the product examined may differ. When a decision has been reached and the price agreement has been signed by both sides, the MoSA 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.

The price agreements have two objectives; first, to fix prices and to avoid price increases and, second, to ensure availability of the medicine on the market; if the product is not available on the market, the manufacturer pays a penalty. By fixing prices through a price agreement, monitoring of expenditure and consumption can also take place.

4.3.4 Negotiations

Negotiations are one part of the price agreement procedure, starting after the preliminary pricing decision of the 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.

The procedures for setting manufacturer prices differ depending on whether the product is a new, in-patent medicine or a generic. There are specific criteria for reimbursement of parallel traded pharmaceuticals and the price for these has to be 10% lower than the price of originator product on the market.

4.3.5 Free pricing

Before 2003 most pharmaceuticals were priced freely; only maximum mark ups for wholesalers and pharmacies were applied, and manufacturer prices were not regulated. The EHIF made an attempt to conclude price agreements for certain pharmaceuticals (e.g. some cardiovascular pharmaceuticals and pain-killers) in 2002, but only seven such agreements were concluded. These agreements were used as the starting point for the conclusion of new price agreements according to the newly introduced legislation in 2003.

Since 2003, free pricing applies (a) to pharmaceuticals only reimbursed at 50% (with a ceiling on reimbursement at 200 EEK/€12.80),[7] (b) to those reimbursed at 75%, 90% or 100% but to those products that are not the cheapest or the second cheapest (with a

[6] Even if EHIF delivers a negative statement, MoSA can still make a contract with the manufacturer and negotiate directly the terms and conditions.
[7] When the drug reimbursed at 50% is also reimbursed at 75% or 100% (and therefore the price is fixed), then that fixed price applies to 50% also.

ceiling on reimbursement at reference price level, calculated by the second cheapest alternative pharmaceutical) and (c) for non-reimbursed pharmaceuticals.

4.3.6 External price referencing

External price referencing is applied for the reimbursed innovative and generic pharmaceuticals, which are the subject of the price agreements. The comparison is carried out at manufacturer price level. (Not only innovative – prices of generic drugs are also compared with their prices in other countries (but, contrary to innovative drugs what are available in other countries before in Estonia, generic drugs arrive here fast and often external comparison is not informative).

The procedure for external price referencing is interlinked both with the process of reimbursement and with the conclusion of price agreements according to the Regulations of the MoSA and based on the Health Insurance Act. External price referencing may include all EU Member States, but examines explicitly the prices of Latvia, Lithuania and Hungary. Latvia and Lithuania were chosen for the price referencing comparison because these are the closest neighbouring countries to Estonia and face a similar economic situation to Estonia. They also have a similar population structure and epidemiological status. Lithuania implements a payback system (manufacturer pays after certain reimbursed period the "overspend" money back to health insurance), and this makes Lithuanian prices less useful for valid comparison in Estonia, as they do not include the effect of the payback. Hungary was chosen because it has a similar pricing procedure (negotiations with manufacturers) to Estonia. At times, prices of pharmaceuticals are lower in other EU Member States than in the Baltic States, in which case these price levels are considered as well. If the product is new and not on the market in any of the countries noted above, then there is no possibility for external price referencing and the situation has to be accepted as it is.

In many cases the price comparison influences the prices of pharmaceuticals, especially the comparisons with Latvian and Hungarian prices, by making the manufacturers lower the prices. It is more complicated to get the manufacturers to offer the same prices for Estonia as they do in other countries and more different situation countries that are considered to have low prices, e. g. Portugal, Spain, Italy and Greece.

The comparisons are made directly on the calculated manufacturer prices (CIF prices used), and no adjustments are made according to purchasing power parities (PPP). Valid exchange rates are used in these calculations.[8]

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 home pages of the other countries.

[8] It is, however, increasingly the case that currency issues may lead to contestable outcomes. Euro-denominated prices are acceptable, but other national currencies within the EU are not always.

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

4.3.7 Internal reference pricing

Internal price referencing is used in reimbursement of pharmaceuticals in Estonia and applies to off-patent molecules. As is the practice in other countries that apply reference pricing (e.g. Germany, France, Spain, the Netherlands, among others), patients are responsible for the share of the price above the reference price in addition to any other statutory co-payments. The reference price for each product cluster is the second lowest in that cluster. Reference pricing and the way it works is discussed in greater detail in the next section.

4.3.8 Pricing of generics

If a generic of an active substance in the current form of administration first[9] 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 the same price level 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. This process also sets the reference price.

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 at least the same price level than the valid reference price. Conceptually, the addition of new generic medicines to the cluster, theoretically leads to a concomitant re-setting of the reference price. All these rules only apply for the reimbursed pharmaceuticals and are set out in the Regulation of MoSA on the procedure for drawing up and amending the list of pharmaceuticals of EHIF, the contents of the criteria for establishment of the list of pharmaceuticals, and the persons to assess compliance with criteria.[10]

4.3.9 Hospital drug procurement

There is no specific pricing system for hospital-only medicine(s) (HOM). Hospitals purchase pharmaceuticals through their own hospital pharmacies, or from retail pharmacies, and different discounts and rebates are applied by the manufacturers and wholesalers, so that low-cost pharmaceuticals can be acquired. Public procurement is the most commonly used purchasing mechanism.

Hospitals carry out pharmaceutical procurement by themselves (except for HIV and TB pharmaceuticals, opioid-dependence pharmaceuticals and vaccines, for which there is central purchasing), as discussed in section 3.3.2. In practice, hospitals are able to achieve lower prices for pharmaceuticals than those that are available for the out-patient

[9] May arise in situations where the originator molecule is patent expired and has had no marketing authorization in Estonia before.

[10] This regulation also outlines the principles of external reference pricing (international benchmarking), namely, taking into account the prices in other countries and prices of other alternatively used pharmaceuticals.

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.

4.3.10 Other categories of medicines

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.

Parallel traded pharmaceuticals have to be 10% cheaper than the price for the original marketing authorization holder (MAH) of the pharmaceutical.

4.4 Issues arising from pharmaceutical pricing policies in Estonia and their comparison with other European countries

An active generics policy necessitates fast approval of generic medicines and, subsequently, their availability on the market place so that patients/consumers can have access to them. It also requires undertaking awareness campaigns from the perspective of MoSA and EHIF to create an atmosphere of unconditional acceptance for generic medicines among patients as well as health care providers.

HTA is important in performing assessments as the cost–effectiveness criterion is used to inform opinions and, subsequently, decisions on product reimbursability. As HTA is used explicitly in the decision-making process, it would be beneficial to develop a national competence centre, which will evaluate not only pharmaceuticals but also other health care technologies. Estonia has the expertise to develop this further building on the Baltic pharmacoeconomic guidelines under the auspices of MoSA and EHIF. An important aspect would be to involve academic expertise in such an initiative as well as expand the knowledge and skills base in Estonia. The establishment of such a competence centre would require thinking around its organizational structure, involvement and direction among others and this is something to be discussed at a later stage.

Finally, it is not clear whether the fact that parallel traded pharmaceuticals need to be 10% cheaper than originator brands, is consistent with EU competition law and MoSA may need to check this.

5. Reimbursement of medicines

5.1 The current policy framework in Estonia

The policy of reimbursement of pharmaceuticals in Estonia is based on the Health Insurance Act and on the Regulation of MoSA 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".

Since 2003 the reimbursement system is characterized by a reference price system, organized around clusters of medicines and based exclusively on patent-expired molecules. There does seem to be a distinction between reimbursable and non-reimbursable pharmaceuticals. All pharmaceuticals used in out-patient care can be included in the reimbursement list, whereas most of the over-the-counter (OTC) pharmaceuticals and a number of lifestyle pharmaceuticals (such as drugs against erectile dysfunction, obesity, smoking cessation therapy, sedatives, and vaccines for overseas travellers) have been excluded from reimbursement. Since 2006 all pharmaceuticals which apply to be covered by 50% must follow the entire procedure (the same as for medicines applying for 75% and 100% reimbursement). OTC medicines included in the list of reimbursement are OTC products for some serious conditions (iron-deficiency anaemia in pregnant women, calcium in renal insufficiency, food preparations for allergic or premature children and for patients with phenylketonuria). The common policy covers the whole country and all institutions.

The Minister of Social Affairs 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 reimbursement. The Minister for Social Affairs is advised by the experts of the State Agency of Medicines (SAM) and EHIF during the reimbursement procedure, and by the independent Pharmaceutical Committee for the final decision (see next section).

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 realization of the reimbursement is very much connected with the ability of the manufacturer to accept the price levels asked.

All pharmaceuticals that are listed in the positive list, have a basic 50% reimbursement, up to a maximum of EEK 200 (€12.80) per prescription. Higher reimbursement levels (75%, 90%, and 100%) are 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 and are based on the severity of illness or suffering as a result of the illness. The list of diagnoses is based on the Regulation of the Government No. 308 of 26 September 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 (75% reimbursement level increased to 90% for 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.

In September 2006 an additional pharmaceutical reimbursement scheme was implemented, notably the reimbursement of pharmaceutical expenses incurred during artificial insemination (in vitro fertilization –IVF) procedures. Additional coverage is provided by EHIF against high OOP payments.[11] 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 EEK 10 million (€ 639 116.5) were foreseen and the patients are reimbursed through the EHIF. In this context, the role of the EHIF is technical/procedural and focuses on receiving the application, verifying the rights for reimbursement and carrying out the payments to the respective applicant patients.

In general, pharmaceutical products with active ingredient and pharmaceutical form already registered for use in Estonia and listed in the reimbursement list will receive the decision on reimbursement within 90 days, starting from the day of application. The reimbursement decision will actually enter into force with the next quarterly change in the positive list and the reference prices, usually taking place within 1–2 months after the decision has been taken. Based on these procedures, the MoSA has the right to supplement the positive list up to seven months following the positive decision on a particular product. New molecules (active substances) can only be listed following a manufacturer's application. The MoSA, EHIF, SAM, manufacturers or other interested parties may initiate changes in a product's reimbursement rate, the change of reimbursement conditions or exclusion of the product from the positive list. For this a particular procedure the MoSA regulation must be followed.

The pharmaceuticals with active ingredient and pharmaceutical form registered for use in Estonia but not listed in the reimbursement list usually receive the reimbursement decision within 180 days of the day of application. The actual change in reimbursement depends not only on the forthcoming changes to the positive list, but also and most importantly on the agreement of the manufacturer with the conditions, set out on the basis of the Pharmaceutical Committee's (PC) decision. Often the relevant negotiations will take a long time and some products will never be reimbursed, even if the decision was positive.

In exceptional circumstances, patients may apply for reimbursement of pharmaceutical products without a valid Estonian marketing authorization or for products that for a variety of reasons are not 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.

[11] Additional coverage is provided by EHIF (see the health insurance act paragraph 47) against high out-of-pocket payments. See description at http://www.haigekassa.ee/eng/health/medicinal.

The criteria for reimbursement eligibility, outlined in the legislation and not falling under the category of exceptional reimbursement, are:

- necessity to use the pharmaceutical product;
- medical and therapeutic value and safety of the pharmaceutical product;
- lack of alternative therapies;
- price and cost–effectiveness of the pharmaceutical product;
- budget impact;
- severity and dangerousness of illness, including the possibility of the illness to spread;
- necessity to reduce pain, improve substantially deteriorated quality of life and other humane considerations.

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.

The body that considers applications for inclusion into the reimbursement list is the Pharmaceutical Committee (see section 5.2 below). Based on the above criteria and the evidence provided by all stakeholders, the PC gives an opinion on whether the product is reimbursable or not. This opinion cannot be appealed against. The Minister of Social Affairs (SA) has the final say on this and can choose to accept the opinion or reject it. If a positive opinion is arrived at and the Minister of SA accepts it, this then becomes a legal act.

If the pharmaceutical is denied reimbursement based on the opinion of the PC, the company has the right to appeal the decision reached by the Minister of SA within one month after the decision is announced. The application may be reissued six months after the negative decision.

There are two groups of diagnoses, classified on the basis of the severity of illness. The criteria of dividing diseases into two groups have been determined by the Health Insurance Act. The diagnoses are determined according to the aforementioned Regulation of Government on the list of diagnoses. Based on this Regulation, pharmaceutical products listed for the most severe diseases (27 indications/groups of indications) receive full (100%) reimbursement, while pharmaceuticals indicated for less severe, but mostly chronic, diseases (44 indications/ groups of indications) are reimbursed at 75% level. 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 aged 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 that do not belong to the diagnoses outlined above are reimbursed at 50% level. In addition, it is often likely that the type of prescribing physician may influence the level of reimbursement. For instance, if a specialist prescribes a product with 75% reimbursement, this level of reimbursement

will be adhered to, whereas if a general practitioner prescribes the same product, the reimbursement offered will be 50%.

There is no official negative list of pharmaceuticals, but there are some groups of pharmaceuticals which will never be added to the positive list (hospital pharmaceuticals, smoking cessation products, pharmaceuticals for the treatment of obesity and sexual disorders, sedatives and vaccination for travelling purposes).

5.2 Pharmaceutical decision-making: The Pharmaceutical Committee

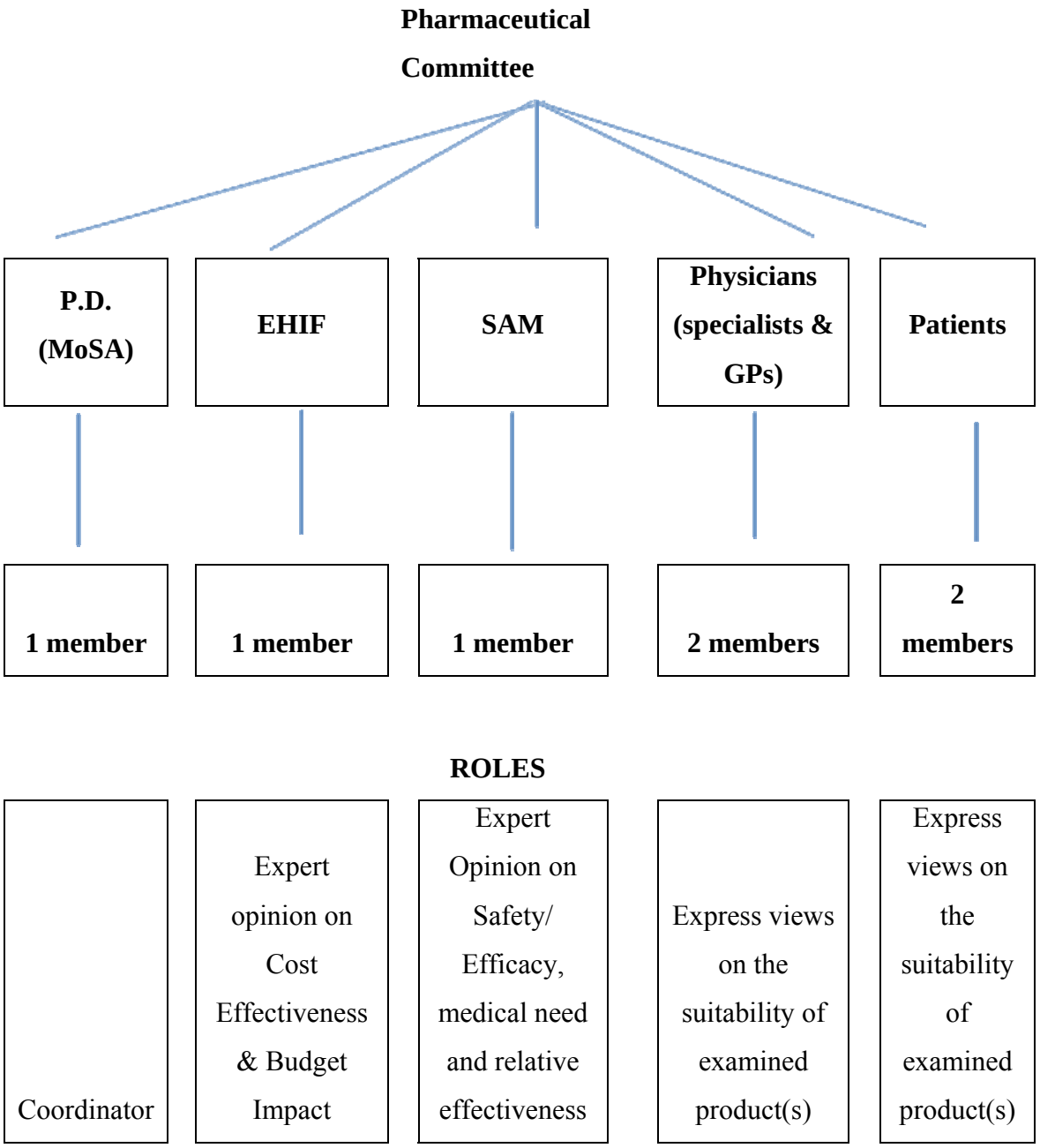
5.2.1 Stakeholders and terms of reference

The main objective of the Pharmaceutical Committee (PC) is to advise the MoSA on the pharmaceuticals list (PL), to debate the use of pharmaceutical products, to change the reimbursement rules for certain products and to advise MoSA on price setting for new drugs. The membership of the Committee is shown on Fig. 5.1 and comprises 3 state agencies (the Department of Pharmaceuticals within the MoSA, the State Agency of Medicines (SAM) and the Estonian Health Insurance Fund (EHIF)), each having a particular remit in the process and each represented by 1 expert, physicians, both specialists and generalists (having a total of 2 seats on the committee), and patients, having 2 seats, one for the patients' association and one for the association of disabled persons1 seat. Members of the PC are nominated by the organizations they represent. Agreements (contracts) with the PC ensure that its members to not have a conflict of interest. The Chair of the PC is the representative from MoSA. The PC ultimately reports to the Minister of Social Affairs. As discussed previously, the Minister takes into account the recommendation of the PC on individual products when reaching his/her decisions.

Within the context of the operation of the Committee and to ensure that the different pieces of the required evidence are available when needed, the different members have assumed certain tasks, prior to a meeting of the Committee. The EHIF is required to provide expert opinion on cost–effectiveness and budget impact of new medicines considered for inclusion on the Estonian drug reimbursement list; the role of SAM is to provide expert opinion outlining a needs assessment and how the medicine under assessment fits within the entire range of alternatives for the approved indication(s). The role of the Pharmaceutical Department at MoSA is to act as coordinator to the process, a secretariat to the PC and participate in decision-making. Patients and physicians also express their opinion and concerns about the topics discussed from their point of view. In practice, the perception is that patients do not participate actively, due to the fact that not everything is clear to them and they are not always absolutely familiar with all concepts discussed.

All members of the PC have the same task during the meeting, notably, to evaluate all aspects of a particular application. The composition of the PC assumes a fair balance between its key constituent components, although its operation and the collaboration are not always without controversy, for a variety of reasons that are elaborated below. The Committee meets on average every two months.

Fig. 5.1 The Pharmaceutical Committee and its members' roles



5.2.2 Roles and responsibilities for admission of new medicines into the Pharmaceutical List (PL)

When considering reimbursement, both economic and clinical criteria are used. Both form part of the requirements for EHIF and SAM respectively. EHIF is providing an expert opinion focusing primarily on economic and budgetary criteria, notably:

- assessment of cost–effectiveness, based on the Baltic pharmacoeconomic guidelines, in which the comparator is most often the most used drug or the best practice; in order to assess cost–effectiveness, manufacturers submit their model and data for EHIF for their results to be replicated;
- determination of consumption of alternatives, based on available data;
- potential misuse and/or overuse from an economic perspective;
- whether the forecast by the manufacturer is realistic;
- implications for the rational use of medicines; and
- budget impact analysis.

SAM is providing an opinion focusing, in particular, on clinical and safety aspects, notably:

- medical need;
- availability of alternative treatments;
- efficacy, including relative efficacy;
- safety, including relative safety;
- data about the actual utilization of the product and alternatives in Estonia and elsewhere;
- overuse and misuse potential and likely consequences;
- need for setting restrictions to prescribing to assure safe and rational prescribing; and
- possibility/probability to successfully ensure rational use.

The discussion concerning the reimbursability of new products focuses mainly on the application information and these two expert opinions and all participating stakeholders offer their perspective.

The Minister takes into account the expert opinion and the recommendation of the PC when deciding to include or not a new treatment in the Pharmaceutical List and is also empowered to overrule the recommendation of the PC if additional evidence so justifies. In all cases, EHIF must implement ministerial decisions and bear the resulting financial consequences.

Indeed, despite the negative opinion on a new pharmaceutical product by the PC, the same product may achieve reimbursement status, in light of information that has emerged *following* the opinion of the PC, but without its direct involvement or approval. Recently, the case of Ezetrol (*esetimib*) offers some insights into this situation. An

application for reimbursement at 75/90% of the drug was rejected unanimously twice by the PC on poor cost–effectiveness grounds based on the expert opinions of the EHIF and SAM. Subsequently, the application was concluded favourably on the advice of the MoSA. This decision was based on a review of the arguments for and against brought forward, the study of clinical guidelines, the comparison of the case with other similar cases and direct negotiations with the manufacturer.

5.3 Pharmaceutical decision-making: The In-Patient Services List (IPSL) of the EHIF

Together with the existence of the Pharmaceutical List, an additional list – the In-Patient Services List (IPSL) – is in operation, comprising pharmaceutical products consumed in hospitals and which are admitted to reimbursement via a completely separate procedure. Applications for inclusion into the IPSL can be made by EHIF directly, hospitals and physicians, in contrast to applications for inclusion to the Pharmaceutical List, which are made by manufacturers. The number of pharmaceutical products/interventions within the IPSL is not known with precision, partly because most services are therapeutic group-based rather than single active substance-based. However, these pharmaceutical services contain only expensive products, which are usually authorized by senior clinicians. As of July 1st, 2009, there exist 50 different health services containing expensive medicines.

The IPSL of EHIF has been established by government regulation on the proposal of the Minister of Social Affairs.[12] The list of health services (medical interventions, including new treatments) contains information on the following:

- the name of the health service;
- the code of the health service;
- the reference price of the health service;
- the limits for the payment obligation of an insured person assumed by the health insurance fund;
- the extent of cost-sharing by an insured person; and
- the conditions for application of the reference price of the health service, the limits for the payment obligation of an insured person assumed by the health insurance fund, and the extent of cost-sharing by an insured person.

Reference prices are set out in the list of health services and they cover all expenses necessary for the provision of the health service, except for expenses on training and research. Cost-sharing may apply to a particular health service and insurees are responsible for paying this. The same extent of cost-sharing applies to all insured persons and the extent shall not exceed 50 per cent of the reference price of a health service.

[12] Article 30 of the Health Insurance Law, 2002.

The criteria used to admit a new service into the list of health services include the following:

- the proven medical efficacy of the health service;
- the cost–effectiveness of the health service;
- the necessity of the health service in society and the compatibility of the service with national health policy; and
- the correspondence to the financial resources of health insurance.

A health service may be entered in the list of health services subject to cost-sharing by the insured person if (a) the aim of the provision of the health service can be achieved by other, cheaper methods which do not involve significantly greater risks or have any other significant adverse effects on the situation of the insured person; (b)the health service is directed more at improving quality of life than at treating or alleviating a disease; and (c) insured persons are generally prepared to pay for the health service themselves and the decision of an insured person to enter into a contract for the provision of the health service depends primarily on the assumption of the obligation to pay for the health service by the health insurance fund or on the extent to which the payment obligation is assumed.

Amendments to the list of health services may be initiated by the associations and professional associations of interested health care providers by entering into negotiations with EHIF, and vice versa, EHIF can also initiate amendments to the list of health services by entering into negotiations with the associations and professional associations of interested health care providers.

With regards to decision-making for including a new service into the list, the expert opinion on the clinical effectiveness of the treatment under consideration is compiled by the expert named by the party submitting the evidence to EHIF, whereas the cost effectiveness expert opinion is usually prepared by EHIF. The MoSA is consulted on the treatments under review and provides its view on their priority and their social value from a health care policy perspective. In the case of health care services, there are no single decisions after evaluating the applications (the evaluating procedure may never end). The proposal is made by the managing board of EHIF, and consists in projecting the completely new updated list of health care services. This is referred to the council of EHIF, which subsequently advises the MoSA on the establishment of the new list. Pharmaceuticals considered for inclusion into the IPSL follow the same procedure as actual services considered for the same list.

The IPSL usually changes once annually, although there are no limitations contrary to the PL. Assessing new medicines for the IPSL resembles more to an abridged procedure. The view, even among EHIF experts, is that the quality of assessment(s) may be inferior under this procedure compared with the one followed under the PC; related to that, a further key concern is how to obtain unbiased expert opinion from clinical experts, because the latter are frequently named by the institution that has submitted the application in the first place.[13]

[13] Personal communication with the EHIF.

5.4 Key trends in out- and in-patient pharmaceutical reimbursement

Compared with the framework of clearly defined policies and procedures regarding reimbursement of new medicinal products and their utilization, as well as the inclusion of new medicines in the in-patient services list, the evidence of what is actually reimbursed in Estonia is quite compelling and presented in Table 5.1.

Table 5.1 Pharmaceutical sales, per capita pharmaceutical spending and effective co-payment in Estonia, 1997–2008, (in EEK million)

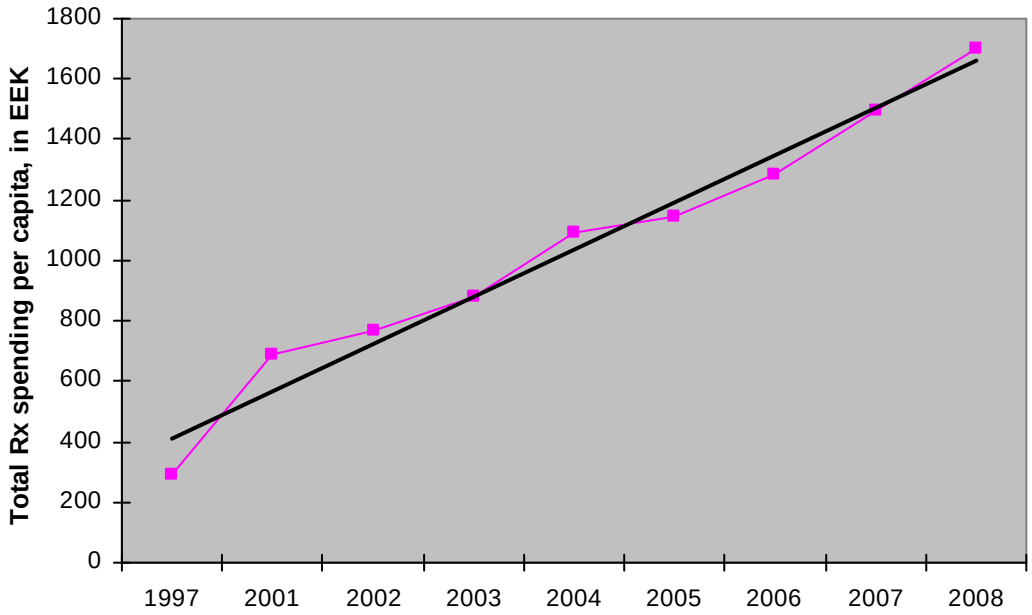
	1997	%	2001	%	2002	%	2003	%	2004	%	2005	%	2006	%	2007	%	2008	%
GENERAL PHARMACIES																		
Medicinal products (total, incl. OTC)	628	36%	1274	10%	1365	7%	1580	16%	1884	19%	1997	6%	2229	12%	2561	15%	2853	11%
Prescription only medicinal products	391	48%	929	22%	1033	11%	1186	15%	1471	24%	1536	4%	1718	12%	2001	16%	2281	14%
Reimbursed medicinal products	310	61%	848	31%	950	12%	1067	12%	1326	24%	1372	3%	1538	12%	1811	18%	2088	15%
Products paid by the sick fund	230	61%	577	32%	658	14%	676	3%	855	26%	870	2%	967	11%	1130	17%	1230	15%
Products paid by patient	80	63%	271	28%	292	8%	391	34%	472	21%	502	6%	570	14%	681	19%	788	16%
Effective co-payment on reimbursed prescription only medicinal products	**25%**		**31.9%**		**30.7%**		**36.6%**		**35.6%**		**36.6%**		**37.1%**		**37.6%**		**37.7%**	
Total effective co-payment on prescription only medicinal products	**41.1%**		**37.9%**		**36.3%**		**43%**		**41.9%**		**43.3%**		**43.6%**		**43.5%**		**43%**	
OTC products	237	20%	341	-11%	328	-4%	390	19%	408	5%	455	12%	505	11%	554	10%	566	2%
Veterinary medicinal products	5	0%	4	-33%	4	0%	5	25%	6	20%	6	0%	6	0%	6	0%	7	11%
HOSPITAL PHARMACIES																		
Medicinal products (total)	70.4	n/a	176	-10%	216	23%	239	11%	288	21%	317	10%	368	16%	495	35%	633	28%
TOTAL (general + hospital pharmacies)	698.4	n/a	1450	7%	1581	9%	1819	15%	2172	19%	2314	6%	2597	12%	3056	18%	3486	14%

Source: SAM, 2009 and compilations from SAM 2009.

Over the period between 1997 and 2008, the total expenditure on POMs consumed in out-patient settings increased nearly six-fold, with an average annual growth rate exceeding 25% and increased from EEK 391 million (€25.2 million) in 1997, to EEK 2 281 million (€147 million) in 2008.

As a result, total per capita out-patient prescription drug spending has also increased significantly over time, from just over EEK 200 (€18.7) in 1997 to over EEK 1700 (€109.8) in 2008 (Fig. 5.2).

Fig. 5.2 Total per capita expenditure for outpatient prescription pharmaceuticals (in EEK) in Estonia, 1997–2008.

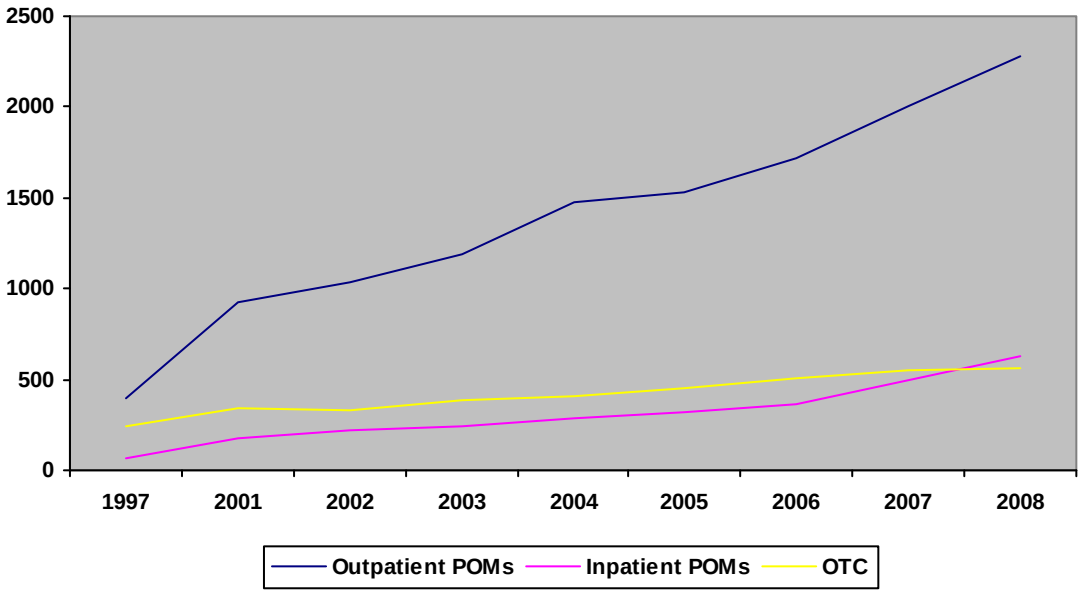


Reimbursed POMs accounted for a significant proportion of the market, reaching 90% in 2008, the remainder accounting for out-patient POMs that are not reimbursed by health insurance, which are an ever increasing figure in absolute terms.

Of the prescription medicines that are reimbursed by health insurance, the total contribution by patients (effective co-payment) exceeded 37% in 2008 and has increased continuously from 1997, when it accounted for 25% of the total reimbursed out-patient prescription drug spending. If one takes into account the non-reimbursed component of out-patient prescription medicines, then the total effective co-payment has ranged between 36.3% (2002) and 43% (2008) (Table 5.1).

Fig. 5.3 summarizes the trends in total expenditure on outpatient and inpatient POMs and OTCs over the 1997–2008 period. In-patient POMs registered a 9-fold increase between 1997 and 2008, from EEK 70 million (€4.5 million) in 1997 to EEK 633 million (€40.8 million) in 2008

Fig. 5.3 Total expenditure on out-patient, in-patient and OTC pharmaceuticals in Estonia, 1997–2008, in EEK million



Finally, consumption of OTC medicines more than doubled between 1997 and 2008 from EEK 237 million (€15.3 million) in 1997 to EEK 566 million (€36.5 million) in 2008. Overall, the total expenditure on prescription (outpatient and inpatient) and OTC medicines increased from EEK 698.4 million (€45 million) in 1997 to EEK 3 486 million (€224.3 million) in 2008. The amount paid out of pocket on outpatient prescription medicines increased from EEK 160.3 million (€10.3 million) in 1997 to EEK 980.8 million (€63.3 million) in 2008.

5.5 Issues arising from the operation of the Pharmaceutical Commission (PC) and the In-Patient Services List (IPSL)

Three broad issues arise from the way the PC operates. First, the operation of the PC has in recent years generated tension among its constituent members, particularly the governmental agencies represented on it as it is often felt that some decisions were taken in a non-transparent manner and were reached outside the scope of the PC.

Second, based on local consultations with stakeholders, it is also possible that not all members of the PC make adequate use of their voice in the decision-making process, particularly patients and medical experts (physicians). Third, the existence of IPSL weakens the PC, lessens its credibility, and creates further tensions among the constituent members of the PC.

These may have implications for the perception of the PC and the broader decision-making process by manufacturers and may compromise the ability of the system to yield conclusive decisions on reimbursement applications and what the precise decision-making levers are in each case.

With regards to physicians and patient representatives, it would be important for them to submit their views and perspectives on new medicines considered by the PC in writing for the benefit of informed and evidence-based discussion. Guidelines could be drafted on what such statements might contain. Overall, the structure and composition of the PC would remain the same with its representative basis, but additional evidence and perspective could be added, and, as a result, the PC could be strengthened procedurally.

With regards to the negotiating capacity of the PC, this could be strengthened by broadening the criteria that it uses to arrive at its recommendations to the Minister. Recent experience from the Pharmaceutical Department of the MoSA, suggests that additional negotiating tools may need to be included in the Committee's deliberations, but these will need to be carefully considered in view of their complexity and procedural difficulties. These could include direct negotiations with the manufacturer, price-volume agreements, or, even, portfolio agreements and price modulations. While these have been used directly by the Pharmaceutical Department, it is important that they occur within the remit and under the auspices of the PC and are in line with conduct in other reimbursement committees in many EU Member States. The expertise of the Pharmaceutical Department could be used in this respect. In this context, the benefit for the PC is manifold: first, it will reinforce its commanding position as an advisory body to the Minister of Social Affairs; second, it will enhance its perception from by manufacturers as a negotiating partner rather than a command-and-control body. And, third, it will satisfy the needs of its constituent members.

Finally, the existence of IPSL and the way decisions are reached has created concerns and tensions among some of the constituent parties of pharmaceutical decision-making as the process is deemed to be non-transparent, not governed by a competent committee empowered with pharmaceutical assessments and can be perceived by many as a back-door entrance to achieving reimbursement with questionable motives and antagonizing the RC. Despite the fact that key stakeholders such as the MoSA and EHIF have the ability to participate in, comment on and validate applications made for inclusion in the IPSL, this occurs in a fragmented manner and at different stages for each stakeholder.

It may be necessary that the IPSL process for prescription pharmaceuticals be phased out gradually and the decisions currently taken under its auspices, be transferred fully to the PC. This will improve both the process through which new applications are assessed as well as the flow of information across the relevant stakeholders.

6. Access to medicines

6.1 Background

Access to medicines can be examined in the context of (a) the extent to which health insurance covers the (pharmaceutical) needs of patients in an adequate manner and at affordable cost and the affordability of medicines by the general population; (b) the availability of prescribed medicines (or the medicines of choice) at appropriate outlets and at affordable cost; and (c) geographical equity, enabling patients to access physician services and pharmacies with ease without being disadvantaged by where they live.

From the view point of total consumption of medicines in the country, we have already seen in section 4 that consumption has increased over the 2002–2007 period and that over the 5-year period expenditure on medicines has practically doubled. Most of that increase is attributable to a price effect (4–14% for individual years), but there is also a modest volume effect (1–7%), as shown on Table 4.2. Average per capita monthly out of pocket expenditure on medicines have also increased significantly over time and have nearly trebled between 2000 and 2007, while all other health related out-of-pocket expenditures have doubled in the same period (Table 6.1). The share of medicines in household health related out-of-pocket spending has increased from 49% in 2000 to just over 53% in 2007. This trend highlights the rising burden to individual or household budgets of expenditure on medicines.

Table 6.1 Average monthly out-of-pocket (OOP) health expenditures, 2000–2007, in EEK

	2000	2001	2002	2003	2004	2005	2006	2007
OOP on Drugs, incl. vitamins	71	75.9	88.1	107.8	129.3	145.6	198.7	205.9
OOP on all other health goods and services[1]	69.1	63.7	68.3	84	97.7	87	149.2	151.2
OOP on medicines as% of total OOP expenditure	**50.7%**	**54.4%**	**56.3%**	**56.2%**	**57.0%**	**62.6%**	**57.1%**	**57.7%**
Ratio of drug spend over all other health-related spend	**1.03**	**1.19**	**1.29**	**1.28**	**1.32**	**1.67**	**1.33**	**1.36**

Source: Authors' compilations from Estonian Household Budget Survey Data, 2000–2007, quoted in Võrk et al, 2009 (Annex 3).

Note: Includes appliances and equipment (i.e. bandages, syringes, eyeglasses, dentures, other therapeutic appliances); outpatient services (i.e. consultations, procedures, visit fees, dental fillings, denture fitting, other dental services, lab services, acupuncture, physiotherapy, massage, and other non-hospital services); and hospital services (divided into hospital and spa services). The majority of these expenditures relate to dental care.

6.2 Income inequality in health care financing

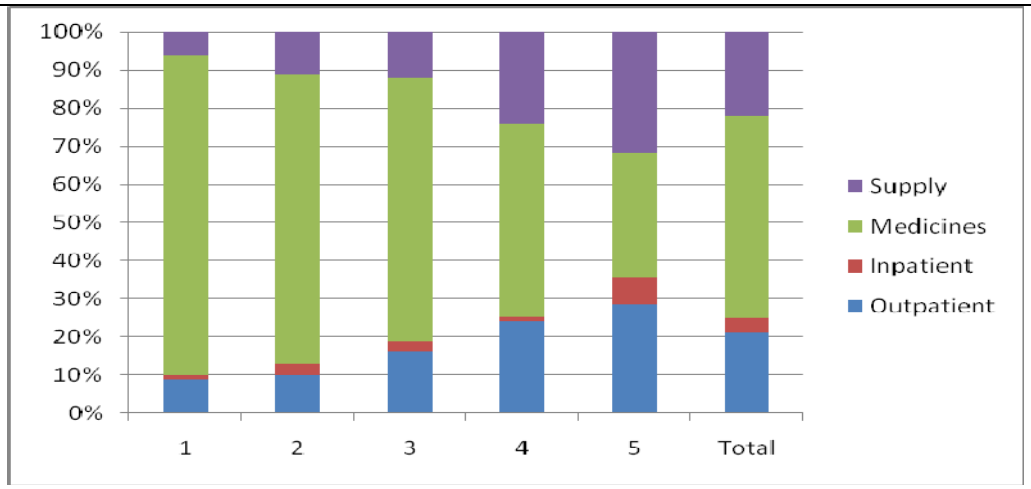
The recent study into income inequality in health care financing and utilization in Estonia, has raised significant equity concerns which are likely to impact on access to medicines in Estonia (Võrk et al, 2009). Not only does 53% of average out-of-pocket household expenditure relate to medicines, but there are concerns that different socioeconomic groups are impacted differently. A disaggregation of these figures by quintile – each quintile including equal number of households – reveals significant differences across different income levels: medicines account for 33% of total out-of-pocket health expenditures for the wealthiest quintile, and 84% for the poorest quintile (Table 6.2). The poorest quintile is also much more likely to be affected, and, in fact, impoverished because of out-of-pocket expenditures. That share approached 8% and 5% in 2006 and 2007 respectively (Table 6.3), and was significantly higher than other income quintiles.

Table 6.4 shows the household out-of-pocket expenditure in EEK by quintile and shows that households in the two wealthiest quintiles spend on average 3 to 4 times more than the lowest 2 income quintiles. The expenditure for the richest households is more than twice the expenditure for the poorer households, although the expenditure on medicines by the poorest cohort accounts for the highest proportion of their out-of-pocket health spending (84%) compared with the richest cohort 33%).

It is clear from the above that there exist significant inequalities in health care financing and utilization and that medicines and medicines financing are at the centre of the debate as they account for a significant proportion of all household out-of-pocket health-related expenditure, ranging between 33 and 84% of that expenditure.

Table 6.2 Structure of out-of-pocket health expenditures by quintile in 2007

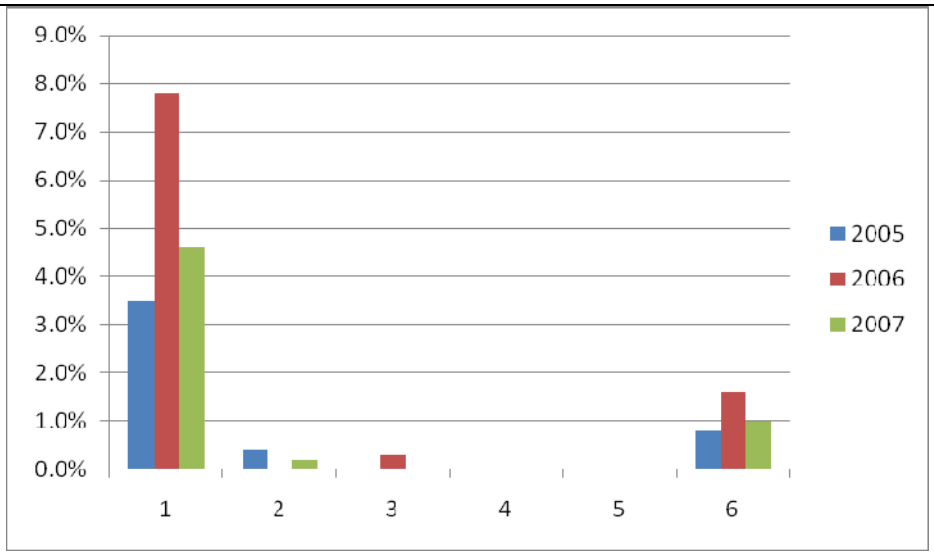
	1	2	3	4	5	Total
Outpatient	9%	10%	16%	24%	29%	21%
Inpatient	1%	3%	3%	1%	7%	4%
Medicines	84%	75%	69%	50%	33%	53%
Supply	6%	11%	12%	24%	32%	22%



Source: Võrk et al, 2009. Quintile 1–5: (poor–rich)

Table 6.3 Proportion of households impoverished due to out-of-pocket payments by quintile

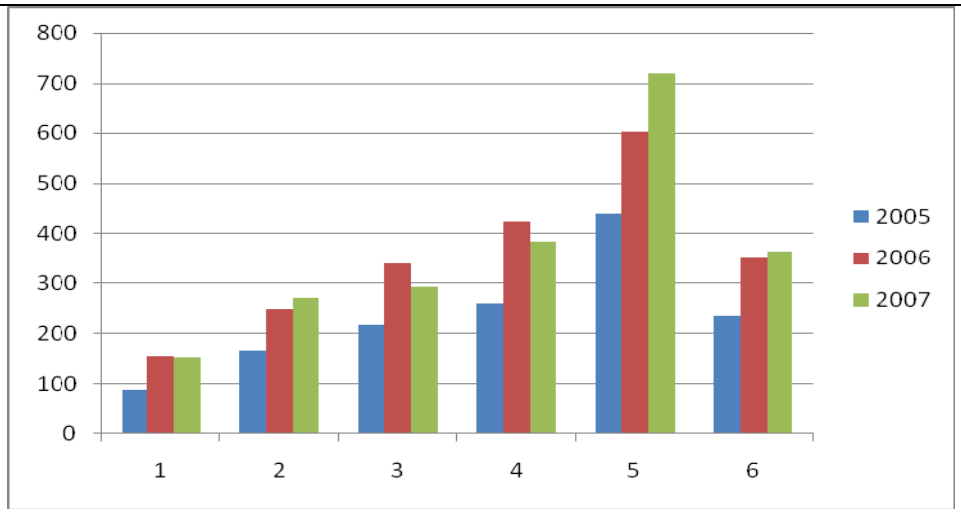
	1	2	3	4	5	Total
2005	3.5%	0.4%	0.0%	0.0%	0.0%	0.8%
2006	7.8%	0.0%	0.3%	0.0%	0.0%	1.6%
2007	4.6%	0.2%	0.0%	0.0%	0.0%	1.0%



Source: Võrk et al, 2009.

Table 6.4 Household out-of-pocket health expenditure in EEK by quintile

	1	2	3	4	5	Total
2005	88	167	218	260	440	235
2006	155	249	339	425	603	354
2007	154	272	294	384	720	365



Source: Võrk et al, 2009.

6.3 Affordability of medicines

There seem to be four specific issues which may negatively affect affordability of medicines, and, through it, equity in access, in Estonia:

1. the level of cost-sharing for prescription medicines that are included in the positive list and are reimbursed by health insurance;
2. the extent to which the positive list is comprehensive or not and the impact this has on the level of out-of-pocket expenses;
3. the coverage by the reference pricing system and the wide availability at pharmacy level of drugs priced at the reference level; and
4. the extent of differential cost-sharing requirements depending on the type of health care provider.

These four factors and their implications for affordability in the Estonian context are discussed in turn.

6.3.1 Patient cost-sharing in Estonia and implications for affordability

Co-payments for pharmaceuticals are widely used in Estonia: they are available in different forms, namely co-insurance, flat fee, and the difference between the reference price and the drug of choice. There are four co-insurance rates in Estonia (0%, 10%, 25% and 50%). In addition, there is a dispensing fee per prescription for all prescriptions; this stands at 20 EEK (or 50 EEK). Fifty-seven% of the total pharmaceutical spending by EHIF is subject to some form of co-payment and 21% of total drug spend is subject to 50% co-payment. This last category affects 50% of the total number of prescriptions. In the case of reference pricing, the patient is responsible for any part of the cost of medicine over the reference level. Co-payments in this particular case are calculated based on the following formula:

$$\textbf{Co-payment} = (RP-FDF)*\text{co-insurance} + (P_{\text{drug of choice}} - RP) + FDF \quad (1)$$

Where RP stands for reference pricing and FDF is the statutory Fixed Dispensing Fee, which currently stands at EEK 20 (50 EEK in case of 50% reimbursement level). Based on available data from health insurance (Table 4.4), the *effective* co-payment[14] in Estonia on drugs available and reimbursed from the positive list is 15.1%, without taking into consideration the effect of reference pricing through the dispensing of products that are more expensive than the reference price (examined in the next section), as well as the effect of non-filled prescriptions due to cost reasons.

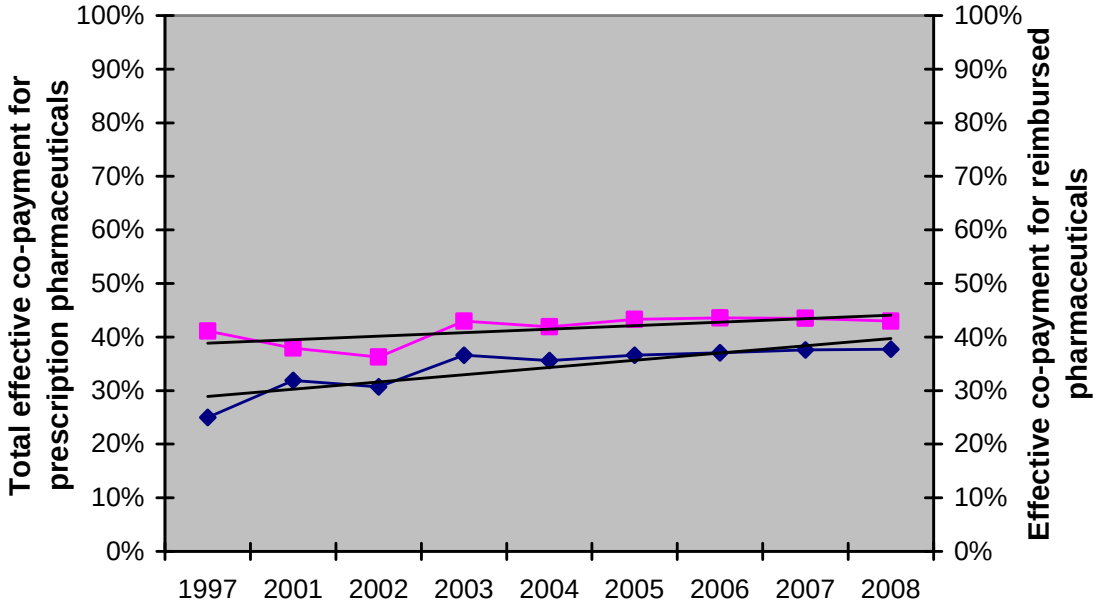
In total, Estonian patients face a cumulative 37% co-payment for the drugs that are reimbursed by EHIF. The effective co-payment for reimbursed prescription medicines has increased gradually from 25% in 1997 to 37.7% in 2008 (figure 6.1). In addition, as discussed in the previous section, not all prescription pharmaceuticals are reimbursed by EHIF and in order to access these, patients need to pay out of pocket. If this amount is also taken into consideration, then the total effective co-payment for prescription

[14] Total co-payment over total drug spend by health insurance.

medicines facing patients in Estonia was 43% in 2008, rising from 41% in 1997 (figure 6.1).

As approximately 50% of the total number of prescriptions dispensed carry a 50% co-insurance, (the average cost per prescription to patient being EEK78), it is probable that co-payments may not be affordable to parts of the population and may create further inequity.

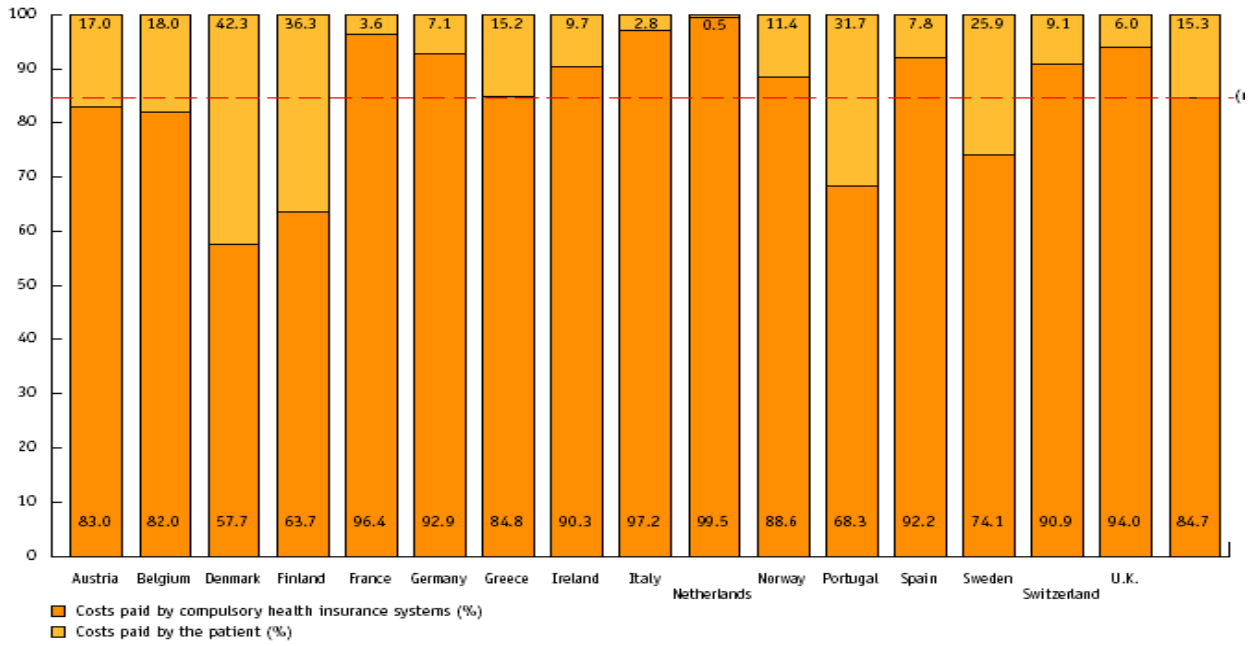
Fig. 6.1 Effective co-payment on reimbursed prescription pharmaceuticals and total effective co-payment on prescription pharmaceuticals in Estonia, 1997–2008



This level of effective co-payment is higher than most western European countries with established reimbursement systems: in the United Kingdom, the effective co-payment is 6%, whereas in France and Spain it is 3.6% and 7.8% respectively (Fig. 6.2). In all these countries, there are extensive exemptions from co-payments, based on disease type, age and income, where applicable. Most chronic diseases are either fully covered by health insurance (if they are deemed life threatening), or subject to a very modest co-payment. Given the inequalities discussed in the previous section, it is probable that co-payments in Estonia may be a barrier to accessing medicines for a share of the population. In order to avoid these, due consideration should be given to their extent and the level of income of those who pay them. It should also be researched to what extent these high levels of co-payments could be reduced without investing additional resources into reimbursement of medicines (e.g. promoting rational drug use and prescribing). Preliminary calculations by EHIF suggest that in the case of hypertension the level of cost-sharing could be reduced from its current rate of 42% to 24% if physicians prescribed on clinical cost–effectiveness criteria and patients chose the least costly alternative at the pharmacy.[15]

[15] Personal communication with EHIF.

Fig. 6.2 Effective co-payment for prescription pharmaceuticals in selected EU Member States, 2006



Source: Authors' compilations from EFPIA, Facts and Figures, 2006.

An additional issue relates to the impact the cost-sharing structure may be having on patients filling their prescriptions at a pharmacy and the broader implications for access. Informal evidence suggests that a significant proportion (between 30 and 50%) of all issued prescriptions is not dispensed. SAM estimates that 18.5% of prescriptions were not reimbursed in 2007. These figures have been widely quoted, but there is no available source for it. Indeed, EHIF issues about 40% more "blank" prescriptions compared to the number it has data about at a later stage, which is about the prescriptions that are reimbursed. There's no data whatsoever why there is a gap. In theory "cost" can be one of the reasons, although additional reasons might be (a) that a drug was prescribed in the first case as a precautionary measure, "just in case there will be a need," particularly in the case of antibiotics or anti-infectives), (b) prescriptions are issued for non-reimbursed drugs (mainly contraceptives), or (c) the prescription is lost and a replacement needs to be issued.

Assuming that this figure relates to drugs on the positive list and the reasons for this are related to cost, this raises significant concerns about affordability. In order to draw any conclusions on that, further study is needed to clarify the issue.

6.3.2 Reference pricing in Estonia, availability and affordability

As discussed, the operating principle of reference pricing in Estonia is similar to that in all other countries operating similar systems, namely that Health Insurance establishes a maximum reimbursement price with the difference between the reference price and the drug of choice born by the patient, should the latter be higher. As reference price is taken the second lowest price on the Estonian market, without any additional qualifying criteria being considered (e.g. ability of the 2nd lowest priced producer to supply a significant proportion of the market.

There is one potentially important problem associated with the operation of RP in Estonia, which may not be reflective of patient choice in favour of more expensive drugs. Random checks in a number of pharmacies and for a small number of medicines revealed that the reference drug was not available and what was available in its place was a more expensive therapeutic alternative.

This further implies that the cost to patient may increase by the additional co-payment required by the reference pricing system, which patients need to incur on an involuntary basis and, depending on the extent of co-insurance plus RP additional co-payment, it can be the source of significant inequity and could render the cost of needed medicines unaffordable. The problem may be further exacerbated by the non-adherence to (or poor implementation of) INN prescribing and the voluntary nature of substitution at pharmacy level, which are two areas that may need to be looked at, particularly the former.

The success of a reference pricing system in delivering savings to health insurance and in ensuring that the cost to patients is affordable, rests to a large extent on the reference price. International practice is in favour of setting a reference price that maintains a balance between the level of it and the ability of manufacturers to supply a considerable share of the market at that price. In the German environment, for example, the reference price is set close to the price in the lowest third of the market, assuming the lowest third of the market can supply a significant proportion of the market. If such limits are not set, it is likely that prices will be significantly higher than the reference price and patients will be worse off given the level of co-pay0ment they need to pay.

6.3.3 Differential reimbursement based on provider type

A final source of potential inequity that was raised by patients and health care professionals during visit in Tallinn, was related to differential reimbursement of the same prescription medicine when prescribed by different health care professionals. For instance, prescribing by family doctors in a PHC setting may warrant reimbursement up to 50%, whereas if the same medicine is prescribed by a specialist, the reimbursement rate is 75%. It is not clear how extensive this phenomenon is, but it is likely that it arises because of the referral system and the likely shortage of specialists near a patient's residence, or the lack of referral from family doctors to specialists, or the delay that patients face to have an appointment with a specialist, as part of their referral from a family doctor. As a result, and in order to save time, patients are able to access the same medicines that would otherwise be prescribed by a specialist, but they incur a higher co-payment because these are prescribed by a family doctor rather than by a qualified specialist.

The conditions to receive a higher reimbursement level are related to a prescriber's specialty as follows: 1) if the competent expert for diagnosis is a specialist, then the **first prescriber** has to be a specialist, possibly followed by a family doctor; 2) if the patient needs a drug in conjunction with intense monitoring by a certain specialist (oncology, severe neurologic or psychiatric illness) then the **only prescriber** is a specialist.

Bearing in mind that the waiting time to see a specialist may be long for certain diagnoses and the fact that the average cost per prescription of drugs in the 75% category is double than the same cost in the 50% reimbursement category, patients will need to pay a significantly higher co-payment that would otherwise be necessary. This appears to be inconsistent with the principle of equality in treatment and may be placing several patients at a disadvantage (financial or other).

6.4 Affordability of medicines: issues and concerns

There are three policy elements related to affordability problems in Estonia: the first is the structure of patient co-payments; effective co-payments in Estonia seem to be higher than in many other EU countries; the majority of medicines dispensed are subject to some form of co-insurance and about 50% of all prescriptions dispensed are subject to a 50% co-insurance. Treatments for a number of chronic diseases are subject to a 25% co-insurance (75% coverage), as discussed in section 5.1. Prior to resorting to measures seeking to reduce the level of co-payments and invest additional resources, which may be very scarce, due consideration ought to be given to mechanisms that could lead to a reduction of such co-payments by promoting rational drug use and cost-effective prescribing.

The second element relates to the determination of the reference price. The EHIF takes as reference the second lowest price on the market, without checking the capacity of the manufacturer to supply the (entire) market. Similarly, pharmacies may not necessarily buy or stock some of the low cost drugs. With the price (and volume) agreements the manufacturers make a commitment to adequately and consistently supply the entire market. Although according to the medicines law pharmacies have to buy in these cheapest medicines, some manufacturers have frequently complained that pharmacies do not do so.[16] By contrast, pharmacies may have an incentive to purchase or stock more expensive drugs. Consumers may be quoted the product with the reference price, but are likely to have to pay out-of-pocket for another product with a higher price that is available at the point of service. In this particular case, the problem of availability is tightly connected with affordability and is also related to the "small market" discussions at EU level.

Third, differential co-payments for the same diagnosis and course of treatment based on the type of provider visited do not appear sensible, particularly if primary care (as opposed to specialist care) is to be further encouraged.[17] Co-payments must be universal for patients suffering from the same disease, regardless of the doctor they visit. Indeed reducing co-payments would be a positive move, given the affordability issues that many face. Thus co-payments should converge downwards rather than upwards and any prescribing and cost-sharing inconsistencies arising due to problems with the referral system will need to be ironed out.

[16] MoSA, personal communication.
[17] The counter-argument in this case is that such differential co-payment is in operation partly on safety grounds and to ensure that the specialist, rather than the family physician, prescribes. However, if safety is a concern, then the right for family physicians to prescribe for certain conditions should be removed. If a specialist is the only way to obtain a prescription for a particular medication, then access to specialists should be timely.

6.5 Availability of medicines

There are four dimensions of availability of medicines in the Estonian policy context:

1. the extent to which the reimbursement list is comprehensive and includes adequate treatment options for the entire population;
2. the extent to which medicines that are prescribed are available at the pharmacy, when patients fill their prescriptions;
3. the availability of medicines irrespective of geographical location; and
4. the availability of medicines with marketing authorization (MA).

These are explored in turn.

6.5.1 The reimbursement (positive) list

The number of drugs covered by health insurance through the reimbursement (positive) list is not considered to be small although, broadly speaking, it has been suggested that the absolute number of substances included in it (approximately 1000 INNs and 3000 products[18]) probably falls short of addressing the needs of the Estonian population fully.[19] However, the completeness of the reimbursement list and the extent to which it addresses the needs of the Estonian population, based on epidemiological/disease profile was not examined in any detail. Similarly, it was not feasible to examine the rate of attrition from the reimbursement list and any likely exclusions from it.

However, it emerged from interviews with SAM that some of the more recently introduced medicines may not be available on the reimbursement list or the IPSL and, as a result, may not be available to Estonian patients at all. Cost was quoted as a key concern in this context; the "small country" effect, namely that products may not marketed in Estonia because of the small size of the population and the consequent limited commercial interest was also quoted. As a result, there may often be significant delays in introducing new products. Officials conceded that in the past and in some therapeutic categories, medicines reached the market after they had gone off-patent and their cost reduced due to generic entry. Concerns exist about rare diseases and their cost, as it is very likely that the small size of the Estonian market as well as the individual cost per case contribute to such treatments not being available in Estonia, whether in the reimbursement list or through the IPSL. The size of the Estonian market is a broader issue affecting availability as manufacturers are not necessarily interested in dedicating resources to be present in a small market with little commercial interest, but the recent conclusion of the Pharmaceutical Forum has provided an agenda focusing on administrative, manufacturing, packaging, language labelling requirements, and transport and wholesaling issues, which are meant to facilitate availability of medicines in smaller countries (European Commission, 2008).

It is important that the whole list is reviewed in order to ascertain whether there are gaps in the availability of medicines that are essential to patient treatment. Guidance on this could be offered by (a) the epidemiological profile of the population as a proxy for need

[18] Does not include pharmaceutical products on the in-patient services list (IPSL).
[19] Kristin Raudsepp, personal communication.

and (b) comparison with lists in neighbouring countries and their principles for inclusion. This could also help rationalize current and future expenditure, identify where gaps exist and highlight ways to fill these.

6.5.2 What medicines are dispensed and at what cost to patients?

Although Estonia does have an "INN prescribing" policy, made explicit in the legislation, in practice this does not seem to be widely followed. Indeed, physicians should prescribe by the generic/international nonproprietary name (INN), but in practice brands are often prescribed either formally on the prescription, or informally, by prescribing the INN on the prescription and separately advising patients on a recommended brand. On several occasions physicians prescribe in accordance with the decree of Minister of Social Affairs, but frequently advise their patients to opt for a particular brand. In such cases the presciber has to justify the option, writing the rationale to the case history and explaining this to the patient. This is not surprising in an environment where even across generics there seems to be a strong element of branding and brand awareness. If originator brands are prescribed, or if physicians advise their patients to prefer them, then there is an obvious out-of-pocket cost issue for patients. In an environment where generic substitution of brands at pharmacy level is not allowed if the doctor has ruled out substitution on the prescription (and explaining the rationale to the patients as well as writing this down to the patient's history notes), even if a cheaper alternative is available, the patient purchases the originator and is liable to paying a much higher co-payment, which includes the fixed dispensing fee (FDF) of EEK 20 (which is fixed for both originator brands and generics), shown in section 6.3.1 and the difference between the brand and the generic. Under these circumstances, the operation of the reference pricing system serves mostly the objectives of health insurance, as it denotes the amount that EHIF will pay for a particular drug, but does not necessarily safeguard the interests of patients.

In order to study market developments in Estonia post-patent expiry and the impact of generic entry on patient cost-sharing, utilization patterns across 6 high volume molecules during the first 10 months of 2007 were studied. The molecules studied were ramipril, amlodipine, simvastatin, quetiapine, valproic acid, and olanzapine. With the exception of quetiapine, all other molecules have been off-patent for more than 2 years.

6.5.2.1 Utilization of Ramipril

Ramipril is an ACE inhibitor used for the treatment of hypertension. A total of 5985 patients were dispensed with ramipril, 10mg, during the study period. There were two competitors for this drug, the originator brand and a generic. Both the originator ramipril (Cardace) and generic Ramipril (manufactured by Actavis Nordic) are available in boxes of 28 pills. The originator was priced 17% above the reference price, while the generic was 10% cheaper. Despite the considerably higher co-payment for the originator (75.94 EEK) vis-à-vis the generic (47.88 EEK), 97% of the patient population were dispensed with the originator brand (Table 6.5). Again, this may be due to the physician prescribing the originator brand (or advising patients in favour of this) and/or pharmacists being unable to substitute for the generic.

Table 6.5 * Use of branded and generic Ramipril, 10 mg – 28 tab, January–October 2007

Company	Reference Price (EEK)	No. of Patients N=5985	% of patients	Retail price (EEK)	total co-payment per pack (EEK)
Aventis-Pharma	145.7	5793	96.7%	170.21	75.94
Actavis Nordic A/S	145.7	192	3.3%	131.53	47.88

Source: The authors based on data provided by MoSA, 2008.
Note: * The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

6.5.2.2 Utilization of Amlodipine

Amlodipine is a medicine used for the treatment of hypertension. It is available in Estonia in 30 tablet packs. The available strengths are either 5mg or 10mg. Tables 6.6 and 6.7 summarize market dynamics in each dosage form. Both the 5 mg and the 10 mg are characterized by multiple manufacturers (at least 6 in each of the 5 and 10 mg segments) and large number of patients (approximately 16 500 in each segment). The drug is reimbursed at 25% by health insurance plus the EEK20 statutory dispensing charge.

In both market segments, originator Amlodipine (Norvasc) which has a co-payment of more than 3 times higher than the corresponding generics and is priced significantly above the reference price, has been dispensed to nearly 40% of all patients taking this drug. This is surprising given that amlodipine is an old medicine with well established generic alternatives. Preference towards generics does not seem to be governed neither by its price, nor by the overall co-payment. The more expensive generics (also resulting in higher co-payment for patients) had a higher market share than the relatively inexpensive generics.

Table 6.6* Amlodipine Sales, 5mg 30 tab, January–October 2007

Company (*brand*)	Reference Price (EEK)	No. of Patients N=16 663	% of patients	Retail price (EEK)	total co-payment per pack (EEK)
Pfizer (*Norvasc*)	64	6482	38.90%	176.16	143.16
Leciva (*Agen*)	64	3277	19.67%	80.24	47.24
Hexal AG (*Amloca*)	64	2999	18.00%	79.15	46.15
Ratiopharm (*Amlodipine-R*)	64	1983	11.90%	84.14	51.14
Worwag Pharma (*Amlodigamma*)	64	47	0.28%	63.06	30.77
Mepha LDA (*Lofral*)	64	7	0.04%	61.4	30.35

Source: The authors based on data provided by MoSA, 2008.
Note: * The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.7* Amlodipine Sales (10mg, 30 tab), January–October 2007

Company (*brand*)	Reference Price (EEK)	No. of Patients (total = 16 502)	% of patients	Retail price (EEK)	total co-payment per pack (EEK)
Pfizer (*Norvasc*)	127.95	6 214	37.65%	269.91	188.95
Leciva (*Agen*)	127.95	3 110	18.85%	138.87	57.91
Hexal AG (*Amloca*)	127.95	3 011	18.25%	138.67	57.71
Ratiopharm (*Amlodipine-R*)	127.95	1 953	11.84%	150.76	69.80
Worwag Pharma (*Amlodigamma*)	127.95	34	0.21%	123.62	45.91
Mepha LDA (*Lofral*)	127.95	10	0.001%	123.45	45.86

Source: The authors based on data provided by MoSA, 2008.
Note: * The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

6.5.2.3 Utilization of simvastatin

Simvastatin is the most widely used statin for the treatment of dislipidemia in Estonia. The available dosages are 10 mg, 20 mg, 30 mg and 40 mg. Available data suggest that the most common simvastatin dose between January and October 2007 was 20mg. This was dispensed to 2567 patients (54.34% of the population receiving Simvastatin), while 1411 patients (29.87%) were dispensed with 10mg, and 716 (15.16%) with 40mg Simvastatin. Only 30 patients (0.64%) were given 30mg Simvastatin. Tables 6.8–6.10 summarize the data from the simvastatin market across the 10, 20 and 40 mg market segments respectively.

For the 20mg (Table 6.8) dose, monthly co-payments varied between 64.6EEK and 104.94EEK. 38.95% of patients taking this dose purchased Zocor Forte which had the highest co-payment. Simgal, which had the lowest co-payment was dispensed to only 6.36% of patients.

Similar findings occur for the 10mg dose (Table 6.9). 40.68% of patients taking this dose pay the highest possible monthly co-payment (71.57EEK) and are dispensed the branded originator drug, while the most selling generic has a market share of 23% and a co-payment similar to that of the originator brand. The cheapest generic has a co-payment of 42.32EEK but is dispensed to only 6.59% of patients. The second cheapest generic alternative has a co-payment of 43.77EEK and is dispensed to 6.45% of patients.

Out of all patients that were dispensed with the 40mg dose (Table 6.10), 33.52% and 45.11% of them purchased Simvacor and Zocor Forte respectively, the latter being the originator drug. The cost-sharing in each case was 121.35EEK and 142.59EEK respectively. At the same time, there were two other products on the market with lower co-payments. Simgal has a co-payment of 112.30EEK was purchased by only 7.54% of patients. Simvor has a co-payment of 112.36 but was also dispensed to only 8.52% of patients.

Overall, originator simvastatin continues to maintain a significant market share (between 40 and 45%), despite the higher cost-sharing it implies for patients. Of the available (branded) generics the ones with the higher market share are also the more expensive ones with prices higher than the reference prices. Generics with prices at or below the reference level have very small market shares.

Table 6.8* Simvastatin 20 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients Treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
MSD[1] (*Zocor Forte*)	28	216.35	2874	38.95%	252.20	104.94
HEXAL (*Simvacor*)	30	231.80	1938	26.26%	242.62	83.77
KRKA (*Vasilip*)	28	216.35	475	6.44%	228.14	80.88
Nycomed (*Simvastatin Nycomed*)	30	231.80	271	3.67%	238.36	79.51
Ratiopharm (*Simvastatin Ratiopharm*)	30	231.80	450	6.10%	238.06	79.21
Ranbaxy (*Simvor*)	30	231.80	902	12.22%	212.91	68.23
IVAX (*Simgal*)	28	216.35	469	6.36%	198.38	64.60

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
* The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.9* Simvastatin 10 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
MSD[1] (*Zocor Forte*)	28	108.15	574	40.68%	137.68	71.57
HEXAL (*Simvacor*)	30	115.90	330	23.39%	144.22	72.30
KRKA (*Vasilip*)	28	108.15	181	12.83%	119.06	52.95
Ratiopharm (*Simvastatin Ratiopharm*)	30	115.90	142	10.06%	124.70	52.78
Ranbaxy (*Simvor*)	30	115.90	91	6.45%	115.07	43.77
IVAX (*Simgal*)	28	108.15	93	6.59%	108.43	42.32

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
* The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.10* Simvastatin 40 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
MSD[1] (*Zocor Forte*)	28	389.3	323	45.11%	419.6	142.6
KRKA (*Vasilip*)	28	389.3	38	5.31%	408.7	131.7
HEXAL (*Simvacor*)	30	417.1	240	33.52%	419.2	121.4
IVAX (*Simgal*)	28	389.3	54	7.54%	389.2	112.3
Ranbaxy (*Simvor*)	30	417.1	61	8.52%	389.4	112.4

Source: The authors based on data provided by MoSA, 2008.Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
* The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

6.5.2.4 Utilization of Quetiapine[20]

Quetiapine is an atypical anti-psychotic, available in doses of 100mg (dispensed to 680 patients in total) and 200mg (dispensed to 53 patients). The drug is reimbursed at 100%, which means that patients are only required to pay the EEK20 dispensing fee. Regarding the 100mg dose, only Ketipinor (100 tabs) is available in the market and leads to a 20EEK co-payment. It is sold to 53 patients (7.23% of all patients taking Quetiapine). For the 200mg formulation (680 patients, 92.77% of all patients taking Quetiapine), the vast majority of patients (97.94%) were dispensed with the originator brand Seroquel, which has a total co-payment of 628.22 EEK. An alternative brand, with a co-payment of EEK20 was dispensed only to 14 patients (2.06% of the total patient population). The difference in out-of-pocket expenditure was originally very large (Table 6.11), but the introduction of reference pricing on Jan 1st, 2008 meant that the list price of Seroquel declined to the reference level, also reducing the level of cost-sharing to EEK 20.

Table 6.11* Quetiapine 200 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
AstraZeneca[1] (*Seroquel*)	60	977.25	666	97.94%	1585.47	628.22
Orion (*Ketipinor*)	100	1628.80	14	2.06%	1581.68	20.00

Source: The authors based on data provided by MoSA, 2008.
Notes: [1]Originator and originator brand. The co-payment was EEK 20 following the introduction of reference pricing on Jan 1st, 2008.
* The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

[20] Although the patent for Quetiapine does not expire until 2011, a generic already exists in Estonia, because Estonia joined the relevant patent convention in 1994. As a result, patents registered before that date do not apply in Estonia. In the case at hand, Ketipinor is a generic.

6.5.2.5 Utilization of Valproic acid

Valproic Acid, an anti-epileptic treatment, is available in 150mg, 300mg, 500mg and 1000mg formulations. These have a market share of 14.1%, 22.4%, 61.1% and 2.4% respectively. Reimbursement is at 100% at the reference level unless patients prefer a higher-priced medicine.

The most popular formulation is 500mg (Table 6.12). Although there are two drugs which have a monthly co-payment of only 20EEK, only 13.55% of patients purchase these cheap generics. 72.70% of patients taking this dose purchase Depakine Chrono which has a co-payment of 78.67EEK. A further 13.58% purchase Desitin Arzneimittel which has a much higher monthly co-payment (216.49EEK).

Tablets of 150mg Valproic Acid is available by two producers, although neither seems to be the originator. All but one patient (99.37%) dispense Orfil long and are burdened with a 78.88EEK co-payment. Only one patient purchased Convulex, which has a less than half co-payment compared to Orfil long (Table 6.13). Again, the cheaper medicine has a significantly smaller market share.

Similar issues are observed in the 300mg formulation (Table 6.14). There are two products, which have a co-payment of 20EEK. Nevertheless, these two together attract only 13.55% of the market. Of the rest, the originator has a 72.5% market share and an equally priced alternative, a 14% market share, both having a significantly higher co-payment (1371EEK).

Overall, the branded product occupies approximately three quarters of the market for this product. Understandably, however, switching to a generic anti-epileptic product may pose certain challenges and could take longer due to potential bioequivalence issues.

Table 6.12* Valproic Acid 500 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
Sanofi-Synthel[1] (*Depakine Chrono*)	30	84.95	498	72.70%	143.62	78.67
Desitin Arzneimitt (*Orfiril long*)	100	283.20	93	13.58%	479.69	216.49
Sandoz (*Valproate Sodium*)	100	283.20	37	5.40%	282.76	20.00
Sandoz (*Valproate Sodium*)	30	84.95	57	8.32%	84.80	20.00

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
* The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.13* Valproic Acid 150 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
Desitin Arzneimitt (*Orfiril long*)	100	84.95	157	99.37%	143.83	78.88
Gerot (*Convulex*)	100	84.95	1	0.63%	99.32	34.37

Source: The authors based on data provided by MoSA, 2008.
Notes: Originator and originator brand.
***** The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.14* Valproic Acid 300 mg sales, January–October 2007

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients Treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
Sanofi-Synthel[1] (*Depakine Chrono*)	100	169.90	182	72.51%	287.04	137.14
Desitin Arzneimitt (*Orfiril long*)	100	169.90	35	13.94%	287.81	137.91
Sandoz (*Valproate Sodium*)	100	169.90	28	11.16%	169.62	20.00
Gerot (*Convulex*)	100	169.90	6	2.39%	146.60	20.00

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
***** The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

6.5.2.6 Utilization of olanzapine

Olanzapine is an atypical anti-psychotic with a 100% reimbursement and is sold in 5, 10 and 15mg tablets. The 10mg Olanzapine (Table 6.15) has been dispensed to 556 patients (77.65% of all patients taking Olanzapine). Cheap generics with a co-payment of 20EEK or 20.86EEK are dispensed to 86.74% of patients. The remaining 13.26% though are burdened with a very large copayment (1166.8EEK).

Tablets of 15mg Olanzapine (Table 6.16) has been dispensed to 110 patients (15.36% of all patients taking Olanzapine). Olanzapine Actavis is a cheap generic with a co-payment of 20EEK. It is dispensed to 83.64% of patients. The remaining 16.34% though take branded Olanzapine (Zyprexa) and are burdened with a very large copayment (1698.1EEK).

The remaining Olanzapine market share (6.98%- 50 patients) concerns 5mg Olanzapine (Table 6.17). 90% of patients taking 5mg Olanzapine purchase the generic alternative and have to pay only the dispensing fee of 20EEK. The remaining 10% purchase the originator brand and are burdened with 676.77EEK out of pocket.

Table 6.15* Olanzapine 10 mg sales, January–July 2008

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
Eli Lilly[1] (*Zyprexa*)	28	623.80	85	13.26%	70.6	1166.8
Ratiopharm (*Olanzapin-Ratiopharm*)	30	668.35	122	19.03%	669.21	20.86
Actavis (*Olanzapine Actavis*)	28	623.80	283	44.15%	622.72	20
Adamed (*Zolafre*)	28	623.80	151	23.56%	622.72	20

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
***** The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.16* Olanzapine 15 mg sales, January–July 2008

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients treated	Retail price (EEK)	Monthly co-payment (EEK)
Eli Lilly[1] (*Zyrexa*)	28	935.70	18	16.36%	2613.8	1698.1
Actavis (*Olanzapine Actavis*)	28	935.70	92	83.64%	896.25	20

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
***** The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

Table 6.17* Olanzapine 5 mg sales, January–July 2008

Company (*brand*)	Number of tabs	Reference Price (EEK)	No. of Patients treated	% of patients Treated	Retail price (EEK)	Monthly co-payment (EEK)
Eli Lilly[1] (*Zyrexa*)	28	311.90	5	10.00%	968.67	676.77
Actavis (*Olanzapine Actavis*)	28	311.90	45	90.00%	311.37	20

Source: The authors based on data provided by MoSA, 2008.
Notes: [1] Originator and originator brand.
***** The data does not reflect the likely impact of discounts given by manufacturers to wholesalers/pharmacists and which might impact on the OOP made by patients.

6.5.3 Geographical availability

The number of pharmacies in rural areas is declining. At the beginning of 2009 the number of pharmacies in rural areas was 138 compared with 158 in 2005. Although distributors usually supply pharmacies within 24 hours, this is mostly the case in urban areas. Rural areas are supplied less frequently and it may take in excess of 48 hours for an order to reach a rural pharmacy. There is no obligation to wholesalers regarding supplies frequency or speed of delivery to pharmacies. This is an important issue and can be negotiated when MoSA establishes margins for wholesalers. Although rural pharmacies account for about 10% of total retail outlets, they service rural populations which, in principle, have greater health care needs. The intensity of the problem as well as the frequency with which it occurs were not examined in depth, but in conversations with stakeholders it concerns were raised and it is advised that this be examined in some detail as it may affect a significant proportion of the more vulnerable rural population.

6.5.4 The availability of medicines with marketing authorization (MA)

The low interest of pharmaceutical manufacturers to apply for or renew marketing authorization (MA) may result in a situation where important or life-saving medicinal products are not available in country and this has occurred on a number of occasions in Estonia. The size of the local market and national language have exacerbated the problem, since translation of information and labelling of medicinal products to national languages is not a problem for big markets, but can be cumbersome for small markets. The size of a market is an obvious reason why pharmaceutical companies are not willing to accept the extra costs involved (pharmacovigilance, translations, scientific service, pricing, country-specific information, etc.) for markets that cannot sustain profitability. The consequences for the patients will depend on the severity of their illness and the availability of generic or therapeutic alternatives. According to EU regulations neither the SAM nor MoSA are in the position to force manufacturers to market any medicinal product and there are not enough legal instruments for the regulatory bodies to handle and solve such situations.

In order to address and regulate the above and the unmet medical need they result in, a mechanism exists in Estonia. Based on this, a physician can order medicines whose marketing authorization has expired from pharmacies after a personal application to SAM (if no MA is available) and EHIF (if reimbursement is sought). Following treatment, any leftover drugs at the pharmacy cannot be dispensed to another patient with similar needs, as the same procedure must be followed from the beginning for additional patients. Therefore, wholesalers need to import these medicines from other countries. The pricing of pharmaceuticals without MA is free but reimbursement by EHIF is uncertain and limited due to the lack of a valid MA certificate.

There is a significant list of active substances which have no authorized product on the Estonian market and which are allowed to be imported based on an application by a professional society. The list is available from the web site of the State Agency of Medicines (http://www.ravimiamet.ee/4789) and contains a multitude of very basic drugs vital for essential health-care services.

In 2008, more than 8000 individual or (health care) institutional applications were made to the State Agency of Medicines for the named patient or named institution use of

unauthorized medicines every year. Largely, these represent two distinct types of medicines – the very recently introduced products supplied for compassionate use in in-patient settings by the industry and, in their majority, several well-known products with limited use and no incentive for the manufacturer to maintain the marketing authorization in Estonia. A sample list of widely used unauthorized basic medicines (based on the 2007 wholesale statistics) is shown on Table 6.18.

Table 6.18 Widely used unauthorized basic medicines, 2007

ATC code	**Active substance (route of admin)**
A03BA01	atropine (Parenteral)
A03BB01	butylscopolamine(P)
A05BA	essential phospholipids(P)
A06AB02	bisacodyl(R)
A06AB06	senna glycosides(Oral)
A11CC01	ergocalciferol(O)
A11DA01	thiamine(P)
A11HA02	pyridoxine(P)
A12AA03	calcium gluconate(P)
A12BA01	potassium chloride(O)
B01AB01	heparin(P)
B02AA01	aminocaproic acid(P)
B03BA01	cyanocobalamin(P)
B05BA03	glucose 40% (P)
B05BA03	glucose 10% (P)
B05XA05	magnesium sulfate(P)
C01AA05	digoxin(P)
C01CA03	norepinephrine(P)
C01CA06	phenylephrine(P)
C01CA24	epinephrine(P)
C01DA02	glyceryl trinitrate(SL)
C01DA08	isosorbide dinitrate(SL)
C02AC01	clonidine(P)
C03CA01	furosemide(P)
G01AF01	metronidazole(V)
G03DA04	progesterone(P)
H01BB01	democytocin(O)
H02AB06	prednisolone(P)
H03BB02	thiamazole(O)
J01CE08	bensathine benzylpenicillin(P)
J01CF04	oxacillin(P)
J01DC01	cefoxitin(P)
J01DE01	cefepime(P)
J01DH03	ertapenem(P)
J02AC01	fluconazole(P)
J06BB01	Anti-D (rh) immunglobulin(P)
L01AA01	cyclophosphamide(P)
M03BX01	baclofen(O)
N01AX01	droperidol(P)
N01BB02	lidocaine(P)
N05AA01	chlorpromazine(O)

ATC code	Active substance (route of admin)
N05AA02	levomepromazine(O)
N05AA02	levomepromazine(P)
N05AN01	lithium(O)
N06BA04	methylphenidate(O)
N07AA01	neostigmine(P)
N07BB01	disulfiram(O)
R03DA05	aminophylline(P)
R06AA02	difenhüdramiin(P)
S01BA02	hydrocortisone(S)
S01EC01	acetazolamide(O)
V03AB14	protamine(P)

Source: Personal communication with SAM, 2009.

Conceptually, two issues arise from the use of unauthorized medicinal products in Estonia: the first is related to availability, as some medicines are not readily available in the country and patients need to go through an application process to ensure these are procured from overseas. As this procedure needs to take place separately for each case, it is cumbersome, time consuming and can lead to duplications. The second, is related to affordability as under these circumstances patients may need to pay out-of-pocket for needed medication because health insurance may not reimburse them in the absence of a valid MA certificate. The three agencies (SAM, EHIF and MoSA) should collaborate to resolve this issue, although it is likely that SAM may need to take the lead in this because of its position as the agency responsible for MA in Estonia. One option would be for EHIF or MoSA to have a special procedure authorizing reimbursement based on medical need.

In practice, within the Estonian context, the availability problems are more likely to be an issue than the affordability, as the majority of unauthorized medicines relate to old products and their low price is one of the reasons why they are not on the market. A fair share of them is mainly for hospital use. In terms of reimbursement, there exist compensation mechanisms from EHIF for both in- and out-patient unauthorized medicines. There is a 90% reimbursement level with a ceiling of EEK19 000. This ceiling might impose indirectly a limitation to using more ‘recent’ products for chronic conditions.

6.6 Availability of medicines: issues and concerns

The four areas discussed in this section have highlighted a number of problems in what concerns access to medicines for Estonian patients.

6.6.1 Issues related to the reimbursement list

It is likely that the reimbursement list caters for the vast majority of the Estonian population, although certain aspects emerged pointing at gaps particularly in newer treatments and some of the rare conditions.

6.6.2 Issues related to utilization patterns post-patent expiry

Several interesting trends have been revealed about the dispensing and utilization patterns of certain medicines for chronic illnesses post-patent expiry, and by implication, the availability of medicines in Estonia.

1. Generic substitution of a branded prescription is not allowed in Estonia if a physician has ticked the relevant box on the prescription. This, combined with the fact that compulsory generic prescribing practice does not work well, results in a continued high penetration of brands post patent expiry. Clearly, there is a discrepancy between the law and its enforcement. This could be captured at the point of prescribing – as long as e-prescribing is available and prescribing can be monitored in real time. Alternatively, physicians can be barred from prescribing brands and the latter can be placed on a list of "prior authorization"[21], whereby physicians can call in and explain to a representative of EHIF the reasons why a brand is necessary.
2. It appears that in the majority of cases, the originator drug continues to maintain a significant market share, and, indeed, is the market leader, despite generic alternatives being in principle available;
3. The originator drug often continues to be priced significantly above the reference price but this does not deter patients from paying the appropriate co-payment, which is often significant;
4. In the majority of cases, the more expensive generics seem to be "preferred" by patients, or simply that patients are dispensed with more expensive generic alternatives, which in most cases results in them paying a significant amount OOP;
5. The cheaper generics, whose prices are closer to the reference prices in almost all cases, have a very small market share, despite being good value for patients in terms of cost-sharing. This may be due to the fact that they may not be available at the pharmacy,[22] which, in turn, could imply that the profit margin for some generic products is lower than that of originators or other generics.
6. Contrary to what is stipulated in the regulations, it may not be the case that the pricing structure for generic medicines is adhered to. This results in most generics examined in the context of this report being priced significantly higher than the reference price and are not always 30% cheaper than the brand; indeed, at times they are priced closer to the brand. There is no explanation for this and, similarly, there is no explanation as to why the regulation concerning price capping of generics does not seem to be implemented.

[21] Prior authorization (PA) is a practice whereby prescribers obtain permission from health insurance to prescribe a particular medication. This can be achieved with a simple phone call or/and by completing the relevant paperwork. Health insurance is responsible for laying down the parameters of such a policy as well as defining the sanctions in case it is not adhered to. The implementation of prior authorization automatically suggests that a generic is always prescribed unless a brand is medically necessary. PA practices are very common in the North American setting.

[22] In principle, if there is a valid price agreement in place, the medicines need to be available, although, in practice, it is unknown whether this is the case.

The above could simply reflect consumer preferences, whereby patients are willing to pay a price premium (the cost between the reference price and the drug of choice) for the originator medicine or the more expensive generic. Although this might be the case for those who are well off, it is unlikely that it is reflective of patients across the entire patient population, particularly elderly patients. Evidence from other countries also suggests that in reference pricing environments, prices of most generics are close to the reference level,[23] whereas prices of originators are slightly above that level. Still, the question remains as to why these trends are observed. To address that, a number of explanations exist.

1. There is lack of generic prescribing and generic substitution is either not allowed or is not incentivised enough for pharmacies to dispense a cheaper generic.
2. Patients and doctors display a degree of "brand loyalty" to originator medicines, despite these drugs' higher price levels;
3. An element of "brand loyalty" for originator medicines, unavoidably implies that there may be either a (perceived) quality issue with (some of) the generics, or that there is no generics "conscience" among the population. While the quality aspect is categorically rejected by the local regulatory authority (SAM), the issue of patients being educated to prefer a generic has a lot of credence and EHIF together with SAM and MoSA can do a lot to educate patients and doctors on the safety and efficacy of generic medicines. This could go alongside supervisory and oversight strategies and would deliver over the longer term.
4. It is very likely that cheaper generics are simply not available in Estonia, or are available at intervals only. Indeed, as discussed earlier, availability spot checks with pharmacies (esp. rural pharmacies) suggested that many of the referenced generic medicines were not available; this, in turn would force patients to purchase the more expensive alternative.

6.6.3 Issues related to geographical availability

The likely problems of availability in rural areas probably reflect the changes in the structure of the distribution chain (discussed further in section 8 below) and the lack of explicit vertical in most (if not all) community pharmacies operating in rural areas. In this light, problems in terms of equal access to medicines based on geography, could be addressed by re-visiting the terms/conditions and frequency of wholesale supply.

6.6.4 Issues related to the use of unauthorized medicinal products

The problem remains in Estonia, whereby each year, several thousand applications are made by physicians on behalf of patients to import medicines for which the MA has expired and, therefore, they are not allowed to be placed on the market. This problem can be addressed either by EU legislation or by national action. In particular, the three agencies (EHIF, SAM and MoSA) should collaborate to resolve this and adopt a procedure whereby reimbursement occurs on the basis of medical need, irrespective of a valid MA certificate, particularly, if the same product has a valid MA certificate in another Member State. Alternatively, SAM in collaboration with other regulatory

[23] This happens particularly when the reference price is not set as the lowest in the group, but above that (second lowest, lowest plus 10% or so), because then the lowest will increase the price up to the reference price and price will drift upwards.

agencies within the EU can award an MA for a medicine which is not readily available in Estonia.

For some of the issues involved there is EU legislation to cater for the availability of medicines on a Member State's market, through Directive 2001/83/EC, and some of the provisions therein, e.g. the sunset clause,[24] the provision on Continuous Supply, and the Cyprus clause,[25] although often some of these may not have been transposed into national legislation or implemented by the Member States.

Although all the above EU law provisions have been transposed into Estonian legislation, they remain very difficult to enforce effectively in an economically unattractive market and may not be enough to solve real availability problems without posing any threat to public health.

National action, on the other hand, relates to implementing measures to keep low profitability products on the market, for instance, exempting low turnover products from annual fees and having favourable provisions or/and practices for re-labelling of out-patient drugs or not having national language labelling in case of hospital products. Exempting manufacturers from marketing authorization application fees might also be an option. Additional issues remain, however, in connection with the maintenance of low turnover products on small markets such as Estonia, notably, the cost of reporting requirements (variations, renewals, periodic safety updates etc).

At EU level "the obligation to market" across the EU products that have an EU MA, could address this problem not only in Estonia, but also in other small markets.

[24] The so-called "Sunset Clause" refers to the statutory requirements to inform the Licensing Authority (SAM in Estonia) of any disruptions to supply of medicines. Under Article 23a of Directive 2001/83EC, as inserted by Article 1(22) of Directive 2004/27EC, the marketing authorization (MA) holder is required to notify the competent authority of the date of actual marketing of the medicinal product, taking account of the various presentations authorized, and to notify the competent authority if the product ceases to be placed on the market either temporarily or permanently.

[25] The Cyprus clause suggests that in the absence of a marketing authorization or of a pending application for a medicinal product authorized in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorize the placing on the market of the said medicinal product. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that it complies with the provisions of EU legislation.

7. Rational use of drugs

7.1 Background, challenges and strategies for promoting rational drug use

The rational use of drugs means that "patients receive medicines appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community" (WHO 2001).

In general, there are many problems that affect efforts towards rational drug use. In some cases, prescription drugs are freely available to the public. This may lead patients to take more medicines than necessary, delay diagnosis or even lead to drug resistance, drug interactions and adverse effects. Inappropriate drug promotion and inducements to prescribers and dispensers and problems relating to scientific accuracy and balance of information cause significant problems. Conflicting interests also emerge, particularly when the prescriber is also the dispenser. Increasing the volume of business (both for physicians and pharmacists) is another major issue. Lack of independent information is a problem too, especially given the high volume of commercial information available. Finally, the complexity of this issue makes the previously mentioned challenges even more difficult to address.

Challenges promoting rational drug use can be educational, managerial or regulatory. Educational strategies include basic training of health professionals, in-service training of health workers, training of drug-sellers, creation of drug information centres, information through drug bulletins, consumer information and education. Managerial strategies include financial as well as non-financial incentives, dispensing standards, essential drugs lists and standard treatments. Finally, regulatory strategies include drug promotion and evaluation of drugs for market approval and scheduling.

7.2 Policy measures promoting rational use of drugs which can be implemented in Estonia

7.2.1 Influencing prescribers

Doctors prescribe medicines for the benefit of their patients. In many (European) countries, the primary criterion that applies in drug selection is therapeutic need, and physicians' freedom to choose is jealously guarded. There are few restrictions as to which medicines may be prescribed, although not all medicines may be reimbursed. Usually, the length of prescription and sometimes the number of items allowed are regulated. Patients are often not involved in the decision-making, although in some countries this is becoming more frequent especially as it is recognized that therapeutic benefit depends greatly on whether the patient understands the disease and the need for medication, but also when alternative therapies involve significant financial implications for the patient, or when the doctor considers that the additional benefits obtained with the best drug do not outweigh its higher cost to the social health fund.

Four categories of measures influence prescribing (Table 7.1). The combination of two is common, and in some countries three out of four are used. The most fundamental category is the restriction of drugs that may be prescribed or those that will be

reimbursed by the use of positive and negative lists. The second, more diffuse, category is that of issuing guidelines which are based primarily on therapeutic considerations; these guidelines influence what medications doctors prescribe and, in some countries, how prescriptions are written. The third category involves budgets that motivate doctors to take costs into consideration when selecting between alternative treatments. Finally, the fourth category involves non-financial policies and incentives enabling health insurance to monitor or/and audit physician prescribing activities and patterns.

Table 7.1 Prescribing, dispensing and consumption of pharmaceuticals, 2007

Country	Positive list	Negative list	Budget*	Guidelines/monitoring	Generic prescribing	Substitution	Incentives	Co-payment
Estonia	**Yes**	**No**	**No**	**Some, limited impact**	**Yes, but not compulsory**	**No**	**No**	**% up to a limit plus a flat dispensing fee of EEK20**
Austria	Yes	No	No	Yes	Not promoted	No	No	Flat fee per script item
Belgium	Yes	No	Yes	Yes	Increasing	In exceptional circumstances	No	%
Denmark	Yes	No	No	Yes	Yes	Mandatory		Tiered deductible +%
Finland	Yes	No	Fixed	Yes	Yes	Yes	No	% up to a ceiling
France	Yes	No	Yes	Yes	Yes (gatekeepers)	Yes	Yes (gatekeepers)	%
Germany	Yes	Yes	Notional	Yes	Yes	Yes	Abolished	Flat fee per pack
Greece	Yes	No	No	Yes; limited impact	No	No	No	%
Ireland	Yes	No	Indicative	Yes; limited impact	Yes	No	No	Depends on scheme: (a) None, (b) Deductible per month
Italy	Yes	No	Yes	Yes	Some, through reference pricing	Yes	No	None other than patients paying excess over reference price
Netherlands	Yes	No	At central level	Yes	Yes	Yes, with financial incentives to pharmacists	Yes	None other than patients paying excess over reference price
Norway	Yes	No	No	Yes	No	No	No	%/max
Portugal	Yes	Yes	No	Yes	Promoted	With doc's agreement	No	%
Spain	Yes	Yes	Yes	Yes, limited impact	Yes	With doc's agreement; also part of ref. price	No	% up to a max per item
Sweden	Yes	Yes	No	Yes	Some	With doctors' agreement	No	Deductible + fixed fee per item
Switzerland	Yes	Yes	No	Yes	Limited	Allowed	No	Mix of deductibles +%
United Kingdom	No[1]	Yes	Yes*	Yes	Yes	No (allowed from 2010)	Yes	Flat fee per script item
Poland	Yes	Yes	Yes	Some	No			% + flat fee
Czech Rep	Yes	No	Yes	Yes	Yes	Limited	Fines imposed	None other than patients paying excess over reference price
Hungary	Yes	No	Yes	Some	No	Allowed		%
Slovenia	Yes	Yes	Yes	Some	Some	In emergencies		%

Source: compiled from national sources.

Note: * Primary Care Trusts (PCTs) are given a global budget to cater for the needs of their patients.

[1]but Health Authorities and Primary Care Groups/Trusts (may) have their own formulary.

Where no data are given, this indicates that data are not applicable or available.

7.2.2 Prescribing guidelines

The aims of prescribing guidelines are to encourage doctors to prescribe rationally and consistently according to the medicine's indications and therapeutic needs of their patients. The main outcomes should be greater consistency in the choice of drugs and length of treatment prescribed for each condition, and a reduction in the volume of drugs prescribed as redundant or duplicate ones are eliminated. Rational prescribing also means that the cheapest drugs are favoured among those that are medically interchangeable for a given condition. When guidelines are first applied, savings may be noticed. Thereafter, sales volumes will depend on the changing morbidity of the population and variations in the guidelines.

Best practice guidelines or protocols are usually issued in association with the medical associations. They recommend how particular conditions should be treated and the drugs that should be prescribed. Many countries have made guidelines for a range of conditions. For serious conditions, the key recommended treatments are common across different countries. In a few countries, medical practice computer systems are in operation, using therapeutic protocols that guide doctors towards selecting one of the recommended treatment options based on the diagnosis entered.

Monitoring of prescribing practices is increasing, both to assess how doctors apply prescribing guidelines and how their treatment costs compare to the average. Evidently, the results are more meaningful in systems where patients are registered with a single doctor who acts as a 'gatekeeper'. Information on doctors' spending by therapeutic class can be collated from the systems used to reimburse pharmacists. Comparisons can also be made to highlight any significant variations in treatment costs between individual doctors and the average for the region. As most prescriptions do not record the diagnosis, it is not possible to determine whether a patient was treated cost-effectively. Prescribers should note the diagnosis on the actual prescription and this should be recorded.

Peer reviews are the primary method of determining whether doctors adhere to prescribing guidelines and treat their patients cost-effectively. These also provide an opportunity for doctors to justify any spending above average. Practices to be reviewed are generally selected at random or on a rotating basis, except where there has been excessive spending. The introduction of patient smartcards and generalized use of medical practice computer systems will make it easier to determine the effectiveness of guidelines, and to carry out more sophisticated analyses of whether and how individual doctors are performing. In some countries, such systems may be in breach of their very strong laws on privacy.

Doctors are sensitive about their freedom to prescribe. They are encouraged to avoid waste and to make decisions in accordance with the latest scientific consensus of best practice. Guidelines are in place primarily to inform and assist doctors in making better decisions. Hence, peer reviews are crucial.

7.2.3 Prescribing budgets

Doctors decide whether to treat a patient or refer that patient to a specialist or hospital. The range of conditions that can be treated in primary care is constantly increasing. In most cases, this is the best and most cost-effective option for patients. However, budgets which only cover treatments in the surgery and prescription medicines may provide an incentive for doctors to refer their more 'costly' patients to specialists and hospitals. As doctors largely determine which types and what quantities of medicines are consumed, it may be surprising that so little emphasis has been placed on how prescribing can be influenced. This fact may be a reflection of doctors' political influence or an indication of the professional esteem in which they are held.

In some countries, doctors are allocated prescription budgets; in other countries, a practice budget will include prescription medicines. Prescription budgets are meant to encourage doctors to consider cost when selecting treatments, while allowing them the discretion of prescribing expensive treatments in individual cases. Managing a budget is much easier if it is set for an individual doctor or group practice, such as in the United Kingdom, rather than collectively for all doctors in a region, as in Germany. In most cases, budgets are not absolute and prescribing does not cease when their limits are reached. However, to make budgets effective, sanctions or rewards can be used. For example, in Germany penalties are rarely applied, despite numerous cases of overspending. In the United Kingdom, doctors are rewarded when they spend less than their budget, by being allowed to use a proportion of the nominal saving to enhance their practice.

Unless doctors are able to monitor the cost of prescribing in relation to their budgets, and to forecast the likelihood of under or overspending, there will be significant variations in the cost of treatment prescribed at different times in the budget cycle. Typically, patients presenting towards the end of a financial year may be prescribed less expensive treatments. Budgets provide an incentive for rational prescribing where the least expensive drug can be selected among those that are interchangeable. However, budgets can also lead to suboptimal treatment; patients may be referred to specialists or hospitals if these costs are outside the prescriber's budget.

From a theoretical point of view, there should be a mechanism of assessing alternative forms of treatment and comparing them within a single budget. However, in practical terms, to include all levels of treatment within a doctor's budget would increase the complexity and cost of administration enormously, and would also potentially undermine the concept of solidarity among doctors.

7.2.4 Advertising

Advertising of pharmaceuticals is regulated by the Medicinal Products Act, which was harmonized with the relevant EC directive(s). The SAM is the national competent institution in charge of supervising pharmaceutical advertising activities. The advertising of pharmaceuticals before receiving marketing authorization is prohibited. Patient information leaflets, summaries of product characteristics and articles in referenced medical or pharmaceutical journals in their unchanged form are outside the scope of the Act. Academic detailing is allowed only to health professionals (that is, medical practitioners, pharmacists and pharmaceutical assistants). Marketing

authorization holders are prohibited to give gifts to health professionals of a value above €6.39 (EEK 100). Higher-value promotion activities are only acceptable in the form of supporting participation in scientific conferences. This support cannot be broadened to encompass people other than health professionals.

7.3 Rational drug use in Estonia: the future

7.3.1 Influencing physician prescribing behaviour

During our visits in Estonia, it was felt that little was done to monitor and evaluate prescribing and that the data on dispensing collected by EHIF from community pharmacists are probably underutilized. An integrated system of monitoring and evaluation needs to be in place, that would provide accurate information on prescribing patterns and dispensing and would guarantee continuous flow of information between prescribers, dispensers and health insurance in real time rather than on an ex-post basis. Considering the level of IT penetration in Estonia and the EHIF, this should be fairly easily done, provided politicians, and physicians are on board. A group of experts within EHIF could assist in this and, importantly, fulfil the following:

- scrutinize, pricing and payments to contractors for the dispensing of prescriptions;
- provide prescribing and dispensing information to the entire health service;
- manage EHIF's income availability;
- prevent prescribing and dispensing fraud within the health service; and
- conduct more frequent audit across physician practices ex ante rather than ex post

7.3.2 Education, training, information

While it is important to understand the principles of (cost-) effective prescribing, these principles must be reinforced through adequate training schemes for prescribers as well as timely information on new technologies and rational prescribing. This role could be played by the body responsible for cost-effective prescribing and may be resource intensive, as well as a collaborative effort between the competent authorities, in particular EHIF, SAM, MoSA and the professional groups.

More precisely, its additional remit would be to facilitate and support the promotion of high quality, cost-effective prescribing through a coordinated programme of activities for health authorities, medical and pharmaceutical advisers, and GPs. Its objectives would be to develop a coordinated programme of activities covering the following five main areas of work:

- training and education: to deliver a coordinated programme of activities with the aim of supporting health authorities and their advisers in their role to improve prescribing and medicine use;
- information: to provide and help coordinate the provision of effective information on medicines and prescribing related issues;
- good practice: to ensure health authorities, GPs, and advisers have accurate and correct information on clinical effectiveness and evidence based care;

- information technology: to help design & develop a prescribing information system, and to assess new technologies;
- research: to help inform national research and development initiatives on prescribing.

Relevant information could also be available, through broader dissemination of systematic reviews of the effects of health care interventions. This can be achieved through the Cochrane Collaboration, among others.

7.3.3 Monitoring the implementation of policies on rational drug use

In principle, the responsibilities regarding monitoring and supervision of rational drug policies is as follows: SAM monitors and supervises the operation of pharmacies (e.g. if medicines are available and at what cost) and the HCB monitors prescribing practices. In practice, however, there are clear bottlenecks as the analysis in the pervious section suggested. As a result, at present there is little or no systematic monitoring of the various parameters of the function of the pharmaceutical sector and only a small sample of practices are surveyed or audited each year and this occurs ex-post. The ability to exercise policy in this way is somewhat compromised in the absence of incentives or disincentives.

Although there does seem to be a (clear) regulatory framework in place, its enforcement seems to be lacking and needs to be practiced by the competent authorities. If issues or problems arise with the division of labour and the allocation of supervisory tasks between the agencies involved (SAM, HCB, EHIF), then a new balance should be identified and agreed upon.

7.3.4 Consumer/patient education

At the other end of the spectrum, patients could also benefit from information campaigns to their awareness about generic medicines and their equivalence to the originators.

Overall, patient education his is a rather complex area which would probably take a long time to give fruits. Consumers/patients need to know basic facts on prevention focusing mostly on lifestyles, but also on the treatment process of different conditions, particularly those of chronic nature. The MS and EHIF could contribute to this improvement in awareness (which is also part of a prevention strategy) among the general population, by designing and distributing leaflets free of charge. Doctors' surgeries would be the obvious place to start with.

7.3.5 E-prescribing

One of the proposed changes for the immediate future concerns the development and introduction of E-prescriptions, which embodies a digital prescription and retail delivery system of pharmaceuticals. This reform is to be carried out in close cooperation with other major initiatives. Since pharmaceutical expenditure is increasing faster than economic growth and other health care components (see Fig. 6.5), containing costs poses a continuous challenge for Estonia. Although reference pricing and price negotiations have been introduced, cost-containment has been limited. The fact that

OOP on pharmaceuticals is increasing could imply increased difficulties in access to pharmaceuticals, mainly for lower-income groups. To meet these challenges, further development of the reimbursement system is needed. The changes in reimbursement system should lead to cost-containment and a decline in OOP, along with simplifying the system of reimbursement and ensuring price controls for all reimbursed pharmaceuticals. Changes in the reimbursement system should aim to protect certain individuals (people with chronic conditions, low-income individuals, for example) against high financial risk and access difficulties. In addition, there is room to improve rational use of pharmaceuticals. In this respect, certain strategies are being considered, including introducing supply-side measures (such as prescription budgets, active feedback to doctors), encouraging rational prescribing (such as use of cheaper generics instead of expensive originator pharmaceuticals), introducing training programmes and promoting rational use of pharmaceuticals by patients.

7.3.6 Overall concluding remarks

The report and the seminar in Tallinn in May 2009 highlighted the need to have more and simpler information available for doctors; the potential utilization of available infrastructure and new e-prescribing systems to support rational prescribing; the need for more local evidence on doctors prescribing practices and behavioural models; the use of incentives for doctors but also pharmacies and other parts in the delivery chain to increase access to medicines; develop system for cost and other information sharing by doctors and patients, as well as transparent and regular monitoring of prescribing practices. Doctors raised the importance to balance regulation (as well different incentives schemes) and trust towards professionals to treat patients using best available evidence. The understanding of complexity of the rational use of medicines is rather well understood but there is need to have agreement of moving to this direction and creation of supportive system.

8. Distribution of medicines

8.1 Wholesaling

In 2007 there were 52 wholesalers in the Estonian market (Table 8.1); of those 44 were active in human and veterinary medicines and 8 in veterinary medicines only. Of these 52, only 6 of them are fully assorted. The above figure (52 wholesalers) also includes "restricted wholesale licencees" and, probably, those that are importers without the right for warehousing. Despite these modifications, this is still a large number, given the small population size of Estonia (1.34 million in 2008), although the activities are highly concentrated with the six-seller concentration ratio (C6) being 92%, which is similar to the situation in other EU countries. There are examples of other countries within the EU with many wholesalers servicing a small population; one of them is Cyprus (Table 8.2).

In most cases though, the ratio of wholesalers/population is much lower than in Estonia. Finland has only two wholesalers (population: 5 201 000), and Denmark has three (population: 5 374 000). Although Greece has many wholesalers (124), its population is eight times the population of Estonia. Thus the ratio of wholesalers/population is still larger in Estonia.

Table 8.1 Number of wholesalers with activity license in Estonia 2003–2007

	2003	2004	2005	2006	2007
Wholesalers (human and veterinary medicines)	36	38	46	45	44
Wholesalers (veterinary medicines only)	9	9	9	8	8
Total number of wholesalers	45	47	55	53	52

Source: State Agency of Medicines, 2008.
Note: A special clause on the activity license is needed to trade veterinary medicines.

There are arguments for and against having a relatively large number of wholesalers. A larger number of wholesalers –in principle- imply more competition in the market, which could potentially lead to lower prices. Margins are determined by the authorities though, so in practice competition does not lead to lower prices. Any competition leads to discounts to pharmacists, but does not reach the consumer. Wholesalers in Estonia though insist that "margins are too low, and that, as a result, many wholesalers struggle to survive in the marketplace". Indeed, the market is driven by just 2 "teams" which own 4 main wholesalers with a market share between 85–90%. Overall, economies of scale seem to do exist already. As a result, the only way for existing players to increase their profitability is through increased mark-ups, or if the situation remains unchanged, further consolidation will need to take place, particularly towards the lower end of the player constituency.

Table 8.2 Number of pharmaceutical wholesalers vs. country population, 2006

Country	Number of Pharmaceutical Wholesalers	Population	Local share of top three wholesalers (%)
Austria	9	8 139 000	95
Belgium	27	10 269 000	50
Cyprus	60/110	715 000	50 (but for top 10)
Demark	3	5 374 000	100
Finland	2	5 201 000	100 (top 2)
Greece	124	10 656 000	n/a
Italy	193	57 474 000	43
Netherlands	9	16 105 000	76
Norway	3	4 538 000	100
Spain	99	40 546 000	36
Sweden	2	8 398 000	100 (top 2)
United Kingdom	20	59 008 000	85

Source: Kanavos, 2006.

Table 8.3 Wholesale distribution and margins, 2006

COUNTRY	AVERAGE MARGIN RX	REGULATED/ NOTREGULATED	FIXED/ DEGRESSIVE
AUSTRIA	7.30%	regulated	degressive
BELGIUM	8.50%	regulated	degressive
CZECH REPUBLIC	4.50%	regulated	fixed
DENMARK	6.60%	not regulated	degressive
ESTONIA	7.90%	regulated	degressive
FINLAND		single channel	
FRANCE	7.30%	regulated	degressive
GERMANY	6.10%	regulated	degressive
GREECE	7.80%	regulated	fixed
HUNGARY	5.30%	regulated	degressive
IRELAND	10%, 15%	regulated	fixed
ITALY	6.60%	regulated	fixed
LATVIA	6.50%	regulated	degressive
LITHUANIA	5.00%	regulated	degressive
LUXEMBOURG	5.20%	regulated	degressive
NETHERLANDS	7.70%	regulated	fixed
NORWAY	5.20%	not regulated	degressive
PORTUGAL	9.20%	regulated	fixed
POLAND	8.90%	regulated	fixed
SLOVAKIA	7.00%	regulated	fixed
SLOVENIA	5.80%	not regulated	
SPAIN	5.50%	regulated	fixed
SWEDEN		single channel	
UK	12.50%	regulated	fixed

Source: GIRP, 2005 and information obtained from GIRP, 2006.

Wholesalers in Estonia 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. Wholesalers (but also pharmacies as discussed below) are paid on a regressive margin basis. Wholesale remuneration methodology and average remuneration levels are in line with practice in other European countries (Table 8.3), although, based on recent trends, it should be borne in mind that overall mark-ups are declining internationally, both for wholesalers and pharmacists.

Typically, regulations relating to wholesaler margins are also accompanied, among other things, by obligations to stock as well as to supply medicines that are included in the formulary and are reimbursed by health insurance. Unless there are specific geographical access problems, wholesalers are usually in a position to supply pharmacies within 24 hours and, in many cases, sooner. This is an important aspect that would ensure a wider availability of medicines. It is not clear whether the Estonian government regulations on wholesaling include the obligation to stock and supply, but it would be beneficial if they did.

8.2 Retailing

The total number of community pharmacies in Estonia is 509 and their distribution is heavily skewed towards urban areas. On average, there is 1 pharmacy per 2600 inhabitants, although this ratio differs in urban and rural areas. There are a total of 146 pharmacies in rural areas, the remainder being located in urban areas. Pharmacists argue that rural pharmacies are not profitable. Pharmacies are deemed to be profitable if their annual turnover exceeds 3 million EEK /191 735 EUR (only selling of drugs considered) = pharmacies who service continuously 1600 patients. Therefore, large pharmacy chains usually prefer to have pharmacies in urban areas rather than remote villages. Lack of pharmacies is these areas can be a serious problem, although MoSA sources maintain that the maximum distance in order to reach a pharmacy is about 30km. Demographic restrictions apply to a pharmacy's location and the maximum ratio is 1 pharmacy per 3000 inhabitants (in rural areas distance between pharmacies has to be 1 km); if this is exceeded, then no other pharmacy is allowed in the same area. Vertical integration is allowed in Estonia and the largest wholesalers have their own pharmacy networks, which, again are widely concentrated in urban areas. Pharmacy ownership is, therefore, not limited to pharmacists.

Because people living in rural areas usually shop in cities, pharmacies located in cities often have better availability, cheaper alternatives are more often available, and, as a result, choice is wider. Physician services are also closer.

If a patient is not able to move/drive, and therefore access a pharmacy, a social worker or a family member may be in a position to fill the prescription on their behalf. Internet pharmacies are not allowed in Estonia yet, but will soon be established. Doctors are not allowed to dispense medicines because of conflicts of interest and the problem of supplier inducement.

Pharmacists are also remunerated through regressive mark ups (as percentage of pharmacy purchasing price (PPP)) and their average remuneration is fixed in the law. 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. Similar 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. No other dispensaries for pharmaceuticals other than pharmacies are allowed in Estonia. Average retail mark ups currently prevailing in Estonia are close to 20% and are comparable to mark ups in other European countries. The Law does not stipulate any obligation for wholesalers and pharmacies to stock and dispense.

8.3 Issues arising from the operation of the distribution system

8.3.1 Structure of wholesale and retail distribution chain and its reimbursement

It cannot be said that Estonia is underequipped or underprovided in terms of wholesale or retail distribution outlets. The total number of wholesalers is 48 and the C6 market concentration ratio is 92%. The leading two wholesalers represent 58% of the market (Tamro, the market leader, represents 31% and Magnum 27% of the market). However, looking at purchases from manufacturers, then Magnum's share is over 50% (because Magnum sells drugs directly to consumers as well as through two other connected wholesalers). About one third of drugs are sold between at least 2 wholesalers before reaching pharmacies/hospitals. It could be argued that the number of available wholesalers needed to serve a country the size of Estonia is relatively high (based on the ratio of population covered by a wholesaler), compared with most benchmark European countries (Table 8.2) and that some consolidation particularly towards the lower end of the existing players over time would lead to greater efficiency. Competition issues may arise in the process, as they have arisen in the past with Magnum, which had to divide itself a few years ago.

An interesting feature of distribution channel remuneration in Estonia is that markups seem to be guaranteed by law; in particular, Estonian law foresees a 7–10% margin for wholesalers and 21–25% for pharmacists.

Wholesalers also argue that their operating margin from prescription drugs is -1%, according to a study conducted on behalf of their trade association (PWC, 2008) and their overall profitability is due to non-drugs, such as vitamins and supplements. Again, the fact that multiple wholesalers operate in Estonia may be inefficient and would require a market correction over time.

8.3.2 Wholesale and retail practices

It is unsurprising that most pharmacies are concentrated in urban areas and that there is a disincentive to maintain pharmacies in rural or remote areas. This could be addressed by incentives as explored in the next subsection; in the meantime, the MoSA may wish to re-visit the claim that the maximum distance of 30 km to a pharmacy does not restrict

access. It could well restrict access to patients who are old or cannot drive and could contribute towards their foregoing necessary treatment.

It is not known how acute this problem is, but if it is it could be addressed with a variety of measures: for instance, both community pharmacies and internet pharmacies could deliver to the patient's door. Alternatively, as pharmacy chains own a large number of pharmacies, a requirement could be that for every certain number of pharmacies maintained by the same ownership in urban areas, a pharmacy in a remote rural area should be opened. This is further explored in the next subsection. Finally, a further option might be for physicians to assume a dispensing role in remote areas as is often done selectively in other countries (e.g. United Kingdom or Japan), but given the relative homogeneity of the country, this should be discouraged as it can lead to supplier-inducement.

The fact that there are extensive vertical links between wholesalers and retailers, particularly in urban areas, renders the statutory margins redundant in many respects, as both sides of the distribution chain can potentially achieve economies of scale and reduced fixed cost structures through these links and the efficiency savings that usually arise. Paying the same markups to structures benefiting from vertical links and to structures that do not, places the latter at a disadvantage compared with the former in terms of financial remuneration.

While consolidation could work particularly well in wholesaling, where there appears to be some excess capacity with a large number of players, the situation is most certainly different in retailing, where over-concentration in urban centres, while justified by market forces, may leave rural areas underserved. This could be a case of tit-for-tat negotiation between the competent authorities and retail chains, for instance, to require adequate service provisions for rural areas in return for a guaranteed margin and could be laid down in existing regulation(s). Otherwise, it is highly likely that rural areas will continue to face access problems, perhaps even more as in the future as there is a tendency to concentrate service points in urban areas.

8.3.3 Wholesale and retail reimbursement

The regressive nature of margins can often give rise to perverse incentives among retailers so that more expensive drugs can be dispensed and cheaper ones not being available. Often, this depends on how the regressive bands are constructed. More often than not, however, this is dependent on other factors operating on the market, notably discounting. In practice more expensive drugs could offer higher discounts to (retail) distributors. Evidence from France and the United Kingdom suggests this is happening on a grand scale. There is no reason to assume that discounting does not occur in the Estonian context; this could be addressed by enabling a clawback policy similar to the ones prevailing in the United Kingdom or the Netherlands, which would allow a co-share of discounts between distributors and Health Insurance. The precise split of revenues would be subject to investigation and further consultation between the parties involved. The alternative would be for EHIF to adopt a preferential-type policy, whereby one or two generics are purchased per product. A preferential policy operates on the basis of a manufacturer winning a tender for a particular product and supplying the totality of the

market at the lowest possible price. In this case, the EHIF would be the beneficiary of any discounts offered by the winner of the tender.[26]

Both wholesalers and pharmacists (but particularly the former) have been complaining that their *average effective* margin is lower than the one stipulated in law. Although Estonian law seems to guarantee a certain level of *average* margins for wholesalers and pharmacists, in practice, these average margins have been 1% lower for wholesalers and 2–2.5% lower for pharmacists than those stipulated in the law. This occurs because actual margins are not fixed but regressive; as more expensive pharmaceuticals are used over time, the percentage that wholesalers and pharmacists receive declines. Since margins are determined by law, both wholesalers and pharmacists could take legal action, making the government directly liable to paying compensation to them for failing to implement the law.

There is no officially guaranteed income for either wholesalers or pharmacists from an international experience, particularly in wholesaling and especially in situations where the market is allowed to operate and adjust the prevailing market structure to the effective market size. The Estonian government should address this by changing the law in the longer term, or/and implement minimum service requirements across the country in the short-term, both in terms of drug distribution, but also drug importation and storage, where the need arises. Where (horizontal and/or vertical) integration is allowed, consolidation may be the most notable outcome to take account of falling margins. This applies most pertinently to wholesaling, where it is probably unrealistic to sustain the current number of players in the market.

Pharmacists have many concerns regarding legislation for their profession –and probably their commercial function (and it seems to be that the chains have concerns over this distribution industry). Pharmacists do not receive additional service fees from Health Insurance for disease management activities, e.g. blood pressure monitoring, although this may be something that Health Insurance may wish to contemplate over the medium-term, particularly in rural areas. Patients could pay a small fee for that, whether it will be covered by insurance or not. Further, pharmacists have to pay for recycling themselves.

With regards to the income of pharmacies, Health Insurance should be in a position to have a clear view of what average incomes for pharmacies (urban, semi-urban and rural) are, based on the number of prescriptions dispensed and the cost of each prescription. Health insurance, in consultation with pharmacies, should also be in a position to know what the required average income is for pharmacies to break even.

Finally, measures should be taken in order to ensure continued presence of pharmacies in rural areas, where this is not profitable, so that equity in access can be safeguarded. Market power itself is unlikely to meet this requirement, but, as discussed previously, incentives could be used in this context. For instance, as pharmacy chains own a large number of pharmacies, a requirement could be that for every certain number of pharmacies maintained by the same ownership in urban areas, a pharmacy in a remote rural area should be maintained or opened. This would ensure geographic availability of facilities and, consequently, contribute to geographical availability of medicines.

[26] The policy is currently implemented in the Netherlands, where it has led to generic prices declining by more than 80% over the short term, but has not been without controversy.

9. Taxation

9.1 Current policy

A value-added tax (VAT) of 9% 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. The VAT for pharmaceuticals has been increased as of January 1st from 5 to 9%.

The recent VAT increase to 9% has coincided with the rapid slowdown in the country's economic growth performance. The 11% GDP increase in 2006 has turned into negative growth in 2008, with negative performance forecast in 2009. As a result the state budget is probably running a deficit and needs additional revenues. In 2007 Estonia had the lowest share of public sector expenses among the EU Member States – 34%. Conservative fiscal policy and a balanced budget have been the corner-stones of general economic and political philosophy in Estonia since the restored independence in 1991. From a political perspective, the economic programme of the current government coalition favours harmonization of VAT rates.

9.2 Issues arising from VAT and VAT increase

VAT on medicines in Estonia is higher than many EU countries. For example, in the United Kingdom, Sweden and Cyprus, the VAT applicable to prescription medicines is 0%, whereas in France, it is a reduced 2%; Hungary, Latvia and Lithuania apply a reduced 5% (Table 9.1).

Understandably some European countries allow the full impact of standard-rate VAT on prescription medicines (e.g. Germany and Denmark), and this is widely seen as a fiscal measure and as part of a balanced budget pursuit. By contrast, over-the-counter (OTC) medicines or medicinal preparations that are not reimbursed by Health Insurance routinely attract the standard VAT rate and this is justifiable on the grounds that they are widely seen as consumer goods rather than goods essential to maintain health.

It is recommended that the government maintains a low-VAT rate for prescription medicines and, in general, for all medicines and medicinal preparations reimbursed by Health Insurance. This is in line with policies in most other European countries, as shown on Table 9.1. There is no theoretical or empirical justification of imposing VAT on medicines, other than this being a levy by the Treasury on the health care budget and the contributions paid for by employers and employees. Within the Estonian setting, where patients face significant or extensive out-of-pocket payments, VAT as an indirect tax is regressive and is, therefore, a tax on the poor and vulnerable, thus potentially adding to inequity.

Given the high rate of out-of-pocket payments for prescription medicines in Estonia, it is likely that the lower socioeconomic groups (poorer households and elderly people) will be most adversely affected. As many patients face problems due to co-payments or extra out-of-pocket payments due to reference pricing, as explained earlier in the paper, a reduced VAT rate would disburden patients facing accessibility problems. Thus, in the

Estonian case, it is recommended that the status quo is maintained and even reverted to the previous status quo of 5% or even reduced to 0% as in other EU countries.

Table 9.1 VAT rates applicable to prescription pharmaceuticals in selected EU countries, 2007

Country	VAT rate
Austria	20%
Belgium	6%
Cyprus	0%
Denmark	25%
Finland	8%
France	2.1%
Germany	19%
Greece	9%
Hungary	5%
Italy	10%
Sweden	0%
United Kingdom	0%
Slovakia	10%
Latvia	5%
Lithuania	5%

Source: The authors.

10. Overview of problems and proposals

10.1 The context

10.1.1 Findings

Pharmaceutical expenditure is increasing faster than economic growth and other health care components, such as hospital care, or ambulatory care. As a result, containing costs and spending existing resources wisely poses a continuous challenge for Estonia.

Although reference pricing and price negotiations have been introduced, cost-containment has been limited.

The fact that out-of-pocket spending on pharmaceuticals has increased over time and currently accounts for 43% of total out-patient prescription pharmaceutical spending could imply increased difficulties in access, mainly for lower-income groups.

10.1.2 Recommendations

- It is important that a comprehensive medicines policy be developed, with clear objectives to address issues of financing, equity in access, macroeconomic efficiency and allocative efficiency. This could be done under the stewardship of the competent authorities, MoSA in particular, and involve all relevant stakeholders in consultations to provide input.
- To meet the above challenges, further development of the reimbursement system is needed. Based on the recommendations of the draft report on the medicines sector review and the debate resulting from the seminar on drug policy held in Tallinn, on May 22nd, 2009, a number of clear proposals emerged to update medicines policy in Estonia. The areas identified for improvement were:
  - the concerns over increasing and significant out-of-pocket expenses for prescription medicines;
  - streamlining of the process for drug selection for positive list inclusion and subsequent reimbursement;
  - stimulate the prescribing and dispensing of generics;
  - facilitate generic substitution;
  - market incentives for pharmacies to dispense generics;
  - simplifying and reducing co-payments for patients;
  - implementing a national program/system to improve prescribing and use of medicines;
  - monitoring the availability of medicines at pharmacy level;
  - ensuring adequate and timely distribution of prescription medicines (both wholesale and retail);
  - reducing VAT on prescription medicines;
  - developing a comprehensive medicines policy to include all important areas.

- The changes in reimbursement system should lead to improved access to medicines and a decline in out-of-pocket spending as well cost containment, along with simplifying the system of reimbursement and ensuring price controls for all reimbursed pharmaceuticals.
- Changes in the reimbursement system should aim to protect certain individuals (people with chronic conditions, low-income individuals, for example) against high financial costs and access difficulties.
- In addition, there is room to improve rational use of pharmaceuticals. In this respect, certain strategies may need to be considered, including introducing supply-side measures (such as prescription budgets, active feedback to doctors), encouraging rational prescribing (such as use of cheaper generics instead of expensive originator pharmaceuticals, use of well established and relatively cheaper substances (in terms of INNs) instead of expensive "me-too" pharmaceuticals, where this is clinically justified), introducing training programmes and promoting rational use of pharmaceuticals by patients.

10.2 Pricing

10.2.1 Findings

A well-established system of pharmaceutical pricing and reimbursement is currently in operation in Estonia. It resembles the policies and practices followed in other EU Member States. Of course, there is always room for some improvement and a few points are raised in the following section.

10.2.2 Recommendations

- An active generics policy necessitates fast approval of generic medicines and, subsequently, their availability on the market place so that patients/consumers can have access to them throughout the country.
- An active generics policy also requires undertaking awareness campaigns particularly from the perspective of MoSA and EHIF to create an atmosphere of unconditional acceptance for generic medicines among patients as well as health care providers.
- Health technology assessment (HTA) is important in performing assessments as the cost–effectiveness criterion is used to inform opinions and, subsequently, decisions on product reimbursability. As HTA is used explicitly in the decision-making process, it would be beneficial to develop a national competence centre, which will evaluate not only pharmaceuticals but also other health care technologies. Taking into account the structure of institutions it still needs to be agreed who steers the process, who is involved, the processes and other details. Estonia has the expertise to develop this further building on the Baltic pharmacoeconomic guidelines under the auspices of MoSA and EHIF. An important aspect would be to involve academic expertise in such an initiative as well as expand the knowledge and skills base in Estonia. The establishment of such a competence centre would require thinking around organizational structure, involvement and direction among others.

- Finally, it is not clear whether the fact that parallel traded pharmaceuticals need to be 10% cheaper than originator brands, is consistent with EU competition law and MoSA may need to check this.

10.3 Reimbursement, the role of the Pharmaceutical Committee (PC) and the In-Patient Services List (IPSL)

10.3.1 Findings

Over the period between 1997 and 2008, the total expenditure on prescription only medicines (POMs) consumed in out-patient settings increased nearly six-fold, with an average annual growth rate exceeding 25% and increased from EEK 391 million (€25.2 million) in 1997, to EEK 2 281 million (€147 million) in 2008.

As a result, total per capita out-patient prescription drug spending has also increased significantly over time, from just over EEK 200 (€18.7) in 1997 to over EEK 1700 (€109.8) in 2008.

Of the prescription medicines that are reimbursed by health insurance, the total contribution by patients (effective co-payment) exceeded 37% in 2008 and has increased continuously from 1997, when it accounted for 25% of the total reimbursed out-patient prescription drug spending. If one takes into account the non-reimbursed component of out-patient prescription medicines, then the total effective co-payment has ranged between 36.3% (2002) and 43% (2008).

In-patient POMs registered a 9-fold increase between 1997 and 2008, from EEK 70 million (€4.5 million) in 1997 to EEK 633 million (€40.8 million) in 2008.

Consumption of OTC medicines more than doubled between 1997 and 2008 from EEK 237 million (€15.3 million) in 1997 to EEK 566 million (€36.5 million) in 2008.

Three broad issues arise from the way the PC operates.

- First, the manner in which the PC operates has in recent years generated some tension among its constituent members, particularly the governmental agencies represented on it as it is often felt that some decisions are taken in a non-transparent manner.
- Second, based on local consultations with stakeholders, it is also possible that not all members of the PC make adequate use of their voice in the decision-making process, particularly patients and medical experts (physicians).
- Third, the existence of IPSL weakens the PC, lessens its credibility, and creates further tensions among its constituent members.

The way the PC operates may have implications for its perception by manufacturers and may compromise its ability to yield conclusive decisions on reimbursement applications. It further creates uncertainty about who the decision-maker is and what are the precise decision-making levers in each case. Finally, it raises concerns about the transparency and

credibility of the criteria used by the PC to arrive at its recommendations to the Minister for Social Affairs.

10.3.2 Recommendations

- With regards to the operation of the PC, action is required on three fronts, notably, (a) transparency of decisions, (b) voice of stakeholders and (c) antagonism with the IPSL; it is critical that the PC should be the only channel that recommends new pharmaceutical products to the Minister of Social Affairs and that its constituent members be seen to contribute to this goal robustly and in a team spirit.
- With regards to physicians and patient representatives, it would be important for them to submit their views and perspectives on new medicines considered by the PC in writing for the benefit of informed and evidence-based discussion. Guidelines could be drafted on what such statements might contain. Overall, the structure and composition of the PC would remain the same with its representative basis, but additional evidence and perspective could be added, and, as a result, the PC could be strengthened procedurally.
- With regards to the negotiating capacity of the PC, this could be strengthened by broadening the criteria it uses to arrive at its recommendations to the Minister of Social Affairs. Recent experience from the Pharmaceutical Unit of the MoSA, suggests that additional negotiating tools may need to be included in the Committee's deliberations. These could include direct negotiations with the manufacturer, price-volume agreements, or, even, portfolio agreements and price modulations. While these have been used recently directly by the Pharmaceutical Unit, it is important that they occur within the remit and under the auspices of the PC and are in line with conduct in other reimbursement committees in many EU Member States. The expertise of the Pharmaceutical Unit could be used in this respect. In this context, the benefit for the PC is manifold: first, it will reinforce its credibility and commanding position as an advisory body to the Minister of Social Affairs; second, it will enhance its perception from by manufacturers as a negotiating partner rather than a command-and-control body. And, third, it will satisfy the needs of its constituent members.
- The way decisions are reached for the inclusion of expensive pharmaceuticals in the IPSL, has created certain concerns and tensions among some of the constituent parties of pharmaceutical decision-making as the process is deemed to be non-transparent, not governed by a competent committee empowered with pharmaceutical assessments and can be perceived by many as a back-door entrance to achieving reimbursement with questionable motives and antagonizing the PC. Despite the fact that key stakeholders such as the MoSA and EHIF have the ability to participate in, comment on and validate applications made for inclusion in the IPSL, this occurs in a fragmented manner and at different stages for each stakeholder.
- It may be necessary that the process through which some specialty and expensive prescription pharmaceuticals are included in the IPSL be phased out gradually and the decisions currently taken under its auspices, be transferred fully to the PC. This will improve both the process through which new applications are assessed as well as the flow of information across the relevant stakeholders. The process

according to which the PC operates needs to be clearly defined and organized, in terms of criteria and principles for drug selection, application process, as well as functioning of the PC.

- A common process that decides what is included in the Reimbursement (positive) List and the IPSL is of key importance. The PC or hospitals need to have a uniform procedure to allow for new drugs to be included the national reimbursement list.

10.4 Availability and affordability

10.4.1 Findings

There are three policy elements related to affordability problems in Estonia: the first is the structure of patient co-payments; at 43% effective POM co-payments in Estonia seem to be higher than in many other EU countries; the majority of medicines dispensed are subject to some form of co-insurance and about 50% of all prescriptions dispensed are subject to a 50% co-insurance. Treatments for a number of chronic diseases are subject to a 25% co-insurance (75% coverage). A reduction in the level of co-payments could be achieved by promoting rational drug use, cost-effective prescribing and patient awareness of cheaper therapeutic options at the pharmacy.

The second element relates to the determination of the reference price and is also related to the supply of medicines in Estonia. The MoSA takes as reference the second lowest price on the market, without checking the capacity of the manufacturer to supply the (entire) market. Similarly, pharmacies do not necessarily have an incentive to buy the cheapest possible medicine and can opt to stock a more expensive drug. Consumers may be quoted the product with the reference price, but are likely to have to pay out-of-pocket for another product with a higher price that is available at the point of service. In this particular case, the problem of availability is tightly connected with affordability and is also related to the "small market" discussions at EU level.

Third, differential co-payments for the same diagnosis and course of treatment based on the type of provider visited do not appear sensible in some cases, particularly if primary care (as opposed to specialist care) is to be further encouraged. In an environment where pharmacy generic substitution rights are not extensive if a branded product is prescribed, even if a cheaper alternative is available, the patient purchases the originator and is liable to paying a much higher co-payment, which includes the fixed dispensing fee (FDF) of EEK 20 (which is fixed for both originator brands and generics), and the difference between the brand and the generic. Under these circumstances, the operation of the reference pricing system serves mostly the objectives of health insurance, as it denotes the amount that EHIF will pay for a particular drug, but does not necessarily safeguard the interests of patients.

Several interesting trends have been revealed about the dispensing and utilization patterns of certain medicines for chronic illnesses post-patent expiry, and by implication, the availability of medicines in Estonia.

1. Generic substitution is not allowed in Estonia. This, combined with the fact that generic prescribing, although compulsory in principle, it is in practice not working

effectively enough, results in a continued high penetration of brands post patent expiry.

2. It appears that in the majority of cases, the originator drug continues to maintain a significant market share, and, indeed, is the market leader, despite generic alternatives being in principle available;
3. The originator drug often continues to be priced significantly above the reference price but this does not deter patients from paying the appropriate co-payment, which is often significant;
4. In the majority of cases, the more expensive generics seem to be "preferred" by patients, or simply that patients are dispensed with more expensive generic alternatives, which in most cases results in them paying a significant amount out-of-pocket;
5. The cheaper generics, whose prices are closer to the reference prices in almost all cases, have a very small market share, despite being good value for patients in terms of cost-sharing. This may be due to the fact that they may not be available at the pharmacy, which, in turn, could imply that the profit margin for some generic products is lower than that of originators or other generics.
6. Contrary to what is stipulated in the regulations, it is not always the case that the pricing structure for generic medicines is adhered to. These results in most generics being priced significantly higher than the reference price and are not always 30% cheaper than the brand; indeed, at times they are priced closer to the brand. There is no explanation for this and, similarly, there is no explanation as to why the regulation concerning price capping of generics does not seem to be implemented.

It is very likely that cheaper generics are simply not available in Estonia, or are available at intervals only. Indeed, as discussed earlier, availability spot checks with pharmacies (esp. rural pharmacies) suggested that many of the referenced generic medicines were not available; this, in turn would force patients to purchase the more expensive alternative.

The problem remains in Estonia, whereby each year, several thousand applications are made by individuals to import medicines for which the MA has expired and, therefore, they are not allowed to be placed on the market.

10.4.2 Recommendations

- Co-payments must be universal for patients suffering from the same disease, regardless of the doctor they visit (specialist or family doctor). If EHIF tries to discourage family practitioners from prescribing certain medications, then it should remove this right from them and enable only specialists to do so. At the same time, access to specialists should be improved and waiting times reduced so that patients can visit the right practitioner for their needs.
- Indeed reducing co-payments would be a positive move, given the affordability issues that many Estonians face. Thus co-payments should converge downwards rather than upwards and any prescribing and cost-sharing inconsistencies arising due to problems with the referral system will need to be ironed out. Such

reductions in cost-sharing would not necessarily be achieved via a further injection of financial resources in the system, but could materialise through (a) rational drug use, (b) more cost-effective prescribing by physicians and (c) raising awareness on the cost of generic drugs.

- It is likely that the reimbursement list caters for the vast majority of the Estonian population, although certain aspects emerged pointing at gaps particularly in newer treatments and some of the rare conditions.
- Pharmacists should have greater generic substitution rights and the rights of physicians to prescribe brands curbed. If physicians wish to prescribe an originator brand when generics are available they could seek prior authorization from EHIF. This could be achieved with a simple phone call or by completing the relevant paperwork.
- Regulation regarding pricing of generic products, stipulating that the generic should be priced lower than the originator, should be enforced. It is not clear whether the pricing of generic drugs follows in practice the methodology stipulated by the regulation, although, by implication, it should. Furthermore, it might be necessary to introduce a more aggressive price reduction for the first generic, e.g. a discount exceeding 50% off the originator price.
- The problem of unauthorized medicinal products can be addressed either by EU legislation or by national action. In particular, the three agencies (EHIF, SAM and MoSA) should collaborate to resolve this and adopt a procedure whereby reimbursement occurs on the basis of medical need, irrespective of a valid MA certificate, particularly, if the same product has a valid MA certificate in another Member State. For some of the issues involved there is EU legislation to cater for the availability of medicines on a Member State's market, through Directive 2001/83/EC, and some of the provisions therein, e.g. the sunset clause, the provision on Continuous Supply, and the Cyprus clause, although often some of these may not have been transposed into national legislation or implemented by the Member States. SAM could also collaborate with other competent regulatory authorities in countries where needed medications have a valid MA and allow the importation of those medicines in the Estonian market.
- National action, on the other hand, relates to implementing measures to keep low profitability products on the market, for instance, exempting low turnover products from annual fees and having favourable provisions or/and practices for re-labelling of out-patient drugs or not having national language labelling in case of hospital products. Exempting manufacturers from marketing authorization application fees might also be an option. Additional issues remain, however, in connection with the maintenance of low turnover products on small markets such as Estonia, notably, the cost of reporting requirements (variations, renewals, periodic safety updates etc).

10.5 Rational drug use

10.5.1 Findings

It appears that little is done to monitor and evaluate prescribing and that the data on dispensing collected by EHIF from community pharmacists are probably underutilized.

In principle, the responsibilities regarding monitoring and supervision of rational drug policies is as follows: SAM monitors and supervises the operation of pharmacies (e.g. if medicines are available and at what cost) and the HCB monitors prescribing practices. In practice, however, there are clear bottlenecks. As a result, at present there is little or no systematic monitoring of the various parameters of the function of the pharmaceutical sector despite the fact that this is part of government function(s). Only a small sample of practices are surveyed or audited each year and this occurs ex-post. The ability to exercise policy in this way is somewhat compromised in the absence of incentives or disincentives.

10.5.2 Recommendations

- Although there does seem to be a (clear) regulatory framework in place regarding rational drug use enabling monitoring to take place, its enforcement seems to be lacking and needs to be practiced by the competent authorities. If issues or problems arise with the division of labour and the allocation of supervisory tasks between the agencies involved (SAM, HCB, EHIF), then a new balance should be identified and agreed upon.
- An integrated and enforceable system of monitoring and evaluation would provide accurate information on prescribing patterns and dispensing and would guarantee continuous flow of information between prescribers, dispensers and health insurance in real time rather than on an ex-post basis. A group of experts within EHIF could assist in this and, importantly, fulfil the following: (a) scrutinize, pricing and payments to contractors for the dispensing of prescriptions; (b) provide prescribing and dispensing information to the entire health service; (c) manage EHIF's income availability; (d) prevent prescribing and dispensing fraud within the health service; and (e) conduct more frequent audit across physician practices ex ante rather than ex post.
- While it is important to understand the principles of (cost-) effective prescribing, these principles must be reinforced through adequate training schemes for prescribers as well as timely information on new technologies and rational prescribing. This role could be played by the body responsible for cost-effective prescribing and may be resource intensive.
- This body's additional remit would be to facilitate and support the promotion of high quality, cost-effective prescribing through a coordinated programme of activities for health authorities, medical and pharmaceutical advisers, and GPs. Its objectives would be to develop a coordinated programme of activities covering the following five main areas of work: (a) Training and education: to deliver a coordinated program of activities with the aim of supporting health authorities and their advisers in their role to improve prescribing and medicine use; (b) Information: to provide and help coordinate the provision of effective information on medicines and prescribing related issues; (c) Good practice: to ensure health authorities, GPs, and advisers have accurate and correct information on clinical effectiveness and evidence based care; (d) Information technology: to help design & develop a prescribing information system, and to assess new technologies; and (e) Research: to help inform national research and development initiatives on prescribing.

- There is need to have more and simpler information available for doctors; potential utilization of available infrastructure and new e-prescribing systems to support rational prescribing; need for more local evidence on doctors prescribing practices and behavioural models; use of incentives for doctors but also pharmacies and other parts in the delivery chain to increase access to medicines; develop system for cost and other information sharing by doctors and patients, as well as transparent and regular monitoring of prescribing practices. Doctors raised the importance to balance regulation (as well different incentives schemes) and trust towards professionals to treat patients using best available evidence. The understanding of complexity of the rational use of medicines is rather well understood but there is need to have agreement of moving to this direction and creation of supportive system.
- Relevant information could also be available, through broader dissemination of systematic reviews of the effects of health care interventions. This can be achieved through the Cochrane Collaboration, among others.
- Patients would also benefit from information campaigns to improve their awareness about generic medicines and their equivalence to the originators.
- Overall, patient education is a rather complex area which would probably take a long time to give fruits. Consumers/patients need to know basic facts on prevention focusing mostly on lifestyles, but also on the treatment process of different conditions, particularly those of chronic nature. The MoSA, SAM and EHIF could contribute to this improvement in awareness (which is also part of a prevention strategy) among the general population, by designing and distributing leaflets free of charge. Doctors' surgeries would be the obvious place to start with.
- One of the proposed changes for the immediate future concerns the development and introduction of E-prescriptions, which embodies a digital prescription and retail delivery system of pharmaceuticals. The fact that OOP on pharmaceuticals is increasing could imply increased difficulties in access to pharmaceuticals, mainly for lower-income groups. To meet these challenges, further development of the reimbursement system is needed. The changes in the reimbursement system should lead to cost-containment and a decline in OOP, along with simplifying the system of reimbursement and ensuring price controls for all reimbursed pharmaceuticals. Changes in the reimbursement system should aim to protect certain individuals (people with chronic conditions, low-income individuals, for example) against high financial risk and access difficulties. In addition, there is room to improve rational use of pharmaceuticals. In this respect, certain strategies are being considered, including introducing supply-side measures (such as prescription budgets, active feedback to doctors), encouraging rational prescribing (such as use of cheaper generics instead of expensive originator pharmaceuticals or prescribing well established INN-s instead of more expensive "me-too" drugs, where this is clinically justified), introducing training programmes and promoting rational use of pharmaceuticals by patients.

10.6 Distribution system

10.6.1 Findings

The total number of wholesalers is 48 and the C6 market concentration ratio is 92%. The leading two wholesalers represent 58% of the market.

Approximately one third of the total volume of drugs consumed in Estonia move through at least 2 wholesalers before reaching pharmacies or hospitals as wholesalers sell directly to pharmacies and sell on to other wholesalers.

It could be argued that the number of available wholesalers needed to serve a country the size of Estonia is relatively high (based on the ratio of population covered by a wholesaler), compared with most benchmark European countries and that some consolidation over time would lead to greater efficiency.

An interesting feature of distribution channel remuneration in Estonia is that markups seem to be guaranteed by law. Estonian law foresees a 7–10% margin for wholesalers and 21–25% for pharmacists and amount to an implicit guarantee of the income of the respective distributor(s).

Wholesalers also argue that their profit margin from prescription drugs is -1%, according to a study conducted on behalf of their trade association, as their profitability is due to non-drugs, such as vitamins and supplements.

Most pharmacies are concentrated in urban areas and that there is a disincentive to maintain pharmacies in rural or remote areas.

The regressive nature of margins in Estonia can often give rise to perverse incentives among retailers so that more expensive drugs can be dispensed and cheaper ones not being available. In practice more expensive drugs could offer higher discounts to (retail) distributors and there are no reasons to suggest that discounting does not occur in Estonia.

10.6.2 Recommendations

- The fact that multiple wholesalers operate in Estonia may be inefficient and would require a market correction over time.
- There is no officially guaranteed income for either wholesalers or pharmacists from an international experience, particularly in wholesaling and especially in situations where the market is allowed to operate and adjust the prevailing market structure to the effective market size. The Estonian government should address this by changing the law in the longer term, or/and implement minimum service requirements across the country in the short-term, both in terms of drug distribution, but also drug importation and storage, where the need arises. Where (horizontal and/or vertical) integration is allowed, consolidation may be the most notable outcome to take account of falling margins. This applies most pertinently to wholesaling, where it is probably unrealistic to sustain the current number of players in the market.

- The MoSA may wish to re-visit the claim that the maximum distance of 30 km to a pharmacy does not restrict access. It could well restrict access to patients who are old or cannot drive and could contribute towards their foregoing necessary treatment.
- In order to maintain access, both community pharmacies and internet pharmacies could deliver to the patient's door. Alternatively, as pharmacy chains own a large number of pharmacies, a requirement could be that for every certain number of pharmacies maintained by the same ownership in urban areas, a pharmacy in a remote rural area should be opened. This is further explored in the next subsection.
- The fact that there are extensive vertical links between wholesalers and retailers, particularly in urban areas, renders the statutory margins redundant in many respects, as both sides of the distribution chain can potentially achieve economies of scale and reduced fixed cost structures through these links and the efficiency savings that usually arise. Paying the same markups to structures benefiting from vertical links and to structures that do not, places the latter at a disadvantage compared with the former in terms of financial remuneration.
- While consolidation could work particularly well in wholesaling, where there appears to be some excess capacity with a large number of players, the situation is most certainly different in retailing, where over-concentration in urban centres, while justified by market forces, may leave rural areas underserved. This could be a case of tit-for-tat negotiation between the competent authorities and retail chains, for instance, to require adequate service provisions for rural areas in return for a guaranteed margin and could be laid down in existing regulation(s). Otherwise, it is highly likely that rural areas will continue to face access problems, perhaps even more as in the future as there is a tendency to concentrate service points in urban areas.
- Potential discounts could be addressed by enabling a clawback policy, which would allow a co-share of discounts between distributors and EHIF. The precise split of revenues would be subject to investigation and further consultation between the parties involved. The alternative would be for EHIF to adopt a preferential-type policy, whereby one or two generics are purchased per product. A preferential policy operates on the basis of a manufacturer winning a tender for a particular product and supplying the totality of the market at the lowest possible price. In this case, the EHIF would be the beneficiary of any discounts offered by the winner of the tender.
- Pharmacists do not receive additional service fees from Health Insurance for disease management activities, e.g. blood pressure monitoring, although this may be something that Health Insurance may wish to contemplate over the medium-term, particularly in rural areas. Patients could pay a small fee for that, whether it will be covered by insurance or not.
- Measures should be taken in order to ensure continued presence of pharmacies in rural areas, where this is not profitable, so that equity in access can be safeguarded. Market power itself is unlikely to meet this requirement, but, as discussed previously, incentives could be used in this context. For instance, as pharmacy chains own a large number of pharmacies, a requirement could be that

for every certain number of pharmacies maintained by the same ownership in urban areas, a pharmacy in a remote rural area should be maintained or opened. This would ensure geographic availability of facilities and, consequently, contribute to geographical availability of medicines.

10.7 Taxation

10.7.1 Findings

VAT on medicines in Estonia (9%) is higher than many EU countries. For example, in the United Kingdom, Sweden and Cyprus, the VAT applicable to prescription medicines is 0%, whereas in France, it is a reduced 2%; Hungary, Latvia and Lithuania apply a reduced 5%.

Understandably some European countries allow the full impact of standard-rate VAT on prescription medicines (e.g. Germany and Denmark), and this is widely seen as a fiscal measure and as part of a balanced budget pursuit. By contrast, over-the-counter (OTC) medicines or medicinal preparations that are not reimbursed by Health Insurance routinely attract the standard VAT rate and this is justifiable on the grounds that they are widely seen as consumer goods rather than goods essential to maintain health.

Within the Estonian setting, where patients face significant or extensive out-of-pocket payments, VAT as an indirect tax is regressive and is, therefore, a tax on the poor and vulnerable, thus potentially adding to inequity.

Given the high rate of out-of-pocket payments for prescription medicines in Estonia, it is likely that the lower socioeconomic groups (poorer households and elderly people) will be most adversely affected.

10.7.2 Recommendations

- There is no theoretical or empirical justification of imposing VAT on medicines, other than this being a levy by the Treasury on the health care budget and the contributions paid for by employers and employees.
- It is recommended that the government maintains a low- or, even a zero-VAT rate for prescription medicines and, in general, for all medicines and medicinal preparations reimbursed by EHIF and for prescription medicines that are not reimbursed by EHIF. This is in line with policies in most other European countries.
- It is recommended that the status quo is maintained and even reverted to the previous status quo of 5% or even reduced to 0% as in other EU countries.

As many patients face problems due to co-payments or extra out-of-pocket payments due to reference pricing, a reduced VAT rate would disburden patients facing accessibility problems.

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Annex 1

PROGRAMME FROM THE SEMINAR ON MEDICINES POLICY DEVELOPMENT IN TALLINN, ESTONIA, 22 MAY 2009

Objectives

- Launch and introduce the medicines sector review performed by WHO Regional Office for Europe in 2008-2009
- Discuss the key findings of the report with key stakeholders
- Set the vision to the future medicines policy in Estonia

Agenda

Opening addresses
Hanno Pevkur, Minister, Ministry of Social Affairs
Jarno Habicht, WHO Regional Office for Europe

Session 1. Medicines sector development in Europe, Estonia and evaluation of the current situation
Chairs: Jarno Habicht, Dagmar Rüütel

Dagmar Rüütel (Ministry of Social Affairs), The changes in the pharmaceutical sector in Estonia over the past years

Kees de Joncheere (World Health Organization Regional Office for Europe), The situation in Europe: policies and comparison of the current trends

Panos Kanavos (London School of Economics, expert to World Health Organization), The results from the evaluation of the medicines sector in Estonia

Discussion of and reflection on the report

Session 2. Rational use of medicines as a critical element in the medicines policy in Estonia
Chairs: Dagmar Rüütel, Jarno Habicht

Erki Laidmäe (Estonian Health Insurance Fund), Rational medicines use in Estonia: the evidence

Reet Teng, Rational medicines use in Estonia: A pharmacist's view

Erki Must (Association of Pharmaceutical Manufacturers in Estonia), How can manufacturers support rational medicines use in Estonia

Alar Irs (State Agency of Medicines), Regulating medicines promotion and supervision of the medicines sector in Estonia

Discussion and reflection

Session 3. The future of medicines policy in Estonia: improving access to and use of medicines
Chairs: Dagmar Rüütel, Jarno Habicht

Take away messages from Kees de Joncheere and Panos Kanavos

Annex 2

SUMMARY OF THE SEMINAR PROCEEDINGS, TALLINN, 22 MAY 2009

The seminar in Tallinn, on 22 May 2009, brought together over 30 experts and stakeholders related to pharmaceutical sector and medicines policy in Estonia with participants from the Ministry of Social Affairs (MoSA), health sector agencies such as EHIF and SAM, representatives of the pharmaceutical industry, pharmacies, doctors, patients and wholesalers.

The seminar provided a unique opportunity to discuss the review of the medicines sector in Estonia that has not been assessed comprehensively over the past 7 years. This is particularly timely, as several issues are currently on the table with a view to reaching decisions. The aim of the seminar was to share the report with stakeholders and launch a longer process starting in 2009, and coordinated by Ministry of Social Affairs, to develop an updated medicines policy in Estonia.

The overall environment in many countries is changing and in pharmaceutical policy more emphasis is placed to need for and value of medicines reimbursed; cost effectiveness evaluations and health technology assessment; price referencing; increasing efficiency of pharmaceutical supply and distribution; price referencing; strengthen appropriate prescribing; setting various incentives to control the raising pharmaceutical expenditures. In the changing health systems and medicines policy more comparative information is available across countries and frameworks to take account are set for European Union countries.

In Estonia, over past seven years extensive changes have taken place in the pharmaceutical sector to address the problems raised in the medicines policy document in 2002 including dissatisfaction of stakeholders due to lack of public consultation, inefficient pharmacy networks, irrational use of medicines, and liberal medicines pricing, among others. Several changes have been introduced since 2002 and in 2009 it is first time to have comprehensive view with a view to assessing how the performance in the pharmaceutical sector has changed vis-à-vis the main objectives such as (a) access to medicines, (b) quality, safety and efficacy, and (c) rational use of medicines. From the result of the review of the pharmaceutical sector in Estonia, it is clear that the performance of the sector can be improved in a number of areas. Many policy instruments are known from literature as well other country experience. The context is supportive for further improvement in Estonia as there is increasing interest in analysing the changes and measuring the impact of policy implementation to shared objectives but which need sharing and agreement.

The draft report on the Estonian situation was presented and discussed according to the themes analysed: expenditures, costs and out-of-pocket payments spent on pharmaceuticals; selection of medicines for reimbursement; access to medicines including availability and affordability; what medicines are dispensed and at what cost; rational use of medicines; distribution of pharmaceuticals; and taxation. Overview of problems was highlighted and proposals for improvement in the report were discussed with stakeholders.

One of the areas that were presented during the seminar and received a great deal of attention in the discussion was the rational use of medicines. The overall conclusion was that there exists significant potential for improvements in this area in the Estonian context. Different views were expressed by individual stakeholders on how rational drug use could be improved, often reflecting individual stakeholder perspectives and the need to take into

account issues such as the impact of medicines on health outcomes, problems related to generic substitution, the impact of individual medicines policies on industry presence in the country, and the availability of medicines, among others. At the same time it was noted by participants that performance can be improved in the rational use of medicines and transparency can be increased. While the latter includes many parameters, the importance of having a patient perspective was underlined, where better structures and information easily accessible and understandable is needed for users. The need for routine measuring was highlighted as was the importance of active purchasing to steer public funds complemented with patient cost sharing for better health outcomes complementing both supply- and demand-side measures.

Further proposals were put forward in discussions by stakeholders on prescribing practices. In particular, there is need to have more and simpler information available for doctors; potential utilization of available infrastructure and new e-prescribing systems to support rational prescribing; need for more local evidence on doctors prescribing practices and behavioural models; use of incentives for doctors but also pharmacies and other parts in the delivery chain to increase access to medicines; develop a system for cost and other information sharing by doctors and patients, as well as transparent and regular monitoring of prescribing practices. Doctors raised the importance to balance regulation (as well different incentives schemes) and trust towards professionals to treat patients using best available evidence. The complexity of the rational use of medicines is rather well understood but there is need to have agreement of moving to this direction and creation of a supportive system.

Overall, the seminar concluded also with number of clear proposals building on the medicines sector review and discussions to update medicines policy in Estonia. The areas identified for improvement were:

- The concerns over increasing and significant out-of-pocket expenses;
- Streamlining of the process for drug selection for positive list inclusion and reimbursement;
- Stimulate the prescription and dispensing of generics;
- Facilitate generic substitution;
- Market incentives for pharmacies to dispense generics;
- Simplifying and reducing co-payments for patients;
- Implementing a national program/system to improve prescribing and use of medicines;
- Monitoring the availability of medicines at pharmacy level;
- Ensuring adequate and timely distribution (both wholesale and retail);
- Reducing VAT on prescription medicines;
- Developing a comprehensive medicines policy to include all important areas.

The seminar concluded that there is need to develop an updated medicines policy paper for Estonia involving all stakeholders and that the current report provides a good analytical basis for follow-up and round-table discussions steered by Ministry of Social Affairs in coming months and year. While there are many ongoing changes in the health care sector and the economic crisis has a significant impact on the health sector, the importance to have a shared objective for the pharmaceutical sector and monitor further changes is crucial.

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