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on Health Systems and Policies

# PHARMACEUTICAL POLICIES IN FINLAND

Challenges and opportunities

Elias Mossialos & Divya Srivastava

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## **Pharmaceutical policies in Finland**

Challenges and opportunities



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# **Pharmaceutical policies in Finland**

## Challenges and opportunities

**Elias Mossialos and Divya Srivastava**

**Prepared at the request of the Health Department,  
Ministry of Social Affairs and Health, Finland**

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## List of abbreviations

|          |   |
|----------|---|
| AFP      | Association of Finnish Pharmacies   |
| ASMR     | Improvement in the medical service rendered (Amélioration du Service Médical Rendu) |
| ATC      | Anatomical therapeutic chemical classification                                      |
| BERD     | Business expenditure in research and development                                    |
| CE       | Cost-effectiveness  |
| CME      | Continuing medical education  |
| CPD      | Continuing personal development   |
| CT       | Computerized tomography   |
| DDD      | Defined daily doses   |
| DoH      | Department of Health (United Kingdom)   |
| Duodecim | Finnish Medical Society   |
| EBM      | Evidence-based medicine   |
| EC       | European Commission   |
| ECJ      | European Court of Justice   |
| EEA      | European Economic Area  |
| EMA      | European Medicines Agency   |
| ETENE    | National Advisory Board on Health Care and Ethics                                   |
| EU       | European Union  |
| EU15     | Countries belonging to the EU before May 2004                                       |
| FCA      | Finnish Competition Authority   |
| FDA      | Food and Drug Administration (United States)  |
| FinOHTA  | Finnish Office for Health Technology Assessment                                     |
| FMA      | Finnish Medical Association   |
| FPA      | Finnish Pharmacists' Association  |

|        |  |
|--------|--|
| GDP    | Gross domestic product   |
| G-I-N  | Guidelines International Network                                       |
| GMP    | Good manufacturing practice  |
| GP     | General practitioner   |
| HDL    | High-density lipid (levels)  |
| HTA    | Health technology assessment   |
| IMS    | Intercontinental Medical Statistics                                    |
| INN    | International Nonproprietary Name                                      |
| IT     | Information technology   |
| Kela   | Social Insurance Institution   |
| LDL    | Low-density lipid (levels)   |
| MEDEV  | Medicine Evaluation Committee  |
| MOF    | Ministry of Finance  |
| MSAH   | Ministry of Social Affairs and Health                                  |
| MTI    | Ministry of Trade and Industry   |
| NAM    | National Agency for Medicines  |
| NAMLA  | National Authority for Medicolegal Affairs                             |
| NHS    | National Health Service (United Kingdom)                               |
| NICE   | National Institute for Health and Clinical Excellence (United Kingdom) |
| OBIG   | Austrian Health Institute  |
| OECD   | Organisation for Economic Co-operation and Development                 |
| OFT    | Office of Fair Trading (United Kingdom)                                |
| OOP    | Out-of-pocket  |
| OTC    | Over-the-counter   |
| PI     | Parallel imports   |
| PIF    | Pharma Industry Finland  |
| PPB    | Pharmaceuticals Pricing Board  |
| PPI    | Proton pump inhibitor  |
| QALY   | Quality-of-life measure  |
| QOF    | Quality-outcomes framework   |
| R&D    | Research and development   |
| RCT    | Randomized controlled trial  |
| ROHTO  | Centre for Pharmacotherapy Development                                 |
| RP     | Reference pricing  |
| SII    | Social Insurance Institution of Finland                                |
| SMC    | Scottish Medicines Consortium  |
| SMR    | Medical service rendered   |
| STAKES | National Research and Development Centre for Welfare and Health        |
| TNF    | Tumour Necrosis Factor   |
| VAT    | Value-added tax  |
| WHO    | World Health Organization  |

# Preface

Finland, like many other countries with well-developed health systems, has struggled with its pharmaceutical policy on issues such as needs-based universal access, cost–effectiveness (CE) and affordability of its growing drug budget. Incremental policy changes have been followed by some fairly drastic measures to control growth in pharmaceutical expenditure. There has been considerable public debate on pharmaceutical issues and the need for a more predictable overall strategy in this policy field.

The Ministry of Social Affairs and Health, whose departments of health and insurance have major responsibilities in pharmaceutical policy, started working towards a coherent longer-term strategy in early 2006. As an integral part of that programme, an external expert review was deemed beneficial on a policy subject that is felt to be full of national particularities. Finland has often relied on such assistance in the field of health policy, engaging the World Health Organization (WHO) or the Organisation for Economic Co-operation and Development (OECD) to advise on policy areas of their best expertise. A considerable amount of international experience in pharmaceutical policy exists. This time the obvious partner of choice was the European Observatory on Health Systems and Policies, which had recently published an outstanding compilation covering the whole field in question – *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*.

We are very grateful to Professor Mossialos and Ms Divya Srivastava for a review that is both comprehensive and in-depth, much beyond our initial expectations. We felt that it would be a pity if the report were not available for a larger readership than Finnish experts in this field and welcomed the idea of publishing it jointly between the Observatory and the Finnish Ministry.

**Kari Välimäki**

Permanent Secretary, Ministry of Social Affairs and Health, Finland



# Executive summary

This report provides a policy review of the regulatory system of pharmaceutical policy in Finland. The aim was to assess the current policy context and prepare options that could be considered as part of the pharmaceutical review currently under way.

The review provided opportunities to meet a wide variety of stakeholders. This was extremely useful, giving us important insight into the policy context in Finland. We observed that there have been significant initiatives to address the policy issues concerning pharmaceutical policy. Important work is being carried out by a variety of stakeholders: the Ministry of Social Affairs and Health (MSAH) and agencies attached to it, such as the Pharmaceuticals Pricing Board (PPB), National Agency for Medicines (NAM), The Centre for Pharmacotherapy Development (ROHTO), and Finnish Office for Health Technology Assessment (FinOHTA); and other stakeholders such as Kela (the Social Insurance Institution), the municipalities, Duodecim (the Finnish Medical Society), the Finnish Medical Association (FMA), Finnish Competition Authority (FCA), pharmacies and pharmacists.

This report was prepared on request by the Health Department, MSAH. We are grateful for the assistance and support we received from them and from all the other stakeholders we met during our project review.

Our review highlights that there is potential to strengthen and improve the current regulatory environment. We identified the following key requirements for a reform package: greater coordination; capacity building; stronger incentives; increased information sharing for implementation of policies; and policies to consider the current challenge for dual financing in Finland.

Our recommendations are not prescriptive but rather give a range of options that could be considered as part of the pharmaceutical review process. We break down our key recommendations as follows.

## **Pricing policies and transparency**

An increased level of capacity is necessary for assessments of the therapeutic value and cost–effectiveness (CE) of medicines. The process could draw on international experience of drug classification methods better to inform pricing and reimbursement decisions. Furthermore, this process requires capacity building in health technology assessment (HTA) expertise in Finland. It would be beneficial if the various stakeholders (such as PPB, FinOHTA, Kela and NAM) shared information on methodologies.

Reference pricing (RP) schemes are used widely in Europe as a means of constraining pharmaceutical expenditure and regulating drug prices, with mixed evidence on their use and many challenges in their implementation. In practice, RP schemes reduce prices of drugs above the limit – patients will choose the cheaper drug when the therapeutic benefit is similar. If payments do not result in selection of the cheapest drug in the RP cluster, RP may impose an artificial floor that impedes further price reductions. Patients' access to drugs may be restricted by their inability to pay for the preferred drugs.

The criteria to define therapeutically equivalent products in RP schemes are not straightforward. Evidence suggests that RP schemes result in short-term savings. One explanation is that volumes and prices of drugs outside the scheme offset savings from drugs within. In principle, RP schemes should stimulate demand-side cost awareness to signal competition between drugs in a cluster.

The RP review currently under way in Finland should consider various aspects of its implementation. It could be used to cluster in a therapeutic category or only with generic equivalents. Premium pricing could be justified by the therapeutic value of drugs that would not be part of a cluster or even clustered on their own (e.g. biotech drugs). RP schemes are used commonly to set reimbursement thresholds but can also be used as a price-setting tool: drug prices are compared with those of alternative products to assist pricing decisions.

The process to determine therapeutic value could draw on international developments. For instance, the classification system in France draws on a drug's therapeutic benefit relative to existing substitutes. The Food and Drug Administration in the United States of America classifies drugs according to two dimensions: chemical type and therapeutic potential. The Dutch system classifies drugs according to whether or not they are interchangeable. This is defined as: identical affliction (clinically relevant properties); identical mode of administration; identical age category; no clinically relevant differences in effects; no clinically relevant differences in side-effects. In Germany, drugs are

classified according to therapeutic classification and comparability. Reimbursement for drugs classified in a reference group is fixed according to the prices of other similar or therapeutically equivalent substances in that group. Innovative drugs and those without any therapeutic equivalent are exempt from categorization in the RP system and are reimbursed in full.

The Office of Fair Trading (OFT) in the United Kingdom recently released a study of the British pharmaceutical pricing and reimbursement system. This recommends that prices of medicines that deliver very similar benefits should be reimbursed at similar levels; off-patent and generically equivalent drugs could be priced similarly. The current arrangement has large price differences between drugs that deliver similar benefits to patients. The OFT recommends that the roles of HTA bodies should be expanded to inform pricing decisions. Such a move would also send correct signals for drug investment in areas of patient need.

In Finland, a drug that may belong to more than one reimbursement category creates a challenge for the fair treatment of drugs based on their therapeutic value for patient subgroups. In practice, the PPB determines the reimbursement level of the drug and Kela determines whether medical criteria for the patient subgroups are met. In principle, this approach attempts to value drugs on the basis that they cure or alleviate a disease or its symptoms. Eligibility and the reimbursement level are based on need and disease severity; they are not contingent on a patient's ability to pay. Whilst these aims are justified, the decision process requires consistency in approach and evaluation. Analysis on these decisions should ensure that such decisions by PPB are not discretionary. NAM should have the opportunity to participate. Furthermore, ROHTO and FinOHTA could play important roles in the three- to five-year drug review period by drawing on information and evidence from studies (e.g. pharmacovigilance) to inform pricing decisions.

Currently, forecast sales data are reviewed on a case-by-case basis. A system of notification, introduced at the beginning of 2007, requires manufacturers to notify PPB if actual sales exceed their forecasts. PPB uses IMS and Kela data; a computerized follow-up system was set up in autumn 2006 and is still under development. Decisions on price volume trade-offs could take the form of repayments or changes in price levels. The PPB's review could consider a comparative perspective, that is whether an increase beyond the forecast resulted in a reduction of use of medicines with similar therapeutic effects or is justified by epidemiological trends. If the analysis does not lead to these conclusions then price reductions could be considered.

More price competition could be encouraged. Our review of competition (see Chapter 3) after the introduction of the generic substitution policy suggests that the majority of drugs have little or no competition but account for half the value of prescriptions dispensed. Unlike countries with substantial generics markets (e.g. United States and the United Kingdom) price competition is less likely given the small size of the Finnish generics market. One option for stimulating initial price competition would be to consider price reductions when drugs go off patent. When there are few generic competitors price reductions may stimulate initial price competition. Such a policy option could take account of the savings realized without such price cuts. A study on the impact of generic substitution is needed.

### **Strengthening the institutional environment**

There is a need for better coordination of activities between the relevant stakeholders. One area that could be strengthened is the MSAH work carried out between the insurance (PPB), health (NAM, ROHTO and the National Authority for Medicolegal Affairs (NAMLA)) and social departments (FinOHTA). We identified the following areas for improvement.

NAM could increase its role on the PPB to provide a statement on the comparative clinical effectiveness of new medicines. ROHTO and FinOHTA could use their knowledge and background in HTA and pharmacotherapy to expand their roles to inform pricing decisions. The verification process for Kela's statements on price volume market forecast that PPB receives from manufacturers could be reported more explicitly.

At a higher level, it would be useful to establish a standing committee. By meeting a few times a year this could provide a permanent forum for stakeholders to exchange views and advise the MSAH. Policy dialogue could consider high-level issues about coordinating activities and anticipating new needs rather than reacting to events. Relevant stakeholders could include PPB, NAM, ROHTO, FinOHTA and Kela. Other stakeholders could be invited according to the issue discussed and could include the FMA, NAMLA, FCA, Parliamentary Ombudsman, the industry, pharmacists and patient associations.

A drug assessment agency could be established as an independent authority to provide expertise. Accountable to the MSAH (which would decide the institutional location), the agency would operate at arm's length from the PPB. PPB stakeholders would have no representation on its board in order to avoid conflict of interest. This separation between drug assessment and financing would provide greater transparency. Our recommendation, therefore, is to separate a medicine's assessment from its appraisal.



PPB currently carries out drug appraisals. We propose that this continues and PPB retains its remit as the pricing and reimbursement authority. Decisions would be informed by the drug assessment agency, acting as a technical body to collect, evaluate and assess information and evidence on the clinical and therapeutic value of drugs.

The drug assessment agency would work with stakeholders to provide PPB with views on the therapeutic value and CE of medicines. The remit could also include advising on reimbursement levels of drugs and the corresponding therapeutic categories. The process would be transparent and opinions would be published. The institutional framework would have to consider these transparency issues and integrate appropriate mechanisms for accountability such as an appeals process.

The agency would work to develop guidelines and draw on the expertise and role of institutions such as Duodecim and FinOHTA to provide a clearer link between reimbursement decisions, guidelines and HTA. ROHTO's work could be expanded to assist in the implementation of these guidelines.

### **Pharmacy market**

The pharmacy fee is currently under review. If retained, 50% of the Ministry of Finance (MOF) pharmacy fee revenue could be given to the MSAH and/or Kela to finance programmes relating to pharmaceutical care, such as: medicine reviews among the elderly (to assess levels of polypharmacy and appropriate levels of prescribing); pharmacotherapy in institutional settings; incentives to encourage doctors to prescribe appropriately; and better information systems. The revenue could also be used to increase capacity in other bodies such as ROHTO and NAM.

We understand that there have been discussions about deregulation in Finland. Before any move towards this, we recommend careful consideration of payment methods to pharmacists as the current incentive system is linked to drug prices. A flat payment could be a suitable alternative because the incentive is linked to the volume of drugs dispensed rather than the price. Pharmacists could be offered incentives for outreach programmes (e.g. medicine review; chronic-disease management programmes). This could also encourage generic dispensing if financial incentives were added to the flat payment.

Moves towards deregulation and the extent of competition should be combined with payment methods for pharmacists, which are linked to incentives for discounting in the distribution chain and for dispensing cheaper drugs. This implies that the current system of regressive margins would require review before deregulation is considered. A study on this topic would be useful to better inform any policy changes.

## **First contact providers**

Our review highlighted levels of inappropriate prescribing that need to be addressed. A system with greater incentives, such as prescribing targets, could encourage physicians to prescribe medicines more appropriately. Furthermore, a formalized system of continuing education would encourage appropriate prescribing.

Rather than using punitive measures, physicians could be rewarded (e.g. through financial incentives) for improved prescribing practices. Although positive reward systems are more successful, we recognize that financial incentives/bonuses for physicians are not viewed favourably. They could be built up with quality indicators as part of a physician's contract. Prescribing targets for generics would provide not only cost reduction but also quality improvements in prescribing practices. These could exclude expensive drugs for patients with life-threatening diseases to ensure that equity would not be compromised. One approach could be to introduce a risk-adjustment mechanism to take account of age/sex, morbidity and socioeconomic indicators.

Kela and the municipalities could agree on a joint framework to address issues on information flows and more elaborate reporting systems. Kela could provide information on inappropriate prescribing. The criteria could include drugs that provide significant therapeutic benefit, high-volume drugs, high-cost drugs, drugs with significant risks/poor safety profiles and uncertainty in appropriate prescribing. Furthermore, monitoring of doctors in all three work settings (public, occupational and private) would identify any differences arising from different work practices. It is important to stress that the contentious nature of the results would require proper assessment and validation of the data before they could be published.

## **Health centres**

Health centres have developed their own guidelines. Of over 70 evidence-based national guidelines, most are directed at primary care and related pharmacotherapy. However, there is a need to focus on neglected areas. ROHTO and Duodecim could collaborate more closely to develop guidelines on pharmacotherapy for health centres and hospitals. These could be connected to patients' risk assessments, for instance, assessment of patients with cardiovascular diseases would require information on both low-density (LDL) and high-density lipid (HDL) levels as well as other possible risk factors such as smoking, family history and other diseases (e.g. diabetes). Duodecim's decision-support system could provide useful guidance in this area. Guidelines could assist the development of chronic disease management programmes for

health centres, drawing on experience from other countries and linked to international activities.

## **Hospitals**

We understand that drug procurement and the trend towards group purchases have resulted in the development of joint formularies. Guidance is needed on standardizing hospital formularies because there are variations in the amounts and types of drugs procured. The formulary could be used flexibly and account for factors such as variations in hospital sizes and local population health needs.

Capacity building in clinical pharmacology is required. Clinical pharmacologists working in hospitals tend to have academically oriented roles. These could be expanded to educate doctors on clinical pharmacology. Similarly, ward pharmacists disseminate information to health-care staff but their roles could be enhanced to coordinate education work with clinical pharmacologists in the hospitals.

## **Dual financing**

This report notes that the dual system of financing creates the potential for cost shifting. Furthermore, it is difficult to monitor quality of care because of physicians' different employment settings. These constraints require more coordination between the relevant financing bodies – the municipalities and Kela.

The high level of user charges is another area of concern in Finland. We recommend careful consideration of either expanding the annual ceiling to families, or a means-tested approach (or rather – system) that would provide full reimbursement for more diseases/conditions. We recognize that there is little current information on the impact of user charges. Further studies are necessary to inform the policy process about effects on the most vulnerable groups.

## **Patients**

There is extensive evidence of inappropriate prescribing levels and polypharmacy among the elderly, particularly in institutional settings. Intervention measures would be an important aspect of the government's pharmaceutical strategy.

Understaffing among resident doctors in institutional settings creates a challenge for such assessments. The pilot project on medicine review of the elderly in home-dwellings is an important initiative that could be formalized into the work of pharmacists and nurses to carry out reviews in institutional settings.

### **Information technology systems**

A great deal of work is under way to strengthen information technology (IT) systems in Finland. We welcome these important initiatives but note that, as these systems are developed, there is potential to include information on over-the-counter (OTC) and herbal medicines. Compatibility between software systems should be ensured. A large range of data is available on patients and prescribing patterns but more studies are needed to assist guideline development, management of chronic conditions and research on epidemiological studies of patient subgroups.

# Chapter 1

## Introduction

- 1.1 The institutional framework of pharmaceutical policy in Finland is currently under review. The Finnish parliament proposed a comprehensive process to consider measures needed to constrain the growth of pharmaceutical costs with the cooperation of authorities and stakeholders. The government's task was to prepare a summary of proposals for revision of the Medicines Act and the pricing and reimbursement system.
- 1.2 The government's recent policy document, Pharmaceutical Policy 2010,<sup>1</sup> identified a number of areas as part of its review of pharmaceutical policy in Finland. The main points include: ensuring access to, and safety of, medicines; rational prescribing; promoting pharmaceutical research; and measures to constrain the growth in medicine costs.
- 1.3 The document states that any reform will secure good access to medicines throughout the country and maintain the safety of medicines. Furthermore, any increases in medicine costs will not weaken the possibilities for society and citizens to use the best pharmacotherapies available.
- 1.4 Rational prescribing and use of medicines will be promoted. Different competent authorities are encouraged to promote good prescribing practices. Comprehensive access to medicines in all regions will be safeguarded through the present type of pharmacy system. Monitoring

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<sup>1</sup> In our discussions with stakeholders, only the Ministry of Social Affairs and Health (MSAH) and the Finnish Pharmacists' Association (FPA) referred to this document.

of the safety of medicinal products will be integrated into the European system of pharmacovigilance.

- 1.5 Further pharmacotherapies will be developed by supporting pharmaceutical research in various ways, e.g. by funding research; securing education and training; and strengthening the operations of the pharmaceutical industry.
- 1.6 It is aimed to reduce medicine costs by abolishing the pharmacy fee thereby reducing pharmacies' gross margins, particularly for sales of the most expensive medicinal products. The drug reimbursement system under health insurance will be clarified and simplified.
- 1.7 As part of this review process, in 2006 policy discussions were held between the relevant stakeholders in Finland including the Ministry of Social Affairs and Health (MSAH) (Health Department), National Agency for Medicines (NAM), the Social Insurance Institution (Kela) and the Finnish Office for Health Technology Assessment (FinOHTA).
- 1.8 One input of this review was our involvement: we acted as external rapporteurs to provide proposals to MSAH's Health Department. These options were developed by international experience of pharmaceutical policy relevant to the institutional environment in Finland. The current MSAH policy review formed the basis of our terms of reference and is attached in Annex 1.
- 1.9 We examined the pharmaceutical policy environment from a health systems perspective because the complexities of the system warranted a more comprehensive approach. Within the regulatory framework we identified relevant stakeholders concerned with supply and demand policies.
- 1.10 We gained a better understanding of the pharmaceutical policy context by making two visits to Finland.
  - 1.10.1 Dr Mossialos made the first visit (23–25 August 2006) to meet with key stakeholders: MSAH, Pharmaceuticals Pricing Board (PPB), NAM, the Centre for Pharmacotherapy Development (ROHTO) and Kela. He collected material on pharmaceutical policy.
  - 1.10.2 Dr Mossialos and Ms Srivastava made the second visit and held meetings (23–28 October 2006) to gather more information and data on pharmaceutical policy issues. A list of the stakeholders consulted is attached at the end of this report.
- 1.11 We are extremely grateful for the information we received and to the stakeholders we met, and were in contact with, during this review.

We appreciated their hospitality and willingness to share their insights and thoughts on pressing pharmaceutical policy matters. These discussions greatly enhanced our understanding of the current policy context.

- 1.12 Meetings were held with the following organizations and individuals: Finnish Competition Authority (FCA) – Mr Jan Nybondas, Mr Martti Virtanen and Ms Liisa Vuorio; Finnish Medical Association (FMA) – Mr Pekka Anttila, Mr Risto Ihalainen and Mr Markku Kojo; FinOHTA – Mr Antti Malmivaara; Finnish Pharmacists’ Association – Mr Harri Ovaskainen and Ms Inka Puumalainen ; Kela – Mr Mikael Forss, Mr Timo Klaukka, Mr Pekka Koivisto, Ms Jaana Martikainen and Mr Timo Maljanen; MSAH – Ms Terhi Hermanson, Professor Jussi Huttunen, Mr Pekka Järvinen, Mr Kimmo Leppo, Ms Marja-Liisa Partanen, Mr Juho Saari and Mr Kari Välimäki; Ministry of Trade and Industry (MTI) – Mr Kristian Tammivuori; NAM – Mr Hannes Wahlroos; Pharma Industry Finland (PIF) – Mr Jarmo Lehtonen and Ms Sirpa Rinta; PPB – Ms Ulla Kurkijärvi, Ms Mareena Paldan, Ms Sinikka Rajaniemi and Mr Matti Toiviainen; ROHTO – Ms Taina Mäntyranta; the Association of Finnish Local and Regional Authorities – Mr Rolf Eriksson and Ms Liisa-Maria Voipio-Pulkki; the Association of Finnish Pharmacies – Mr Klaus Holttinen and Mr Reijo Kärkkäinen; Vallila Health Centre – Ms Seija Grönqvist and Ms Kati Kobler.
- 1.13 In particular we would like to extend our gratitude to our contacts in the MSAH’s Health Department: Mr Kimmo Leppo, Ms Terhi Hermanson and Mr Pekka Järvinen. We very much appreciated the arrangements made for our visits. The meeting schedule was comprehensive and gave us the opportunity to encounter a wide variety of issues and perspectives on the challenges facing pharmaceutical policy in Finland.
- 1.14 In our meetings, we enquired about references on academic research concerning pharmaceutical issues. We examined these academic resources and others we found to understand better the current research environment. We would like to thank those who provided extremely useful information, including: Ms Sirkka Kivelä, Ms Leena Lahnajärvi, Mr Ismo Linnosmaa, Ms Minna Väänänen and Mr Han de Gier.
- 1.15 Stakeholders kindly provided English translations of Finnish documents where possible. Where these could not be provided easily, we arranged for these documents to be translated. We thank Mr Markus Ketola for his assistance in translation.

- 1.16 We were reimbursed for our travel and accommodation during our visits to Finland and received no further fees from the MSAH for our work.
- 1.17 We aimed to provide a policy, rather than a systematic, review through a comprehensive assessment and understanding of the current policy environment. We gathered information from a wide range of sources and stakeholders. In many areas little information was readily available; in these cases we collected information and asked for information to be produced. For some of our requests, no information was available, including studies on user charges and their effect on access; detailed price and volume data for generics, branded and over-the-counter (OTC) drugs; studies on drug interactions; and hospital admissions due to adverse events.
- 1.18 We feel that this report exceeds our initial aims and terms of reference. We have looked in detail at issues concerning the regulatory environment and considered the broader implications of health-policy planning rather than pharmaceutical policy in isolation. We consider the context of this environment with respect to policy implications of both supply- and demand-side policies, including the regulatory environment; actors in the provision of services; expenditure patterns; implications for patients; prescribing trends; consumption patterns; price trends; and information technology (IT) systems.
- 1.19 Our recommendations are based on the current arrangements, having given careful consideration to the complexities of the policy environment. Pharmaceutical policy is one aspect of health system and policy planning. Proposals are within the terms of reference but we realize that our options were restricted because of higher-level health policy issues that could not be addressed. These issues, for instance, concern problems of dual health-system financing. Any comprehensive set of proposals would have to take account of these factors.
- 1.20 As non-Finnish external reviewers, we recognize that the proposals may not capture fully the current context. There are likely to be contextual factors concerning the local situation, or political and historical issues that are outside our understanding.
- 1.21 Our purpose was not to provide prescriptive solutions but rather a range of options to assist policy-makers in the review process. Our work is a minor part of the overall process, but we hope that this assessment offers a range of views from an international perspective that might stimulate further debate on pharmaceutical policy in Finland.



## Chapter 2

# Overview of the pharmaceutical system in Finland

- 2.1 The health-care system in Finland is financed mainly from taxation and decentralized largely to the municipalities. These are responsible for the provision of in patient and out patient care, financed by taxes, state transfers, various charges and sales revenues. Municipalities levy income and property taxes and receive a share of corporate taxes that together account for almost half of all municipal revenues; fees and charges account for about a quarter.<sup>2</sup> State transfers even out revenue-raising differences between municipalities and account for one fifth of municipal revenues. Municipalities' annual expenditure was €31 billion and state public expenditure was €38 billion in 2006.<sup>3</sup>
- 2.2 Municipalities have principal responsibility for organizing the delivery of public health services, including primary, specialist and long-term care; nursing homes; and social services for the elderly. Primary care is provided in health centres owned by one or more municipalities. Hospitals provide secondary care; each municipality is a member of one of 21 hospital districts. Municipalities purchase services from their hospital districts and may also purchase services from private providers. Physicians may provide services in the public system in health centres, as occupational doctors in health centres or in private practice. Municipalities account for about two thirds of total health-care expenditure.<sup>4</sup>

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<sup>2</sup> Most customer charges are collected for services such as water supply, waste disposal, power supply and public transport.

<sup>3</sup> Association of Finnish Local and Regional Authorities.

<sup>4</sup> Häkkinen, 2005.

- 2.3 Pharmaceuticals, private health care, medical aids, prostheses and occupational health care are financed by Kela, out-of-pocket (OOP) payments and employers.<sup>5</sup>
- 2.4 Kela is the second main source of funding, responsible for financing the cost of medicines prescribed in outpatient care in the public system (health centres), by occupational health doctors or in private practice. Its budget is drawn from employer and employee contributions and the state. The latter ensures Kela's solvency and over time its contribution has increased.
- 2.5 There are many actors in the pharmaceutical system. The MSAH and key subordinate agencies within it – NAM and PPB – are involved directly in the regulation of pharmaceuticals. Kela also plays a regulatory role. Key areas of government with indirect involvement in the pharmaceutical system include: ROHTO, FinOHTA and the National Authority for Medicolegal Affairs (NAMLA) within the MSAH; the Ministry of Education; and the FCA within the MTI. This introductory section provides a brief overview of three of these actors: NAM, Kela and the PPB. Each has different roles in regulating and financing pharmaceutical reimbursement.

### **National Agency for Medicines**

- 2.6 NAM is attached to the MSAH and has wide responsibility for controlling pharmaceutical and medical devices in Finland. It provides regulatory approval for the market authorization of drugs which may be originator products, parallel products or generics. The national procedure takes up to 210 days excluding time for pricing and reimbursement.
- 2.7 NAM also controls the supply and location of pharmacies licensed to sell medicines. In 2005, there were 600 retail pharmacies with 200 subsidiaries.<sup>6</sup> A pharmacy permit grants a monopoly of the sale of OTC and prescription medicines. Pharmacies are owned privately by pharmacists except those at Helsinki and Kuopio universities which are owned by the universities themselves (about 18 outlets). Needs-based criteria legislated in the Medicines Act are used to regulate the supply of pharmacies and include: the reasonable availability of medicines, population size, existing pharmacies and the provision of health services in the area.

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<sup>5</sup> Häkkinen, 2005.

<sup>6</sup> OECD, 2005.

2.8 Overall, NAM oversees the operations of those involved in distributing pharmaceuticals, that is: pharmaceutical wholesalers, pharmacies, branch outlets, hospital pharmacies, dispensaries in municipal health centres and pharmaceutical manufacturers.<sup>7</sup> It ensures that these parties meet the obligations and standards of the Medicines Act.

## **Kela**

2.9 Kela is an independent body under public law and reports directly to parliament. Established in 1937 and intended initially to provide pension security, its remit has expanded over the years. Kela operates under a management board overseen by a parliamentary appointed committee. It finances not only pharmaceuticals but also private and occupational health care, loss of income during illness and some other services. Health expenditure funds are financed by employer and employee contributions and central government. The state ensures Kela's solvency.

2.10 Kela finances the cost of medicines prescribed in outpatient care. Its share of pharmaceutical expenditure is increasing and accounted for 74% of public pharmaceutical expenditure in 2005.<sup>8</sup> Kela is responsible for the cost of these medicines whether they are prescribed in the public system (health centres), by occupational health doctors or privately by a doctor.

2.11 Finland has a three-level reimbursement system for medicines: a basic refund category and two special refund categories: one lower, one higher.<sup>9</sup> For the basic refund category, Kela finances 42% of the drug cost and patient co-payments cover 58%. For the next level, Kela reimburses 72% of the cost and patients pay 28%. In the highest refund category Kela reimburses 100% of the drug cost but the co-payment is €3 per medicine per purchase. There is an annual limit: if a patient paid more than €616.72 (in 2006) then Kela covered the entire drug cost and patients paid €1.50 per medicine per purchase. In 2005, reimbursement levels were higher but came with a deductible co-payment: 50% of the basic category with a €10 co-payment; 75% of the lower special-refund category with a €5 charge; and 100% of the higher special-refund category with a €5 charge. A zero reimbursement level is a recent introduction and is, in effect, a negative list.

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<sup>7</sup> Pekurinen & Häkkinen, 2005.

<sup>8</sup> Kela, 2006.

<sup>9</sup> Lower special refund category: drugs that treat 10 chronic conditions such as asthma and hypertension. Higher special refund category: drugs that treat 34 severe or life-threatening illnesses such as diabetes or cancer.

- 2.12 Medicines administered in health centres are covered by the municipal budget. Hospital budgets cover medicines administered in hospitals but these are financed by municipalities to purchase services, who transfer funds to hospitals, which include the cost of administering medicines provided in inpatient care.

### **Pharmaceuticals Pricing Board**

- 2.13 PPB is responsible for pricing and reimbursing medicines and is subordinate to the MSAH's insurance department which appoints its seven-member board. The members are diverse and provide legal, medical, pharmaceutical, economic and insurance expertise. Although the PPB board draws on the opinion of an attached expert group, these opinions are not binding and the PPB can make its own decisions.
- 2.14 All applicants that NAM approves for market authorization are required to submit an application to the PPB if seeking reimbursement. Drugs reimbursed outside the public system are not subject to pricing restrictions.<sup>10</sup> Applicants approved for market authorization via the European Medicines Agency (EMA) are similarly required to apply to the PPB for reimbursement by Kela. PPB decides whether a drug will be reimbursed and approves its wholesale price. The process is the same for generics, parallel trade and patented products. The PPB is also responsible for responding to applications to increase the wholesale prices of medicines. Reimbursement and pricing decisions take up to 180 days.
- 2.15 A drug can be reimbursed in one of the three reimbursement categories defined by the Health Insurance Act. When a drug is considered to have a reasonable price and has met the necessary criteria it is grouped into the basic category. A manufacturer must submit evidence on the therapeutic value and cost-effectiveness (CE) of a drug before it can move to one of the special refund categories. In practice, drugs are usually sold in the basic category for an average of two years; in a very few cases a drug has been granted a higher level of reimbursement immediately.
- 2.16 The expert group evaluates drugs seeking reimbursement in one of the two special refund categories. Criteria for this higher level include the severity of disease; necessity and CE of the medicinal product; proven therapeutic value of the medicinal product; funds available for special reimbursement products; and whether there is supporting evidence.

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<sup>10</sup> Some OTC products used for long-term treatment are reimbursed. The PPB is responsible for assessing whether their prices are reasonable (Pekurinen & Häkkinen, 2005).

- 2.17 The reimbursement rate is based on the wholesale price: the maximum price to pharmacies and hospitals. PPB determines whether this is reasonable using the following criteria: economic evaluation to compare the drug with existing available treatments; wholesale price of major competitors, including parallel imports (PI) and generics; list price of the product in other European Union (EU) countries; budget impact on Kela; and clinical judgement.<sup>11</sup> Medicines administered only in hospitals are not part of the reimbursement system; pharmaceutical companies negotiate directly with the hospitals to determine these prices.<sup>12</sup>
- 2.18 The PPB decision-making board considers input from Kela and the expert group. Kela is required to submit a written statement on a drug's price level and the extent to which its associated costs will impact on its budget.
- 2.19 A drug's price is usually set for a certain period but can be reviewed within this time. Reviews can take place at any time, on a group of drugs or on an individual basis. In general, drug reviews take place within 3 years for active ingredients and up to a maximum of 5 years.

## Regulatory framework

- 2.20 The previous section provided a brief overview of the key bodies involved in regulating the Finnish pharmaceutical system. This section develops the regulatory framework, discusses the actors involved and highlights observations made in our meetings with key stakeholders. We present the actors involved in policy-making, financing and delivering services and discuss the policies that influence them.
- 2.21 Figure 2.0 (see p.47) illustrates the regulatory bodies. MSAH is the central ministry for pharmaceutical policy, responsible for the overall direction of social and health policies at the national level. It defines policies, monitors their implementation and prepares proposals for legislation and reform.<sup>13</sup>
- 2.22 Five subordinates within MSAH have varying degrees of autonomy and influence on overall pharmaceutical policy. The two most important actors are NAM and PPB. ROHTO and FinOHTA have their own areas of expertise in developing practice guidelines and

<sup>11</sup> MSAH, Legislation of the Pharmaceuticals Pricing Board (available at: <http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/legislation.htm>, accessed 23 August 2007).

<sup>12</sup> Kanavos & Gemmill, 2005.

<sup>13</sup> Järvelin, 2002.

health technology assessment (HTA). NAMLA handles disciplinary matters. These bodies are discussed in more detail below.

## Pharmaceutical financing

2.23 Finland has two separate public funding streams. The main distinction is that Kela finances outpatient pharmaceuticals while municipalities finance medicines administered in institutional and inpatient care. It is not always clear whether a treatment is outpatient or inpatient and this creates the potential for cost shifting between municipal, hospital and Kela's budgets.

### Kela's financing

2.24 Parliament appoints 12 trustees to supervise administration and operation, although Kela has considerable autonomy. Below the trustees, Kela is governed by a Board: eight of the ten members are appointed by the Parliamentary Trustees. The remaining members are the Director General of Kela and his/her deputy. A staff representative attends board meetings but has no voting power.

2.25 Kela's central administration is divided into nine departments: administration; pension and income security; health and income security; information systems; economic; human resources; actuarial and statistical; research; and office services. Every director is responsible directly to the board. The research department provides information on reimbursement decisions directly to the PPB.

2.26 Health expenditure funds are financed by employer and employee contributions and central government.<sup>14</sup> The Health Insurance Act determines contribution rates. The state ensures Kela's solvency and has paid an annual contribution since 1998. In 2005, the government paid about 54% of Kela's total budget for health, pension and other social security schemes; and about 26% of health expenditure.<sup>15</sup> The share of revenue generated from employers' and employees' contributions has fallen steadily since the 1990s as the state's share has increased (Table 2.0). A large drop occurred between 2000 and 2004: employees' share fell from 43% to 29% and employers' fell from 37% to 29%. The state's share increased from about 16% to 22%.<sup>16</sup> In particular, the state's share to ensure Kela's solvency grew from 2% in 1990 (€38 million) to 21% in 2004 (€711 million).

<sup>14</sup> Adult Finns, including pensioners, are required to contribute to Kela (OECD, 2005).

<sup>15</sup> Kela, 2006.

<sup>16</sup> Kela, 2004.

**Table 2.0** *Kela's income, 1990–2004 (€ millions and share, %)*

|             | <b>TOTAL</b> | <b>Employees level (share)</b> | <b>Employers level (share)</b> | <b>State total level (share)</b> | <b>State solvency transfer level (share)</b> |
|-------------|--------------|--------------------------------|--------------------------------|----------------------------------|--|
| <b>1990</b> | 1 833        | 815 (44.5)                     | 792 (43.2)                     | 174 (9.6)                        | 38 (2.1)                                     |
| <b>1995</b> | 2 139        | 1 364 (63.8)                   | 639 (34.3)                     | NA                               | NA   |
| <b>2000</b> | 2 307        | 996 (43.2)                     | 845 (36.6)                     | 378 (16.4)                       | 335 (14.5)                                   |
| <b>2004</b> | 3 401        | 987 (29.0)                     | 984 (28.9)                     | 744 (21.9)                       | 711 (20.9)                                   |

Source: Kela, 2004.

**Table 2.1** *Kela's refund payments, 1990–2004 (€ millions and share, %)*

|             | <b>TOTAL refunds</b> | <b>Medicines level (share)</b> | <b>Doctors level (share)</b> | <b>Examinations level (share)</b> | <b>Dentists level (share)</b> | <b>Transport share</b> |
|-------------|----------------------|--------------------------------|------------------------------|-----------------------------------|-------------------------------|------------------------|
| <b>1990</b> | 487                  | 308 (63.2)                     | 48 (9.9)                     | 50 (10.3)                         | 15 (3.1)                      | 65 (13.3)              |
| <b>1995</b> | 658                  | 455 (69.1)                     | 51 (7.8)                     | 45 (6.8)                          | 28 (4.3)                      | 79 (12.0)              |
| <b>2000</b> | 944                  | 678 (71.8)                     | 60 (6.4)                     | 58 (6.1)                          | 41 (4.3)                      | 108 (11.4)             |
| <b>2004</b> | 1 371                | 1 015 (74.0)                   | 65 (4.7)                     | 56 (4.1)                          | 95 (6.9)                      | 141 (10.3)             |

Source: Kela, 2004.

- 2.27 Kela finances pharmaceuticals, private health care, occupational health care, loss of income during illness and some other services. In principle, these services should be available throughout the country but, in practice, most private and occupational care is offered in the largest cities in the south of Finland. Other benefits are available throughout the country.
- 2.28 Kela's expenditure on outpatient medicines has increased over time: expenditure on outpatient medicines was €678 million in 2000 and just over €1 billion in 2005 – an increase of almost 50%, in nominal terms (Table 2.1). Expenditure on outpatient medicines increased steadily from 63% of total refunds paid in 1990 to 74% in 2004. The growth in expenditure on pharmaceuticals has increased Kela's (state-reimbursed) deficit (Table 2.0).
- 2.29 Kela is involved in pricing decisions as a member of the PPB. The research department has direct involvement in informing pricing decisions as it issues a written statement on a drug's therapeutic value. Kela has capacity in health economics and employs health economists or those who have received training in health economics.
- 2.30 Kela has an exhaustive database on medicines, expenditures, prescription and consumption patterns at the micro level. For instance, it monitors and validates doctors' certificates requesting special

reimbursement for prescriptions issued to patients. Kela also provides physicians with information on their prescribing practices, summarized according to the patient population; cost of medicines; volume prescribed; most commonly prescribed and the highest-cost medicines. These figures are presented relative to the average among doctors within and outside health centres and to doctors in their own hospital district.<sup>17</sup> The final section covering 2005 provided a summary of results of statin prescription: number prescribed; cost; and clinical information.

- 2.31 Kela is collaborating with the University of Kuopio on a municipal-level pilot project to collect patient information on drug use among the elderly. This will be very important for measuring outcomes. Kela produces useful summary statistics in its reports on medicines in Finland, but its database has much untapped potential to inform pharmaceutical policy decisions.

#### Municipal financing

- 2.32 Municipalities provide the second main funding stream. By law, they have principal responsibility for organizing the delivery of public health services as well as education (except university) and social services.
- 2.33 Municipalities have the authority to levy their own taxes and about half of their revenue is generated in this way. Income tax varies but the average was 18.3% in 2005, varying between 16% and 21%.<sup>18</sup> Municipalities also levy property taxes and receive a share of corporate tax revenues.
- 2.34 Municipal health expenditure accounted for 42% of total health expenditure in 2003: about 18% from the state; 17% from Kela; and the remaining 24% from private sources.<sup>19</sup> Municipalities spend about one fifth of their budget on health care.<sup>20</sup> Local authorities are responsible for the operations of 257 health centres: 191 municipal health centres and 56 that are the responsibility of more than one local authority.<sup>21</sup>

<sup>17</sup> Information presented: age, sex and the number of patients. These figures are presented relative to the average among doctors within and outside health centres as well as relative to the doctors in the hospital district to which a doctor belongs. The information also provides year on year changes for: the number of prescriptions; total cost of medicines, average cost per prescription; and Kela's refunds of prescription payments. This information is also presented relative to the average among doctors. A breakdown of the medicines prescribed is based on those prescribed most often and those with the highest expenses, and also presented relative to the doctor averages (*Source*: Kela provided details of the type of information disseminated to physicians).

<sup>18</sup> OECD, 2005.

<sup>19</sup> MSAH, 2006.

<sup>20</sup> Järvelin, 2002.

<sup>21</sup> The Association of Finnish Local and Regional Authorities.



- 2.35 State subsidies and user charges also contribute to financing services. State subsidies are lump-sum non-earmarked grants, calculated prospectively using a need-based capitation formula.<sup>22</sup> Municipalities with low revenue-raising capacities (< 90% of the per capita average) receive equalization payments to reach the per capita average. The state makes higher contributions to less affluent municipalities so its share of municipal health expenditure varies from 10% to 60%.<sup>23</sup> On average, state subsidies accounted for about one fourth of municipal health expenditure in 2005.<sup>24</sup> Less than one tenth of social and health expenditure is covered by patient charges.
- 2.36 At the beginning of 2007 there were 416 municipalities. Plans are under way to amalgamate some and restructure their services to prepare for the challenges of demographic and economic change. Municipalities generally have small populations: about 75% have fewer than 10 000 inhabitants; 20% have fewer than 2000. The proposal aims to increase the size of the municipalities to at least 20 000 inhabitants. The arrangement between central government and municipalities will allow the government greater input into the reorganization of municipal boundaries. However, revenue-raising capacity will be increased at municipal level with offsetting reductions at state level. This proposal was presented to government in early 2007.<sup>25</sup>
- 2.37 Municipal services include primary, specialist and long-term care; nursing homes; and social services for the elderly.<sup>26</sup> Primary care is provided at health centres owned by one or a group of municipalities. The remaining services cover medicines, private health care, medical aids and occupational health, financed mainly by Kela, OOP payments and employers.
- 2.38 Each municipality is a member of 1 of 21 hospital districts which provide institutional care.<sup>27</sup> The municipalities purchase services from their districts on an annual basis. It is difficult to compare prices and services between hospitals and their districts as prices are defined by the hospital district. An equalization mechanism helps municipalities to

<sup>22</sup> The current formula is adjusted for the population age structure and one morbidity factor and geographical remoteness. (Häkkinen, 2005). The indicator of morbidity is the age-standardized index of invalidity pension for persons under 55 (OECD, 2005).

<sup>23</sup> Municipalities above the per capita average pay 40% of the difference above the 90% figure (OECD, 2005).

<sup>24</sup> Häkkinen, 2005.

<sup>25</sup> The proposal will make changes to the Restructuring Local Government and Services Act, Local Authority Boundaries Act and Asset Transfer Tax Act.

<sup>26</sup> Some homes have private provision or are run by non governmental organizations (Järvelin, 2002).

<sup>27</sup> Häkkinen, 2005.

cover the cost of expensive treatments. Municipalities may also purchase services from private providers.

- 2.39 Decision-making occurs at municipal-council level. Elected every four years, the council appoints an executive board and members of municipal committees. These officials are accountable to the municipality's inhabitants. Health-policy decisions are made by the health committee, municipal council and municipal executive board. The state is not involved in these decisions, partly because state subsidies are not very large.

### **Pharmaceutical policy-making and the pharmaceutical industry**

- 2.40 Two bodies within the MSAH – NAM and PPB – play key roles in pharmaceutical policy in Finland. The MTI provides policy input for regulating the pharmaceutical industry but otherwise is not a major actor.

### **Market authorization of pharmaceuticals**

- 2.41 As a subordinate of the MSAH, NAM is one of the major decision-making bodies in the regulation of the Finnish pharmaceutical market. It is charged with overseeing the operations of those involved in the distribution of pharmaceuticals: manufacturers, wholesalers, pharmacies, branch outlets, hospital pharmacies and dispensaries in municipal health centres. It ensures that they meet the requirements of the Medicines Act. NAM approves market authorization of drugs and controls the number and location of pharmacies licensed to sell medicines.
- 2.42 Drugs that NAM approves for market authorization are subject to approval by the PPB which sets the wholesale price and reimbursement amount. Applicants may be originator products, parallel products or generics. The national procedure takes up to 210 days,<sup>28</sup> but this does not cover additional information that may be needed from the applicant. An applicant approved for market authorization via EMEA similarly is required to submit an application to the PPB for reimbursement by Kela. NAM also approves dispensing changes from prescription to OTC.
- 2.43 NAM controls the supply and location of pharmacies. In 2005, there were 600 retail pharmacies with 200 subsidiaries. A pharmacy's permit

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<sup>28</sup> This does not include the time for pricing and reimbursement.

grants a monopoly on the sale of OTC and prescription medicines. Pharmacies are owned privately by pharmacists, except for those in Helsinki and Kuopio universities which are owned by the universities themselves. In principle, the universities are allowed to own one pharmacy but the University of Helsinki has 16 branch outlets around the country. Each owner can hold one main pharmacy and up to three subsidiary pharmacies at one time. The licence is not transferable and expires when the pharmacist reaches the age of 68.

- 2.44 Needs-based criteria legislated in the Medicines Act are used to regulate the supply of pharmacies – the most important is the reasonable availability of medicines. NAM's decision considers the population, existing pharmacies and the provision of health services in the area as well as an applicant's career, management experience and academic qualifications (e.g. publications).
- 2.45 NAM seldom receives an application for a new pharmacy. Municipalities may also propose the establishment of a new pharmacy. NAM looks at each applicant on a case-by-case basis and handles around 60 applications per year, receiving an average of 20 applications per licence. Fewer than five cases per year are taken to court because the applicants do not agree with NAM's rulings.
- 2.46 NAM supervises the industry's marketing activities according to the Medicines Act and Decree. Recently, NAM fined a manufacturer that had misrepresented information on the safety of its product.<sup>29</sup> This initiative is welcome and has much scope for further development. The Supervisory Commission for the Marketing of Medicinal Products is the industry's voluntary control body that works separately from the authorities.
- 2.47 NAM has prioritized specific areas as part of its remit for overseeing the market authorization of pharmaceuticals over the period of 2006–2012. It is working in the EU as the rapporteur for paediatric and biological products, focusing on their research capacity and increased dissemination and promotion of these products. Pharmacies and the industry will undergo more frequent monitoring including increased inspection of pharmacies and guidance on good manufacturing practice (GMP) for the industry. NAM intends to increase its work in pharmacovigilance by providing up-to-date information to health-care professionals and consumers. NAM also plans to disseminate more information on medical devices to health-

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<sup>29</sup> NAM, 2006a.

care professionals and patients and to launch an electronic system for manufacturers' submissions.<sup>30</sup>

- 2.48 The pharmacy fee is a public charge that pharmacies pay to the state and university pharmacies pay to their owner universities. The fee is progressive and based on turnover; pharmacies with a small turnover keep a larger share of their margins.
- 2.49 NAM has proposed gradual removal of the pharmacy fee, halved in the first instance.<sup>31</sup> It argues that such an approach would limit the negative effects on pharmacies. At the same time, the gross margin on the sale of the most expensive medicines would be reduced, taking these margins closer to the Nordic average. This proposal would disadvantage around 200 pharmacies, benefit about 400 and reduce the amount collected by the state from €131 million to around €65 million. The MSAH is reviewing alternative proposals such as this.

### **Pricing and reimbursement of pharmaceuticals**

- 2.50 The PPB is involved in pricing and reimbursement decisions on medicines. It is attached to the MSAH's insurance department which appoints seven members to the PPB: two from the MSAH, two from Kela and one each from the MOF, NAM and the National Research and Development Centre for Welfare and Health (STAKES). These members provide legal, medical, pharmaceutical, economic and social insurance expertise. Board members serve for three years but can be renominated. The board meets at least once a month.
- 2.51 The PPB secretariat presents applications to the board. Members of the secretariat have expertise in pharmacology, pharmacoepidemiology and pharmacoconomics. There are no clinical pharmacologists but clinical pharmacologists on the board and in the expert group provide expertise to the secretariat.
- 2.52 The MSAH appoints an expert group (seven members maximum) to inform PPB decisions. Members are nominated on the basis of their expertise, not as representatives of a specific institution or organization, and provide medical, pharmaceutical, health economics and social insurance knowledge. Members of the current expert group come from the MSAH, Kela, STAKES, university hospitals and universities.

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<sup>30</sup> NAM, 2006b.

<sup>31</sup> NAM, 2004.

## Reimbursement of drugs

- 2.53 Companies that receive NAM's market authorization are required to apply to the PPB for their product to be reimbursed by the public system. Companies granted market authorization via EMEA's integrated system can set their wholesale prices freely but are required to apply to the PPB for reimbursement by the public system.
- 2.54 The PPB takes up to 180 days to make a joint decision on pricing and reimbursement. Drugs can be reimbursed at three possible levels: basic reimbursement and two special refund categories, one lower and one higher. An expert group evaluates the drugs that are submitted for reimbursement approval. The PPB draws on this opinion but it is not binding.
- 2.55 The lower special refund category consists of drugs that treat 10 chronic conditions such as asthma and hypertension. The higher special refund category consists of drugs that treat 34 severe or life-threatening illnesses such as diabetes or cancer. Criteria for the higher level of reimbursement include the severity of disease; necessity and CE of the medicinal product; proven therapeutic value of the medicinal product; funds available for special reimbursement products; and whether there is supporting evidence. The PPB looks at the price and CE evidence.
- 2.56 A drug considered to have a reasonable price and be valid for reimbursement is grouped in the basic reimbursement category. A company must submit evidence on the drug's therapeutic value and CE before it can move to one of the special refund categories. In practice, drugs are usually sold in the basic category for an average of two years, with only a few exceptions. Recently, about seven drugs received higher-level reimbursement status without undergoing the waiting period – an immunosuppressant and drugs to treat conditions such as diabetes, cancer, Parkinson disease and respiratory infections.
- 2.57 The three reimbursement categories have varying co-payments,<sup>32</sup> which apply to each purchase.<sup>33</sup> Changes to these categories have increased patients' share of user charges over the years. As recently as 2003, the basic category refund covered 50% of the drug cost with a fixed deductible of around €8; in 2006 the basic refund covered 42%. The lower special refund category coverage has fallen gradually from

<sup>32</sup> Applications for reimbursement are not required for medicinal products used for the treatment of a disease of a temporary nature or with mild symptoms; medicinal products with minor therapeutic value; medicinal products used for purposes other than treatment of a disease; herbal medicinal, homeopathic or anthroposophic products.

<sup>33</sup> A purchase may include more than one prescription.

90% in the late 1980s to 72% in 2006.<sup>34</sup> The fixed deductible in the upper special refund category has decreased by about €1 and the upper limit for the annual ceiling has increased from €594 in 2002 to €616 in 2006. The reimbursement categories are classified according to the severity of the illness and the necessity of the drug treatment, as presented below.

- Basic refund of 42% (of the full drug price); co-payment of 58%.
- Lower special refund of 72% for severe and chronic diseases; co-payment of 28%.
- Higher special refund of 100% for drugs for life-threatening chronic conditions; co-payment of €3 per medicine per purchase.
- Additional refund: if a patient pays more than the annual limit of €616.72 (in 2006), Kela covers all costs with a co-payment of €1.50 per medicine per purchase.<sup>35</sup>
- A zero-level reimbursement for drugs has been introduced recently. This could be considered to be a negative list.

2.58 A government decree specifies the diseases that are classified according to the special reimbursement categories. Until January 2004, manufacturers were required to submit an application for wholesale price alone. Once a drug's price was considered reasonable, it was grouped automatically in the basic reimbursement category. A drug that received special reimbursement did not require an application procedure. The applicant did not have a right to be heard during the process and decisions were not open to appeal. A European Court of Justice (ECJ) ruling found that the process for drugs in the special reimbursement category was not transparent.<sup>36</sup> Also, clear transparency measures were needed for drugs that qualified for special reimbursement.

2.59 In response, the Finnish government presented new legislation to clarify the procedure and actors' involvement in the process.<sup>37</sup> The MSAH amended the Health Insurance Act and established an application procedure for reimbursement in the special refund categories. The government also established an expert group to inform PPB's decisions, although its opinion is not binding. Since 2004, the PPB has been responsible for granting special reimbursement status; previously

<sup>34</sup> As recently as 2003 this category had a fixed deductible of around €4 (Jämsén, Järvelin & Mikkola, 2003).

<sup>35</sup> Individuals unable to cover their costs may apply to the social welfare system for assistance. Besides the annual limit, there are no other exemptions for vulnerable groups.

<sup>36</sup> ECJ case C-229/000 (Kanavos & Gemmill, 2005). The ECJ ruling found that the Finnish government had not complied with Council Directive 89/105/1988, Article 6, subparagraphs 1 and 2.

<sup>37</sup> Pharmaceuticals Pricing Board Act 1151/2003, Decree 1377/2003; MSAH Decree 1393/2003.

the responsibility of the Council of State.<sup>38</sup> A fixed budget for new products in the special reimbursement category (€8.4 million for 2007) is set in the annual negotiations for the state budget, proposed by the MSAH and negotiated with the MOF. The final state budget (including the fixed budget) is confirmed by parliament.

- 2.60 In collaboration with medical experts in various specialties, Kela decides the criteria by each disease for patients entitled to special reimbursement, including the therapeutic value of a drug and the costs of treatment. This requires a specialist's statement on the severity of disease and Kela checks that the criteria have been met. In principle, the distinction of reimbursement based on severity addresses the need for, and access to, high-cost life-saving treatments. Implementation of this approach requires a transparent and clear process on the criteria for approving reimbursement.
- 2.61 Doctors are required to issue a medical certificate to justify a patient's need for a drug in one of the higher reimbursement categories. Patients must submit this certificate to Kela in order to qualify for higher reimbursement; a basic refund is paid if this is refused.
- 2.62 Under current legislation, PPB's decisions on drug reimbursements can affect clinical practice. A decision to limit a medicine's reimbursement status has implications for less expensive medicines in the same drug class. A recent example is PPB's decision to limit the reimbursement status of more expensive statins: atorvastatin and rosuvastatin. These are reimbursed only if lifestyle changes (e.g. food, exercise) and cheaper treatment alternatives have not been effective enough or cannot be used (contraindicated). Consequently, low-cost statins (such as generic simvastatin) have become the preferred first-line treatment in clinical practice. After introduction of the policy, the proportion of patients on generic simvastatin has increased.
- 2.63 Limitations usually apply to a specific patient group. In this situation, the decision on statins was unique because it had implications for treatment alternatives in clinical practice. PPB anticipates that this form of limited reimbursement may become common as more expensive medicines enter the market. Kela is monitoring the data on statin use. Further analysis on this policy will be useful to assess its impact. PPB's move to consider low cost statins confirms findings elsewhere.<sup>39</sup>

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<sup>38</sup> Kanavos & Gemmill, 2005.

<sup>39</sup> A recent Department of Health (DoH) report in England suggested that the National Health Service (NHS) could save up to £84 million per year by prescribing the low-cost generic versions of statins: simvastatin and pravastatin (PharmaTimes, 2007).

- 2.64 Decisions on reimbursement are not well-linked to clinical guidelines. The PPB makes its own independent decisions and does not issue guidelines. This may be considered but could be restricted by the three reimbursement categories – it may be difficult to differentiate guidelines depending on the patient's condition. PPB decisions clarify the use of drugs (for instance any restriction for a certain indication or patient subgroup) but the official decision is a short written summary. Kela may make further decisions on the documentation required and the medical criteria to be met to justify reimbursement.
- 2.65 One challenge for the current system is that a drug can belong to more than one reimbursement category. Government decree defines the severe and chronic illnesses that entitle patients to be reimbursed under the special refund categories; criteria are defined in the Health Insurance Act. According to Kela, in principle anyone can submit a proposal to the MSAH or the Council of State. In practice, they are made by patients, patient associations, physicians and Kela. Kela is requested to submit an opinion before the decree is amended.

### Pricing of drugs

- 2.66 The PPB is responsible for approving the price of drugs that are covered by Kela. The process is the same for generics, parallel trade and original products.<sup>40</sup> Applicants must provide information including the therapeutic value of the drug; proposed wholesale price; product price information from other countries; and a pharmacoeconomic evaluation.<sup>41,42</sup>
- 2.67 Drugs reimbursed outside the public system are not subject to pricing restrictions. The PPB determines whether a drug meets a reasonable wholesale price on which the reimbursement rate is based. The wholesale price is the maximum price charged to pharmacies and

<sup>40</sup> If the proposed wholesale price for generics is 40% less than the original product and below existing generics in the market, the Secretary General of the PPB can make a decision without the board's approval. However, generic competition and penetration is low in Finland (see Chapter 3).

<sup>41</sup> The complete list is: cost and benefits gained by use of the drug; calculation of average daily dosage and cost of medication based on wholesale price and retail price including value added tax (VAT); budget impact analysis of expected sales, volume and number of users; report on economic efficiency of the medicine and its market forecast compared to other medicines; term and validity of the patent or supplementary certificate; brand names under which the product is marketed in other European Economic Area (EEA) countries and their prices; clinical expert opinion of the medical substance if it is not present in any products with a confirmed reimbursement status; pharmacoeconomic report; account of R&D expenses; copy of the latest marketing authorization decision; copy of receipt of the evaluation charge; any other documentation deemed necessary by the PPB (MSAH decree on applications for a reasonable wholesale price and the reimbursement status of a medicinal product and on the documentation to be attached to the application – unofficial translations, MSAH Decree 1111/2005).

<sup>42</sup> Applicants can choose the economic evaluation used in the submission of its pharmacoeconomic report: cost minimization; CE; cost-utility; or cost-benefit analysis. The comparator should be the existing alternate treatment but, if this is not the most commonly used therapy, the evaluation should also include the most common therapy. If the evidence of the benefits of the commonly used therapy is not clear, the comparator can be one of the top available treatments or the minimum therapy, provided that there is evidence of their benefits. Health effects and costs of the product and the comparison therapies should be presented as incremental benefits and costs and as total benefits and costs.



hospitals although medicines administered in hospitals are not part of the reimbursement system – their price is negotiated directly between the pharmaceutical companies and the hospitals. The PPB also deals with applications that request to increase the wholesale prices of medicines by considering economic evaluations to compare drugs with other available treatments; the wholesale price of major competitors including PI and generics; list price of the products in other EEA countries; budget impact on Kela; and clinical judgement.<sup>43</sup>

- 2.68 International price information is taken from countries belonging to the EU before May 2004 (EU15) as well as Norway and Iceland. Finland focuses on keeping its prices in the lower half of European prices. When new products are reviewed in Finland, applicants often submit only comparatives from high-price countries, namely the United Kingdom, Germany and Denmark, but the PPB may reject drug applications if it considers that wholesale prices are too high. CE data from another country have less value because they are not evidence from a Finnish setting; submissions that model CE data with a comparator will not be verified if the pharmacoeconomic evaluations are of poor quality.
- 2.69 Despite a comprehensive list, the process does not make it easy to identify the criteria most important for pricing decisions. The PPB does not explicitly weight the criteria used in CE evaluation or the assessment for price setting. The Finnish government improved the process for reimbursement decisions in response to an ECJ ruling (Case C-229/00). The European Commission (EC) had also argued that the PPB used vague evaluation criteria but the ECJ found that the EC had failed to prove how Finnish legislation did not comply with the directive. The industry has argued that the PPB's decisions need more clarity and openness.
- 2.70 The quality of submissions received is an issue related to the evaluation criteria. An internal assessment of manufacturers' pharmacoeconomic evaluations submitted to PPB was carried out in 2005. Among the 22 evaluations assessed, two thirds were of poor quality and could not be taken into account for pricing decisions.<sup>44</sup> Half of the evaluations used cost-minimization analyses; half used cost-utility or CE analyses. The study concluded that the quality of pharmacoeconomic evaluations should be improved.

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<sup>43</sup> Pekurinen & Häkkinen, 2005.

<sup>44</sup> PPB, 2005.

- 2.71 The PPB requires Kela to submit a written statement on a drug's price level and the extent to which its associated costs will impact on Kela's budget. The decision accepts that a drug's price is reasonable or rejects it. Early negotiations reduce the need for appeals: if a negative decision looks likely, a draft is issued to the applicant who may provide more evidence or suggest a lower price. PPB will not change negative decisions unless the company lowers its price. Applicants can reapply but the process starts again.
- 2.72 Any appeals go directly to the Supreme Court. Between 1993 and 2003 there were 35 appeals; since 2005, 10 cases have gone to court. The Supreme Court examines the process rather than the grounds for the PPB decision and, generally, companies do not win. On average, PPB gives positive recommendations to 75% of applications concerning new active ingredients.
- 2.73 Although a drug's price usually is set for a certain time, this is not fixed and drug reviews can take place before the period ends. This implies that reviews can take place at any time, on a group of drugs or individually. In general, drug reviews take place within three years for active ingredients and up to a maximum of five years. Manufacturers can request a price increase which is answered within 90 days; they are obliged to apply for a drug review, otherwise the drug is removed from its reimbursement category.
- 2.74 A drug review (termination procedure) can be triggered if a drug goes off patent; a new product enters the market (on-patent or generic); the product's sales and reimbursement expenses exceed the forecasts provided in the application; or the product expands its licensed indications. PPB will consider the price of existing drugs because review decisions are coordinated so that renewal applications for medicines in the same therapeutic group are evaluated together.
- 2.75 After a drug review, the PPB can choose to terminate the wholesale price and reimbursement status of the drug. Before such a decision, the PPB must hear submissions from the holder of the market authorization and Kela. The criteria for terminating the wholesale price and reimbursement status require the PPB to assess the therapeutic value of the drug and the reasonability of the wholesale price on the basis of the new information. At present, two drugs are under review for exceeding sales forecasts.

- 2.76 The PPB's last (renewal procedure) review began in 2003 and ended in 2005. This covered drugs with generic competition and 'me-too' drugs, including proton pump inhibitors (PPIs) and statins. The wholesale price was reduced for both classes of drugs but was larger for the generic versions than for those on patent.
- 2.77 Since 2006, the PPB has created a negative list of non-reimbursable drugs which can be used for re-evaluations. Before a drug is placed on the negative list, PPB considers information from the holder of the market authorization and Kela.

### **Competition policy in the pharmaceutical market**

- 2.78 The FCA operates under the MTI. It promotes market competition, supports a reduction in barriers to entry and promotes regulation where necessary to make markets work better.
- 2.79 The FCA supports a comprehensive reform of the pharmaceutical market and has been involved in some cases concerning the pharmaceutical sector. One FCA ruling concluded that it was unlawful for drug companies to offer rebates to pharmacies.<sup>45</sup> This bargaining arrangement provided pharmacies with large discounts in return for meeting set sales targets which increased sales of specific drugs. These agreements were tied to the preceding year's sales to encourage increased dispensing of particular drugs. Discounts could not be passed onto consumers because the Medicine Act sets identical retail prices for drugs in every pharmacy, therefore the savings were retained by the pharmacies. There is anecdotal evidence that pharmacists attend educational seminars to compensate for the rebates lost as a result of the FCA ruling, but we were unable to verify these claims.
- 2.80 Another study assessed the average two-year initial evaluation period.<sup>46</sup> The PPB considers this an opportunity for clinical evidence and observational use to inform the board on the effectiveness and financial implications of prescribing a drug. The FCA criticised this practice because it skews competition between drugs in the special reimbursement category and those in the evaluation period. The rule weakens the motivation to bring new drugs to the Finnish market and limits choice particularly in the treatment of the most serious illnesses. The FCA concluded that this rule should be removed from law but noted that it is natural to take health economics studies (necessity, effect and financial implications, etc.) as the basis for deciding whether

<sup>45</sup> FCA, 2005.

<sup>46</sup> FCA, 2006a.

a drug should fall under ‘special compensation’. The amount of funds available for such compensations should not be the criterion. If insufficient funds are available, the FCA argued that all drugs that qualify for special compensation should be affected equally.

- 2.81 The FCA is currently reviewing some cases concerning pharmaceutical policy and other health-sector issues.<sup>47</sup> One complaint asserts that a medicine’s basic reimbursement status was restricted to certain patients and it was denied higher reimbursement status. The FCA will assess whether the decisions on reimbursement status hinder market access and whether this undermines access and treatment for patients. Part of the complaint rests on the PPB’s cost calculation methods.
- 2.82 Another case concerns the problem of cost shifting between various financing streams depending on where the drug is prescribed. The pharmaceutical company claims that its drug is being treated unfairly and is dependent on the current reimbursement system for drugs dispensed via in patient or out patient care. As hospital budgets cover drugs dispensed in hospitals and Kela’s budget covers drugs dispensed in outpatient care, hospitals prefer a drug to be dispensed in outpatient care.

#### Pharmaceutical industry in Finland

- 2.83 PIF is the trade association representing the industry’s interests, aiming to influence economic, industrial and social policy legislation. In 2006, it had 64 members representing the research-based, generic, OTC and veterinary pharmaceutical industry. Groups affiliated with PIF include the Pharmaceutical Information Centre, The Supervisory Commission for the Marketing of Medicinal Products and The Finnish Cooperative for the Indemnification of Medicines-Related Injuries.
- 2.84 PIF’s latest figures show continuing growth in pharmaceutical sales. Sales of medicines in 2005 (based on wholesale prices) were close to €1.8 billion, with prescription medicines sales close to €1.6 billion and self-care medicine sales of €208 million. According to therapeutic groups, the three drug categories with the highest sales in 2005 were those to treat the nervous system (€334 million, 8.5% year on year increase); cardiovascular system (€264 million, 1.8% decrease); and alimentary tract and metabolism (€207 million, 6.8% increase).

<sup>47</sup> A recent FCA decision on the public and private practice of laboratories was to open up the market for these services within a health care district. Another case is considering whether public providers of laboratory services will enter into competition with private laboratories. Public sector bodies are not subject to the same constraints as private providers in areas such as cost-accounting standards.

- 2.85 Pharmaceutical imports and exports have continued to rise. In 2005, imports were €1.4 billion and exports just over €600 million. In 2005, Russia accounted for about 58% of the increase in Finland's exports, followed by Switzerland. Imports make up 85% of the value of drugs. About 40% of packaging is manufactured domestically. The higher level of imports also indicates that the majority of domestic consumption is drawn from imported products rather than domestic products.
- 2.86 Research and capacity within the pharmaceutical industry suggest that Finland has retained a strong position in the later stages of research and development (R&D).<sup>48</sup> Since the mid 1990s, the total number of clinical trials has remained fairly steady at just under 500 trials annually. The largest proportion of trials in Finland tends to occur in the later stages of development (Phase III). As a percentage of gross domestic product (GDP), overall pharmaceutical R&D is low compared to other European countries – 0.06% in 2003 when overall business expenditure in R&D (BERD) was one of the highest (2.5% of GDP, second to Sweden's 2.52%).<sup>49</sup>
- 2.87 Wholesale prices are regulated in Finland, but some studies show low levels while others report higher. The Organisation for Economic Co-operation and Development (OECD) health data suggest that the public share of total health expenditure attributed to medicines in Finland was around 54% – in the middle to lower half relative to other selected countries.<sup>50</sup> Chapter 3 gives a more detailed discussion of prices and reimbursement trends.

### Policy issues

- 2.88 PIF has been active in a number of policy areas, in particular, expressing concern over the current system of pricing and reimbursement in Finland: the decision-making process to determine the wholesale price was not transparent enough for drugs in the special reimbursement categories. This led to the ECJ case (C-229/00) mentioned earlier in this report.
- 2.89 In general, PIF considers the reimbursement system to be too complicated. The PIF views the classification of diseases to be unfair and that drugs are not necessarily recognized for their therapeutic

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<sup>48</sup> PIF, 2007.

<sup>49</sup> OECD, 2006b.

<sup>50</sup> PIF, national health insurance reimbursements (available at [http://www.pif.fi/tiedostot/share\\_of\\_public\\_expenses\\_of\\_total\\_expenditure\\_in\\_medicines\\_2003.pdf](http://www.pif.fi/tiedostot/share_of_public_expenses_of_total_expenditure_in_medicines_2003.pdf), accessed 5 September 2007).

value: preventive drugs (e.g. for hypertension, statins) are in a lower reimbursement category but should be higher because of their therapeutic value for risk reduction. PIF would prefer all drugs to face the same reimbursement coverage rather than three separate categories.

- 2.90 A working group was set up with the PPB to assist companies with their submissions. PIF would like PPB to give more information on how their decisions are made. PIF endorsed the proposals in an expert report on pharmacotherapy; it proposed the creation of an evaluation body, equivalent to the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom, which could inform the PPB's pricing decisions.<sup>51</sup>
- 2.91 PIF's Supervisory Commission for the Marketing of Medicinal Products monitors compliance and enforces the Code for Marketing of Medicinal Products.<sup>52</sup> The first code of practice was established in 1959; an update to the current code came into effect in February 2007. The PIF and municipalities developed joint guidelines on activities targeted inside and outside hospitals which were incorporated into the update. The new code stipulates conditions including the responsibilities of sales representatives (e.g. the content of their presentations and the supply of samples provided during a visit), employer approval and reporting of financial support from the industry. However, there are no clear guidelines for educational events on clinical trials or those agreed separately between a company and a health-care unit.
- 2.92 Both PIF and the municipalities monitor activities. The code of conduct organization has a supervisory commission consisting of lawyers, doctors and pharmacists. This works with two inspection boards: one monitors promotional activities to consumers, the other monitors promotional activities to health-care professionals. The inspection boards include pharmacists, doctors and marketing experts. The majority of complaints about prescription medicines are initiated by competing pharmaceutical companies. Recently, there have been about a dozen complaints per year; the usual complaint process lasts about two months. The board can impose fines ranging from €1000 to €50 000,<sup>53</sup> and fines were imposed in 19 cases in 2006.
- 2.93 NAM has the legal power to regulate the industry's marketing activities and has identified increasing this supervisory role as a key part of its strategy for 2006–2012 (see section on NAM for further information).

<sup>51</sup> Huttunen, 2006.

<sup>52</sup> Segercrantz M, Harsu J, 2006.

<sup>53</sup> We enquired about evidence of fines but received no information before submission of the report.

NAM will also monitor the quality and procedures for counselling patients in pharmacies.

- 2.94 Our meetings with stakeholders suggested that the industry targets medical students heavily during their training; a study came to similar conclusions.<sup>54</sup> The study contacted all medical students at varying levels of study; one third (952) responded to the anonymous questionnaire. The responses indicate that the students attended pharmaceutical company presentations frequently: close to half (44%) at least twice a month. The respondents weighted information from the industry as one of their most important sources of information. Most favoured promotion and believed that such activities would affect their future prescribing behaviour. The authors concluded that because medical students are exposed commonly to pharmaceutical promotion, the medical education system should ensure a balanced view of drug information as part of their training.
- 2.95 Another study on the quality of marketing claims found that the majority lacked proper scientific evidence.<sup>55</sup> The study examined 245 advertisements from four major Finnish medical journals published in 2002. Each advertisement made between one and ten claims. In a total of 883 marketing claims close to two thirds did not provide a supporting reference. The majority could be characterized as vague, emotive statements or non clinical claims. Those claims that did provide a reference (about 38%) gave a mix of scientific and non-scientific information. Furthermore, no single claim was supported by strong scientific evidence. The study concluded that the regulatory authorities in Finland must play a greater role in monitoring the quality of drug marketing and apply sanctions where appropriate.

### **Measures to influence prescribers**

- 2.96 Within the MSAH, ROHTO and FinOHTA are charged with various aspects of economic evaluation and evidence-based medicines; each has different HTA functions. The Finnish Medical Society (Duodecim) also plays a key role in the development and dissemination of scientific information including clinical guidelines.

#### ROHTO

- 2.97 ROHTO was established initially as a pilot programme between 1998 and 2003 to collect and disseminate evidence-based practices to

<sup>54</sup> Vainiomaki, Helve & Vuorenkoski, 2004.

<sup>55</sup> Lankinen et al., 2004.

promote rational and appropriate prescribing among general practitioners (GPs).<sup>56</sup> The programme was funded by Kela and the MSAH, and led by Duodecim, as part of a continuing medical education initiative for doctors. Kela provided doctors with prescribing feedback: the cost and number of prescriptions written were benchmarked against the average doctor in the relevant specialty.<sup>57</sup> Kela continues to collect this data and forward them to doctors. Since 2003, ROHTO has been an independent expert unit within the Health Department under the MSAH. ROHTO also works with NAM and has access to its files on drug assessments.

- 2.98 ROHTO's goal is to promote rational prescribing among health-care practitioners via education and development activities – providing drug information and monitoring prescribing practices. This is an important and necessary initiative for pharmacotherapy. From a policy perspective, the importance and implementation of its work and activities should be expanded.
- 2.99 GPs facilitate ROHTO's educational work by promoting rational prescribing practices at regional and local levels. ROHTO sponsors workshops in health centres and doctors undergo training to carry out educational workshops for their peers. Workshops may cover topics which have large variations in clinical practice or on conditions with a high burden of disease. Information on cost-effective drugs is used with information drawn from reviews of scientific evidence and current national guidelines. The workshops are designed to be tailored to local situations and health-care priorities; 218 workshops were carried out in 2006. These focused largely on two priority areas: cardiovascular risks and uncoordinated polypharmacy, as well as infections. Other workshop topics included drug promotion, asthma and diabetes. The majority of participants were doctors but a small proportion of pharmacists also took part.
- 2.100 ROHTO uses critical appraisals to develop methodologies and draws information from NAM and from national clinical treatment guidelines (Current Care). Duodecim has issued around 69 guidelines for common diseases and health problems.<sup>58</sup> Generally, guidelines do not contain an economic evaluation but three recent guidelines included an economic evaluation using CE.<sup>59</sup> Content is also based on

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<sup>56</sup> Helin-Salmivaara et al, 2003.

<sup>57</sup> Kela sends a summary to any doctor who writes prescriptions amounting to more than €20 000 per annum.

<sup>58</sup> Duodecim, 2007: Finnish current care guidelines (available at: [http://www.kaypahoito.fi/kotisivut/sivut.koti?p\\_sivusto=6&p\\_navi=3038&p\\_sivu=3237](http://www.kaypahoito.fi/kotisivut/sivut.koti?p_sivusto=6&p_navi=3038&p_sivu=3237), accessed 23 August 2007).

<sup>59</sup> Pekurinen & Häkkinen, 2005.



the electronic Evidence-Based Medicine (EBM) Guidelines. These cover primary care and are updated continually to reflect changes and developments in clinical practice. ROHTO is legally permitted to obtain submissions to PPB but currently does not.

- 2.101 ROHTO produces and disseminates relevant information on drugs and rational prescribing on its web site, in the *Journal of Duodecim* and the *Finnish Medical Journal* – published by the FMA. Recent topics have included the rational use of statins; medication review among elderly people; and the pharmacotherapy of osteoporosis (based on an original text adopted from NICE).
- 2.102 ROHTO plans to expand this communication tool to include pharmacy and nursing journals. The drugs identified include new entries whose therapeutic value is unclear; those for which new data are available; and those used by large numbers of patients. ROHTO operated activities in 6 out of 20 hospital districts in 2005 and would like to expand its work to cover the remaining parts of the country. At the beginning of 2007, ROHTO was working in 10 hospital districts.
- 2.103 The organization has nine staff but would welcome more resources to increase its personnel.<sup>60</sup> Technical expertise is provided by staff with medical backgrounds but at least one part-time health economist is required in order to carry out drug reviews that include an economic component. ROHTO works with 9 doctors who act as regional facilitators, and over 100 local facilitators – doctors with experience in primary care and nurses who work in cooperation with GPs. It also contracts work with experts in clinical pharmacology and medical advisers. ROHTO's initial work involved international collaboration with similar initiatives; current international collaboration activities involve bodies in Denmark, the United Kingdom and Sweden.<sup>61</sup>
- 2.104 ROHTO's effect on rational prescribing remains to be seen.<sup>62</sup> This could be assessed using Kela data on prescribing patterns – before and after intervention. ROHTO is developing tools to monitor its activities.
- 2.105 ROHTO has two priorities in 2006–2007: cardiovascular risk factors (treatment and prevention) and uncoordinated drug treatment for patients with multiple conditions. These were decided in cooperation with ROHTO's advisory board comprised of representatives of major

<sup>60</sup> Technical staff posts include doctors holding a specialization in public health (1); general practice and primary care (3); or clinical pharmacology (1); and development managers with a background that includes nursing.

<sup>61</sup> Denmark: Institute for Rational Pharmacotherapy; United Kingdom: National Prescribing Centre; Sweden: Karolinska Institute and Stockholm County Council. ROHTO is also a member of G-I-N (Guidelines International Network).

<sup>62</sup> FinOHTA, 2006a; FinOHTA, 2006b.

stakeholders such as MSAH and Kela, and agreed in the annual contract with the MSAH. There is a need to link the reimbursement process to ROHTO and to decide how much of its work focuses on new medicines relative to existing treatments.

- 2.106 ROHTO has been partly financing Duodecim's project on a prescribing-decision support system. This is discussed further in the section on Duodecim.

#### Finnish Office for Health Technology Assessment

- 2.107 FinOHTA is a public agency established within the STAKES in 1995. In turn, STAKES is attached to the MSAH (and the Social Affairs Department).
- 2.108 FinOHTA's goal is to promote the use of evidence-based methods to enhance the effectiveness of medical technologies in health-service provision. Its main functions involve producing, supporting and disseminating HTAs at national and international levels. FinOHTA cooperates with members in the health-care field both within and outside Finland, and monitors developments in HTA research in Finland and the international HTA community. It prepares rapid reviews to evaluate new, emerging methods, especially those of importance to public health or the national economy. Evidence is drawn from international data and applied to the Finnish context.
- 2.109 An advisory board directs FinOHTA's activities and develops proposals for national and international joint assessment projects. The board consists of 26 members representing various stakeholders: hospitals, medical societies, consumer groups, medical technology associations and national health-care institutes. A scientific committee consisting of 13 members from the medical-scientific community evaluates FinOHTA's work and assists in the dissemination of results.
- 2.110 The MSAH contributes to setting priority areas for FinOHTA, and the MOF finances its work. Topics are selected using a formalized process.<sup>63</sup> They are weighed against a set of criteria which includes impacts on public health and budgets and the quality of proposed research methods.<sup>64</sup> For technologies in the hospital sector, FinOHTA

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<sup>63</sup> FinOHTA, 2006a.

<sup>64</sup> Full list of criteria: impacts on public health or national economy; appropriate and good quality proposed research methods; feasibility of study; adequate study aims in terms of assessing effectiveness; and other considerations including social, ethical, legal and quality of life implications, researcher(s) conflict of interest, qualifications of research group or organization, appropriate funding structure, timely study completion, usability of study results and effective plan for dissemination, implementation and follow-up of results.

presents hospitals with a list and the hospitals select those that should be assessed. The entire process takes from two to six months.

- 2.111 FinOHTA employs around 30 skilled staff, half of whom are permanent. Most have a clinical background in primary or secondary care, a few have backgrounds in health economics. FinOHTA agrees that it would be useful to have more staff with economics expertise and has recently begun building knowledge and expertise in CE evaluation.
- 2.112 Under a new programme launched in 2005, all 20 health districts participate in assessments of new technologies. The project is developing rules for the uptake of new medical technologies. By November 2006, six evaluations had been presented: endovascular laser for varicose veins, therapy for wounds, therapy for hepatic insufficiency, length of antithrombotic treatment after hip replacement, 64-slice computerized tomography (CT) for coronary disease and Herceptin for breast cancer. The appraisals will be published as a series in the Finnish Medical Journal.
- 2.113 FinOHTA considers all forms of economic evaluation: cost minimization, cost utility, CE and cost–benefit analysis. It uses the 15-D health-related quality-of-life measure rather than QALYs. However, health economics has not been used much in its analysis and FinOHTA would like to expand this expertise and methodologies. A method paper is developed after reviewing information in the literature. One method paper on paediatrics published in 2006 commented on the quality of reporting of randomized controlled trials (RCTs) on rehabilitation for cerebral palsy. In January 2007 FinOHTA published two papers: one on endoscopic thoracic sympathectomy for blushing and sweating; the other on the first RCT on the effectiveness of surgery for spinal stenosis. FinOHTA will review medicines if they are compared with other technologies or if there is uncertainty on the use of high-cost drugs in secondary care.
- 2.114 FinOHTA publishes its reports in scientific papers but no monitoring tools are in place so the impacts of implementation are not clear. It felt that HTAs could encourage the involvement of practitioners and influence uptake and implementation. FinOHTA would find it useful to coordinate information on economic evaluations and methodologies with other actors (discussed further in Chapter 6).
- 2.115 FinOHTA works with Duodecim and the FMA to develop clinical treatment guidelines and its own assessment evidence feeds into this process. Some guidelines include CE assessments but few include an economic component.

- 2.116 An external review of FinOHTA published in 2004 made a number of recommendations for strengthening its role and influence in decision-making. A key finding relevant to this study was that it should take responsibility for reviewing pharmaceuticals using CE analysis.<sup>65</sup> The review presented a series of recommendations for pharmaceutical policy. The MSAH could hold discussions with FinOHTA and other organizations (such as NAM and ROHTO) to clarify their roles and responsibilities. Formal international collaboration could be initiated and built on Nordic collaboration, and resources within Finland should be coordinated better. FinOHTA could include pharmaceuticals as part of its remit and should ensure that it has expertise in clinical pharmacology. It suggested that FinOHTA and ROHTO could be amalgamated, and to consider closer collaboration with Duodecim on guideline development (Current Care project). The committee argued in favour of FinOHTA as an independent agency (based within STAKES).
- 2.117 Hospital districts, health centres and medical and health organizations employ HTA in policy-planning and decision-making.<sup>66</sup> FinOHTA's research and analytical output is communicated to a wide and diverse audience of health-care professionals, policy-makers and patients. For instance, its findings are used to change health-care practice on the development of clinical guidelines. Thus, FinOHTA plays a central role in dissemination but is not involved directly in the implementation of its work.
- 2.118 The external review recommended that while FinOHTA should not be the primary body responsible for implementation, it should ensure that its information is used. This could involve supporting hospital districts, health centres, the development of guidelines, medical schools and other organizations. A national strategy could be put in place to assist with implementation. There is a need to clarify the role and coordination of actors in their strategies for implementation, advice, training and help with evaluations. The current extent of this is unclear.

### Duodecim

- 2.119 Duodecim is a scientific organization established in the late 1880s and with a current membership of over 18 000 physicians and medical students. Its mission is to assist physicians to develop their professional skills through further education, publications and research grants.<sup>67</sup>

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<sup>65</sup> Eskola et al., 2004.

<sup>66</sup> Lauslahti et al., 2000.

<sup>67</sup> Duodecim, 2006.

Duodecim's decision-making body is a committee of its own members. A 12-member board of directors executes the committee's decisions.

- 2.120 Duodecim's main activities involve education and a range of workshops and courses. It also offers research grants for education, training or drafting clinical guidelines (about €2 million annually). Duodecim publishes a medical journal as well as a patients' magazine that provides information on medical science and health care. The society also publishes educational materials such as textbooks and handbooks for health-care professionals and the general public.
- 2.121 Ongoing work includes the development of clinical guidelines – the Current Care project. Around 69 guidelines are available now, 100 are expected to be published by 2010.<sup>68</sup> Medical specialist societies advise on topic selection and a group of health-care professionals carry out a systematic review (including FinOHTA assessments) to assist their development. The Current Care project involves an extensive cooperative network including doctors' specialist organizations, national health and patient organizations, hospital districts, ROHTO and FinOHTA.
- 2.122 In one study, a quarter of health centres evaluated had structures in place for the positive uptake of guidelines.<sup>69</sup> Useful, reliable, practical and available guidelines contributed to their uptake among health professionals.<sup>70</sup> However, there is a need for further study of the adoption of guidelines in practice.
- 2.123 In addition to the Current Care guidelines, Finland has more than 1000 electronic EBM Guidelines. Over 500 guidelines are in place at local level, linked to the Current Care and EBM Guidelines. Use of the electronic portal suggests that a physician reads an average of 1.5 guidelines per day.<sup>71</sup>
- 2.124 As part of a national project to develop a strong IT base of health-care data, legislation passed in early 2007 requires all electronic patient data to be stored in a national archive by 2010. Patient data including diagnoses, medications, laboratory tests and treatment plans will be stored in a standard format.
- 2.125 Duodecim is involved in developing and pilot-testing a decision-support system that will link patient health data with database information on prescriptions, guidelines and evidence. Electronic

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<sup>68</sup> Duodecim, 2007a.

<sup>69</sup> Miilunpalo, Toropainen & Moisio, 2001.

<sup>70</sup> Elovainio et al., 2000.

<sup>71</sup> Duodecim, 2007b.

patient health data are being developed. The decision-support system will cover all aspects of clinical work. Drug therapy will be key: the system will draw on several drug therapy databases that are in place or under development including drug interactions, allergy information and adverse events.<sup>72</sup>

- 2.126 The system is intended to account for co-morbidities by means of patients' risk assessment information. It will include automatic alerts for physicians and health-care professionals; interactive tools (e.g. access to guidelines); and reminders for possible treatment interventions or follow-up. The system will also have the potential to generate letters covering test results, medication information updates and reminders to schedule appointments. Duodecim will be responsible for the management of these databases.

#### Finnish Medical Association

- 2.127 Established in 1910, the FMA is a professional organization for physicians in Finland. Its activities support the advancement of medical expertise as well as humanity, ethics and collegiality. Membership is voluntary but covers almost all practising physicians. The FMA represents members' interests in three key areas: professional, social and economic. These include medical ethics and safeguarding the interests of doctors and patients.
- 2.128 Physicians can work for the public system either in health centres, or as an occupational health doctor or in private practice. The FMA had 20 294 members at the beginning of 2006, about 94% of all Finnish physicians.<sup>73</sup> The level of doctors has steadily increased. Among 21 285 doctors at the beginning of 2006, about 85% (18 245) were of working age (<63 years). Physician density is high in comparison to other countries – 1 active physician per 309 inhabitants.
- 2.129 The age/sex breakdown for 2006 is presented in Table 2.2. The numbers suggest a higher proportion of women in the lower age group. This could have longer-term implications for the level and distribution of the physician workforce because the pattern of female retirement in other countries shows that women tend to retire earlier.<sup>74</sup>

<sup>72</sup> Databases built or under development: drug interactions (in use); drug indications (completed, under peer-review); drug contraindications (completed, under peer-review); drug allergy grouping (under review); adverse effects of drugs (international databases will be used to build the database); use of drugs during pregnancy and breastfeeding (Finnish database available but needs updating); database of drug treatment for the aged (to be constructed as subsets of the above, with extra contents addressing use of drugs among the elderly).

<sup>73</sup> FMA, 2006c.

<sup>74</sup> It would be useful to have in-depth analysis of the movement of physicians in and out of the workforce. Kela's database on doctors' claims would provide useful insight.

**Table 2.2** *Physicians in Finland by age and sex, 2006.*

| Age   | Male level (share, %) | Female level (share, %) | Total level (share, %) |
|-------|-----------------------|-------------------------|------------------------|
| <30   | 443 (32)              | 933 (68)                | 1 376 (7)              |
| 30–39 | 1 730 (37)            | 2 980 (63)              | 4 710 (22)             |
| 40–49 | 2 482 (42)            | 3 398 (58)              | 5 880 (28)             |
| 50–62 | 3 742 (59)            | 2 537 (41)              | 6 279 (29)             |
| >62   | 2 122 (70)            | 918 (30)                | 3 040 (14)             |

Source: FMA, 2006c.

2.130 The FMA has guidelines to support continuing medical education (CME). This training is voluntary for physicians but ten days a year are recommended. The average was seven days for all doctors in 2005.<sup>75</sup> The FMA board sets out the criteria for CME and is responsible for approving the events and organizers. The main organizers should be medical professionals, medical bodies or universities. Physicians are required to document and assess their CME and learning activities but neither the FMA nor any other central body has any system to monitor how this is carried out. Despite its support for CME, the FMA has no formalized professional development requirements for physicians, such as relicensing or revalidation.

2.131 The FMA published a set of guidelines in 2006 to address the code of conduct of physicians in commercial enterprises.<sup>76</sup> This aims to address conflicts of interest that may arise within commercial entities, including the pharmaceutical industry. Physicians may attend industry-sponsored events but the funding source must be made public and the main sponsor must be a professional medical body. Physicians can be involved in research sponsored and funded by the industry but they cannot be paid or receive benefits for directing patients to clinical research. Published work must declare any sponsors. Physicians may act as consultants but are required to declare such relationships; they can accept gifts of nominal value but are not required to declare them.

### **Actors in the delivery of pharmaceutical services**

2.132 This section discusses actors in the delivery and purchasing of pharmaceutical services: doctors, health centres, hospitals, pharmacies and pharmacists. Each has an important role; the policies in place have a number of implications for the delivery of services.

<sup>75</sup> FMA, 2006a.

<sup>76</sup> FMA, 1999.

## First contact providers

- 2.133 At the regulatory level, two bodies have a close relationship concerning the supply and activities of health professionals. The Ministry of Education is responsible for human-resource planning and partly subsidizing the education of health personnel. NAMLA handles disciplinary matters concerning health professionals (e.g. doctors can receive letters and be reprimanded) and provides legal safeguards for the protection of patients.<sup>77</sup> Also, it is responsible for legal matters concerning the registration of health professionals.
- 2.134 Physicians have the greatest concentrations in urban centres and close to teaching hospitals.<sup>78</sup> Most Finnish municipalities employ a family-doctor system, launched as a pilot project to ensure greater access to doctors. Under the current arrangement, each family doctor is responsible for 2000 patients, and they should be able to have contact with a doctor within three working days. Population coverage has increased and has strengthened relationships between doctors and patients.<sup>79</sup> However, there are reports of inequities in access to doctors in municipal health centres after allowing for income and need. Access to occupational doctors had relatively higher rates of consultations.<sup>80</sup>
- 2.135 The majority of physicians worked in hospitals (7373 – about 47%) and in municipal health centres (3564 – 23%) in 2005. About 10% (1611) of all physicians were in full-time private practice. Close to one third of all physicians had part-time private practices, the majority of whom had a full-time occupation in either a hospital setting (66% of all part-time physicians) or in a municipal health centre (about 11%). Occupational health doctors accounted for 6% (886). Other doctors worked in research and teaching.
- 2.136 Payment systems vary. There are two salary systems for the public system: one covers family doctors; the other is for fixed hours. Among the physicians who work in the public sector, 70% of them are covered under a collective agreement with the municipalities. Municipalities may operate their own bonus system but this is used rarely. In Helsinki, the bonus system considers the patient experience (e.g. from a survey), operational costs, organization of the provision of services and the health-care professionals' experiences (e.g. could include offer of additional training). The reward system requires that all components

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<sup>77</sup> Järvelin, 2002.

<sup>78</sup> FMA, 2006a.

<sup>79</sup> FMA, 2006b.

<sup>80</sup> Häkkinen, 2005.



have defined areas of measurement and are prepared under close cooperation with supervisors of the health unit in question. The bonus component is a small proportion of pay – up to a maximum of 5% of a physician's annual salary.<sup>81</sup>

- 2.137 Doctors in the family-doctor system receive payments comprising a basic salary (less than 60%), capitation payment (10%), fee for service (15%) and for on-call (5%). The balance consists of an optional element and a guaranteed element determined by the duration of service.<sup>82</sup> In the fixed-hour system about 75% of the salary is task-specific, 7% is based on procedures and 5% is for on-call. The balance consists of an optional element and a guaranteed element determined by the duration of service.
- 2.138 Contractual arrangements for doctors who work in the municipal centres are set between the FMA and the Municipal Delegation for Collective Bargaining.<sup>83</sup> The government is not involved.
- 2.139 Occupational doctors provide services to those whose employers have elected to provide them. These doctors can be either employees or self-employed in private medical stations. The majority receive a fixed monthly salary; a small number receive fees for service. About one fifth (187) of all occupational doctors (886) were in private practice in 2006.
- 2.140 Municipal or hospital doctors may practise privately outside their normal hours, subject to their employers' approval. Hospital doctors work in private settings for an average of about five hours per week. The majority of private doctors work part-time (4331 – 27.5%); a smaller number work only privately (1611 – 10%). Most private doctors work from facilities rented from private chains or companies which have developed recently. We asked Kela about the distribution of private physicians working in private chains – whether the majority work for one or two companies – but this was not known. According to FMA numbers, the proportion of male and female full-time private physicians is similar in all age groups.<sup>84</sup> They work primarily in southern Helsinki; one third of all private doctors work in greater Helsinki. The majority of private physicians are 50 years or older.

<sup>81</sup> Instructions relating to results-based bonuses for health care centres for 2007 (Terveyskeskuksen Tulospalkkio-Ohjeet Vuonna, 2007).

<sup>82</sup> Commission for Local Authority Employers, 2005.

<sup>83</sup> One collective agreement is in force for occupational health doctors with a private sector service provider. This covers 20% of doctors in private occupational health care.

<sup>84</sup> For the youngest age group (aged 30 and under), however, the sample size was 6 so it is difficult to conclude whether this gender split was accurate.

- 2.141 Private doctors set their own fees endorsed by other stakeholders. Our discussion with the FMA established that the association endorsed private practice but is not involved in fee setting. The FCA was supportive of private doctors setting their own fees. Kela reimburses 60% of the fee for private consultations according to a fixed scale of charges and reimburses the cost of medicines prescribed in line with public practice.
- 2.142 Patients do not have the opportunity to choose the doctor assigned to treat them at health centres. Within private practice, patients can choose their doctor, specialist or hospital.<sup>85</sup> In general, higher socioeconomic groups tend to use private doctors and their services, generally in large urban centres and areas near public hospitals because the majority of private doctors have hospital posts.
- 2.143 In principle, the MSAH, NAMLA, social and health departments of the State Provincial Offices and local health authorities are responsible for monitoring the quality of private practice. Kela indicated that they were not aware of any systematic monitoring of practices.

#### Municipal health centres

- 2.144 Health service delivery is organized out of health centres. Often, services are offered in different locations. A health centre is owned by one municipality or may be owned jointly by more than one. Health centres are publicly owned and not-for-profit entities although municipalities may borrow money to finance their needs.
- 2.145 There are approximately 257 health centres. Physical size, staffing levels and types of specialists and other health-care professionals (e.g. public health nurses, social workers, physiotherapists, etc.) depend on the size of the population they serve and local circumstances. The average number of inhabitants per doctor is about 1500 to 2000.
- 2.146 Services offered range from outpatient care, inpatient care, preventive services, dental care, physiotherapy and occupational health care. Also, specific services cover maternity, child and school health care; care of the elderly and specific patient groups (e.g. clinics for diabetes or hypertension). The way in which services are offered is not clearly defined in legislation and is decided by the municipalities.
- 2.147 As well as consulting rooms for doctors and nurses, health centres have facilities for minor surgery and X-rays, a clinical laboratory and a

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<sup>85</sup> Häkkinen, 2005.

pharmacy. A health centre pharmacy stocks drugs for the inpatient services provided; drugs prescribed for use at home are purchased at retail pharmacies.

- 2.148 Doctors in health centres tend to be GPs. Nurses play an important role not only working with doctors but also carrying out their own consultations for services including measuring blood pressure, giving injections, maternal and child health, preventive services such as family planning, school and occupational health care and healthy living. Chronic diseases are managed by coordinated doctor/nurse teams headed by older, experienced physicians. We understand that nurses do not prescribe drugs.
- 2.149 We visited the Vallila Health Centre in Helsinki. Here, doctors and nurses have developed clinical guidelines for certain procedures such as the management and monitoring of pregnancy. Standardized guidelines are being developed but are not in place in all centres.
- 2.150 A programme for using prevention measures in the treatment of patients with cardiovascular diseases was launched in 1994, sponsored by Novartis Finland. The programme involves 60 health centres and 4 hospitals and covers about half of the Finnish population. About 20 quality indicators were identified, such as cholesterol levels and blood pressure. The programme requires regular audit of patient consultations, and this helps medical staff to improve local process models in the prevention and treatment of cardiovascular diseases. In 2005, about two thirds of participating health centres completed the audit, and the results suggest that participation in the quality programme led to somewhat better indicator results.<sup>86</sup>
- 2.151 Health centres use an electronic patient record system that includes information on patients' conditions and details of their medications. The system provides automatic reminders for repeat prescriptions but does not include OTC drugs. There is no information on drugs prescribed by private doctors or on herbal medicines that may interact with prescription or OTC drugs. Patients can request that medical records are shared and, in general, hospitals do follow up and share medical records with health centres. The system identifies which drugs have been prescribed but doctors must ask patients whether they have taken them.
- 2.152 Patients request preventative check-ups but health centres will initiate annual check-ups for patients with chronic conditions such as coronary heart disease, diabetes, high blood pressure and asthma.

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<sup>86</sup> Varilo et al., 2006.

2.153 Despite the initiative we observed at the Vallila Health Centre, there appears to be a lack of national-level guidance on disease-management programmes or on coordinated approaches to managing chronic conditions. We noted varying levels of communication and interaction between social and health services. In many municipalities, health and social services were merged into one organization but different approaches to work, sometimes even competition for resources, affect cooperation.

### Hospitals

2.154 There is a tight network of 21 hospital districts as well as 5 university hospital districts. Pharmaceuticals used in hospitals account for 20% of the total pharmaceutical expenditure.<sup>87</sup> Hospital pharmacies have soft budgets and pharmaceutical expenditures are also included in departmental budgets. We understand that an indicative budget was tried for beta interferon but phased out. There are about 24 hospital pharmacies and 224 medicine centres.<sup>88</sup>

2.155 Hospital pharmacies are required to have a drug formulary. There is no national standard guidance for these but ROHTO is developing guidance for expensive drugs. Pharmaceutical boards within hospitals and health centres assist purchasing decisions by evaluating and recommending medicines for entry into a formulary. Hospitals and health centres are obliged to hold stocks of medicines sufficient for six months of average consumption.<sup>89</sup> Under the current arrangement for procuring pharmaceuticals, contracts between hospitals and suppliers can last for two to three years.<sup>90</sup> The MSAH has initiated a project to develop cooperation between hospital districts for joint procurement of medicines.<sup>91</sup>

2.156 There is a developing trend for hospitals and health centres to group together to purchase pharmaceuticals. This can strengthen negotiating power and take advantage of economies of scale.<sup>92</sup> Purchases are made at district level (although there is bulk purchasing between a few

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<sup>87</sup> Pekurinen & Häkkinen, 2005.

<sup>88</sup> Ovaskainen, Airaksinen & Närhi, 2004.

<sup>89</sup> Around 100–800 active substances are found in a typical regional hospital formulary. Most hospitals stock around 150–800 active substances; a typical dispensary in a regional hospital would have around 100–1100 active substances. (Hermanson et al., 2005; Pekurinen & Häkkinen, 2005).

<sup>90</sup> Ovaskainen, Airaksinen & Närhi, 2004.

<sup>91</sup> Ovaskainen, Airaksinen & Närhi, 2004.

<sup>92</sup> Hospitals and municipal health centres either prepare or import medicines that are not commercially available (Pekurinen & Häkkinen, 2005).

districts) and by public tender.<sup>93</sup> Tenders should ensure safety and a sustainable supply of medicines. Hospital districts work with municipal authorities for primary health care, and municipalities, in the tendering process. New regulations on public competition appear to have reduced variations in discounts.<sup>94</sup>

## **Pharmacy operations in Finland**

### Association of Finnish Pharmacies

2.157 The Association of Finnish Pharmacies (AFP) represents the interests of pharmacy owners. Membership is voluntary but only about four pharmacies are not members. Traditionally, the association applies no self-regulation as this is covered by either the Medicines Act (1987) or government measures. Pharmacies in hospitals and universities have their own trade union and manage their own labour contracts. AFP is not involved in setting contracts. The trade union is responsible for contractual negotiations with employees.

2.158 About 70% of pharmacy owners are women. An owner is required to hold an MSc in pharmacy; approximately 10% hold a PhD. Employees generally hold a BSc. A typical pharmacy has one or two pharmacists with a master's degree and four to five with a bachelor's. Hospital pharmacy managers must have an MSc(Pharm.); medical centre managers are required to have either an MSc(Pharm.) or a BSc(Pharm.). In 2006 there were 600 independent and 200 subsidiary pharmacies, including university pharmacies (18 in outlets).<sup>95</sup> A pharmacy serves an average population of around 6500 inhabitants.

2.159 NAM regulates the control, inspection and supply of pharmacies. The licence is terminated when the owner reaches 68 years of age.<sup>96</sup> The AFP has no role in this process. About 95% of pharmacies move into the location of a previous pharmacy. The opportunity to move a pharmacy depends on factors such as career development. Professional development is mandated in the law. Pharmacies may own up to three subsidiaries, generally located in low-service areas. If a subsidiary's turnover exceeds 50% of the average pharmacy turnover, it becomes a pharmacy.

2.160 Pharmacies purchase medicines from two pharmaceutical wholesalers in Finland: Tamro Finland and Oriola Oy.<sup>97</sup> Wholesale prices are fixed

<sup>93</sup> Legislation is currently being reformed to meet EU directives (Suominen, 2006).

<sup>94</sup> Pekurinen & Häkkinen, 2005.

<sup>95</sup> Kostiainen, 2006.

<sup>96</sup> The licence cannot be sold or renewed (AFP, 2006).

<sup>97</sup> Pharmacies may also purchase PI, subject to NAM's approval (Kostiainen, 2006).

so these two companies compete with manufacturers on margins. There is a one-channel distribution system: these two companies cover orders and distribution. Wholesalers and manufacturers negotiate ex-factory prices but this information is not publicly available. The final wholesale margin is estimated to be 4% of the wholesale price.<sup>98</sup> Our discussions suggested a 2% to 4% range but we were unable to confirm this.

- 2.161 Pharmacies used to benefit from rebates on wholesale prices. In early 2006, an amendment to the Medicines Act required pharmaceutical companies to sell their medicines at the same price to all pharmacies; rebates and other benefits from drug procurement are not permitted.<sup>99</sup>
- 2.162 Retail prices are fixed and are a function of the wholesale price as shown in Table 2.3. Pharmacists are paid a flat fee of €0.42 for dispensing a drug and receive a regressive margin – the higher the wholesale price, the smaller the pharmacy margin. The average margin is around 24%.<sup>100</sup>
- 2.163 Pharmacies pay a fee to the state calculated on net drug sales including the pharmacy margin.<sup>101</sup> The tax was originally introduced to subsidize the cost of pharmacies in remote parts of the country and larger pharmacies pay a greater proportion of their turnover. The fee ranges from 0% to 11% but the average is 7%. The AFP reports that the average pharmacy fee collected was about €205 000 in 2005.<sup>102</sup> Average turnover was €3 million.
- 2.164 The pharmacy fee is collected and retained by the MOF.<sup>103</sup> University pharmacies make up 15% of the market share but they are exempt from the fee and pay income tax to the university. Small pharmacies pay less and therefore have higher margins. Other goods sold in pharmacies are not taxed for pharmacy fee purposes. The structure of the pharmacy fee is presented in Table 2.4.
- 2.165 The Finnish Pharmacists' Association (FPA) provided a breakdown of pharmacy costs: the majority were due to purchases (68%), staff salaries (12%) and pharmacy fee (6.6%), with the remaining covering rent and other expenses.

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<sup>98</sup> Martikainen, Kivi & Linnosmaa, 2005.

<sup>99</sup> Kostiaainen, 2006.

<sup>100</sup> AFP, 2006.

<sup>101</sup> In 2004 private pharmacies paid €116 million pharmacy fees to the state, up from €93.1 million in 2000. The aggregate of VAT and the pharmacy fee collected by the state accounts for about 13.8% of the medicine price.

<sup>102</sup> AFP, 2006.

<sup>103</sup> AFP, 2003.

**Table 2.3** Wholesale price and pharmacy margins

| Wholesale price (€) | Retail price excluding 8% VAT  |
|---------------------|--------------------------------|
| 0–9.25              | 1.5 wholesale price + €0.50    |
| 9.26–46.25          | 1.4 wholesale price + €1.43    |
| 46.26–100.91        | 1.3 wholesale price + €6.05    |
| 100.92–420.47       | 1.2 wholesale price + €16.15   |
| >420.47             | 1.125 wholesale price + €47.68 |

Source: AFP, 2006.

**Table 2.4** Structure of the pharmacy fee

| Pharmacy's annual turnover (€) | Pharmacy fee at lower limit | Fee % exceeding lower limit |
|--------------------------------|-----------------------------|-----------------------------|
| 672 662–784 398                | –                           | 6                           |
| 784 398–1 008 620              | 6 704                       | 7                           |
| 1 008 620–1 232 591            | 22 400                      | 8                           |
| 1 232 591–1 569 792            | 40 317                      | 9                           |
| 1 569 792–2 017 238            | 70 665                      | 9.5                         |
| 2 017 238–2 465 929            | 113 173                     | 10                          |
| 2 465 929–2 914 371            | 158 042                     | 10.25                       |
| 2 914 371–3 699 516            | 204 007                     | 10.5                        |
| 3 699 516–4 819 872            | 286 447                     | 10.75                       |
| >4 819 872                     | 406 886                     | 11                          |

Source: AFP, 2006.

2.166 The AFP's Annual Review for 2005 reported that the average number of prescriptions dispensed was close to 61 700. Pharmacy subsidiaries dispensed an average of about 20 000–25 000 and most pharmacies dispensed between 30 000 and 100 000 prescriptions. About 90 (15%) dispensed more than 100 000 prescriptions while 118 (20%) community pharmacies dispensed fewer than 30 000. Moves towards deregulation would impact on these small pharmacies. NAM raised this issue in their assessment of the pharmacy fee and this is discussed in Chapter 2.

2.167 Between 2001 and 2005, the number of prescriptions increased by 11.4% (37.8 million to 42.1 million). The total turnover in community pharmacies increased from €1419 million to €1820 million (estimated), a 28% increase. Their number remained stable over this period, implying that turnover to each pharmacy increased. The AFP attributes this growth to new and expensive medicines.

2.168 The majority of pharmacy sales are medicines. In 2004, 81% of sales were prescription medicines.<sup>104</sup> Cosmetics account for about 4.5% of

<sup>104</sup> AFP, 2006.

total revenue; medical devices are a small part of sales. Pharmacies are regulated indirectly so that sales of non-pharmaceutical products are taxed (at a rate that may render them unprofitable) if they exceed 15%. Pharmacists prepare about 15% of the medicines sold. Homeopathy is a small proportion of products sold but there is some evidence to suggest that complementary therapies are used among patients with cancer and children with chronic diseases.<sup>105,106</sup> Recent findings suggest that little is known about possible drug interactions with complementary therapies. Furthermore, health-care practitioners are not well-equipped to advise patients of possible adverse reactions.

- 2.169 Pharmacies provide dispensing and counselling services. About 90% of customers visit the same pharmacy each time. Pharmacies have computer systems that hold patient information for up to 13 months, and these can check for drug to drug (but not multi-drug ) interactions but do not include information on the use of OTC or herbal medicines.
- 2.170 Pharmacies provide discounts to war veterans and to those defined as permanent customers (criteria set by individual pharmacies) – up to 4% of patients registered with the pharmacy.

#### Pharmacists and the dispensing of medicines

- 2.171 The FPA represents pharmacists working in retail and hospital pharmacies and in the industry. About 50% of community, 20%–25% of industry and 5% of hospital pharmacists hold an MSc.<sup>107</sup> About 70%–75% of community, 10%–15% of hospital and 10% of those in the industry have a BSc. Of approximately 9000 members, 6000 are working, 1000 are students and 2000 have retired. Among working pharmacists, about 1000 hold a BSc and 5000 hold an MSc.
- 2.172 Contractual arrangements for community pharmacies involve direct negotiations with their trade union. Hospitals and the industry negotiate indirectly (as part of broader negotiations for all health professionals).
- 2.173 No public information is available on the cost allocation of the pharmacy margin. The gross monthly salary was €2300 for pharmacists with a BSc, €3300 for those with an MSc. The average gross monthly salary in Finland in 2005 was €1752.<sup>108</sup>

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<sup>105</sup> Salmenperä, 2002.

<sup>106</sup> Ernst, 1999.

<sup>107</sup> AFP, 2006.

<sup>108</sup> Statistics Finland, 2005.



- 2.174 Pharmacists provide drug information to patients and health-care professionals. A pharmacy's computer-based information system produces instructions for patients: checking for repeat prescriptions and drug (but not multi-drug) interactions. It does not hold information on OTC or herbal products. Since 1997, pharmacists have become involved in national health programmes such as those for diabetes and asthma.<sup>109</sup>
- 2.175 Ward pharmacists have a BSc(Pharm.). They issue drug bulletins and disseminate drug information to staff but are not involved in advising or training doctors or nurses. Few pharmacists are trained as clinical pharmacologists; those who are undertake academic or research roles rather than training doctors or nurses.
- 2.176 About 26 pharmacists are involved in a medication review system pilot project. This is part of a continuing education course (in cooperation with ROHTO) held at the University of Kuopio, coordinated and administered by a centre for training there. Another two courses have begun and two more are planned.
- 2.177 The FPA considers itself an important actor in the health system and would like to be more integrated. It has released a report on the need for more clinical pharmacologists and also recognizes the need for further education for specialists, currently provided by the pharmaceutical industry alone.
- 2.178 The law requires all pharmacists to update their professional knowledge.<sup>110</sup> However, there is no formalized system to count credits for continuing education or attendance at events. A recent study reported that access to training is a problem for about 20% of community pharmacists.<sup>111</sup> The FPA mentioned that industry promotion is restricted to educational activities.

### **Relationships within the regulatory framework for pharmaceuticals**

- 2.179 This report has presented a detailed overview of the regulatory, financing and provision mechanisms in place for pharmaceutical services in Finland. One important observation is that it has a fairly complex system, like most well-developed health systems. This is due in part to Finland's unique dual system of health-care financing, relative to other EU countries.

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<sup>109</sup> Pekurinen & Häkkinen, 2005.

<sup>110</sup> Ovaskainen, Airaksinen & Närhi, 2004.

<sup>111</sup> Savela, 2003.

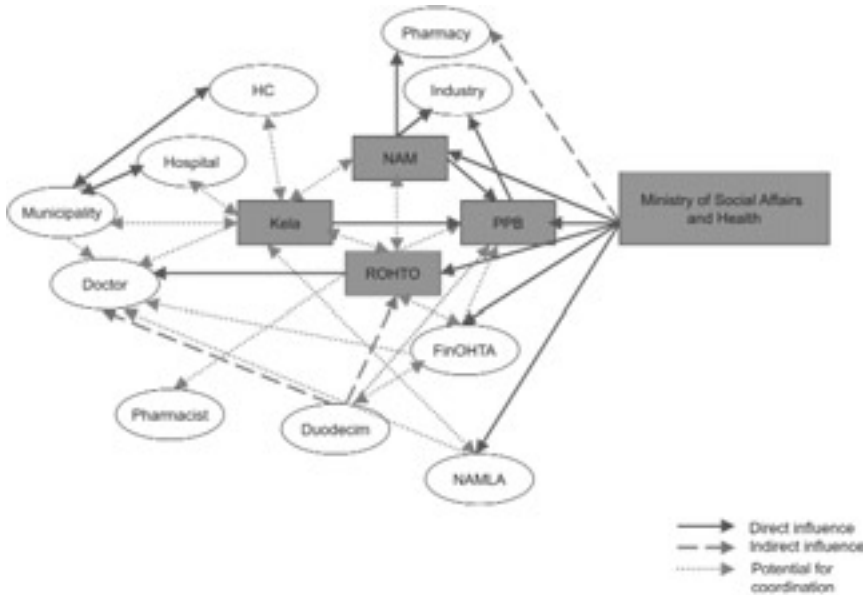
- 2.180 Our discussions with key stakeholders provided considerable insight into this complex relationship. Our assessment of this system is illustrated in Fig. 2.0 and Fig. 2.1.
- 2.181 Figure 2.0 provides an overview of government departments, organizations and institutions involved directly or indirectly in the pharmaceutical system. Solid lines indicate a direct influence on pharmaceutical policy, dotted lines show an indirect influence. MSAH and Kela have direct roles. Within MSAH, NAM and PPB have direct influence; other subordinate agencies play important but indirect roles. The MTI and certain departments within it play important but indirect roles (e.g. FCA). The solid arrows present direct regulatory relationships in policy influence, the dashed line represents indirect influence and the dotted lines present the potential for such relationships.
- 2.182 Figure 2.1 does not include all possible stakeholders. We have identified key relationships among a select number of important stakeholders. This diagram indicates strikingly that half of these relationships could be defined better and there is potential for greater coordination within the existing framework. The arrows between the four bodies in the middle of the diagram (NAM, PPB, ROHTO and Kela) indicate the potential for greater coordination between them and with MSAH.
- 2.183 NAM has a direct relationship with pharmacies, the industry and the PPB but potential for more coordination with Kela and ROHTO. PPB has a direct relationship with Kela, but potential for more collaboration with NAM. Furthermore, there is considerable opportunity for feedback on clinical guidelines, economic evaluation and evidence from ROHTO, FinOHTA and Duodecim.
- 2.184 ROHTO has potential for better coordination with NAM, Kela and PPB. Moreover, it could collaborate with FinOHTA and Duodecim to disseminate a larger evidence base to doctors and pharmacists. Kela is an extremely important data resource for drug expenditure and consumption in Finland. There is potential for greater collaboration with NAM, ROHTO, health centres and doctors. To maintain the clarity of the graph, the FCA's potential indirect influence on the following stakeholders is not indicated: NAM, PPB, industry, pharmacies, health centres, municipalities and doctors.

**Fig. 2.0** Regulatory arrangement of relevant bodies in the pharmaceutical system in Finland



Source: Authors' discussions with stakeholders.

**Fig. 2.1** Relationship between actors regulating the pharmaceutical system in Finland



Source: Authors' analysis.

Notes: Industry: Pharmaceutical industry includes originator companies, parallel importers, generic firms and wholesalers. Pharmacy includes community, hospital and health centre pharmacies. HC: Health centre.

2.185 It is important to address the outstanding issues of accountability within the existing dual-financing arrangement. This is problematic because doctors may be employed by municipalities or public and private enterprises (occupational health) or are self-employed but reimbursed by Kela. They can also work in both public and private sectors. These, and other, regulatory issues will be discussed in more detail in the following chapters.

## Chapter 3

# Trends in pharmaceutical expenditure and consumption

3.1 Discussion of the regulatory framework provides context for the current institutional framework of pharmaceutical policy. Trends in expenditure, user charges, consumption patterns and price trends provide a more comprehensive picture of some of the stylized facts of the pharmaceutical market in Finland. These issues are discussed below.<sup>112</sup>

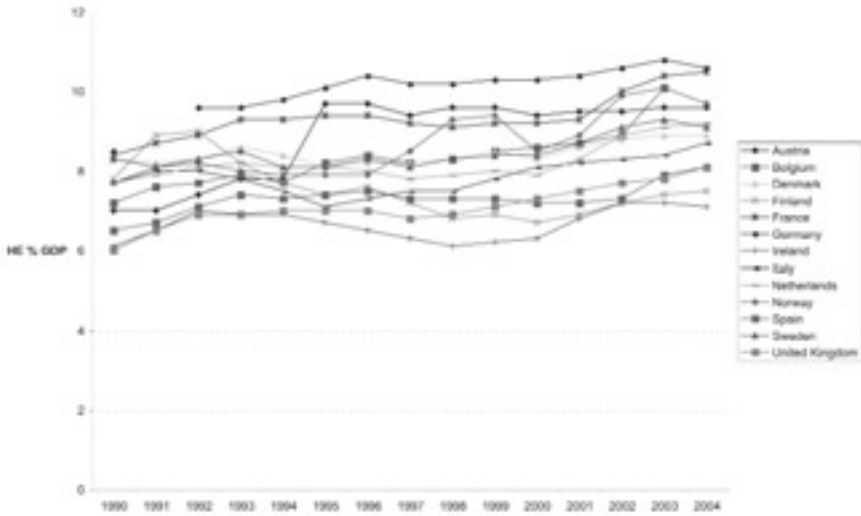
### Expenditure trends

- 3.2 Pharmaceutical expenditure has grown rapidly in Finland in the past decade and is the fastest growing component of total health expenditure. This is common in countries with well-developed health systems both within and outside Europe. This section provides an overview on selected indicators of pharmaceutical trends in Finland in order to convey a better sense of these changes and movements.
- 3.3 Total health expenditure as a proportion of Finland's GDP has been relatively low by international comparisons. Relative to other European countries it has been the second lowest since 1998 but has begun to increase steadily in recent years (Fig. 3.0).

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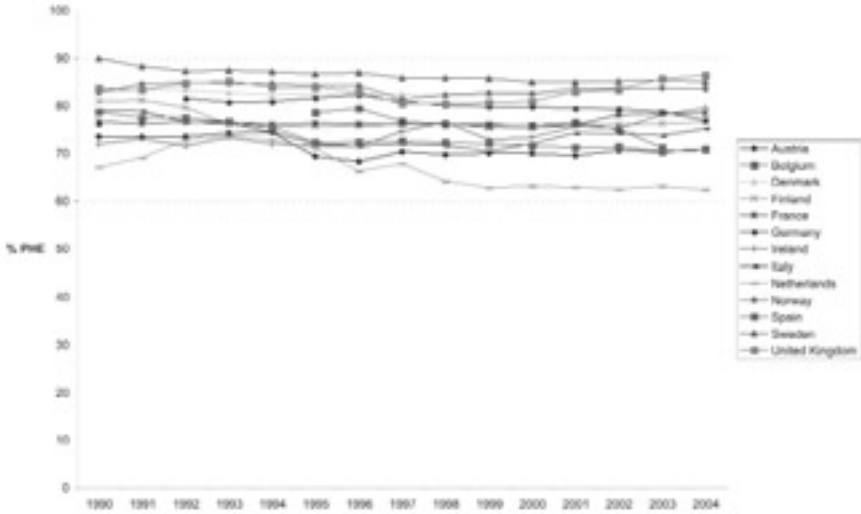
<sup>112</sup> We requested data from relevant stakeholders. These were not available for: inappropriate prescribing; recent medicine and public pharmaceutical expenditure; method patents; products per capita; prescription volume by physician occupation; volume growth of medicines (OTC, generic and branded); distributional impact of user charges; drug interactions and hospital admissions due to adverse events; prices of medicines where patients refused generic substitution; and summaries for prices and volumes of on-patent, off-patent and generic drugs.

**Fig. 3.0** Total health expenditure (HE) as percentage of GDP in selected countries, 1990–2004



Source: OECD, 2006a.

**Fig. 3.1** Public health expenditure (PHE) as percentage of total health expenditure in selected countries, 1990–2004



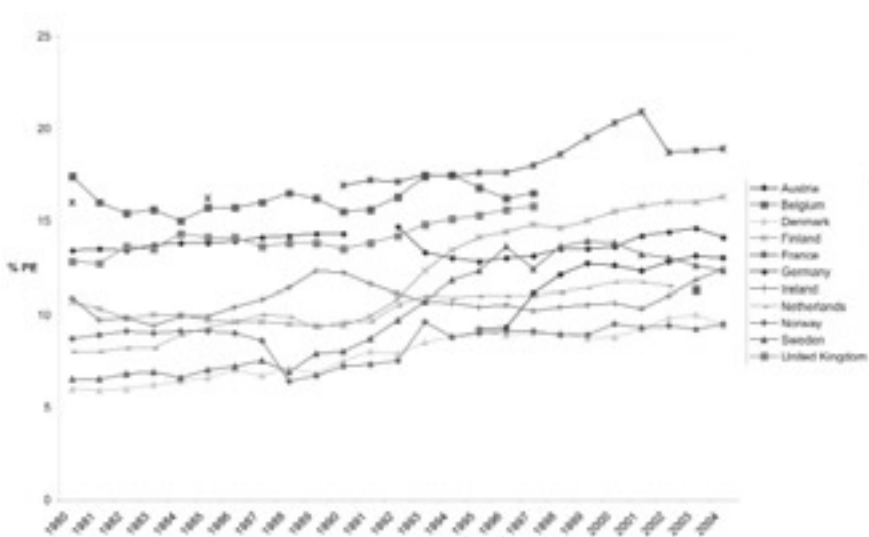
Source: OECD, 2006a.

3.4 The public share of total health expenditure in Finland has stayed close to 75% since the early 1990s. Finland ranks in the middle relative to other selected western European countries (Fig. 3.1). OECD data measure public expenditure as health expenditure covered by public funds.

**Table 3.0** Average annual nominal growth rate of pharmaceutical expenditure as a share of total health expenditure, 1990–2004

| Countries   | Growth rate |
|-------------|-------------|
| Finland     | 3.8%        |
| Sweden      | 3.2%        |
| Norway      | 2.6%        |
| Denmark     | 2.3%        |
| Netherlands | 1.7%        |
| France      | 0.9%        |
| Ireland     | 0.1%        |
| Italy       | -0.1%       |
| Germany     | -0.3%       |
| Spain       | -0.6%       |

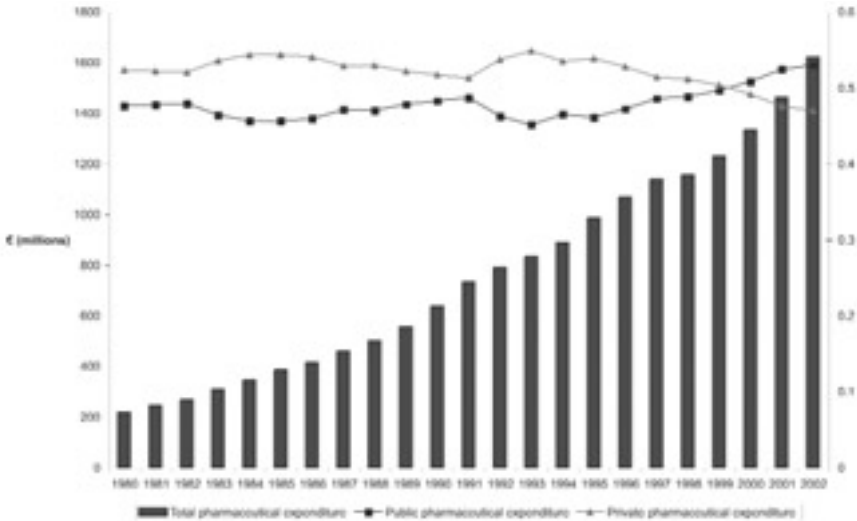
Source: OECD, 2006a.

**Fig. 3.2** Pharmaceutical expenditure (PE) as percentage of total health expenditure in selected countries, 1980–2004

Source: OECD, 2006a.

3.5 A different picture emerges for pharmaceutical expenditure. Finland had the fastest average annual growth rate as a share of total health expenditure (in nominal terms) between 1990 and 2004 at around 3.8% (Table 3.0). As a proportion of total health expenditure pharmaceutical expenditure was second highest in Finland, accounting for close to 16.3% in 2004 (Fig. 3.2).

**Fig. 3.3** Total pharmaceutical expenditure and share of private and public expenditure, 1980–2002



Source: Kela, 2002.<sup>114</sup>

3.6 These figures show an increasing rise in both the level and share of pharmaceutical expenditure in Finland, but it is useful to consider the rate at which pharmaceutical expenditure has grown. Between 1994 and 2003, pharmaceutical expenditure grew at an average annual rate in real terms of 5.4% (7.4% nominally).<sup>113</sup> In comparison with Denmark, France and Germany (countries with data available for this period), Finland had the highest nominal and real growth rates. High growth rates in the past could suggest similar trends in the future. Indeed, a simple linear projection until 2010 based on data from 1990 to 2003 suggests that the real average annual growth could be 4.2% (5.4% nominally). The high growth rates observed have implications for the distribution of the public and private shares of pharmaceutical expenditure.

3.7 The composition of public and private expenditure provides useful information on total pharmaceutical expenditure. Data for Finland suggest that private expenditure accounted for a slightly larger proportion than public (Fig. 3.3): just over 50% in the past two decades. At the beginning of 2000 the trend reversed as in 2002 public expenditure accounted for 53%. Furthermore, if the contribution and

<sup>113</sup> Total pharmaceutical expenditure data were the sum of prescription and OTC medicines. Data in national currency units at constant GDP prices (base year 2000) were used to calculate the real growth rate; the nominal growth rate used data in national currency units at current prices (OECD, 2006a).

<sup>114</sup> Data beyond 2002 were requested but not available.



**Table 3.1** *Time series data on pharmaceutical expenditure, 1980–2002*

| Year | Total expenditure<br>(€ million) | Per capita<br>expenditure<br>(€ 2000 prices) | Annual change of per<br>capita expenditure<br>at 2000 prices | Pharmaceutical<br>expenditure<br>(% of GDP) |
|------|----------------------------------|--|--|---|
| 1980 | 219                              | 76   | –  | 0.7   |
| 1981 | 246                              | 80   | 4.4  | 0.7   |
| 1982 | 267                              | 81   | 1.9  | 0.6   |
| 1983 | 309                              | 89   | 9.1  | 0.7   |
| 1984 | 345                              | 93   | 5.2  | 0.7   |
| 1985 | 385                              | 100  | 6.9  | 0.7   |
| 1986 | 416                              | 104  | 4.0  | 0.7   |
| 1987 | 459                              | 112  | 8.2  | 0.7   |
| 1988 | 502                              | 120  | 7.1  | 0.7   |
| 1989 | 557                              | 129  | 7.6  | 0.7   |
| 1990 | 638                              | 140  | 8.2  | 0.7   |
| 1991 | 734                              | 154  | 9.8  | 0.9   |
| 1992 | 791                              | 162  | 5.1  | 1.0   |
| 1993 | 833                              | 168  | 3.7  | 1.0   |
| 1994 | 890                              | 176  | 4.9  | 1.0   |
| 1995 | 987                              | 192  | 9.5  | 1.0   |
| 1996 | 1069                             | 207  | 7.4  | 1.1   |
| 1997 | 1138                             | 219  | 5.9  | 1.1   |
| 1998 | 1156                             | 223  | 1.8  | 1.0   |
| 1999 | 1231                             | 236  | 6.2  | 1.0   |
| 2000 | 1333                             | 258  | 9.0  | 1.0   |
| 2001 | 1465                             | 282  | 9.4  | 1.1   |
| 2002 | 1621                             | 309  | 9.7  | 1.2   |

Source: Kela, 2006.

share of VAT and the pharmacy fee were deducted from government revenue, then public expenditure would likely be lower than private. The OECD measures private expenditure as sources of funds that include OOP payments (OTC and cost-sharing), private insurance programmes, charities and occupational health care.

3.8 Table 3.1 provides information on pharmaceutical expenditure.<sup>115</sup> In nominal terms pharmaceutical expenditure grew at an average rate of about 10% between 1980 and 2002. However, in real terms per capita pharmaceutical expenditure grew at an annual rate of about 7%. It is noteworthy that real per capita expenditure grew during Finland's recession in the early 1990s. As a share of total health expenditure, pharmaceutical expenditure grew from about 10% to 16% between 1980 and 2002. Similarly, pharmaceutical expenditure as a share of GDP grew from 0.7% to 1.2%.

<sup>115</sup> Excludes hospital expenditure.

- 3.9 During this period, VAT dropped from 12% to 8% in 1998. This partly explains the reduction in total pharmaceutical expenditure and the low growth in real per capita terms (1.8%) in that year. It appears that this was an isolated reduction because real per capita expenditure continued to grow after 1998.
- 3.10 As a share of GDP pharmaceutical expenditure in Finland remained below the OECD average. The opposite was true for total health expenditure. In level terms, Finland (16.3%) was above the Nordic average (12%) and closer to the OECD average (17.6%) by 2004.<sup>116</sup>
- 3.11 NAM provided a breakdown of drug sales for 2005. Total pharmaceutical sales were €2.4 billion: €1.75 billion for prescription medicines in outpatient care; €360 million in sales to hospitals; €319 million for OTC medicines.<sup>117</sup> All figures (except hospital sales) were retail prices. The Association of the European Self-Medication Industry reported a lower estimate for OTC sales (€282 million).
- 3.12 Finland entered a recession in 1990: real GDP per capita fell for four consecutive years, reaching 87% of its 1990 value by 1994.<sup>118</sup> Since then, total health expenditure as a share of GDP has fallen steadily – from 9% in 1992 to 7.5% in 2004. In 2004, this was below the Nordic (8.8%) and OECD (8.9%) averages.<sup>119</sup>
- 3.13 The recession coincided with health care being devolved to the municipalities in 1993. Health-care financing from municipal taxes increased but state subsidies decreased, mainly because of the sharp increase in unemployment expenditure and a decrease in tax revenues in the state budget.<sup>120</sup> During the recession, revenue-raising capacity was reduced for the municipalities and the state.<sup>121</sup> Both exercised fiscal discipline which resulted in a reduction in total health expenditure over this period. After the recession, continued fiscal control at municipal level dampened total health expenditure until 2000, despite strong growth in GDP.<sup>122</sup> The share of health expenditure borne by municipalities and the state fell from 70% to 60% by 2003; Kela's expenditure increased from 11% to 17%.<sup>123</sup>

<sup>116</sup> For countries without 2004 estimates the following were used: 2003 – Belgium, Germany, Japan, Slovakia; 2002 – Australia, Czech Republic, Hungary, Netherlands. Turkey and the United Kingdom were excluded because data were before 2000 (OECD, 2006a).

<sup>117</sup> NAM, 2007.

<sup>118</sup> OECD, 2005.

<sup>119</sup> 2003 estimates were used for countries without 2004 estimates: Australia, Belgium, Germany, Japan and Slovakia (OECD, 2006a).

<sup>120</sup> During this period, net government borrowing also increased (Häkkinen, 2005).

<sup>121</sup> Häkkinen, 1999.

<sup>122</sup> OECD, 2005.

<sup>123</sup> OECD, 2005.

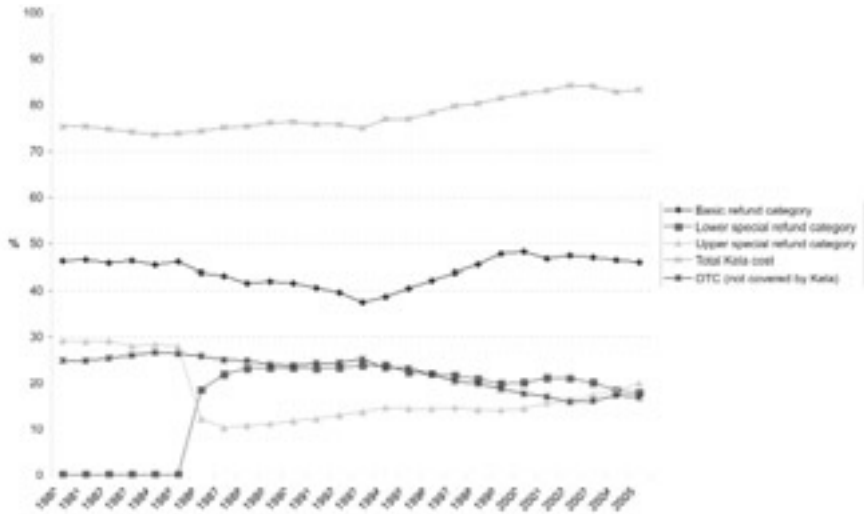
**Table 3.2** *Public expenditure on pharmaceuticals in outpatient care, 1980–2003*

| Year | Total public expenditure<br>(€ million) | Pharmaceutical expenditure as % of public expenditure | Public pharmaceutical expenditure as % of total pharmaceutical expenditure | Kela expenditure as % of pharmaceutical expenditure |
|------|---|---|--|---|
| 1980 | 104.3                                   | 6.3   | 47.7   | 63.4  |
| 1981 | 117.6                                   | 6.1   | 47.9   | 63.6  |
| 1982 | 128.0                                   | 5.7   | 48.0   | 64.3  |
| 1983 | 143.4                                   | 5.7   | 46.4   | 62.7  |
| 1984 | 157.5                                   | 5.6   | 45.6   | 62.1  |
| 1985 | 175.6                                   | 5.5   | 45.7   | 61.9  |
| 1986 | 191.1                                   | 5.4   | 45.9   | 61.8  |
| 1987 | 216.2                                   | 5.6   | 47.1   | 62.7  |
| 1988 | 236.1                                   | 5.5   | 47.1   | 62.5  |
| 1989 | 266.5                                   | 5.5   | 47.9   | 62.9  |
| 1990 | 308.2                                   | 5.5   | 48.3   | 63.3  |
| 1991 | 357.6                                   | 5.9   | 48.7   | 64.2  |
| 1992 | 366.1                                   | 6.2   | 46.3   | 61.1  |
| 1993 | 376.0                                   | 7.2   | 45.1   | 60.3  |
| 1994 | 413.7                                   | 8.1   | 46.5   | 60.4  |
| 1995 | 455.3                                   | 8.4   | 46.1   | 60.0  |
| 1996 | 504.8                                   | 8.8   | 47.2   | 60.3  |
| 1997 | 553.1                                   | 9.3   | 48.6   | 60.9  |
| 1998 | 564.9                                   | 9.2   | 48.9   | 60.9  |
| 1999 | 611.3                                   | 9.8   | 49.7   | 61.0  |
| 2000 | 677.8                                   | 10.4  | 50.9   | 61.7  |
| 2001 | 768.2                                   | 10.7  | 52.4   | 63.1  |
| 2002 | 859.4                                   | 11.1  | 53.6   | 63.7  |
| 2003 | 917.5                                   | –   | –  | 64.5  |

Source: Kela, 2006.

- 3.14 The rise in pharmaceutical expenditure was due largely to the rise in volume (cost at constant prices) per user between 1980 and 2000.<sup>124</sup> Per capita, the annual increase of pharmaceutical expenditure at constant prices grew faster than both GDP and total health expenditure almost every year over this period.
- 3.15 With devolution to municipalities and fiscal restraint, public expenditure on pharmaceuticals grew but was due mainly to the increase in Kela's expenditure on pharmaceuticals. This grew from 60% in 1995 to 65% in 2003.
- 3.16 Table 3.2 provides a summary of the implications for public financing of pharmaceuticals. Public expenditure increased at an average annual rate of 10% in nominal terms, similar to the growth rate of total

<sup>124</sup> Pekurinen & Häkkinen, 2005.

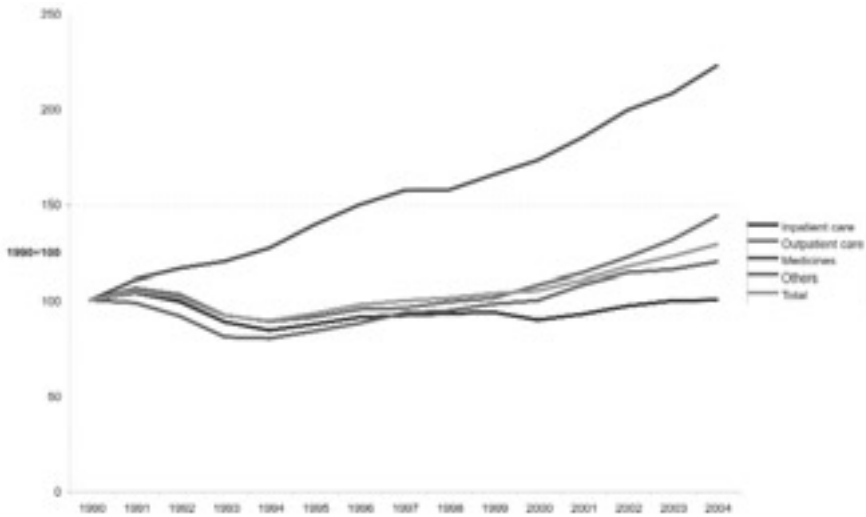
**Fig. 3.4** *Kela's reimbursement costs, 1980–2005*

Source: Kela, 2006.

pharmaceutical expenditure. This high growth affected the share of public funds available – public health expenditure on pharmaceuticals increased from 5.5% in 1990 to 11% in 2002.<sup>125</sup> The increase in Kela's share is also highlighted in Table 3.2. Public pharmaceutical expenditure covered by Kela was about two thirds – growth was just under 7% between 1993 and 2003. Public expenditure accounted for about half of total pharmaceutical expenditure, increasing by 8.5% between 1993 and 2002 (45.1% to 53.6%). Despite this growth there was a reduction in reimbursement levels. The interaction of these changes on user charges and access has not been studied and should be conducted.

- 3.17 Figure 3.4 illustrates Kela's reimbursement costs according to the three reimbursement levels. Prescription costs do not include hospital data. The trend suggests that while the basic reimbursement category accounts for the largest share of Kela's reimbursement costs, its share has remained fairly steady since 2000. The special refund categories, particularly the higher, have increased steadily.
- 3.18 Some OTC medicines qualify for reimbursement if they are used for long-term treatment but, generally, these medicines are not reimbursed. OTC medicines' share of total pharmaceutical expenditure fell over time but has risen slightly since 2003 (Figure 3.4).

<sup>125</sup> Average annual growth rate of less than 3%.

**Fig. 3.5** Breakdown of trends in health expenditure in Finland, 1990–2004 (1990=100)

Source: Kela, 2006.

- 3.19 Kela's reimbursements grew from 2004. The highest special refund category experienced the largest growth of 12.8% to €370 million in 2005.<sup>126</sup> The basic refund category grew by 2.7% to a total of €370 million. The lower special refund category remained steady (0.2% drop from 2004) at €237 million. Reimbursement payments for those who hit the annual ceiling grew similarly to the highest special refund category – by 12.5% to close to €100 million in 2005.
- 3.20 The volume increase (cost per user) is driven by factors such as the number of prescriptions dispensed; number of users; reductions in inpatient and institutional care; and the value of prescriptions dispensed (i.e. new and expensive drugs with varying effectiveness).<sup>127</sup>
- 3.21 It is reported that the main factor driving up medication-use costs is the arrival of replacement drugs.<sup>128</sup> For example, in recent years the costs of treating psychoses have soared dramatically in Finland. In 2005, around 64% of all neuroleptics were new medications which accounted for 91% of the total cost for neuroleptics. Expensive new medicines are increasingly available for cardiovascular diseases, diabetes, asthma, cancer and certain hormone deficiencies. The rising cost of medicines relative to other health services is presented in Fig. 3.5.

<sup>126</sup> Kela, 2005.

<sup>127</sup> Deinstitutionalization may have been a factor – responsible for about 6% of the increase in pharmaceutical expenditure between 1990 and 2002 (OECD, 2005; Häkkinen, personal communication).

<sup>128</sup> Klaukka, 2006.

**Table 3.3** Prescription trends, 1980–2005

| Year | Prescriptions per capita | Prescriptions per capita reimbursed by Kela | Proportion of population reimbursed by Kela (%) |
|------|--------------------------|---|---|
| 1980 | 4.9                      | 4.3   | 62.8  |
| 1981 | 5.1                      | 4.2   | 64.5  |
| 1982 | 5.1                      | 4.3   | 64.2  |
| 1983 | 5.3                      | 4.5   | 65.5  |
| 1984 | 5.3                      | 4.4   | 62.9  |
| 1985 | 5.6                      | 4.6   | 65.4  |
| 1986 | 5.5                      | 4.6   | 65.1  |
| 1987 | 5.8                      | 4.9   | 66.6  |
| 1988 | 5.9                      | 4.7   | 64.9  |
| 1989 | 5.9                      | 4.6   | 66.0  |
| 1990 | 6.1                      | 4.9   | 65.3  |
| 1991 | 6.3                      | 5.1   | 66.5  |
| 1992 | 6.0                      | 4.9   | 64.7  |
| 1993 | 5.9                      | 4.6   | 63.6  |
| 1994 | 5.8                      | 4.4   | 61.4  |
| 1995 | 6.0                      | 4.5   | 63.0  |
| 1996 | 6.3                      | 4.7   | 63.9  |
| 1997 | 6.4                      | 4.8   | 63.9  |
| 1998 | 6.6                      | 5.0   | 63.0  |
| 1999 | 6.8                      | 5.0   | 63.4  |
| 2000 | 7.3                      | 5.2   | 64.2  |
| 2001 | 7.3                      | 5.3   | 64.8  |
| 2002 | 7.4                      | 5.4   | 64.4  |
| 2003 | 7.7                      | 5.4   | 63.1  |
| 2004 | 7.8                      | 5.5   | 62.5  |
| 2005 | 8.0                      | 5.5   | 62.1  |

Source: Kela, 2006.

- 3.22 We were unable to analyse the relative importance of key factors in pharmaceutical expenditure. This requires more detailed data to separate the effect of prices, volumes, product mix and changes in disease/population patterns.
- 3.23 The number of prescriptions dispensed per capita was relatively stable (Table 3.3), growing at an average annual rate of 2%. The number of prescriptions per capita reimbursed by Kela remained steady over this period (1% average annual growth rate). Similarly, the population reimbursed by Kela did not fluctuate.
- 3.24 The distribution of the user population shows rising numbers of those receiving higher special reimbursements and those exceeding the annual ceiling. Kela's figures show 828 200 recipients in the lower special refund category in 2005, growing by 1.3% from 2004. There were 454 500

recipients in the higher special refund category in 2005, a growth of 3.9%. There was a small drop (-0.4%) in the number of users in the basic refund category at 3 100 200. The number of users exceeding the annual ceiling experienced the largest growth (5.8%) – to 167 600 in 2005.

- 3.25 The unit amounts of prescriptions dispensed did not fluctuate although the average cost per prescription increased. In 2005 the average cost was €56 up from the previous year of €54. The value of prescriptions dispensed depends on the drugs accounting for the largest share of the bill. Data suggest that a small number of new and expensive therapies contributed significantly to the drugs bill: the ten top-selling drugs between 2000 and 2004 accounted for about 40% of the growth in pharmaceutical expenditure; half of these had been newly introduced.<sup>129</sup> This is discussed further in the section on consumption trends.
- 3.26 These trends suggest that one of the main factors contributing to the increase in pharmaceutical expenditure is the value of the top-selling drugs in the Finnish market. The use of generics has the potential to slow this growth. A review of the European market indicates that Finland's generic market is very small by value (7.6%) and by volume (13.2%).<sup>130</sup> Finland ranks in the lowest category of generic penetration with just over 10% by volume, similar to countries such as France, Ireland and Belgium. Denmark, Germany, the Netherlands, Sweden and the United Kingdom are examples of countries with a market share of 10%–40%. The data show the potential for increasing the generics market in Finland.
- 3.27 During our meetings it was common for Finland's small generic market to be attributed to the country's size. However, bigger countries such as France and Spain have small generic markets while Denmark's is sizeable. Examination of the data does not reveal the relative importance of country size and policies that encourage generic prescribing. Finland could encourage generic prescribing by introducing measures to stimulate demand-side cost-awareness; changing doctors' attitudes and the level of patient co-payments; and providing incentives for generic prescribing and dispensing. Countries that have sizeable generic markets have introduced measures such as

<sup>129</sup> Of these drugs, four treat cardiovascular conditions, two are antipsychotic drugs, two treat respiratory disease, one is a PPI and one is an immunosuppressant (OECD, 2005).

<sup>130</sup> The extent of generic penetration depends on a variety of factors: their pricing and reimbursement systems; patient co-payments; the attitudes and prescribing behaviours of doctors towards generic medicines; regulations for pharmacists to dispense generics, and conditions for market authorizations (European Generic Medicines Association, 2005).

medical education and training in generic prescribing for physicians (United Kingdom); profit caps on the overall revenue of the pharmacy market (Denmark); and lower level co-payments for generic medicines (United States).

- 3.28 In April 2003, a policy measure was introduced to slow the growth in the drugs budget by introducing generic substitution in Finland. This was intended to promote cost-effective drug therapies to increase competition between pharmaceutical companies and thereby produce cost savings. Generic substitution means that a pharmacy dispenses the cheapest, or close to the cheapest, generic alternative for a prescribed medicinal product.<sup>131</sup> Finland has a policy to encourage product prices to differ by only a few euros – the price corridor.<sup>132</sup>
- 3.29 According to Kela data, savings from substitution and drug price reductions in the first year generated savings of around €88 million.<sup>133</sup> Patients' share of the savings was €39 million (44%) and €49 million in reimbursement payments were saved. The amount saved was about 6% of the total cost of all reimbursed medicines. Savings generated from the introduction of this policy are presented in (Table 3.4). After the first year, savings were calculated from substitution alone,<sup>134</sup> comparing prices between the dispensed and the prescribed product.
- 3.30 Savings on the total cost of reimbursed medicines remained steady at around 2%. The number of prescriptions dispensed also remained steady at roughly 12%. The number of patients with at least one substitution did not fluctuate significantly. This policy allows both physicians and patients to refuse substitutions. Drugs were not substituted in many (around 74%) cases because the physician had prescribed the cheapest, or close to the cheapest, generic alternative. Around 11% of patients refused substitutions.<sup>137</sup>

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<sup>131</sup> Kela, 2007.

<sup>132</sup> A medicinal product's price is considered to be close to the cheapest when the price difference to the cheapest substitutable medicinal product, costing less than €40, is less than €2; less than €3 when the cheapest substitutable medicinal product costs €40 or more.

<sup>133</sup> Savings from price reductions were calculated by comparing the prices of the dispensed and the prescribed products valid in March 2003, before the introduction of generic substitution (Kela, 2007).

<sup>134</sup> According to Kela, savings from price reductions cannot be calculated because product selection and drug price levels changed dramatically after the implementation of generic substitution. As several original products have been withdrawn from the market and several new generic products have been launched, many dispensed products have no comparison prices valid before the introduction of generic substitution.

<sup>137</sup> The physician population remained stable over this period (< 0.5% change).



**Table 3.4** Savings generated through generic substitution, 2003–2006 (€ millions)

|   | 2003    | 2004    | 2005    | 2006 <sup>135</sup> |
|---|---------|---------|---------|---------------------|
| Substitution  |         |         |         |                     |
| For the patient   | 12.7    | 13.7    | 12.0    | 14.8                |
| For the drug reimbursement  | 16.0    | 16.9    | 13.8    | 14.6                |
| Total   | 28.8    | 30.5    | 25.7    | 29.4                |
| Substitution and reduced drug prices                              |         |         |         |                     |
| For the patient   | 39.2    | N/A     | N/A     | N/A                 |
| For the drug reimbursement  | 49.1    | N/A     | N/A     | N/A                 |
| Total   | 88.3    | N/A     | N/A     | N/A                 |
| Savings as % of total cost of reimbursed medicines <sup>136</sup> | 2.0     | 2.0     | 1.6     | 2.3                 |
| Prescriptions that generated substitution (%)                     | 12.6    | 12.0    | 11.5    | 12.2                |
| Number of patients with at least one substitution                 | 708 553 | 691 222 | 751 593 | N/A                 |

Source: Kela, 2006.

- 3.31 One study on the use of generic substitution reported that most patients and physicians supported this reform measure to increase savings.<sup>138</sup> The main reason for patients' refusal of substitutions was positive experiences with medicines they had used before. About half of all physicians felt that not all substitute products were equally effective or safe.
- 3.32 In our discussions with Kela it was noted that new generic products have low prices at launch and therefore offer small savings from price reductions. Kela estimates that savings for the coming year will be in line with last year. A Canadian study reported that generics' prices in Finland declined by 23.9% between 2002 (generic substitution introduced) and 2005.<sup>139</sup> This is a significant drop but, as we discuss below, generic market penetration is low.
- 3.33 The size of the generic market and the number of competitors have implications for the degree of price competition. We requested data on generic substitution in order to analyse competition in the generics market. Data from Kela indicate that just under half (411 or 45%) of the potential substitutable products had no generic competitors (Table 3.5). The prescribed product had no competitor in 14% of prescriptions; by value these accounted for 18% of all prescriptions.
- 3.34 In Table 3.5, column one refers to the number of products including the originator. This means that where there are two products, there is

<sup>135</sup> Published data available until November 2006.

<sup>136</sup> Savings from substitution only. In 2003, savings from substitution and price reductions were 6%; the 2% figure only arises from substitution alone.

<sup>138</sup> Heikkilä et al., 2007.

<sup>139</sup> Patented Medicine Prices Review Board, 2006.

**Table 3.5** Prescriptions<sup>a</sup> and costs of reimbursable substitutable products, 2003–2004

| No. of products      | Substitution groups <sup>b</sup> | Prescriptions for substitutable products reimbursed | %          | Prescription costs (€) | %          | No. of substitutions | %         | No. of patient refusals | %         |
|----------------------|----------------------------------|---|------------|------------------------|------------|----------------------|-----------|-------------------------|-----------|
| 1                    | 411                              | 1 786 590   | 14         | 84 877 028             | 18         | 442                  | 0         | 1 275                   | 0         |
| 2                    | 272                              | 3 372 007   | 27         | 145 003 727            | 30         | 159 213              | 5         | 237 843                 | 7         |
| 3                    | 109                              | 2 116 741   | 17         | 96 855 381             | 20         | 293 857              | 14        | 222 693                 | 11        |
| 4                    | 35                               | 1 173 862   | 9          | 26 152 176             | 5          | 127 910              | 11        | 80 185                  | 7         |
| 5                    | 20                               | 625 926   | 5          | 15 688 158             | 3          | 74 997               | 12        | 55 522                  | 9         |
| 6                    | 23                               | 890 069   | 7          | 22 678 965             | 5          | 169 735              | 19        | 132 883                 | 15        |
| 7                    | 12                               | 389 102   | 3          | 12 038 850             | 2          | 119 578              | 31        | 121 152                 | 31        |
| 8                    | 14                               | 668 524   | 5          | 21 721 547             | 5          | 235 255              | 35        | 209 978                 | 31        |
| 9                    | 6                                | 208 348   | 2          | 10 204 652             | 2          | 78 947               | 38        | 44 721                  | 21        |
| 10                   | 7                                | 499 231   | 4          | 17 426 001             | 4          | 157 062              | 31        | 90 424                  | 18        |
| 11                   | 3                                | 323 793   | 3          | 18 154 639             | 4          | 93 890               | 29        | 71 148                  | 22        |
| 12                   | 1                                | 145 033   | 1          | 4 547 793              | 1          | 38 981               | 27        | 35 802                  | 25        |
| 13                   | 1                                | 47 630  | 0          | 859 939                | 0          | 12 228               | 26        | 16 608                  | 35        |
| no data <sup>c</sup> |                                  | 147 298   | 1          | 5 619 753              | 1          | 2 143                | 1         | 2 312                   | 2         |
| <b>Total</b>         | <b>914</b>                       | <b>12 394 154</b>                                   | <b>100</b> | <b>481 828 610</b>     | <b>100</b> | <b>1 564 238</b>     | <b>13</b> | <b>1 322 546</b>        | <b>11</b> |

<sup>a</sup> Prescription: one prescribed medicinal preparation purchased during one transaction.

<sup>b</sup> Price list at 15 March 2004; only substitution groups with reimbursed prescriptions.

<sup>c</sup> Products not substitutable at 15 March 2004.

Source: PPB, 2006.

one additional licensed product besides the originator. There is little price competition because every prescription will likely fall under the price corridor (€2–€3). Combining the top two rows gives 683 substitutable products: this suggests that about 75% of potential substitutable products have no, or only one, competitor; about 41% of prescriptions face little competition, and their value accounted for 48% of all prescriptions. It is not clear to what extent a substitution policy will increase savings through price competition. This is partly because of the current low level of generic penetration in the Finnish market.

- 3.35 We noted that NAM reported €319 million in retail prices for pharmacy sales of OTC products. The Association of the European Self-Medication Industry reported €282 million in wholesale prices, accounting for less than 12% of the total pharmaceutical market.<sup>140</sup> Sales at consumer level (includes wholesale and retail margins and VAT) are lower relative to other EU countries. Many OTC products available in other EU countries remain on prescription in Finland (e.g. anti-inflammatory products).<sup>141</sup>
- 3.36 One study on physicians' attitudes to products changing from prescription to OTC suggests that Finnish doctors are moderately supportive. However, they are cautious of drugs with recent OTC status.<sup>142</sup> Doctors' opinions were influenced by the current OTC status of a drug; public discussion; place of work; case mix; and patient load. GPs working in health centres supported drugs for self-medication more than other physicians.

### **Out-of-pocket payments and user charges**

- 3.37 User charges finance a significant portion (about 20%) of total health-care expenditure in Finland. This is relatively much higher than in other industrialized countries.<sup>143</sup> Finland's recession impacted on household expenditure on health care: increasing from 13% to 20% between 1991 and 1993. After 1993, the household share for health care remained stable at around 20%. The increase was due largely to the removal of a tax deduction on medical expenses in 1992 and an increase in user charges in municipal health services in 1993.<sup>144</sup>

<sup>140</sup> European Self-Medication Industry, 2007a.

<sup>141</sup> European Self-Medication Industry, 2007b.

<sup>142</sup> Sihvo & Hemminki, 1999.

<sup>143</sup> Pekurinen & Häkkinen, 2005.

<sup>144</sup> Häkkinen, 2005.

- 3.38 As mentioned above, Kela's increased share in health-care financing (11% in 1990 to 17% in 2003) was due mainly to reimbursements for medicines. The increase in OOP payments resulted from the legislative change that reduced reimbursement levels and increased the annual ceiling on OOP payments.
- 3.39 Growth in pharmaceutical expenditure affected the share of household health-care financing. In absolute and in relative terms, household health expenses for prescribed medicines increased from 20% to 26% between 1990 and 1999.<sup>145</sup> Furthermore, the household share of payments for prescribed medicines has varied between 37% and 40% since 1980. It is reported that patients facing high medical expenses have sought assistance through the social welfare system.<sup>146</sup>
- 3.40 There have been no studies on the effect of user charges and their relationship with utilization and access in Finland. However, results from a 1995/1996 health-care survey indicate that about 6% of families were obliged to discontinue or reduce their use of medicines.<sup>147</sup> One study on coronary heart disease suggests that these patients have twice the average health-care expenses, mainly due to the cost of prescribed medicines.<sup>148</sup> A survey of people with diabetes found that the total cost of their medications was 3.5 times higher than for those without. The higher costs were explained by the prevalence of comorbidities and the need for medications other than diabetic treatments.<sup>149</sup>
- 3.41 Pharmaceutical expenses tend to be concentrated largely on chronically ill persons. Table 3.6 provides a summary of the reimbursement of medicine costs to provide a sense of OOP payments. Between 2002 and 2005, Kela's reimbursement costs grew at an average annual rate of around 8% in nominal terms. However, Kela's reimbursement share remained stable: increasing slightly to around two thirds for Kela and decreasing slightly to around one third for patients. The total number of recipients did not fluctuate. At the individual level, the real effect of rising pharmaceutical expenditure is clearer: share per recipient increased in real terms from €149 to €160 (2005 base year).

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<sup>145</sup> Häkkinen, 2005.

<sup>146</sup> Järvelin, 2002.

<sup>147</sup> Arinen et al., 1998.

<sup>148</sup> Keskimäki et al., 2004.

<sup>149</sup> Reunanen et al., 2000.

**Table 3.6** *Reimbursement of medicine costs, 2002–2005*

| Year | Total costs of reimbursed purchases (€) | Reimbursement (€) | Number of recipients | Kela's share | Patients' share | Cost per recipient (€ 2005 prices) |
|------|---|-------------------|----------------------|--------------|-----------------|------------------------------------|
| 2002 | 1 348 902                               | 859 364           | 3 353 792            | 63.7         | 36.3            | 149                                |
| 2003 | 1 422 160                               | 917 478           | 3 292 672            | 64.5         | 35.5            | 155                                |
| 2004 | 1 538 009                               | 1 014 566         | 3 271 568            | 66.0         | 34.0            | 161                                |
| 2005 | 1 598 998                               | 1 076 908         | 3 261 540            | 67.3         | 32.7            | 160                                |

Source: Kela, 2006.

- 3.42 Medicine use tends to be concentrated in older age groups and those with poor health tend to be concentrated in lower socioeconomic groups. In Finland, this is confirmed with high co-payments among older age groups. According to Kela figures for 2005, patients aged 60 and over faced an average co-payment of more than €200. Moreover, patients aged 60 to 80 accounted for almost half of the patients who exceeded their annual limits. Close to one third of patients aged 65 had annual costs equal to, or more than, €600. About half of those aged between 70 and 84 belonged to the lowest income quintile; and about 60% of those aged 85 and over.
- 3.43 Studies are needed to ascertain whether user charges create access problems and affect the quality of care. Kela data suggest that socioeconomic inequities are likely to exist among the elderly relative to the rest of the reimbursed population. There is limited current literature on cost-sharing policies in Finland; the most recent studies were carried out in the 1980s or 1990s.<sup>150</sup> There is potential to analyse this issue through data available in Finland and the high level of user charges makes this a pressing issue.

### Consumption trends

- 3.44 We requested more detailed data from Kela on drug costs and the user population. The 2005 data indicate that the 50 drugs with the highest reimbursement costs accounted for 55% (€1.1 billion) of the total reimbursement costs for prescription medicines. Kela's average cost share was around 76% so the patient co-payment was 24%.
- 3.45 We examined the ten drugs with the highest reimbursement costs in more detail to get a better sense of the breakdown. These accounted for

<sup>150</sup> Jämsén et al., 2003.

20% (€216 million) of the total reimbursement costs. Patient co-payments ranged from 4% to 44% with an overall average share close to 20%. Seven of these drugs also had the highest total costs (Kela's reimbursements + patient co-payments): psycholeptic (3), cardiovascular (2), immunostimulant (2), immunosuppressive (1), asthma (1) and diabetes (1) drugs. Table 3.7 provides a summary.

- 3.46 The 50 drugs with the highest total costs accounted for 51% (€1.6 billion) of the total cost of prescription medicines in 2005. Kela's average share was 72% and the patient co-payment was 28%. The top ten of these accounted for 18% (€281 million) of costs in 2005 – Kela's expenditure plus patient co-payments. These were cardiovascular medicines (3), psycholeptics (3) and a PPI as well as treatments for diabetes, asthma and bone disease. Patient co-payments ranged from 4% to 48% with an overall share of 28% (Table 3.8).
- 3.47 Half (25) of the drugs with the highest total costs had no generic alternatives. Furthermore, 5 of these 25 drugs were among the 10 most expensive drugs in 2005. The high costs of the top ten drugs are reflected in some of the disease areas in the Nordic data.<sup>151</sup> Retail pharmacy sales suggest that Finland had the highest level of sales for cardiovascular agents (€407; Nordic average: €276) and musculoskeletal drugs (€166; Nordic average: €110). Finland had one of the higher sales levels for alimentary tract drugs and metabolism drugs (e.g. for diabetes; PPIs), and middle range sales for respiratory drugs and those related to the nervous system. These indicate sales by the anatomical therapeutic chemical classification (ATC) system and are not adjusted for population characteristics or need.
- 3.48 There is no clear analysis of whether these high costs are reflected in better health outcomes. For instance, one study reported mixed evidence on whether rising sales of antidepressants in Nordic countries have contributed to a drop in suicide rates. In Finland, decreases in male and, to a lesser extent, female suicide rates began around the time of increased antidepressant sales.<sup>152</sup>
- 3.49 The costs and reimbursements of drugs with the highest number of users provided a slightly different picture. The top 50 drugs accounted for 40% of the total cost of prescription medicines in this group. Kela's average share was 45%; patient co-payments were 55%. The top ten were cardiovascular (3 drugs), anti-inflammatory (2), antibiotic (3), respiratory

<sup>151</sup> NOMECSO/NOSOSCO, 2006.

<sup>152</sup> Reseland et al., 2006.

**Table 3.7** Ten drugs with the highest reimbursements costs, 2005

| Chemical name                   | Kela's reimbursements (€) | Cumulative percentage (%) | Total cost (€)     | Kela's share (%) | Patients' payment (€) | Patients' share (%) | Condition/disease/ type of drug |
|---------------------------------|---------------------------|---------------------------|--------------------|------------------|-----------------------|---------------------|---------------------------------|
| Olanzapine                      | 33 557 648                | 3.2                       | 34 895 916         | 96.2             | 1 338 068             | 3.8                 | Psycholeptic                    |
| Atorvastatin                    | 32 757 937                | 6.3                       | 58 593 858         | 55.9             | 25 835 921            | 44.1                | Cardiovascular                  |
| Salmeterol and fluticasone      | 26 371 394                | 8.8                       | 36 056 312         | 73.1             | 9 684 918             | 26.9                | Asthma                          |
| Human insulin                   | 19 580 191                | 10.7                      | 20 320 799         | 96.4             | 740 608               | 3.6                 | Diabetes                        |
| Amlodipine                      | 18 825 120                | 12.4                      | 27 946 195         | 67.4             | 9 121 075             | 32.6                | Cardiovascular                  |
| Risperidone                     | 18 203 663                | 14.2                      | 19 937 008         | 91.3             | 1 733 345             | 8.7                 | Psycholeptic                    |
| Quetiapine                      | 17 519 671                | 15.8                      | 19 604 302         | 89.4             | 2 084 631             | 10.6                | Psycholeptic                    |
| Interferon beta-1a              | 17 025 173                | 17.5                      | 17 813 722         | 95.6             | 788 549               | 4.4                 | Multiple sclerosis              |
| Etanercept                      | 16 664 777                | 19.0                      | 17 316 506         | 96.2             | 651 729               | 3.8                 | Arthritis                       |
| Factor VIII                     | 15 608 263                | 20.5                      | 15 612 409         | 100.0            | 4 146                 | 0.0                 | Haemophilia                     |
| <b>Reimbursements (top ten)</b> | <b>216 114 037</b>        | <b>20.5</b>               | <b>268 097 027</b> | <b>80.6</b>      | <b>51 982 990</b>     | <b>19.4</b>         |                                 |
| <b>Total reimbursements</b>     | <b>1 053 231 953</b>      |                           |                    |                  |                       |                     |                                 |

Source: Kela, 2006.

Table 3.8 Ten drugs with the highest total costs, 2005

| Chemical name              | Total costs (€)      | Cumulative percentage (%) | Kela's reimbursements (€) | Kela's share (%) | Patients' payments (€) | Patients' share (%) | Condition/disease/ type of drug |
|----------------------------|----------------------|---------------------------|---------------------------|------------------|------------------------|---------------------|---------------------------------|
| Atorvastatin               | 58 598 858           | 3.8                       | 32 757 937                | 55.9             | 25 835 921             | 44.1                | Cardiovascular                  |
| Salmeterol and fluticasone | 36 056 312           | 6.1                       | 26 371 394                | 73.1             | 9 684 918              | 26.9                | Asthma                          |
| Olanzapine                 | 34 895 916           | 8.3                       | 33 557 848                | 96.2             | 1 338 068              | 3.8                 | Psycholeptic                    |
| Amlodipine                 | 27 946 195           | 10.1                      | 18 825 120                | 67.4             | 9 121 075              | 32.6                | Cardiovascular                  |
| Esomeprazole               | 24 498 034           | 11.7                      | 12 803 271                | 52.3             | 11 694 763             | 47.7                | PPI                             |
| Human insulin              | 20 320 799           | 13.0                      | 19 580 191                | 96.4             | 740 608                | 3.6                 | Diabetes                        |
| Metoprolol                 | 20 211 728           | 14.3                      | 12 639 268                | 62.5             | 7 572 460              | 37.5                | Cardiovascular                  |
| Risperidone                | 19 937 008           | 15.6                      | 18 203 663                | 91.3             | 1 733 345              | 8.7                 | Psycholeptic                    |
| Ketiapine                  | 19 604 302           | 16.8                      | 17 519 671                | 89.4             | 2 084 631              | 10.6                | Psycholeptic                    |
| Alendronate                | 19 266 913           | 18.1                      | 10 243 132                | 53.2             | 9 023 781              | 46.8                | Bone disease                    |
| <b>Costs (top ten)</b>     | <b>218 331 065</b>   | <b>18.1</b>               | <b>202 501 495</b>        | <b>72.0</b>      | <b>78 829 570</b>      | <b>28.0</b>         |                                 |
| <b>Total costs</b>         | <b>1 557 561 178</b> |                           |                           |                  |                        |                     |                                 |

Source: Kela, 2006.



Table 3.9 Ten drugs with the highest number of users, 2005

| Chemical name          | No. of annual users | Total costs (£)   | Kela's reimbursements (£) | Kela's share (%) | Patients' payments (£) | Patients' share (%) | Condition/disease/ type of drug |
|------------------------|---------------------|-------------------|---------------------------|------------------|------------------------|---------------------|---------------------------------|
| Cephalexin             | 417 880             | 7 226 292         | 1 564 459                 | 21.6             | 5 661 833              | 78.4                | Antibiotic                      |
| Amoxicillin            | 377 580             | 6 252 353         | 1 123 417                 | 18.0             | 5 128 936              | 82.0                | Antibiotic                      |
| Ibuprofen              | 340 915             | 6 533 807         | 1 966 285                 | 30.1             | 4 567 522              | 69.9                | Anti-inflammatory               |
| Bisoprolol             | 242 184             | 11 541 124        | 6 105 245                 | 52.9             | 5 435 879              | 47.1                | Cardiovascular                  |
| Estradiol              | 234 822             | 17 232 822        | 6 691 426                 | 38.8             | 10 541 396             | 61.2                | Hormone                         |
| Simvastatin            | 212 154             | 13 900 205        | 6 084 415                 | 43.8             | 7 815 790              | 56.2                | Cardiovascular                  |
| Azithromycin           | 183 479             | 3 215 439         | 665 702                   | 20.7             | 2 549 737              | 79.3                | Antibiotic                      |
| Metoprolol             | 177 797             | 20 211 728        | 12 639 268                | 62.5             | 7 572 460              | 37.5                | Cardiovascular                  |
| Salbutamol             | 155 987             | 5 425 694         | 3 163 630                 | 58.3             | 2 262 064              | 41.7                | Respiratory                     |
| Diclofenac             | 154 661             | 3 768 280         | 1 300 964                 | 34.5             | 2 467 316              | 65.5                | Anti-inflammatory               |
| <b>Costs (top ten)</b> | <b>2 497 459</b>    | <b>95 307 744</b> | <b>41 304 811</b>         | <b>43.3</b>      | <b>54 002 933</b>      | <b>56.7</b>         |                                 |
| <b>Total costs</b>     | <b>436 078 717</b>  |                   |                           |                  |                        |                     |                                 |

Source: Kela, 2006.

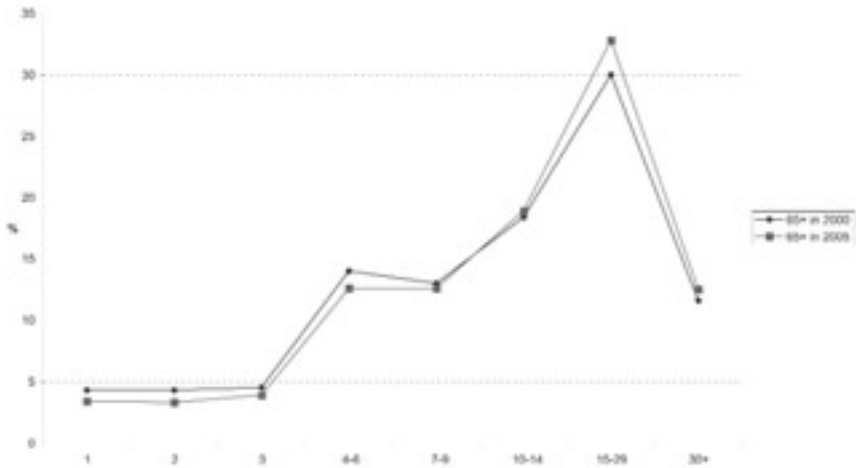
(1) and hormone (1). One of these cardiovascular drugs (Metoprolol) also has high total costs (Table 3.8). Table 3.9 provides a summary.

- 3.50 None of the ten most expensive drugs with the highest reimbursement costs appeared among the ten drugs with the highest number of users. This implies that most drugs with the highest total costs or highest reimbursement costs were not necessarily used by a majority. In other words – a small proportion of users contributed to the high reimbursement costs.
- 3.51 Kela covered close to 100% of the drug costs per user for drugs in the special refund category (life-threatening diseases or conditions). Kela's average share was around 98% among the 50 drugs which had the highest cost per user.
- 3.52 The highest concentration of drug use tends to be among the older age groups. Among those aged 75+, more than half use between one and four items. Less than 10% use eight or more (Table 3.10).

**Table 3.10** *Distribution of prescription users aged 75+, 2005*

| No. of substances | No. of patients | Share (%) | Cumulative share (%) |
|-------------------|-----------------|-----------|----------------------|
| 1                 | 39 491          | 11.8      | 11.8                 |
| 2                 | 48 337          | 14.5      | 26.3                 |
| 3                 | 50 446          | 15.1      | 41.5                 |
| 4                 | 47 481          | 14.2      | 55.7                 |
| 5                 | 41 240          | 12.4      | 68.1                 |
| 6                 | 32 988          | 9.9       | 78.0                 |
| 7                 | 24 907          | 7.5       | 85.4                 |
| 8                 | 17 717          | 5.3       | 90.7                 |
| 9                 | 11 863          | 3.6       | 94.3                 |
| 10                | 7 749           | 2.3       | 96.6                 |
| 11                | 4 816           | 1.4       | 98.1                 |
| 12                | 2 903           | 0.9       | 98.9                 |
| 13                | 1 597           | 0.5       | 99.4                 |
| 14                | 888             | 0.3       | 99.7                 |
| 15                | 522             | 0.2       | 99.8                 |
| 16                | 256             | 0.1       | 99.9                 |
| 17                | 153             | 0.0       | 99.9                 |
| 18                | 67              | 0.0       | 100.0                |
| 19                | 55              | 0.0       | 100.0                |
| 20+               | 46              | 0.0       | 100.0                |
| <b>Total</b>      | <b>333 522</b>  |           |                      |

Source: Kela, 2006.

**Fig. 3.6** Share of annual prescriptions among the elderly, 2000–2005

Source: Kela, 2006.

- 3.53 Between 2000 and 2005, the distribution of the annual number of prescriptions used by those aged 65+ was stable. There was a slight increase in the 15–29 range of prescriptions (Fig. 3.6).<sup>153</sup>
- 3.54 Pharmacotherapy is an important issue of drug consumption, including the appropriate use of drugs and rational prescribing. There is evidence of over-consumption of drugs in certain therapeutic areas such as psychotropics and antibiotics. Moreover, there is evidence of polypharmacy among older age groups.<sup>154</sup>
- 3.55 Psychotropic drugs are used widely in Finland, particularly among elderly people. Reimbursement and cost data on pharmaceuticals confirm this with a high number of reimbursements for psychotropic drugs (see section on expenditure). One study found anxiolytics and sedatives used commonly, instead of antidepressants, to treat anxiety disorders. This is contrary to clinical guidelines.<sup>155</sup> In particular, psychotropic drug use increases with age and evidence suggests an inappropriate level of prescribing among the elderly.<sup>156</sup> Hypnotic and sedative drugs are prescribed commonly for those aged 65 and over; consumption of such drugs is higher among older people. Guidelines recommend short-term use of such drugs for insomnia but evidence

<sup>153</sup> Between 2000 and 2005 there was a stable distribution of prescriptions among all women.

<sup>154</sup> Polypharmacy – the practice of prescribing too many medicines to treat a single condition or disease.

<sup>155</sup> Sihvo et al., 2006.

<sup>156</sup> Hartikainen & Klaukka, 2004.

suggests that they are used for unnecessary and extended periods. Moreover, the elderly have a high risk of adverse reactions to these drugs, such as falls, sedation or orthostatic hypotension.

- 3.56 Antibiotic resistance has become a pressing public health issue. Evidence indicates a strong correlation with high use.<sup>157,158,159</sup> Reimbursement data confirm that antibiotics accounted for three of the ten drugs used most in Finland: cephalosporin was the most widely used, followed by a penicillin; a macrolide was the seventh most widely used drug.
- 3.57 One study on antibiotic resistance in outpatient use found that narrow-spectrum penicillins and first-generation cephalosporins were prescribed widely in northern European countries for the treatment of community acquired infections.<sup>160</sup> In this study, Finland ranked in the middle for total outpatient antibiotic use among 26 European countries. In general, antibiotic resistance was higher in southern and eastern European countries; these have higher antibiotic consumption than northern countries. There is a shift from old narrow-spectrum to new broad-spectrum drugs that do not necessarily offer substantial improvements. Evidence showed hospital use of antibiotics in Finland was high relative to other European countries, including Nordic countries. National hospital consumption ranged from 3.9 defined daily doses (DDD) per 1000 inhabitants in Finland and France to 1.3 in Norway and Sweden. The median was 2.1.<sup>161</sup>
- 3.58 National guidelines could provide more guidance on antibiotic use. One study examined whether the implementation of new treatment guidelines changed prescribing practices. It concluded that there were moderate improvements but no decrease in inappropriate prescribing for conditions such as acute bronchitis.<sup>162</sup>
- 3.59 Other evidence suggests the need for strategies to promote appropriate prescribing. For instance, drug utilization data indicate that routine prescribing of expensive new antiarthritis drugs increased pharmaceutical expenditure without clear evidence of therapeutic benefits in health status.<sup>163</sup> The use of antihypertensives varied relative to guidelines and existing guidelines do not take proper account of

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<sup>157</sup> Goossens et al., 2005.

<sup>158</sup> Vander Stichele et al., 2006.

<sup>159</sup> Molstad et al., 2002.

<sup>160</sup> Goossens et al., 2005.

<sup>161</sup> Vander Stichele et al., 2006.

<sup>162</sup> Rautakorpi et al., 2006.

<sup>163</sup> Helin-Salmivaara et al., 2005.

current utilization.<sup>164</sup> Similarly, prescribing patterns for non-steroidal anti-inflammatory drugs (NSAIDs) found variations between physicians and between geographical areas that could not be explained solely by differences in the condition or patient need.<sup>165</sup>

- 3.60 Polypharmacy is common among older people. They use an average of at least three substances and four or more drugs are used by more than 55% of the population of older people.<sup>166</sup> Polypharmacy increases with age: one study reported that prevalence (>5 medicines) increased from 54% to 67%; excessive polypharmacy (>10 medicines) increased from 19% to 28%.<sup>167</sup> The prevalence was higher in institutional care and for central nervous system medicines. Cardiovascular medicines were used most commonly.
- 3.61 Polypharmacy increases the chances of adverse reactions to drugs in the absence of proper monitoring and appropriate prescribing. One study reported that greater intervention from physicians and nurses is necessary because of alcohol-medication interactions among the elderly with chronic conditions.<sup>168</sup>
- 3.62 Another study investigated the potential of inappropriate prescribing among home-dwelling elderly patients.<sup>169</sup> The results indicated high use of certain drugs considered inappropriate for different medical conditions: for instance, 20% of patients with chronic obstructive pulmonary disease were taking sedatives in addition to other medications.
- 3.63 University of Kuopio studies on the elderly population achieved similar results. Close to 40% of the home-dwelling elderly were using one psychotropic medication; 12% were using two or more concurrently.<sup>170</sup> The use of such drugs was common among those aged 85 or over and who were most vulnerable to adverse events. The study cautioned that careful consideration is needed before prescribing psychotropics to the elderly. Furthermore, concomitant use with analgesics increases with age and is a potential risk factor for adverse drug events.<sup>171</sup>

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<sup>164</sup> Stolk et al., 2006.

<sup>165</sup> Mäntyselkä et al., 2001.

<sup>166</sup> Kela, 2006.

<sup>167</sup> Jyrkkä et al., 2006.

<sup>168</sup> Aira et al., 2005.

<sup>169</sup> Pitkala et al., 2002.

<sup>170</sup> Hartikainen et al., 2003.

<sup>171</sup> Hartikainen et al., 2005.

- 3.64 The findings suggest that the use of psychotropic drugs is more common than the condition for which they are indicated. Some key barriers to effective prescribing have been identified, including poor knowledge of elderly people and pharmacology among physicians and nurses, and a lack of continuing care from physicians.<sup>172</sup>
- 3.65 Another concern is whether repeat prescribing leads to inappropriate drug use. Repeat prescribing allows the patient to continue a medication without direct contact with the doctor. A review of 28 health centres in Finland suggests that, generally, there was no agreement on drug-use review, a lack of local guidelines and doctors had varied approaches to reviewing repeat prescriptions.<sup>173</sup> A regular review of long-term medication is necessary – nurses and pharmacists should verify repeat requests systematically and local and national guidelines should be put in place.<sup>174</sup>
- 3.66 Encouragement of appropriate prescribing practices will require effort and coordination from a variety of actors. This approach was adopted as part of the national asthma programme in Finland.<sup>175</sup> The broad strategy involved key components such as early diagnosis, prevention, treatment and education. The intervention integrated identified tasks within routine clinical and administrative practice. The programme's results indicated that the 10-year programme saw a reduction in the observed increase in the costs of treating asthma. Total direct costs fell from €218 million in 1993 to €213.5 million in 2003. Cost per patient fell too – from €1611 in 1993 to €1031 in 2003. Hospitalizations fell and the use of improved asthma medications that entered the market in the 1990s contributed to better disease management. However, asthmatic medications increased the special reimbursement costs: the annual cost of medication per patient with persistent asthma was 1.8 times higher in 2003. Medicine sales were €44 million in 1993 (20% of total costs) and had almost doubled to €79 million (37% of total costs) by 2003.
- 3.67 Our discussions with Kela indicated that despite the asthma programme's positive results it has examples of inappropriate prescribing. The majority of asthmatic patients have a mild form of the disease, but 46% of all those using specially reimbursed antiasthmatics in 2005 used fixed combination products intended for more severe cases.

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<sup>172</sup> Kivelä, 2006.

<sup>173</sup> Lahnajärvi, 2006.

<sup>174</sup> Lahnajärvi, 2006.

<sup>175</sup> Haahntela et al., 2006.

- 3.68 The policy to encourage cheaper alternative generic products has shown an increase in the use of statins. Their cost per DDD fell after the introduction of generic substitution in 2003, most notably for simvastatin. In Kela's data of retail prices including VAT, simvastatin cost €1.3 per DDD in 2001 but fell to €0.2 per DDD in 2005. The more expensive statins (such as atorvastatin) cost €1.06 per DDD in 2001 but €0.96 in 2005. The policy to encourage the uptake of simvastatin has increased the number of users: Kela data for 2005 indicate that almost half of all patients on statins were taking simvastatin, with widespread use throughout Finland.
- 3.69 Studies indicate poor compliance among statin users but compliance in Finland was high, estimated at around 72% in 2003.<sup>176</sup> There is a need for better evaluation of the public health impact of the high use of statins as there is mixed evidence on whether their benefits have been overstated. International evidence suggests no strong correlation between statin use and deaths from ischaemic heart disease.<sup>177</sup> A study in Finland found regional differences in health outcomes from statin use.<sup>178</sup>

### Price trends

- 3.70 Price regulation operates in Finland. Pharmaceutical regulation can affect prices at different stages in the supply chain: ex-manufacturer, wholesale or retail prices. Wholesale and retail prices are regulated but the wholesale margin is not.
- 3.71 Industry data indicate that Finland had some of the lowest wholesale prices but some of the highest retail prices in 2003. PIF referred to an annual index of wholesale prices prepared by Statistics Finland, but we were unable to locate these data.<sup>179</sup> According to PIF the data show that prices of all medicines (prescription and self-care) fell by about 5% between 1998 and 2005 (using 1998 as the base year). A breakdown shows that the price index of reimbursable prescription medicines fell by about 8% but self-care medicine prices increased by 15%.
- 3.72 This was a period of policy changes: the imposition of price cuts and the introduction of the generic substitution policy contributed to changes in overall price levels, and a reduction in VAT came into effect.

<sup>176</sup> Walley et al. (2005) and Häkkinen et al. (2005) found varying rates of acute myocardial infarction as a result of statin use, but this study was limited because it was cross-sectional and captured data in one period rather than accounting for longer-run effects.

<sup>177</sup> Folino-Gallo et al. (forthcoming).

<sup>178</sup> Häkkinen et al., 2004.

<sup>179</sup> Tamminen, 2006.

- 3.73 International price comparisons have shown Finland to have high and low rankings. The results vary depending on who prepares them and the approach adopted. We illustrate this point by drawing on various sources of international evidence on price comparisons.
- 3.74 In comparisons of wholesale prices Finland has low prices; comparisons of retail prices rank Finland quite high. A study reported by PIF compared the prices of the best-selling medicines in Finnish pharmacies with those in other western European countries in 2005.<sup>180</sup> The findings suggested that Finland had the second lowest wholesale price index – only Greece's was lower.
- 3.75 A study by the Swedish Association of the Pharmaceutical Industry concluded that the Finnish price level for the 180 top-selling pharmaceuticals was about 3% higher than in Sweden.<sup>181</sup> However, the type of prices used for comparison purposes is unclear from these results. Similarly, an industry report by the Norwegian Association of Pharmaceutical Manufacturers does not state explicitly the prices used for comparison. The report suggests that prices in Finland in 2004 were in the top quarter of selected countries: higher than all the Nordic countries but behind Switzerland, Ireland, the United Kingdom and the Netherlands.<sup>182</sup> Another Norwegian study using pharmacy purchase prices showed Finland to have very low prices.<sup>183</sup>
- 3.76 A Finnish study on newly launched reimbursable products found that wholesale prices in Finland are close to the European average.<sup>184</sup> The study reported that wholesale prices were high in countries where pharmaceutical companies are free, or largely free, to price their products. Wholesale prices were highest in Ireland and Denmark. Between 2002 and 2003, Finnish wholesale prices were low relative to Sweden, Ireland and Denmark; similar to France; and higher than Belgium and Spain (these two countries have strict price controls).
- 3.77 The same study found the opposite for retail prices. In Finland these are a function of wholesale prices but also include the pharmacy mark-up, pharmacy-fee tax and VAT. With or without VAT, pharmacy retail prices were high. Without VAT, Finland was ranked second to Denmark and higher than Belgium, France, Ireland, the Netherlands,

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<sup>180</sup> The study was prepared by IMS Consulting, 2005 (Tamminen, 2006).

<sup>181</sup> Swedish Association of the Pharmaceutical Industry, 2006.

<sup>182</sup> Norwegian Association of Pharmaceutical Manufacturers, 2006a.

<sup>183</sup> Norwegian Association of Pharmaceutical Manufacturers, 2006b.

<sup>184</sup> Martikainen et al., 2005.



Spain, Sweden and the United Kingdom. Including VAT gave Finland, Ireland and Denmark the highest retail prices.

- 3.78 Another approach is to consider price–cost margins: to examine whether more regulation cuts into pharmaceutical company profits. Evidence from Finland and the United States shows no difference in price–cost margins in regulated and unregulated environments.<sup>185</sup> One study found that the inclusion of generics can significantly decrease price differences between such markets.<sup>186</sup> Linnosmaa, Hermans, Hallinen et al. (2004) propose that the inclusion of generics could be one possible explanation for the finding for Finland and the United States, which has a very developed generic market.
- 3.79 A Canadian study by the Patented Medicine Prices Review Board used pharmacy retail prices for comparison.<sup>187</sup> This found that Finland had the second largest drop (after the United Kingdom) in the average annual rate of price change for generic prescription drugs between 2003 and 2004. The three-year average was 26% but less than 4% in 2002. The generic-substitution policy was introduced in 2003 and likely contributed to the observed change. The report also calculated the price ratio between foreign and Canadian prices for non-patented branded drugs. The data indicate a median ratio between Finnish and Canadian prices relative to other countries.
- 3.80 The Department of Health (DoH) in the United Kingdom prepares international price comparisons. These were presented in a recent Office of Fair Trading (OFT) report.<sup>188</sup> The data provide useful information on trends by using ex-manufacturer prices to compare prices relative to the United Kingdom over time. Between 1999 and 2004, Finland was below the United Kingdom and generally ranked higher relative to other countries. By 2005, Finland was above the United Kingdom, the Netherlands, Austria, Belgium, France and Spain but below Germany, the United States and Ireland (Table 3.11).<sup>189</sup>
- 3.81 In summary, these studies highlight the difficulty of drawing conclusions and explaining price differentials. Every study may have relative differences between countries (e.g. above Finland in one and below it in another). The data indicate significant changes in the results

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<sup>185</sup> Linnosmaa et al., 2004.

<sup>186</sup> Danzon & Chao, 2000.

<sup>187</sup> Patented Medicine Prices Review Board, 2006.

<sup>188</sup> OFT, 2007.

<sup>189</sup> DoH, 2006.

**Table 3.11** *Bilateral comparisons of ex-manufacturer prices, 1999–2005*

| Country               | 1999       | 2000       | 2001       | 2002       | 2003       | 2004       | 2005       |
|-----------------------|------------|------------|------------|------------|------------|------------|------------|
| France                | 84         | 80         | 81         | 81         | 91         | 84         | 96         |
| Germany               | 97         | 91         | 94         | 95         | 102        | 106        | 108        |
| Italy                 | 83         | 79         | 82         | 86         | 90         | 78         | 84         |
| Netherlands           | n/a        | 81         | 84         | 88         | 93         | 92         | 95         |
| Spain                 | 67         | 64         | 67         | 75         | 81         | 80         | 84         |
| United States         | 184        | 209        | 217        | 201        | 190        | 176        | 198        |
| Austria               | 83         | 77         | 81         | 83         | 94         | 94         | 96         |
| Belgium               | 84         | 78         | 81         | 86         | 91         | 90         | 95         |
| Finland               | 85         | 83         | 84         | 88         | 98         | 96         | 101        |
| Ireland               | 88         | 83         | 88         | 93         | n/a        | 99         | 103        |
| <b>United Kingdom</b> | <b>100</b> | <b>100</b> | <b>100</b> | <b>100</b> | <b>100</b> | <b>100</b> | <b>100</b> |

Sources: OFT, 2007; DoH, 2006; unpublished data from DoH (United Kingdom).

according to methodological differences such as the range of products considered – whether generics were included; data time series; method of calculating price indices; and whether ex-manufacturer, wholesale or retail prices are used.<sup>190,191</sup> Such differences make it difficult to identify causal effects because of the many factors that influence drug prices: differences in health-system structures and financing; pharmaceutical subsidies; cost-containment policies; product mix; and production costs.<sup>192</sup> We report these results to highlight the variations in price comparisons.

3.82 In general, price trends show mixed results when wholesale prices are used. Some data suggest that retail prices are high in Finland but fewer studies have examined these. Within this exercise we have been unable to identify any key reasons to explain the low wholesale prices suggested by some international comparisons. It would be useful to carry out a similar study with price data from Finland to obtain a better sense of the possible factors that drive the analysis.

<sup>190</sup> Danzon, 1998.

<sup>191</sup> Kanavos & Mossialos, 1999.

<sup>192</sup> Productivity Commission, 2001.

## Chapter 4

# Supply-side policies concerning pharmaceuticals

- 4.1 The subsequent sections raise high-level issues based on information presented in the previous chapters and on our assessment and discussions with key stakeholders. These are separated into supply- and demand-related points in the next two chapters. The first raises issues concerning the regulation of the supply of medicines and the actors involved; the subsequent chapter is a discussion on the policies concerning demand for medicines.

### **Regulatory issues concerning the supply of medicines**

#### Pricing and reimbursement

- 4.2 The pricing and reimbursement process in Finland aims to set medicine prices that offer value for money. There is potential to improve the existing arrangement and we have identified five key areas that should be addressed in any options-for-reform package – process; evaluation period; drug review; appeal process; and HTA.

#### Process and improved transparency

- 4.3 Although low prices are not an explicit policy objective, our discussions with stakeholders suggest that this is implicit in pricing and reimbursement decisions. This process requires input and information from different levels of government. Administrative responsibility is divided between Kela and the MSAH. Various sections within MSAH (such as the PPB and NAM) are involved in formulating

pharmaceutical policies but there is a need for better coordination, both within and outside the ministry.

- 4.4 Board members provide different levels of input for the PPB's decision. Their engagement would increase if each were given a similar chance for appropriate and necessary input. Under the current arrangement, for instance, only Kela provides a written statement. The process would improve if this applied to all members, particularly if NAM submitted a written statement on the comparative clinical effectiveness of new medicines.
- 4.5 The process improved after the ECJ required requests to be submitted via an application procedure and the establishment of an expert group to determine reimbursement levels. Although these have increased transparency, reimbursement decisions involve the PPB and Kela who have different degrees of autonomy in government. The need for more transparency in reimbursement decisions was raised during our meetings with stakeholders; some felt that the PPB has too much discretion.
- 4.6 One concern was the way in which decisions are given. PPB's official decision is a short summary but transparency could be improved by providing a more detailed report that includes the evidence considered. Of course, any increase in PPB's output would have implications for capacity, requiring additional staff. The PPB secretariat consists of nine staff members with backgrounds in pharmacology, pharmacoepidemiology or pharmacoeconomics. This technical expertise is necessary but there is a lack of health economics capacity (one staff member has training in pharmacoeconomics).
- 4.7 Doctors are required to issue medical certificates to patients to justify their need for drugs in the higher reimbursement categories. These certificates must be submitted to Kela and special reimbursement is not guaranteed. Reimbursement levels are complex – the same medicinal product (even for the same indication) can belong to any, or all, of the reimbursement categories. These criteria are defined in the Health Act and draw on input from medical experts in various specialties. Kela decides the criteria for patients and requires a specialist's statement on the severity of disease. It appears that there are no explicit guidelines for specific groups of patients; their development would clarify this process.
- 4.8 Reimbursement decisions are not linked to the development of practice guidelines. This process could be coordinated better with PPB

and ROHTO activities. PPB should take account of ROHTO and FinOHTA guidelines, as well as international evidence, in their periodic reimbursement reviews (e.g. every 3–5 years) or when there is an application for a price increase. These guidelines would inform PPB's own independent decision. It is less clear how much consideration Kela gives to guideline information in their recommendations or decisions about reimbursement at a higher level.

- 4.9 A concerted effort to make more use of guidelines has implications for capacity within these organizations, which have small numbers of staff. Greater coordination could mitigate some work but will require closer collaboration. It would be easier to implement a process that could coordinate these reimbursement decisions more effectively, increase transparency and draw on relevant clinical information.
- 4.10 The reimbursement process creates tension as the industry claims that it is too complicated. These claims are justified if drugs that treat severe or life-threatening conditions are held back from inclusion in the higher reimbursement categories but are not justified if the evidence they produce for reimbursement is insufficient. However, we came across no evidence to support the industry's claim.

#### Initial evaluation period

- 4.11 A reimbursable new drug that meets the necessary criteria is placed in the basic refund category. It moves to one of the special refund categories when the company has submitted evidence on its therapeutic value and CE. In practice, drugs are sold in the basic category for an average of two years.
- 4.12 The industry has raised concerns that this initial placement in the basic reimbursement category imposes a barrier on companies' ability to compete with others supplying drugs in the same therapeutic category. The FCA investigated (see chapter 2) and concluded that this policy should be abandoned as it skewed competition between drugs in the special reimbursement category and the basic category; weakened motivation to bring new drugs to the market; and limited drug choice for the treatment of the most serious illnesses.
- 4.13 Approximately seven drugs have been placed immediately in one of the special refund categories. These treat conditions such as diabetes and cancer.

### Drug review

- 4.14 In principle, drug reviews take place after three, but up to a maximum of five, years. In certain conditions they can be brought forward – if a new product enters the market (on-patent or generic) or a product's sales and reimbursement expenses exceed forecasts.
- 4.15 Under current arrangements, reviews are usually carried out on a case-by-case basis. A system of notification introduced at the beginning of 2007 requires manufacturers to notify the PPB if actual sales exceed forecasts.<sup>193</sup> This mechanism verifies trends for reimbursement purposes once a drug enters the market. The PPB uses IMS and Kela data; a computerized system for follow-up began in autumn 2006 and is still under development. The PPB should also review the comparative perspective: whether any increase on forecasts resulted in reduced use of medicines with similar therapeutic effects or is justified by epidemiological trends. Price reductions should be considered if these cannot be proven.

### Appeal process

- 4.16 The PPB shares its draft decision with the applicant. Further evidence may be submitted but it is unclear whether this interim period includes a formalized internal appeal system sufficient to address issues before moving onto the appeal stage. The appeal process sends claims directly to the Supreme Court. This considers whether due process has been followed but does not pass judgement on the grounds for the PPB decision.
- 4.17 There have been moves to assist companies with their submissions, by establishing a PPB working group. These are positive steps to engage in better dialogue with companies.

### HTA

- 4.18 In general, HTA capacity varies between organizations. It should be strengthened to build capacity, coordinate useful information and share methodologies. Capacity building is needed to improve the assessment of drugs' therapeutic values. This is recognized as a key issue for pricing and reimbursement authorities in Europe. The EC's Pharmaceutical Forum will focus on clarifying concepts of relative effectiveness and additional therapeutic value.<sup>194</sup> At this stage of the process, it is unclear whether this is achievable.

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<sup>193</sup> PPB, 2007.

<sup>194</sup> Wahlroos, 2006.

- 4.19 The PPB does not clearly weight the criteria used in CE evaluations or in the assessment of setting prices for drugs. Company submissions provide CE models but the PPB does not verify any of poor quality. Verification would ensure that sound evidence is supplied so that the CE evidence could be more binding in its decisions. There is a need for the PPB to strengthen its health economics capacity to support decisions that draw on CE evidence: at present one member of PPB staff has training in pharmacoeconomics.
- 4.20 One key observation from the discussion with stakeholders is the need for greater health economics capacity in other institutions. Kela has some health economics capacity but other groups such as ROHTO do not.<sup>195</sup> FinOHTA has begun to increase knowledge and expertise in CE evaluation. This small capacity raises conflict-of-interest issues as both the industry and public organizations draw from the same small pool of technical expertise. The current arrangement does not appear to have a formalized system for declaration of interests and such an arrangement should be implemented.
- 4.21 As drug reviews take place, there will be a need for greater collaboration with ROHTO and other bodies involved in working with health-care practitioners, such as Duodecim and FinOHTA. This will convey information on the appropriate and rational use of drugs and ensure consistency with clinical guidelines.
- 4.22 Our meetings with stakeholders underscored the need to coordinate and share knowledge, expertise and methodologies. Increased dialogue and coordination would facilitate more informed use of appropriate measures in HTA and CE evaluations. This would produce more consistent approaches and policies for implementation, particularly for the main bodies involved in pharmaceutical policy: NAM, PPB, Kela and ROHTO. At present, each of these works with one or a few actors without much overlap (Fig. 2.1, on p.47). Kela works with the PPB and NAM; FinOHTA works with the FMA, Kela and NAM; ROHTO works with the FMA on practice guidelines and FinOHTA on education but not HTA. ROHTO does not work with the PPB.
- 4.23 Another important implication of HTA in Finland is communication with public health professionals and the public. Recent studies on *in vitro* fertilization and hormone therapy used HTA.<sup>196,197</sup> Their results

<sup>195</sup> Kela has four health economists, two of whom are involved in preparing price statements for the PPB. Many of the pharmacists and doctors who provide input into the statement process have had some training in health economics.

<sup>196</sup> Hemminki, 2002.

<sup>197</sup> Hemminki, 2004.

indicated that these treatments were not cost-effective and met much resistance in Finland where there is strong support for continuing treatment.

### **Reference pricing proposal**

- 4.24 A working group was established to consider the adoption of a reference pricing (RP) system in Finland. This has a variety of representatives from both within and outside government and is chaired by the MSAH.<sup>198</sup> This working group was appointed to consider how RP could be integrated into the current pricing and reimbursement system in order to contain reimbursement costs.
- 4.25 Integration could be achieved in a number of ways. The main issue is to define the reference cluster as part of the RP scheme: only generics, in-patent and generics or according to therapeutic categories. Our meetings with stakeholders reflected a variety of views. Some favoured expanding the clusters as broadly as possible to consider therapeutic categories; others felt that they should be defined narrowly. It was also suggested that any implemented RP scheme should replace the price corridor for generics rather than leaving both schemes in place.
- 4.26 Broad or narrow definitions of categories have important implications for the interaction between drug prices and their reimbursement levels. For instance, if the RP system is used as a reimbursement tool it will have to be integrated into the current system in order to avoid further complexities. Some stakeholders felt that further complications would be inevitable. The discussions have not yet considered whether the RP scheme could be used simply as a tool to inform pricing decisions. We develop this issue further in Chapter 6.

### **Financing streams**

- 4.27 The dual system of health funding creates problems for financing, raising revenue and monitoring expenditures on pharmaceuticals. Any changes in the current structure would have political complications. Stakeholders raised this issue and recognized some problems of cost shifting. Accountability problems are equally important – doctors are not employed by Kela.
- 4.28 One example of cost shifting is whether a patient is given a prescription in the outpatient setting so that Kela, rather than the municipalities,

<sup>198</sup> Members include representatives from the MSAH, MOF, PPB, Kela, NAM, PIF, AFP, FPA and the FMA (PIF, 2006).



covers the cost. Stakeholders provided only anecdotal evidence so its extent is unclear. Proper monitoring systems should be considered to identify the frequency of this form of cost shifting and the implications for Kela's budget. Kela has data on patient prescriptions, which could be linked with patient/doctor data in municipal health centres to identify areas of possible cost shifting.

- 4.29 Monitoring systems are needed for cost shifting between municipalities and hospitals. This happens within the overall municipal health budget. A hospital may avoid the cost of dispensing an expensive drug in inpatient care by shifting it to outpatient care where costs are borne by municipalities. According to Kela researchers, certain expensive medicines dispensed in outpatient care could be dispensed from hospitals. However, these apply to a small number of patients and include interferon and most orphan (used in the treatment of rare diseases), antineoplastic and anti-TNF.<sup>199</sup>
- 4.30 Kela had proposed that it should be responsible for all health financing but the municipalities were not supportive. Similarly, Kela did not support the municipalities' proposal for greater financial responsibility. It is necessary to address this dual financing system but, until amalgamation is considered, coordination between the two main funding streams is the next viable option.
- 4.31 The OECD put forward a proposal to transfer budgets to doctors.<sup>200</sup> This creates problems for the dual practice of public and private doctors and occupational health doctors. The OECD proposed that the estimated 6% saving on pharmaceutical expenditure be used to employ more physicians. These assumptions about the possible level of savings drew on evidence from the United Kingdom which observed a one-time reduction of 6%. The report assumed that this level of savings could be applied directly, without adjusting for the contextual factors and characteristics of the Finnish health system.
- 4.32 Evidence from the United Kingdom's experience indicates that in the first three years of the scheme, absolute costs in GP fundholding practices grew at a slower rate than in practices outside the scheme. Fundholders showed reductions in costs of about 6% relative to non-fundholders.<sup>201</sup> After the first three years these differences disappeared because of the move towards generic prescribing or simple therapeutic

<sup>199</sup> Kela 2005 data for the number of patients: blood coagulation factors (200 patients); antineoplastic agents (8143); TNF blockers (2167); interferon (2862).

<sup>200</sup> OECD, 2005.

<sup>201</sup> Harris & Scrivener, 1996.

substitution, one-time shifts in prescribing patterns. The scheme appeared to have no negative effects on patient care but this was partly because the fundholding practices were larger, well-organized and located in affluent areas. The scheme produced cultural change through physicians' willingness to consider the costs of their prescribing patterns and provide better direction for primary care services. Some argue that the overall success was unclear because other aims were not evaluated due to lack of data on patient outcomes, equity or general efficiency.<sup>202</sup>

- 4.33 Hence there is a key policy trade-off in reducing prescribing costs at the expense of quality of care. A review of prescribing policies and incentive schemes in Europe concludes that a transparent, clear and enforced incentive scheme appears to have the most effect.<sup>203</sup> Furthermore, positive schemes met more success than punitive schemes. The authors note that ethical and quality considerations must be taken into account when formulating incentive policies and that a key component of evaluation is the development of improved information systems. By tracking prescribing, these allow greater policy implementation and analysis.
- 4.34 In the long term, if pharmaceutical expenditure continues its rapid growth, the dual system will likely place unequal pressures on Kela's and municipal budgets.

### **Supply issues of pharmacies and pharmacists**

- 4.35 The supply and location of pharmacies is regulated strictly in Finland, supervised and approved by NAM. This section considers some of the key regulatory issues concerning the liberalization of pharmacies; pharmacy fees; mail order; and pharmacists in under-serviced areas.

#### Liberalization of pharmacies

- 4.36 Pharmacy liberalization is being reviewed by the MSAH. At present, the pharmacy market is tightly regulated so that the supply of pharmacies limits their movement and expansion. Liberalization would have implications for this control of supply and ownership as the pharmacy sector would be treated like other markets.
- 4.37 Currently there are certain barriers to entry such as the needs-based criteria used for NAM's decisions according to the Medicines Act.

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<sup>202</sup> Gosden & Torgerson, 1997.

<sup>203</sup> Mossialos et al., 2005.

For instance, only those with a graduate degree in pharmacy are allowed to own pharmacies. From a competition perspective, this is a barrier to entry as it limits ownership.

- 4.38 One key implication of liberalization is whether such a scheme would create a market where pharmacies focus on maximizing profits rather than patient-oriented services. Might non-pharmacist owners behave differently and focus on building commercial entities? There is a common concern that patient safety might be compromised. From our discussions, we noted that some of these concerns could be addressed as pharmacists already supervise medicine cabinets in remote areas. This service could be applied in a deregulated environment.
- 4.39 One study attempted to simulate the effects of opening up the pharmacy market and concluded that a regulated market has no empirical support.<sup>204</sup> The study used Belgium as a representative of many countries with geographical restrictions. The results estimated that removal of entry restrictions would reduce the regulated mark-up (from 28% to 10%–18%). This would shift the rent to consumers without reducing geographical coverage throughout the country.
- 4.40 Competition authorities have shown renewed interest in liberalization of this sector in Europe. For instance, an OFT report in the United Kingdom supported the removal of entry and exit restrictions on community pharmacies.<sup>205</sup> The report concluded that increased competition would lead to improvements in quality and lower prices. Although there would be limited reduction in local access, the impact on low-income and elderly groups would be the same as for the general population.
- 4.41 However, a study prepared for the OFT report noted less clear evidence of competition in more deregulated markets.<sup>206</sup> The authors found that the extent of competition also depends on payment methods for pharmacists, linked to incentives for discounting in the distribution chain and the dispensing of cheaper drugs. The pharmacy market is complex and the effects of strict or more open regulatory systems have implications for the interactions of actors in this market.
- 4.42 In practice, country evidence from those that have moved towards liberalization does not always confirm the common economic arguments supporting deregulation (Box 4.0).

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<sup>204</sup> Schaumans & Verboven, 2006.

<sup>205</sup> OFT, 2003.

<sup>206</sup> Mossialos & Mrazek, 2003.

**Box 4.0** *Evidence on deregulation of pharmacies***Pharmacy supply and market concentration**

A study by the Austrian Health Institute (OBIG) found that the number of pharmacies increased faster than the supply of pharmacists in Norway and the Netherlands. Pharmacists experienced difficulties with workloads and overall satisfaction among pharmacy staff has lessened.<sup>207</sup>

OBIG's findings on market concentration are echoed in other studies on deregulation.<sup>208,209</sup> Deregulation in Norway led to vertical integration of the pharmacy market where all pharmacy chains were owned by three wholesalers (97%). In Iceland two pharmacy chains owned 85% of the market in 2004.<sup>210</sup> Similarly, the Dutch experience shows that deregulation led to insurers owning pharmacies in order to take advantage of manufacturers' discounts.<sup>211</sup>

**Distribution and access**

There were distributional problems in the Irish and Norwegian experience: a greater concentration of pharmacies in urban centres and insufficient numbers in rural areas.<sup>212,213</sup> Anell came to similar findings about greater concentrations in urban areas following deregulation in Iceland.

**Price competition**

The Austrian study found that deregulation did not necessarily reduce the price of OTC medicines.<sup>214</sup> In contrast, in Iceland, Anell found that competition led to discounts on co-payments for those who were chronically ill and had high drug use. Another study in Norway found that deregulation did not have a negative impact on prices because the majority of drugs were subject to price regulation. However, the study noted that it was difficult to introduce competition between producers due to the vertically integrated system of pharmacy chains, or to lower the retail prices of generic drugs.<sup>215</sup>

*cont'd. . .*

<sup>207</sup> Vogler et al., 2006.

<sup>208</sup> Anell, 2005.

<sup>209</sup> Dalen & Strøm, 2006.

<sup>210</sup> Anell, 2005.

<sup>211</sup> Mossialos & Mrazek, 2003.

<sup>212</sup> Vogler et al., 2006.

<sup>213</sup> Dalen & Strøm, 2006.

<sup>214</sup> OTC medicines were examined because the observable effect after liberalization would be more apparent than for prescription medicines where prices are negotiated by state governments.

<sup>215</sup> Dalen & Strøm, 2006.

**Box 4.0** *cont'd***Access and quality**

The Austrian study found that regulated countries had better accessibility to pharmacies,<sup>216</sup> although there appeared to be similar levels of quality of services between deregulated and regulated countries. A study in Norway found that deregulation benefited consumers: the number of pharmacies grew; opening hours increased by an average of two hours per week; and a selection of OTC drugs became available in supermarkets and fuel stations.<sup>217</sup>

- 4.43 Another option for pharmacy liberalization would be to increase the supply of OTC products in retail settings. Our discussions with stakeholders indicate that only selected products should be considered. A legal framework may be necessary to identify drugs that could be sold in retail settings. NAM already approves changes from prescription to OTC and could offer guidance on allowable medicines. At the European level, information on prescription to OTC switches would be helpful but country contexts vary, partly because of differences in reimbursement rates.
- 4.44 Finland has moved towards selling nicotine replacement therapy in retail settings. An MTI study found that the market worked in favour of consumers as competition drove down prices by 15% to 20%.<sup>218</sup> However, this drop in retail prices was dependent on not only the number of competitors in the market but also their price-setting behaviour.
- 4.45 A move towards selling some OTC drugs outside of pharmacies is common in the United Kingdom and several other European countries. This requires monitoring to ensure quality and patient safety and concerns have been raised about the safety of certain products sold in retail settings in Denmark. The Danish Medicines Agency recently removed seven drugs (from the current list of 16) because too many products remained on shelves well beyond their expiry dates: cough medicines, nicotine patches and pain killers.<sup>219</sup>

<sup>216</sup> The study used Austria, Finland and Spain as reference countries that have tight regulation.

<sup>217</sup> Dalen & Strøm, 2006.

<sup>218</sup> State Provincial Office of Southern Finland, 2007.

<sup>219</sup> Copenhagen Post, 2006.

- 4.46 Increasing the number of products sold outside of pharmacies may address access issues in remote areas. Retailers could sell approved products although this might require some intervention from pharmacists. Online access to pharmacists could answer the need for more information and approval.

#### Pharmacy fee and remote pharmacies

- 4.47 The initial aims of the pharmacy fee were to provide a mechanism to subsidize pharmacies in remote and low-service areas and to support research and development in universities. It is unclear how much of the fee is used for these subsidies now. The MOF collects this tax but it is not transferred to the MSAH. Furthermore, it is not clear how many savings would result from a reduction in the pharmacy fee: it may be a one-off reduction, similar to that observed in overall pharmaceutical expenditure when VAT was reduced.
- 4.48 The pharmacy fee is calculated on top of the 24% margin excluding VAT. Larger pharmacies pay a greater proportion of their turnover. Data from 2005 indicate that average turnover was €3 million and the average pharmacy fee was about €205 000 (about 7% of the average turnover). There is no public information on how this margin is distributed over the various pharmacy costs.
- 4.49 Our discussions with stakeholders indicated that those who supported removing or reducing the fee felt that such a move would favour patients by lowering retail prices. Removal or reduction of the fee raises issues about how to provide financial support to pharmacies in remote areas. Any other explicit subsidies (i.e. tax incentives or social insurance contributions) to private entities may contravene EU law. The current system may already contravene EU law but the FCA has not examined its legality.

#### Mail-order pharmacies

- 4.50 Mail-order pharmacies are allowed, in certain circumstances, for OTC products only. Greater use of mail-order pharmacies will need to consider the implications of a 2004 ECJ ruling which stated that EU members cannot prohibit non-prescription medicines from being advertised and sold over the Internet.<sup>220</sup> In this case a Dutch pharmacy sold prescription and non-prescription medicines to patients in

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<sup>220</sup> Case C-322/01, 2003. ECR I-14887.

Germany.<sup>221</sup> Following the ruling, DocMorris (the Dutch Internet pharmaceuticals retailer) was granted a licence to continue operations.

- 4.51 DocMorris acquired a pharmacy in Germany in June 2006. An interim order by a regional administrative court required the company to close down its operations in Germany,<sup>222</sup> as there was no ECJ ruling on the legal provisions concerning operations within Germany itself. The court considered that public health interests and the interests of local pharmacists could not be subjected to unfair competition from DocMorris and its financial interests. This interim ruling raises concerns about possible deregulation of the pharmacy market and the entry of discount chains. Supporters claim that a deregulated market will reduce overall health costs; others cite concerns about undermining the safe provision of medicines.

### **First-contact providers**

- 4.52 The dual system of financing has implications not only for shifting prescription costs but also for whether a public or private doctor writes a prescription. Kela reimburses the costs of doctors' prescriptions irrespective of whether they are issued by private or public doctors. A private doctor's prescription requires Kela to pay the reimbursement costs of medicines. These are the same whether the prescription is issued in public or private practice.
- 4.53 This issue is compounded further because private doctors in Finland are not regulated and have the authority to set their own fees. An FMA survey of physicians in 2005 found that the most commonly charged fee among private physicians was €60 for a doctor's visit.<sup>223</sup> In principle Kela will reimburse 60% of a doctor's fee; in practice the level is around 30%.
- 4.54 Data indicate that most private doctors are specialists and are aged between 50 and 53. Private practice appeals to female physicians due to the flexible working hours. A greater number and proportion of doctors engage in both public and private practice. In level terms, a smaller number of physicians are only private doctors. This is partly because of the recent trend to establish private companies that rent facilities for the private provision of health services, and these hire only private doctors with no engagement in public practice.

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<sup>221</sup> Kempton, 2004; Hatzopoulos & Do, 2006

<sup>222</sup> Freshfields Bruckhaus Deringer, 2006.

<sup>223</sup> FMA, 2005.

- 4.55 The current arrangement of public and private doctors is problematic for monitoring drug costs. Kela is a passive payer and no quality indicators are in place to monitor private doctors' prescribing. In principle, this is the responsibility of many actors: the MSAH, NAMLA, the social and health departments of the State Provincial Offices and local health authorities. However, there appears to be no proper coordination and strict enforcement measures are not in place.
- 4.56 NAMLA is one possible monitoring and enforcement mechanism. This agency has the authority to take away a doctor's licence. There is potential to monitor private doctors' activities in order to identify prescribing trends and any necessity for intervention. NAMLA would need to sanction this proposal and provide a legal framework.
- 4.57 Kela could provide information on the prescribing patterns of private and occupational health doctors. Private doctors could be required to use the same electronic system and the same code of practice as public doctors.

### **Wholesale market, patent process and parallel imports**

- 4.58 Finland's pharmaceutical distribution market operates under strict regulation. This section presents issues concerning the current arrangement of the wholesale market, the patent process and PI.
- 4.59 NAM oversees the operations of pharmaceutical distribution, including wholesale operations. Wholesalers require a permit to carry out their operations. In Finland two wholesalers – Oriola Oy and Tamro Finland – provide a full selection of medicines and a nationwide distribution system.
- 4.60 The wholesale system operates under a single-channel distribution. One wholesaler is responsible for the order and distribution of a manufacturer's entire medicine selection. Wholesale distribution covers pharmacies and their subsidiaries, hospital pharmacies, health centres and medicine dispensaries.
- 4.61 The wholesale price is fixed and regulated so the two wholesale companies compete on margins. Wholesalers and manufacturers negotiate ex-factory prices but this information is not publicly available. The final wholesale margin is estimated to be 4% of the wholesale price. Wholesalers use a modern automated IT-based system to process orders. Competition has led to efficiency gains and contributed to low wholesale prices.<sup>224</sup> Distribution margins are low by European standards.

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<sup>224</sup> Vatanen, 2006.



- 4.62 The FCA investigated this market in the mid 1990s and in 2000.<sup>225</sup> The first report in 1997 found strong support among the actors in the distribution chain. While the nature of the single-channel system restricted competition, its negative impact was no greater than the positive impact produced by greater efficiency. The FCA concluded that measures against the single-channel system were not warranted. NAM's role in controlling and monitoring the production, importation, distribution and sale of drugs, as well as control of drug pricing through the drug fee, contributed to this decision.
- 4.63 In the second report, not all actors were equally supportive of the single-channel distribution system. The FCA did not deem it necessary to take action although it noted that efficiencies of distribution could be achieved in both single- and multi-channel systems. Pre-wholesale operations have improved the efficiency of the division of labour between wholesale companies and producers.
- 4.64 Pharmacies used to benefit from wholesale price rebates. In early 2006, an amendment to the Medicines Act required pharmaceutical companies to sell their medicines at the same price to all pharmacies; rebates and other benefits from drug procurement were not permitted.<sup>226</sup>
- 4.65 Finland's patent system did include process patents but since 1995 it has been possible to apply for a product (method) patent. These protect only a particular production method for six years after the drug is on sale. Product patents cover 20 years from the date of application for market authorization and protect the active substance irrespective of production methods.<sup>227</sup> Our discussions revealed that method patents permit a company to have continuing market exclusivity as long as it holds patents in at least three other European countries.<sup>228</sup>
- 4.66 The FCA commented on method patents in the context of the generic substitution bill. Generic manufacturers can develop a new process that circumvents some method patents. This enables them to sell generic copies of the original if they are produced by a different method. The FCA noted that only a few drugs still hold a method patent and the system will end in the next four to five years. Other sources indicate that the majority of drugs hold method patents and

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<sup>225</sup> FCA, 2006c.

<sup>226</sup> Kostiaainen, 2006.

<sup>227</sup> Aitlahti, 2006.

<sup>228</sup> We contacted the MTI to verify this information but received no response.

the transition period will continue until 2014 when the Finnish range of drugs will be covered by European patent protection.<sup>229,230</sup>

- 4.67 PI account for a small portion of the Finnish pharmaceutical market: 1.6% of the wholesale market and about 5% of total consumption in 2005.<sup>231</sup> Four companies were involved in PI in Finland in 2005; the main therapeutic categories treated asthma, indigestion and depression. Our meetings with stakeholders indicated concerns that PI reduce pharmacy margins although, at present, there is only a small number of drugs. Savings accruing from PI were found to be low because they have not intensified price competition.<sup>232</sup>

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<sup>229</sup> Access my library, 2007.

<sup>230</sup> Helsingin Sanomat International Edition, 2004.

<sup>231</sup> Aaltonen, 2006.

<sup>232</sup> Linnosmaa, Karhunen, Vohlonen et al., 2003.

## Chapter 5

# How to influence providers

### Measures to influence providers

5.1 This section discusses the policy implications of mechanisms in place to influence prescribers. It presents issues concerning doctors, nurses, hospitals, pharmacists, health centres, patients and IT systems.

Activities to influence doctors' behaviour in pharmaceutical services

5.2 Policy measures to influence physicians are more recent phenomenon in Finland. In large part, physicians prescribe drugs without being evaluated – Kela provides prescribing data for information purposes only.<sup>233</sup> No formalized mechanisms, such as clinical audit or peer review, are in place to offer guidance on inappropriate prescribing. The prior authorization required for higher reimbursement requests could be extended to monitor doctors in public, private or occupational settings.

5.3 Physicians reacted positively to a recent policy requiring them to prescribe generic simvastatin or other less expensive statins as a first-line treatment. The FMA was supportive but noted that it was difficult to switch patients who were on different lipid-lowering treatments. This applied to some cases but was not generally a problem. Widespread use of statins has been reported elsewhere,<sup>234</sup> as has the

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<sup>233</sup> Kela sends a summary to every physician who has written at least 200 reimbursed prescriptions during the year. These figures are not adjusted for morbidity and show only averages.

<sup>234</sup> Walley et al., 2005.

benefit of prescribing them as a first-line treatment.<sup>235</sup> Prescribing of low-cost statins such as simvastatin or pravastatin is promoted in the United Kingdom.

- 5.4 In Finland, a high proportion of new patients take generic simvastatin. Kela data indicate close to 200 000 patients in the first half of 2006. During the same period, the average cost per patient was the lowest relative to other statins (€16 compared with prices ranging from €31 to €133). The National Public Health Institute noted that average cholesterol levels in the working-age population fell until the mid 1990s but then increased among men, partly due to rising obesity levels.
- 5.5 Practice guidelines have not been developed fully but have potential to provide guidance for physicians' prescribing practices. ROHTO is involved in pharmacotherapy issues but its role is to educate physicians. It hopes to expand its work in hospital districts and to work with pharmacists but it remains to be seen whether such measures will increase appropriate prescribing among physicians. Kela, ROHTO and Duodecim could work together to link prescribing patterns with guidelines. For the moment, there is no clear link between reimbursement decisions and clinical guidelines. It is necessary to establish a formal relationship between them.
- 5.6 Chronic disease management is a key area of relevance for prescribing. Our discussion at a health centre suggests that doctor/nurse teams led by older, experienced physicians are in charge of monitoring these patients' conditions. One health centre we visited has developed its own practice guidelines (in areas such as pregnancy) in the absence of national guidelines. Guidelines for other disease/conditions using input from doctors and nurses were being developed.
- 5.7 The production of guidelines and CE studies could be combined with input from actors such as ROHTO, FinOHTA and Duodecim to inform the PPB's pricing decisions. As these bodies have different reporting lines, this would require clear guidance on their working relationships and centralized reporting to one unit within the MSAH.
- 5.8 In general, incentives and guidelines for physicians are weak. Financial bonuses in physicians' salaries are not used to influence prescribing behaviour; such measures are neither endorsed by the FMA nor viewed favourably by health practitioners in Finland. Other activities to

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<sup>235</sup> NHS indicators, 2006.

influence physicians, such as educational and promotional activities exist. The FMA recently established guidelines to support CME but this is not compulsory for physicians and the benefits are unclear. The current arrangement does not require the FMA or another central body to review or monitor CME. A formal monitoring mechanism is required because, at present, physicians document and assess their own CME.

- 5.9 CME training in Finland is voluntary; unlike pharmacists physicians are not required to revalidate their skills as part of their professional development. No system of accreditation is in place if a physician chooses to enrol in a CME event and incentives are weak because relicensing is not required. This is confirmed by the low participation numbers: less than 10% of doctors.
- 5.10 Promotional activities by the pharmaceutical industry are related to concerns about CME training. In 2006 the FMA published a set of guidelines to address the code of conduct between physicians and commercial enterprises and any conflicts of interest that may arise. The industry has a self-regulatory body – the Supervisory Commission for the Marketing of Medicinal Products.
- 5.11 One answer would be greater involvement of NAM. This has the legal power to regulate industry-marketing activities and has indicated that monitoring of the industry will be part of one of the key targets of its strategy between 2006 and 2012. This initiative is welcome and offers much scope for development: for instance, NAM fined a company that misrepresented information on the safety profile of its drug.<sup>236</sup>

#### Self-dispensing doctors and nurse prescribing

- 5.12 The availability and access to medicines could be enhanced by increasing the roles of doctors and nurses. Doctors are not permitted to dispense but self-dispensing doctors could increase the availability of medicines, particularly in health centres in remote areas.
- 5.13 Similarly, nurses are not allowed to prescribe medicines in Finland. A government proposal on this topic met resistance from the medical profession. In the United Kingdom, nurse prescribing for minor conditions was extended to cover a broader range of drugs after further training. This came into effect in 2006.<sup>237</sup>

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<sup>236</sup> NAM, 2006a.

<sup>237</sup> Barclay, 2005.

## Hospital formularies and drug procurement

- 5.14 Neither the government nor the Association of Finnish Local and Regional Authorities provide national guidance on drug formularies. This occurs at hospital level, implying that formularies are likely to vary from region to region. Hospitals and health centres have pharmaceutical boards to assist them in purchasing decisions. This local-level capacity requires standards to be set at the national level to minimize rationing. The problem is compounded because there are no guidelines on expensive drugs. ROHTO has begun work on this topic.
- 5.15 One study on hospital formularies found that processes and decisions vary greatly between hospitals. There could be a 10-fold difference in the volume of drugs in use at any given time.<sup>238</sup> The study reported that the smallest hospitals had the biggest formularies with no apparent rational selection of drugs. The number of drugs in the primary drug list varied between 100 and 800. Most hospitals also had a utility drug list consisting of 100 to 1100 drugs. The study noted that selections should comprise drugs with proven CE.
- 5.16 The study reported that positions on the advisory committee are normally permanent. One to three meetings are held each year and these focus on reviewing the content of the primary selection. Given the infrequent meetings, these committees are unable to provide much input. Larger, regional committees comprising a wider range of health-care representatives should be set up instead – or as a coordinating body. The study also recommended centralization of procurement groups' invitations for tenders and the offers returned by drugs companies. Minimum content and IT standards should be agreed for both invitations and offers.
- 5.17 We understand that there is a trend to coordinate purchasing between hospitals and health centres in order to take advantage of economies of scale. Group purchasing has wider implications because hospitals are joining together to create their own formularies without national guidance.
- 5.18 Purchases are made at district level (although there is bulk purchasing between a few districts): hospital districts work with municipal authorities to invite public tenders.<sup>239</sup> The tendering process should ensure that safety issues are resolved and that there is a sustainable

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<sup>238</sup> Hermanson et al., 2001.

<sup>239</sup> Legislation is currently being reformed to meet EU directives (Suominen, 2006).

supply of medicines. New regulations on public competition appear to have reduced variations in discounts. These have no upper limit but they tend to be no more than 60% of the wholesale price.<sup>240</sup> These purchases are made by public bodies, hospitals and municipal health centres and therefore are considered to be outside competition law, partly on welfare grounds. It is not clear whether this coordination of practice could be challenged as an abuse of market dominance under EU law.

The capacity of pharmacists and policies to influence pharmacists

- 5.19 Pharmacists play a central role in dispensing medicines but there is potential to enhance their roles and develop stronger links with physicians for rational prescribing practices.
- 5.20 Pharmacists are legally required to update their professional knowledge. They undertake continuing education but, as for physicians, there is no formalized system to count credits and attendance at events. One source of information is the Pharmaceutical Learning Centre. This non-profit organization was founded in 1980 to provide educational courses for professionals in the pharmaceutical field.
- 5.21 Pharmacist's involvement in clinical pharmacy could be developed. There is potential for counter detailing in Finland where pharmacists and doctors could work together to share knowledge and carry out drug reviews. Pharmacists receive no financial incentives – this is discussed in the section on recommendations (Chapter 6).
- 5.22 At present, clinical pharmacological knowledge and skill are weak. Those with training play more of an academic role in Finland. Clinical pharmacologists do not advise doctors; anaesthetists have some training in this area but this is insufficient. Ward pharmacists must hold a BSc(Pharm.) but do not advise or train doctors. Pharmacists could play a greater role in counselling and providing advice to patients. Medicine review is a recent voluntary initiative (see Chapter 2).
- 5.23 The current pharmacy margin is regressive. Financial incentives could be linked to increased quality of care in appropriate dispensing. The introduction of the generic substitution policy is one example although it is not linked to clear incentives for pharmacists. This policy requires pharmacies to dispense only cheap generic (or original) products if the price lies within a €2 or €3 price corridor set by the lowest-priced generic. Data suggest that savings have been realized (Chapter 3).

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<sup>240</sup> Hermanson et al., 2001.

Savings could be greater but the majority of drugs by value were not subject to generic competition – about 75% had no or little competition.

- 5.24 Pharmacies have access to a highly developed and detailed database. These systems check for prescription refills and drug (but not multi-drug) interactions. No information on OTC and herbal products is collected. There will be potential to exchange information with patients and to check other IT drug information once the national initiatives are in place.

#### Health centres

- 5.25 Health centres are patients' first point of contact for primary-care services. Our visit to a health centre indicated that patients with chronic conditions are assigned to an experienced doctor/nurse team and scheduled for regular check-ups. There is potential for them to develop a more active role in monitoring medicines prescribed to patients. It was unclear whether there are formalized chronic-disease management programmes. Our understanding was that such programmes are left for local health centres to develop and implement.
- 5.26 Health centres have a developed IT system that includes information on patients' conditions and lists their medications. There are knowledge gaps – the system does not record OTC drugs or visits to private doctors. Doctors in health centres can verify a patient's total medication only by direct enquiries.
- 5.27 Hospitals have a more formalized system to share medical records with health centres. Our assessment indicates that, in general, there are pockets of information on drug use – in the health centre, pharmacy or at the hospital. There is need for better coordination of patient information between hospitals and health centres.

### **Patients' access to pharmaceutical services**

- 5.28 This section discusses some key issues concerning access and use of medicines facing patients in Finland. Our meetings with stakeholders stressed the high level of user charges, and this has resulted in Finnish patients becoming quite price sensitive.

#### User charges and access to medicines

- 5.29 User charges seem quite high in Finland: around 33% in 2003 according to Kela data. Similarly, our analysis of the 50 drugs with the highest reimbursement costs showed a co-payment of 28%. The 50



drugs with the highest number of users indicated an average co-payment of 55%.

- 5.30 The generic substitution policy is one example of the effect of user charges for patients. The price corridor was shown to be effective in reimbursement categories where patients pay a bigger share. In the higher special reimbursement category where patients pay only a fixed-deductible of €3 per purchase per medicine the price corridor does not seem to work. Small fixed-deductibles offer patients less financial incentive for substitution.
- 5.31 As discussed in Chapter 3, studies on the effect of user charges and their relationship to utilization and access have not been carried out in Finland. The trend of rising pharmaceutical costs will pressurize patients to absorb the costs of medicines. This raises equity issues because the costs will be borne disproportionately by those less able to afford them. Medicine consumption tends to be concentrated in lower socioeconomic and older age groups (mainly with chronic conditions).
- 5.32 This is confirmed by high co-payments among older age groups in Finland. In 2005, patients aged 60 and over faced an average co-payment of more than €200. In 2005, about half of all those aged between 70 and 84 belonged to the lowest income quintile; about 60% of those 85 and over belonged to the lowest income quintile. These figures suggest a strong correlation between poor health and low income. This problem may be partly offset by the annual ceiling – Kela bears all drugs costs once patients have reached the annual spending limit.

Initiative to monitor drug compliance and promote patient safety

- 5.33 Drug compliance is an important area of pharmacotherapy. Doctors know if patients take their medicines only by asking directly during appointments at health centres. Patients on antihypertensive therapy show poor drug compliance. Studies indicate that both perceived health-care system and patient-related problems contribute to poor compliance.<sup>241,242</sup> For instance, hypertensive patients in primary health care commonly perceive problems with negative attitudes and experiences.<sup>243</sup> Another study found that hopelessness, frustration with treatment and perceived tension with blood pressure measurement were associated with poor blood-pressure control.<sup>244</sup>

<sup>241</sup> Jokisalo et al., 2002.

<sup>242</sup> Enlund et al., 2001.

<sup>243</sup> Jokisalo et al., 2002.

<sup>244</sup> Jokisalo et al., 2003.

- 5.34 ROHTO and pharmacists could become involved in expanding drug services for the elderly in institutional care, for whom polypharmacy is a particular problem (see Chapter 3). GPs have few incentives to monitor the drug consumption of patients in institutional settings and there is a low level of skilled specialists in care of the elderly in Finland. This is complicated by the large number of psychotropic medicines available. ROHTO and Duodecim could provide physicians with proper guidance to identify the best treatments.
- 5.35 A pilot project on medication review is under way, currently focusing on those aged 75 or more. This is welcome because studies on polypharmacy among elderly people indicate a high level of inappropriate prescribing and a high risk of adverse events (see Chapter 3). This is a voluntary programme in which about 26 pharmacists conduct medication and patient safety reviews in patients' homes. Although neither this project nor the current IT systems necessarily reveal any shift towards OTC medicines, this information could be included easily. This outreach programme is part of a continuing education course in cooperation with ROHTO. It has the potential to become formalized and for the pharmacists involved to receive appropriate remuneration.
- 5.36 The medicine review programme highlights the need for better coordinated guidance on safe practices and to clarify the roles of health-care professionals providing pharmacotherapy. The MSAH published a guide to safe pharmacotherapy in 2006 and plans to work on a national policy on patient safety and develop a strategy in 2007.

#### Voice mechanisms for patients and political enforcement

- 5.37 A complaint about public authorities and officials, including health-care doctors can be sent to the Parliamentary Ombudsman or the Chancellor of Justice: both supervise authorities' compliance with the law, but there are minor differences. No systematic review of government agencies takes place (e.g. government audit). An ombudsman decision can be given as a reprimand, the expression of an opinion or a proposal. In 2006, close to one third of cases involved some form of action. In 2006, complaints related to shortcomings in the availability of health services and access to, and the quality of, treatment.<sup>245</sup> The Parliamentary Ombudsman assesses the legality of health care against medical criteria, always consulting medical experts (usually from NAMLA) before arriving at a decision.

<sup>245</sup> Parliamentary Ombudsman of Finland, 2007.

- 5.38 The Ombudsman also considers complaints between public authorities and officials. One case concerned a complaint about NAM's submission to Finnish Customs that a company required a licence to use Finland as a point of transit for medicines to be re-exported outside the EU.<sup>246</sup> The Ombudsman concluded that a licence for wholesale distribution was not required because no importation of goods took place.
- 5.39 NAMLA is another agency that could influence behaviour as it has the authority to reprimand doctors. There is potential to monitor the activities of private doctors to identify prescribing trends and any need for intervention. NAMLA would need to sanction this proposal and provide a legal framework.

### **IT systems**

- 5.40 Finland's IT systems have the potential to draw useful information on prescribing trends and to better inform policy decisions. Computerized information is held in various forms and different locations with no integration mechanisms.
- 5.41 Health centres and pharmacies have an IT system containing information on prescribed medicines but not OTC or herbal medicine. Hospitals have their own tailored systems to record medicines dispensed to patients in inpatient care. Incompatibilities between the systems prevent online purchasing of medicines from wholesalers.
- 5.42 Kela, the PPB and NAM house key areas of price and drug information as discussed previously. More effective information sharing would inform their work and that of other important actors such as ROHTO and FinOHTA.
- 5.43 Two important initiatives to integrate this information are the development of a national electronic patient record system and a national archive. Furthermore, a prescribing decision support system is currently under development. This will also strengthen the health intelligence infrastructure in Finland. Initiatives that include e-prescribing are very important and will be a much needed resource in the future.

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<sup>246</sup> Parliamentary Ombudsman of Finland, 2006.



## Chapter 6

# Evaluation of options and recommendations

6.1 The previous chapters have highlighted some of the issues that were raised in our meetings with stakeholders or that we identified subsequently. Within the constraints of the overall health system we present options that could be considered as part of the review process.<sup>247</sup>

### **Pricing policies and transparency**

6.2 **Therapeutic value of the drug.** Transparency in the HTA process is necessary to ensure that procedures for assessment, involvement of stakeholders and production of guidance are well-communicated and understood.<sup>248</sup> Transparency could be improved if PPB board members were required to provide written statements on a drug's therapeutic value as part of the process to inform pricing and reimbursement decisions.

6.3 Information on the therapeutic value of a drug could be coordinated better between board members. NAM's market authorization data could inform this process. The PPB expert group could integrate a more rigorous input from NAM (on the therapeutic value of drugs) into its strategic policy.

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<sup>247</sup> Professor Huttunen identified areas where the Pharmaceutical Policy 2010 document could be improved – medicine reimbursement system and the effectiveness and efficiency of medicines. Some proposals for reimbursement suggest replacing the current three-level system with one similar to those in Denmark and Sweden where the reimbursement percentage increases as costs grow. The proposal calls for strengthened HTA capacity within central government. FinOHTA could be charged with leading this (PIF, 2006a).

<sup>248</sup> Drummond, 2006.

- 6.4 Drugs that belong to more than one reimbursement category create a challenge for the fair treatment of drugs based on their therapeutic value for patient subgroups. In practice, the PPB determines the reimbursement level and Kela decides whether the medical criteria for the patient subgroups have been met. In principle, this approach values drugs on the basis that they cure or alleviate a disease or its symptoms. Reimbursement and eligibility to receive them are not dependent on either a patient's age or financial status. The decision process requires consistency in approach and evaluation. Analysis on these decisions should ensure that such PPB decisions are not discretionary and should be open to input from NAM. ROHTO and FinOHTA could provide important information over the three to five year drug-review period – data and evidence from studies (e.g. pharmacovigilance) could inform pricing decisions.
- 6.5 This process should also draw on international sources of pricing and reimbursement processes to evaluate the interchangeability of drugs and their classification system. For instance, the classification system in France draws on therapeutic benefits, possible side-effects, the severity of the disease treated and the drug's benefits relative to existing substitutes.<sup>249</sup> However, this system does not weight CE, but only clinical effectiveness.<sup>250</sup>
- 6.6 The Food and Drug Administration (FDA) in the United States classifies drugs according to two dimensions: chemical type and therapeutic potential. The chemical type considers new compounds that have never been approved; those that have been altered to produce a drug with new features; and those whose active ingredients may already be available in identical products on the market. Therapeutic potential considers a medicine's clinical improvement in innovation. The FDA uses such improvement as a basis for assigning drugs to either a standard or a swifter priority review track. The agency uses a broad set of criteria to identify clinical improvement: evidence of increased CE; reduced side-effects and interactions; enhanced compliance; or use in a new subpopulation. Using these criteria, a study that examined FDA approval of drugs found only a minority (15%) that were considered highly innovative with new active ingredients that provided significant clinical improvement between

<sup>249</sup> SMR score (medical service rendered) is used in classifying the drug. Drugs are evaluated on whether they have therapeutic benefit relative to existing treatment. This scoring system (ASMR – improvement in the medical service rendered) has a five-level classification system ranging from no incremental benefit to life-saving drug. Drugs that offer therapeutic benefit will be granted price premiums.

<sup>250</sup> Drugs with a major or important ASMR can be awarded a 65% reimbursement rate; drugs with a moderate or low SMR are awarded only a 35% reimbursement rate.

1989 and 2000. Over the same period, drugs with modest innovation were the most common among FDA drug approvals.<sup>251</sup>

- 6.7 The Dutch system classifies drugs according to whether or not they are interchangeable. This is defined as: identical affliction (clinically relevant properties); identical mode of administration; identical age category; no clinically relevant differences in effects; no clinically relevant differences in side-effects. The therapeutic value, CE and budgetary impact of non-interchangeable drugs are evaluated for any reimbursement decision.
- 6.8 The German system classes drugs according to therapeutic classification and comparability. Reimbursement is fixed according to the prices of other similar or therapeutically equivalent substances within the same reference group. Innovative drugs and drugs without any therapeutic equivalent are exempt from categorization in the RP system and are reimbursed fully. During the review period – from four weeks (for me-too drugs) to two years (for more complicated substances) – the drug is reimbursed fully. In 2004, the health law reintroduced the possibility of including on-patent drugs in the RP system: a single RP group can include on-patent, off-patent and generic drugs for similar (but not necessarily equivalent) therapeutic usage. Statins and PPIs were some of the first drugs to be reviewed and reference priced due to their high sales volumes.
- 6.9 The recently released OFT study on pharmaceutical pricing reimbursement in the United Kingdom recommends moving from a system of profit controls, and across the board price cuts, to a value-based approach to pricing. Manufacturers are free to set medicine prices in the current system. The OFT identified a number of large price differences between drugs that deliver very similar benefits to patients (e.g. cholesterol-lowering; reducing stomach acid).
- 6.10 The OFT study argues the need for reform so that medicines with very similar benefits are reimbursed at similar levels. It recommends a value-based approach to inform pricing decisions because the price of a medicine would reflect the benefits it delivers. One key proposal is to reimburse prices of off-patent brands, including originator brands and branded generics, at the generic reimbursement price.<sup>252</sup> The OFT also recommends an expansion of HTA's role in informing pricing

<sup>251</sup> National Institute for HealthCare Management Foundation, 2002.

<sup>252</sup> The OFT report recognizes that differing prices between branded and non-branded generics should be brought in line. HTA bodies in the United Kingdom currently issue guidance but their remit does not inform pricing decisions.

decisions. This would send correct signals for drug investment in areas of patient need.<sup>253</sup>

- 6.11 The Canadian system for pricing patented drugs considers whether the price submitted by manufacturers is excessive according to the prices of comparators and price information in other countries. In Finland, prices could reflect the income level of the population by using GDP as a guide for price adjustments, for example.
- 6.12 Another source of information is pharmaceutical cooperation between statutory health insurance institutions in Europe. The Medicine Evaluation Committee (MEDEV) was established in 1998 as an official committee of the European Social Health Insurance Forum. The MEDEV network provides a forum for national health insurance institutions to discuss the value of drugs.<sup>254</sup> This network provides an opportunity for Kela to engage with other countries and to inform the policy process with NAM and the PPB in Finland.
- 6.13 **Building capacity.** Finland would benefit from enhanced capacity in health economics, clinical pharmacology and pharmacoepidemiology. The building process could develop links with the regulatory authorities in countries such as the Netherlands, United Kingdom, Sweden and Canada. This exchange would be useful for both NAM and the PPB and would enable the latter to improve the evaluation of manufacturer's data. Currently, the quality of such submissions is poor and greater expertise would provide a stronger evidence base for PPB decisions.
- 6.14 **Appropriate methodologies.** We recommend that relevant stakeholders, such as the PPB, draw on international developments in assessing therapeutic value. The health-related quality-of-life measure (QALY) has become a common metric in many countries. Methodologies that underpin therapeutic-value assessments are important inputs but any adopted methodology has limitations. The use of international developments (for instance, factors such as equity considerations and social value judgements) will affect the relative weighting of such approaches. The criteria should consider not only CE but also patient access and inequity in the light of high user charges in Finland.

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<sup>253</sup> OFT, 2007.

<sup>254</sup> The network provides a forum for information flow including the opportunity to draw on country experiences in pharmaceutical policy and timely analysis of drug-related events. Areas that require the development of strategies include drug evaluation; definition of parameters in economic evaluation and price analysis; and intercountry comparisons of drug benefits.



- 6.15 **Initial evaluation period.** The criteria for this process should be well-explained. Effectiveness data for this policy would mitigate concerns about the average two-year delay for reimbursement purposes. Decisions should be made systematically. The criteria for changing the reimbursement classification from basic to a special refund category could be evaluated as a means of improving the transparency of this process.
- 6.16 **Forecast sales data.** Interactions with the pharmaceutical industry are a key issue in pricing and reimbursement decisions. Transparent decisions would add credibility to this process. Under current arrangements a review is usually carried out on a case-by-case basis. A system of notification introduced at the beginning of 2007 requires manufacturers to notify the PPB if actual sales exceed forecasts. Price-volume trade-offs could take the form of repayments or changes in price levels. The latter would be easier to implement but the industry could be given the option to provide repayments in the second year of evaluation. The industry could be permitted to revise their forecasts to take account of changes in need and competition in the market (e.g. new entrants).
- 6.17 The PPB uses IMS and Kela data and a computerized system, created for follow up in autumn 2006 and still under development. PPB should also consider a comparative perspective: whether an increase on the forecasts resulted in less use of medicines with similar therapeutic effects or is justified by epidemiological trends. If the analysis does not lead to these conclusions then price reductions should be considered.
- 6.18 **Pricing competition and generic substitution.** Our review of generic competition (see Chapter 3) following the introduction of the substitution policy suggests that the majority of drugs have little or no competition but account for half the value of prescriptions dispensed. Given the small generics market, price competition is less likely to occur than in countries with substantial generics markets (e.g. United States, United Kingdom).
- 6.19 The United States and the United Kingdom provide a variety of incentives for doctors, pharmacists and patients. Targeting policies are needed to encourage demand-side awareness because there are few incentives in Finland. As elsewhere, physicians could be given additional incentives to prescribe generics (e.g. prescribing guidelines, monitored prescribing, information to promote generics). Similarly, pharmacists could receive incentives such as a margin to encourage

generic prescribing or a ceiling for pharmacy sector profits. Patients could benefit from lower generic prices if reimbursement levels were set at a lower tier of co-payments.

- 6.20 At the moment, there is limited potential to develop a strong generics market in Finland. One option to address the lack of competition would be to consider price reductions of drugs once they go off patent. This would drive down prices given the low level of generic competition. Such a policy option could take account of the savings realized already without such price cuts. A study on the impacts of generic substitution is needed.
- 6.21 **OTC products.** OTC prices are not regulated. Currently they make up a small proportion of medicines and there is wide variation in the number of products sold within European countries. Switches do not necessarily lead to savings: patients may not buy the cheaper OTC product, preferring a more expensive higher-dose prescription from the doctor.<sup>255</sup> Furthermore, any price drops in OTC products may be offset by volume increases that drive up overall pharmaceutical expenditure. Our review could not establish whether these issues are under policy discussion. A NAM-based working group could be established to consider OTC policy in Finland: products with and without OTC status, their safety issues and implications for pharmaceutical expenditure.
- 6.22 **Reference pricing and reimbursement.** This is under review in Finland. RP schemes are used widely in Europe as a means of constraining pharmaceutical expenditure and regulating price levels. There is mixed evidence on their use and many challenges for their implementation.
- 6.23 RP aims to constrain pharmaceutical expenditure by setting a maximum reimbursement level of a drug to be paid by a third party. The difference between the reimbursement level and the drug price is borne by the patient. In principle, this creates an incentive for doctors and patients to be cost conscious about drug prices. Products are clustered by either a cheaper generic or therapeutic equivalent.
- 6.24 Patients may choose to avoid paying the difference if the therapeutic benefit of a drug is similar to the one priced above the RP limit.<sup>256</sup> As a result, these schemes may reduce prices of drugs above the RP limit. If payments do not result in selection of the cheapest drug in the

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<sup>255</sup> Bond et al., 2004.

<sup>256</sup> Lopez-Casasnovas & Puig-Junoy, 2000.

- RP cluster, RP may impose an artificial floor to impede further price reductions.<sup>257</sup> Patients' access to drugs may be restricted by their inability to pay for a preferred drug.
- 6.25 The criteria to define therapeutic equivalent products in RP schemes are not straightforward but evidence suggests that these schemes produced short-term savings.<sup>258,259,260</sup> One explanation is that the volumes and prices of drugs outside the scheme offset savings from drugs within it.<sup>261</sup>
- 6.26 RP schemes also face the challenge of stimulating demand-side cost awareness to signal competition between drugs in the cluster. Norway and Sweden have found it difficult to implement such policies and found lack of satisfaction a reason to abandon such schemes.<sup>262</sup> However, this measure was implemented only in the generics market and therefore its potential was limited.
- 6.27 Various options could be considered to implement an RP approach in Finland, for instance, cluster either by therapeutic category or by generic equivalents. Premium pricing could be considered if justified by the therapeutic value of drugs outside a cluster (e.g. biotech drugs).
- 6.28 While RP schemes are used commonly to set reimbursement thresholds, they can also be a price-setting tool before reimbursement – drugs are compared with existing alternatives. Therapeutic clustering can aid the identification of price differences and whether prices of drugs with similar benefits should be standardized. Clustering operates at various levels and draws on the ATC system. It could be useful to group medicines by drug class in order to compare those with similar chemical compositions.<sup>263</sup> The definition of such clusters would be undertaken by the relevant bodies.
- 6.29 Some drugs are relicensed every five years via a centralized procedure with EMEA. This could provide an opportunity for NAM to review the therapeutic value of these drugs as new evidence becomes available. These reviews could also inform the work of ROHTO, Duodecim and FinOHTA.

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<sup>257</sup> Mrazek, 2001.

<sup>258</sup> Lopez-Casasnovas & Puig-Junoy, 2000.

<sup>259</sup> Nink, Schroder & Selke, 2001.

<sup>260</sup> Donatini et al., 2001.

<sup>261</sup> Mossialos et al., 2004.

<sup>262</sup> Mrazek & Mossialos, 2004.

<sup>263</sup> OFT, 2007.

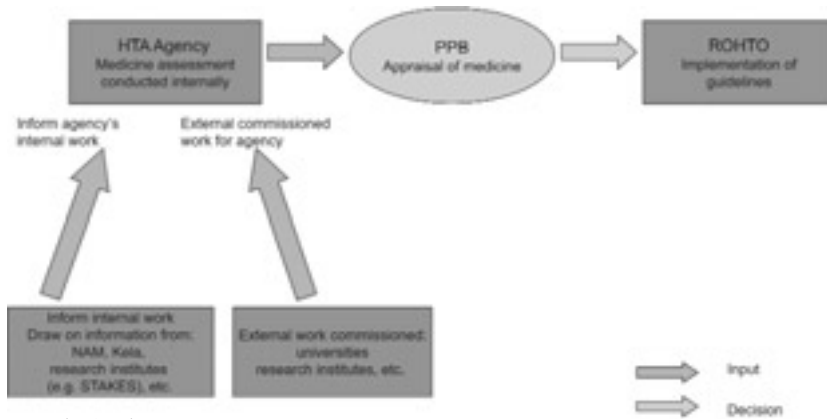
- 6.30 It is particularly important to confirm the information submitted by manufacturers. Evidence suggests that the majority of studies sponsored by the pharmaceutical industry favour the sponsors' drugs and do not necessarily reflect their true therapeutic value relative to existing treatments.<sup>264</sup>

### **Strengthening the institutional environment**

- 6.31 **Improved coordination.** As already proposed, there is a need for better coordination of activities with the relevant stakeholders. One area that could be strengthened is MSAH's work carried out between the insurance (where PPB is accountable), health (NAM, ROHTO and NAMLA accountable) and social departments (FinOHTA accountable).
- 6.32 We have identified several areas that could be improved. NAM could increase its role on the PPB board by providing a statement on the comparative clinical effectiveness of new medicines. ROHTO and FinOHTA could expand their roles to inform pricing decisions with their knowledge and background in HTA and pharmacotherapy. Kela already provides statements on the price–volume market forecast estimates that manufacturers submit to PPB but the verification process could be conveyed more explicitly.
- 6.33 At a higher level, the establishment of a standing committee (meeting a few times each year) would provide a permanent forum for stakeholders to exchange views, and could advise the MSAH. The policy dialogue could consider high-level issues concerning how to improve coordination of their activities and anticipate new needs, rather than reacting to events arising, in pharmaceutical policy. Relevant stakeholders could include the PPB, NAM, ROHTO, FinOHTA and Kela. Other stakeholders could be invited depending on the issue discussed and could include the FMA, NAMLA, FCA, Parliamentary Ombudsman, the industry, pharmacists and patients' associations.
- 6.34 A more radical approach would be to establish an agency to inform pricing and reimbursement decisions, working with the expert group and the PPB. The agency for drug assessment would provide expertise as an independent authority accountable to the MSAH which would decide on its institutional location. The agency would avoid conflicts of interest by operating at arm's length, with no representatives from PPB stakeholders on its board.

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<sup>264</sup> Smith, 2005.

**Fig. 6.0** *Process for assessment of medicines by an HTA agency*

Source: Authors' analysis.

- 6.35 In essence, our recommendation is to separate the assessment of a medicine from its appraisal. This separation of clinical assessment and financing would build greater transparency into the process (Fig. 6.0).
- 6.36 An HTA agency could replace the current medical expert group and become a central point in the assessment process: acting as a technical body for collecting, evaluating and assessing information and evidence on the clinical and therapeutic values of drugs.
- 6.37 The agency would assess the manufacturers' evidence of clinical effectiveness (CE) submitted to the PPB. It would also conduct its own independent evaluations of the evidence available on the clinical and therapeutic value of these drugs. Resulting assessments of drugs' clinical and therapeutic values would be passed to the PPB to inform pricing and reimbursement decisions.
- 6.38 The PPB would continue its current role in appraising medicines, retaining its remit as the pricing and reimbursement authority but drawing on advice and information from the agency. The separation of assessment and appraisal would allow the PPB to use its existing resources and staff more effectively in the appraisal process.
- 6.39 The agency would require capacity in drug assessment. This could be built by drawing on evidence and data on medicines, prices and volume information from relevant authorities (e.g. NAM, Kela); research institutes (e.g. STAKES); and on lessons from other HTA bodies. A small HTA body such as the Scottish Medicines Consortium (SMC) in the United Kingdom could provide a starting point. As capacity developed, the agency could develop more rigorous methods, drawing from institutions such as NICE. The agency could

also coordinate some of its work by commissioning external academic centres.

- 6.40 The agency would work with stakeholders and provide the PPB with summaries on medicines' therapeutic value and CE. The remit could also include advice on reimbursement levels and corresponding therapeutic categories. The process would be transparent and the agency would publish its views. The institutional framework would have to consider these transparency issues by integrating appropriate accountability mechanisms, such as an appeals process.
- 6.41 Over time the agency could become involved formally in the reimbursement process and advise government and parliament on the definition of reimbursement categories. As its expertise and capacity developed, the agency's remit could be expanded to include other aspects of health-care such as medical devices and intervention procedures.
- 6.42 The agency could work to develop guidelines and draw on the expertise and role of institutions such as Duodecim and FinOHTA to provide a clearer link between reimbursement decisions, guidelines and HTA. In this regard, ROHTO's work could be expanded to assist implementation of these guidelines.
- 6.43 An external review of FinOHTA made recommendations to increase its remit.<sup>265</sup> This agency could take on the assessment role recommended by the external reviewers and, more recently, by Professor Huttunen. FinOHTA's current remit involves HTAs of medical technologies but this could be expanded to consider all interventions, including medicines. FinOHTA's suitability for this role would need to be discussed by the relevant authorities and it would require stronger capacity in health economics and clinical pharmacology. This discussion could also consider whether FinOHTA should remain in its current arrangement at STAKES. If FinOHTA is to become involved in the appraisal process, we recommend a reorganization to separate medicine appraisals from HTA appraisals of other technologies. Two separate units would avoid conflict of interest with the formal appraisal process.
- 6.44 An alternative to the establishment of a drug assessment agency would be to separate the PPB from the insurance directorate and establish it as an independent authority. However, this would mean that drug

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<sup>265</sup> Eskola et al., 2004.

assessment and appraisal would be carried out by one body. We believe that it would be more appropriate to separate assessment and appraisal to avoid conflicts of interest. This would be addressed by the establishment of a new agency on drug assessment.

## Pharmacy market

- 6.45 We have raised issues and current proposals under consideration for the pharmacy market: the pharmacy fee, pharmacy margin and deregulation issues. Now we present some options that could be considered for regulating this market.
- 6.46 **Pharmacy fee.** Proposals are being considered on whether to retain or remove the pharmacy fee. NAM has proposed a 50% reduction (see Chapter 2).
- 6.47 If the fee is retained, 50% could be given to the MSAH and/or Kela.<sup>266</sup> This revenue could finance pharmaceutical-care programmes such as medicine reviews among the elderly (to assess levels of polypharmacy and appropriate levels of prescribing); pharmacotherapy in institutional settings; incentives for doctors to prescribe appropriately; and better information systems. The revenue could also be used to increase capacity in bodies such as ROHTO and NAM.
- 6.48 If the fee is abolished, income tax incentives may be necessary to ensure the financial viability of pharmacies. The FCA would need to be confident that any other forms of government subsidy were consistent with EU law and could not be considered anticompetitive.
- 6.49 **Pharmacists' margin.** Pharmacists receive a regressive margin under the current arrangement: receiving less for dispensing expensive drugs. The incentive system is linked to the price of a drug. A flat payment could be an alternative because the incentive would be linked to the volume of drugs dispensed. Incentives could be introduced for outreach programmes (e.g. medicine review, chronic disease management programmes) and could encourage generic dispensing if additional financial incentives enhance the flat payments.

<sup>266</sup> In Austria, the Ministry of Finance transfers VAT revenue to the sickness funds to finance programmes.

- 6.50 Other countries such as the United Kingdom, the Netherlands and Germany have adopted this approach.<sup>267</sup> Germany managed to move towards a flat-payment system despite extensive lobbying from pharmacies.<sup>268</sup>
- 6.51 **Deregulation.** Evidence on pharmacy deregulation suggests that any moves should be staged so as to minimize unintended consequences. Evidence and issues arising from deregulation (market concentration, supply of pharmacists, access and price competition) are discussed in Chapter 4. One implication is the possibility of geographical inequities. NAM did consider that a reduction in the pharmacy fee would affect pharmacies' turnovers. A similar exercise on geographical location could help to inform this discussion.
- 6.52 The expansion of mail-order pharmacy could partly offset the potential equity issue that deregulation would produce a concentration of pharmacies in urban centres. Alternatively, policies affecting the provision of health-care providers could be considered: self-dispensing doctors could be approved in areas with problematic access. Another approach would be to build dispensing capacities in municipal health centres in remote areas where pharmacies may not locate. Alternatively, pharmacists and nurses could be given the right to dispense drugs that treat simple conditions. We recognize that these options are not under policy discussion but evidence from other countries (e.g. United Kingdom, Canada) may prove useful if the situation changes.
- 6.53 Before proceeding towards deregulation, country experience on this policy change should be considered carefully in the context of the Finnish pharmacy market. Moves towards deregulation and the extent of competition should also be linked to payment methods for pharmacists, which are linked to incentives for discounting in the distribution chain and the dispensing of cheaper drugs. This implies

<sup>267</sup> The Netherlands provides an example of a system that rewards cost-conscious dispensing as pharmacists' pay is not linked to the cost of prescription items. Pharmacists are paid a fixed fee for dispensing each item on a prescription. The fee is set by the government and takes account of the cost of running a pharmacy. In addition, chemically identical and therapeutic equivalent products are grouped in clusters in which the most expensive product is called the reference product. If a cheaper product in the cluster is dispensed the pharmacist may charge the insurance funds an extra amount calculated as one-third of the difference between the RP price and the retail price of the dispensed product. Pharmacists in the United Kingdom receive a dispensing fee (varying inversely to the number of prescriptions dispensed) and a profit component (5% of ingredient cost). Brands are reimbursed at the manufacturer's list price and generics at tariff prices. However, pharmacists can better these prices so the DoH uses annual discount enquiries and a claw back scheme to recoup excessive profits. The claw back operates on an average basis and acts as a price deflationary pressure that forces pharmacists to negotiate better prices with their suppliers. Price competition in the generics markets provides pharmacists with significant incentives to purchase and dispense, provided that doctors prescribe them. Profits can be higher in areas where doctors prescribe more generics than the national average. The United Kingdom's incentives could be improved if pharmacists were permitted to substitute generic for original products. Currently pharmacists can only substitute products prescribed with an INN name. Another option is to establish negotiated income targets for pharmacists as in Denmark. If pharmacists were allowed to substitute there would be greater potential to economize on generic dispensing.

<sup>268</sup> Busse, Schreyögg & Henke, 2005.



that the current system of regressive margins for pharmacists would require review before deregulation was considered. A study on this topic would be useful to better inform any policy changes. The pharmacy market is complex and the interaction with strict or more open regulatory systems will have implications for the interactions of actors in this market.

### First contact providers

- 6.54 **Prescribing targets.** We have highlighted that the interaction between the dual systems of financing with doctors raises problems for accountability and monitoring. It was beyond our remit to consider whether doctors could be brought within the same employment scheme with one system of financing.
- 6.55 In view of these constraints, and evidence of inappropriate prescribing (Chapter 3), doctors could be set prescribing targets. These are mechanisms for setting benchmarks rather than constraining costs (e.g. hard budgets) that may have implications for quality of care. Targets aim to improve prescribing practices and resource allocation.<sup>269</sup>
- 6.56 The system could reward physicians for improved prescribing practices (e.g. through financial incentives) rather than impose punitive incentives. Positive reward systems have met with more success.<sup>270</sup> We recognize that financial incentives/bonuses for physicians are viewed unfavourably but they could be built up with quality indicators as part of their contracts. Prescribing targets for generics could produce cost reductions and quality improvements in prescribing practices.
- 6.57 Prescribing targets could exclude expensive drugs for patients with life-threatening diseases to ensure that equity concerns are not compromised. A risk-adjustment mechanism could be introduced to take account of age/sex, morbidity and socioeconomic indicators.
- 6.58 A joint framework agreed between Kela and the municipalities could address issues on information flows and more elaborate reporting

<sup>269</sup> In England, a new GP contract provides financial incentives linked to quality of care. A new quality-outcomes framework (QOF) is used to assess performance and determine large parts of GPs' payments. This has 76 clinical quality indicators in 10 areas (many of which affect prescribing), 56 organizational indicators and 4 patient experience indicators. It replaces prescribing incentive schemes and encourages GPs to diagnose and treat chronic diseases in line with specific numerical targets. Rewards for delivering all of these targets can be substantial – up to £42 000 per GP (includes all additional practice expenses such as employment of nurses to deliver much of the chronic care). For the moment, these indicators do not emphasize cost containment. Initial concerns include the incentives for a move towards target- rather than patient-focused activity; the diagnosis and treatment of milder cases in order to achieve targets more easily; the opportunity of moving resources and time from conditions outside the targeted areas; and a general increase in costs for uncertain benefit. However, the incentives are likely to deliver at least short-term change since they are remunerative and support professional aims. The sustainability or usefulness of any change remains to be seen.

<sup>270</sup> Mossialos, Walley & Rudisill, 2005.

systems. Kela could provide information on inappropriate prescribing with criteria including drugs that provide significant therapeutic benefit, high-volume drugs, high-cost drugs, drugs with significant risks/poor safety profiles and uncertainty in appropriate prescribing. Furthermore, monitoring of doctors in all three work settings would ensure that any differences arising from different work practices could be identified in the data. It is important to stress that the contentious nature of the results would require proper assessment and validation before the data could be published. This would be an equity exercise rather than a focus on cost control. Evidence on prescribing practices could be shared with the municipalities and ROHTO to inform their work.

- 6.59 Information on inappropriate prescribing could require the involvement of higher authorities in government. NAMLA could pass formal decisions to encourage doctors to adopt more appropriate prescribing practices. The Parliamentary Ombudsman examines issues in the health sector and could investigate if necessary. Decisions from either authority would be more effective if presented to promote best practices and benchmarking. Legal sanctions should be considered as the last resort.
- 6.60 **Prescribe low-cost generic equivalents.** The policy on simvastatin encouraged the prescribing of a low-cost statin in Finland and evidence suggests a high level of uptake. Similar policy measures could be introduced in other therapeutic areas where evidence suggests that low-cost generics yield the same therapeutic benefit (e.g. low-cost generic PPIs are available). Other potential therapeutic classes could be assessed to inform any changes in reimbursement.
- 6.61 **Revalidation and relicensing.** Overall professional development and educational training for doctors is an important component of improved prescribing practices. Revalidation and relicensing practices are common in other countries with well-developed health systems (e.g. United States, United Kingdom, Ireland). A more formalized system could be introduced to require all physicians to undergo CME training. In the medium to long term, a system of relicensing and revalidation could be developed and integrated into the health system.
- 6.62 **Industry promotional activities.** While guidelines cover promotional activities, it is hard to measure the industry's financial support for them. One approach might be to encourage the industry to contribute to an independent continuing personal development (CPD) fund that could identify activities and report on the use of funds. A more

proactive role is necessary to ensure monitoring rather than responding to company complaints. Monitoring activities could be supported by collaboration with NAM given its overall strategy to increase monitoring of the industry.

## Health centres

- 6.63 **Guideline development.** Guidelines developed by closer collaboration between ROHTO and Duodecim could provide health centres and hospitals with improved information for pharmacotherapy. These could be connected to risk assessments: for instance, assessment of patients with cardiovascular diseases would require information on low-density (LDL) and high-density (HDL) lipid levels as well as other possible risk factor such as smoking, family history and other diseases (e.g. diabetes). The decision-support system developed by Duodecim provides useful guidance. Guidelines could assist health centres to develop chronic-disease management programmes. Furthermore, these could draw on experience from other countries and be linked to international activities.

## Hospitals

- 6.64 The current system for drug procurement was discussed and we have highlighted issues concerning pharmaceuticals within the hospital sector. We present some considerations as part of our review.
- 6.65 **Standard formulary.** We understand that drug procurement and the trend towards group purchases have resulted in the development of joint formularies. Variations in the amounts and types of drugs purchased require guidance on standardization. The standard formulary could be used in a flexible way and account for factors such as variations in hospital sizes and local population health needs.
- 6.66 Procurement policies could be assessed to ensure that the FCA would not declare them anticompetitive. This may be necessary to ensure that coordination of such activities does not run counter to EU law.
- 6.67 **Clinical pharmacology.** We have indicated the need for capacity building in clinical pharmacology. Clinical pharmacologists in hospitals tend to have academically oriented roles but these could be expanded to include educating doctors on clinical pharmacology. Similarly, ward pharmacists disseminate information to health-care staff but their role could be enhanced to coordinate education work with clinical pharmacologists in the hospitals.

## Dual financing

- 6.68 Dual-financing streams for pharmaceuticals have been raised already, arising either from Kela or from the municipalities and the implications for cost shifting. The other key point concerns accountability problems that arise from these two streams among doctors who practise both publicly and privately.
- 6.69 **Prescribing budgets.** The OECD report of 2005 presented an option to introduce drug budgets for physicians. This was based on only one country experience (GP fundholding in the United Kingdom discussed in Chapter 4). One study indicated that savings of 6% resulted from the introduction of this policy. The report recommended that the same percentage could be achieved in Finland but we consider that it failed to consider the implications of such a policy.
- 6.70 The policy initiative in the United Kingdom was intended to regulate physicians' entrepreneurial behaviour and to improve responsiveness between hospitals and other health services. The policy was not centred on expenditure but rather the introduction of a system to improve resource allocation. This policy would not necessarily result in similar savings in Finland because of the various differences in the financing and provision of the health system and the behaviour of health-care professionals in these two countries. Finland has a dual system of financing which complicates implementation because of the potential for cost shifting between the municipalities and Kela.
- 6.71 Finland has a multiple employment system: doctors may work in public health centres, as occupational doctors or in private practice. The lack of a single system of employment complicates the possibility that such a policy transfer would result in the savings outlined in the OECD report. In the United Kingdom, a single system of employment facilitated measures for monitoring the implementation of the policy. Accountability measures were put in place in the United Kingdom, features that are absent under the current arrangements in Finland.
- 6.72 The United Kingdom's approach was to encourage behavioural changes by providing incentives to reward quality and improved decision-making. Finland has no clear system for monitoring the quality of physicians. ROHTO's pharmacotherapy role is an important initiative but there are no clear systems of audit and clinical peer review to encourage quality improvements in the public and private system of GP/specialist practices.

- 6.73 It is unclear whether the proposal considered cultural attitudes to such a policy. Doctors could perceive these budgets to be restricting their autonomy and clinical practice in order to achieve cost reductions. Furthermore, administrative reforms would be necessary – a move towards a single financing system (such as a transfer of funds from Kela to the municipalities) could be considered but we recognize that this would be a political decision.
- 6.74 In our view, this proposal did not take proper account of the financial flows or institutional and employment arrangements of physicians. The benefits of the proposal in the Finnish context are not clear in light of the current constraints. Financial incentives for quality improvements may have greater impact because of the multiple levels of accountability.
- 6.75 **Cost shifting.** The dual system of financing and its implications for cost shifting have been discussed. A review of this system was outside the scope of our review. We raise this issue to highlight that any policies to minimize cost shifting should consider policy options to address the problems in the dual-funding system. Any broad-based reform package of pharmaceutical policy will need to consider the implications of operating within this system of financing, unique among western European countries.

## Patients

- 6.76 **User charges.** Data suggest that user charges in Finland rank high relative to other western European countries. However, it is not known how much these user charges create socioeconomic inequities in access for low-income and vulnerable groups. Information on patients' ability to finance OOP payments for medicines would be useful for policy purposes.
- 6.77 The high level of user charges raises equity concerns about access to care and medicines. Currently, individuals have an annual ceiling but equity might be improved by applying this to families instead. This proposal is being considered as part of the MSAH review of pharmaceutical policy,<sup>271</sup> but may not be sufficient as the vast majority of patients that reach the annual limit are elderly and, quite possibly, living alone.
- 6.78 A means-tested programme could be another approach to provide greater coverage to those who cannot afford their medicines. However,

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<sup>271</sup> MSAH, 2003.

a set threshold could produce problems such as unintended consequences for individuals just at or above the threshold – they would rather be below in order to qualify for greater reimbursement coverage.

- 6.79 Within the current arrangements, certain diseases or conditions could be placed in the upper special reimbursement category. Alternatively, lower level co-payments could be introduced for generic medicines. This would address equity and access concerns given the high level of user charges in Finland. These lower co-payments would offer patients access to important medicines for which lower priced generic alternatives are already on the market. Systematic analysis would be required in order to identify the affected population groups; drugs that create access problems; and whether certain medicines in the lower reimbursement category should be shifted towards higher levels of reimbursement.
- 6.80 There is a need for a systematic analysis of how user charges affect individuals' access. This could take account of income levels, age/sex profiles, health state characteristics (e.g. whether access is impeded for groups with certain chronic conditions relative to the general population) and geographical locations. These socioeconomic and population indicators could be compared to the reimbursement levels. Kela's longitudinal data on patient payments could be a useful starting point. This analysis is particularly important because of the changes in the reimbursement levels; time series data would provide useful information about their impact on access and ability to pay.
- 6.81 These exercises could inform policy decisions addressing inequities in access and their implications for patients' health. The reimbursement level for certain drugs may need to be re-examined. This analysis could also reveal consumption patterns for self-care medicines and provide important input for the development of an OTC policy in Finland (as proposed earlier). Patients with financial difficulties may avoid expensive prescription medicines and purchase less expensive OTC/self-care medicines that may not treat their conditions.
- 6.82 **Appropriate prescribing and patient compliance.** Evidence on inappropriate prescribing levels and polypharmacy among the elderly, particularly in institutional settings, has been discussed. The government's pharmaceutical strategy could consider intervention measures to address this important issue.

- 6.83 Understaffing of resident doctors in institutional settings creates a challenge for such assessments. The pilot project on medicine review of elderly people in home-dwellings is an important initiative in this area. This project could be formalized into the work of pharmacists and nurses who could carry out medicine reviews in institutional settings.

### **IT systems**

- 6.84 Systems in health centres, hospitals and pharmacies collect very useful information but these databases could be developed to include OTC and herbal medicines.
- 6.85 Initiatives that are under way as part of the decision-support system (supervised by Duodecim) will have the potential to generate a system of alerts and check-up invitations for patients. These welcome initiatives will significantly enhance the health intelligence infrastructure as part of the government's programme for an electronic patient-record system, e-prescribing and a national archive system.
- 6.86 Guidelines could be promoted by promoting their relevance to patient organizations and the general public. Dissemination strategies could include making the guidelines accessible via the Internet and local distribution to health centres, hospitals and pharmacies.
- 6.87 Increased data collection and IT strategies in e-health will require policies for better coordination and information sharing between relevant actors. Furthermore, guidelines on pharmacovigilance could assist in data collection and indicator selection for analyses. One implication will be the need for compatible software and systems to assist data sharing between, for example, health centre and hospital medical records, Kela and pharmacies. This would inform policy decisions on pharmaceutical trends such as costs, doctors' prescribing practices in public and private settings, and data on patients.
- 6.88 Furthermore, this information could aid the development of guidelines on the management of co-morbidities and chronic disease. Shared information on pharmaceutical data could have relevance for the broader health system and policy planning in service provision too. The data could be used to carry out and research epidemiological studies of patients and specific patient groups (e.g. those with chronic conditions, rare diseases, etc.). The development of IT systems could draw on Finland's strong tradition of health service and epidemiological research to identify and support new areas of investigation.





# **Background information on the review of pharmaceutical policy prepared by the Ministry of Social Affairs and Health**

## **Pharmaceutical expenditure**

Under the direction of Mr Kimmo Leppo, Director-General at the MSAH, pharmaceutical cost containment has been discussed between relevant authorities over the past year (health and insurance departments at the MSAH, NAM, Kela and FinOHTA). Pharmaceutical costs consist of the price of the medicine (the share of the pharmaceutical company and the medicine wholesale, i.e. the wholesale price; the sales margin determined by the drug tariff; 8% VAT; and the pharmacy fee of around 7%) and the costs of using it. Pharmaceutical expenditure grows continuously more rapidly than other health expenditure. The growth is caused mainly by new and expensive medicines but also by the increasing use of medicines among the ageing population and the development of medicines against illnesses that previously were not covered by pharmacotherapy.

The Parliament has issued an opinion stating that the Government conducts a thorough review of measures needed to contain the growth of pharmaceutical costs in cooperation with authorities and other stakeholders (such as the pharmaceutical industry, pharmacies, and patient organizations) and prepares necessary proposals for a revision of the Medicines Act and the medicine reimbursement system in accordance with the review.

The G10 Process of the EU aims to improve the competitiveness of the pharmaceutical industry, while taking account of public health concerns. The challenge is to identify and reward innovations and at the same time contain the growing medicine costs.

#### 1. Increasing information and utilizing statistics

- It is important to know the relative effectiveness of a medicine (therapeutic added value of a medicine compared to a comparator and considered in relation to the costs incurred by the medicine) when the pricing, reimbursement and use of the medicine are contemplated. Reviewing the relative effectiveness of medicines is one of the tasks of the EU G10 High Level Group on Innovation and the Provision of Medicines. Project funding within the EU Public Health Programme could be used to finance projects related to this issue.
- Utilization of the health insurance statistics and the research of the Social Insurance Institution of Finland (SII): analysing the background of the growth of pharmaceutical expenditure, the development of health care expenditure as well as the consumption of medicines according to illnesses, medicine groups and regions. The statistics provided by SII facilitate accurate analyses according to regions and (groups of) physicians with regard to prescription practices. The Research Department at SII intends to analyse the reasons behind the growth of pharmaceutical costs according to medicine groups (whether cost increases within a certain medicine group are caused by, for example, a transition to expensive medicines or an increase in the number of users). The present feedback data collected by Kela on prescription practices can be developed by enclosing guidance on how to use the medicine, for example.

#### 2. Rationalization of prescription practices

- The ROHTO will continue to develop the operation forms presently under construction. However, it wants to be able to modify its practices if necessary. The ROHTO workshops review each medicine/illness group, including pharmacotherapy costs, with the aim of creating a code of conduct for pharmaceutical practices that have cost effects and of following up whether this code of conduct is adhered to. Cost comparisons that are a part of the national Current Care guidelines will be included in printed material; electronic recommendations will be linked to information on costs. An electronic decision-making support system will suggest the least expensive medicine suitable for the patient.

This system will also be linked to Current Care and cost data. Kela's feedback system for physicians' prescription practices will be developed.

- A regular total review of pharmacotherapy will be launched, in particular multiple-medicine use by the elderly needs to be examined. The attending physician bears responsibility with support from a team of other professionals.

### 3. Medicine reimbursement system

- The reform of the medicine reimbursement system and the 5% cut in wholesale prices came into effect on 1 January 2006.
- The definition of the 0 refund category excludes certain medicines and groups of medicines from the reimbursement system (including medicines for temporary minor illnesses as well as hypnotics).
- The grounds for reimbursement will be examined in light of international experience in order to create an RP model applicable in the Finnish system to facilitate increased competition between pharmaceutical companies. It will be easier to incorporate an RP price system in the reimbursement system as the latter was simplified in early 2006. A working group at the Insurance Department at the MSAH will complete its work in early 2007 with the purpose of incorporating the proposal into the next government programme.
- Under an RP system, an authority defines the medicines belonging to a specific group and determines a reference (or reimbursement) price for it. Such a group can consist of products with the same active substance; containing active substances that belong to the same medicine group; or with the same therapeutic effect. The price of an individual medicinal product can be higher than the RP, but a patient purchasing the product is reimbursed solely on the basis of the RP. The difference between the RP and the actual price is borne entirely by the patient. This system is intended to encourage the prescription and use of cheaper generic drugs.

### 4. Pharmacy system

- The pharmacy fee that evens out the variations in financial performance of community pharmacies will be replaced by a new method of securing a comprehensive system of community pharmacies that does not raise medicine prices and allocates effective support to pharmacies in need. The proposal will be included in the next government programme.

- In 2004, the NAM proposed that the pharmacy fee should be halved and that the future of the community pharmacy network should be secured primarily by developing the system of subsidiary pharmacies. One option is an internal adjustment between the pharmacies where bigger pharmacies finance a fund to support smaller pharmacies. In this way support would not circulate from one pharmacy to another and medicine prices would drop by 7%. If the present adjustment system is preserved for longer, it will be assessed whether private pharmacies will have to pay their pharmacy fee in advance (at present, the fee is paid in the following year).
- The drug tariff determining the sales margin of a pharmacy will be revised to correspond with the present medicine price structure. During 2006, the drug tariff will be made more regressive than at present. It will also become fixed-term. According to the preliminary proposal by NAM, the pharmacies' profit would have been cut by €8 million in 2003. A ceiling for the pharmacies' sales margin is being considered.

#### 5. Financial responsibility for medicines

- Proposals for solving the problems created by the two-way financing of medicines are being considered. In spring 2006, the health and insurance departments at the MSAH appointed a rapporteur to make proposals concerning a revision of the guidelines or legislation on financial responsibility and, if necessary, to propose other potential measures such as a further review of the financial system for medicines.
- In outpatient and private health care patients and the health insurance system pay for the medicines elsewhere medicines are financed by municipal health care. This causes confusion about the financier, variations in practices and cost transfers to other parties as well as inefficiency. In the present system, physicians prescribing the medicines have little interest in influencing drug costs in outpatient care.

#### 6. Constraining the growth of pharmaceutical expenditure to a percentage agreed beforehand

- In the budget framework, the growth of total expenditure has been confirmed to be no more than 5% per year. The growth percentage would be based on, for example, Kela's assessment of the effects of demographic change on the growth of expenditure. If the measures explained in this memo are not sufficient to ensure that the growth of expenditure remains within the defined framework, further measures

should be examined. These could include, for example, medicinal-product specific agreements (in particular for expensive medicines and medicines with no established use) which would require a pharmaceutical company to refund the surplus or cut the price of a medicine when a certain reimbursement sum is exceeded.

## 7. Marketing

- Influencing pharmaceutical companies' marketing practices: in 2006, NAM conducted a survey on international regulations and policies regarding pharmaceutical marketing. On the basis of the survey, certain measures such as a revision of provisions and/or tightening of supervision will be considered.

## 8. Assessment and further work concerning the proposals presented in the OECD Country Review for the development of pharmaceutical services

- In 2006, the health and insurance departments at the MSAH, as well as Kela, conducted a survey regarding intermediate forms between information steering and the physician-specific drug budgets proposed by the OECD. One solution could be drugs budgets for health-care centres or hospital districts in the context of the present financing system for medicines. The drugs budget would be either directive or binding and it would include incentives such as the possibility of using the savings on pharmaceutical expenditure for other tasks. The specific characteristics of occupational health services and the private sector would be taken into consideration.

## 9. Pharmacoeconomic research

- Possibilities to intensify pharmacoeconomic research are examined. Also the possibilities of incorporating this research into political decision-making are studied. Financing may be available from the rehabilitation resources of Kela.

## 10. External rapporteur

- In spring 2006 Professor Elias Mossialos, an international expert on health economics, prepared proposals on assignment by the Health Department at the MSAH regarding measures that Finland should take in order to contain the growth of pharmaceutical expenditure, in light of international experience.

### 11. Common forum for different stakeholders

The MSAH held a seminar where different stakeholders came together to consider different ways to contain pharmaceutical expenditure.

## Annex 2

# Stakeholders consulted

### Finnish Competition Authority (FCA)

- Mr Jan Nybondas
- Mr Martti Virtanen
- Ms Liisa Vuorio

### Finnish Medical Association (FMA)

- Mr Pekka Anttila
- Mr Risto Ihalainen
- Mr Markku Kojo

### FinOHTA (Finnish Office for Health Technology Assessment)

- Mr Antti Malmivaara

### Finnish Pharmacists' Association (FPA)

- Mr Harri Ovaskainen
- Ms Inka Puumalainen

### Kela (Social Insurance Institution)

- Mr Mikael Forss
- Mr Timo Klaukka
- Mr Pekka Koivisto
- Mr Timo Maljanen
- Ms Jaana Martikainen

Ministry of Social Affairs and Health (MSAH)

- Ms Terhi Hermanson
- Professor Jussi Huttunen
- Mr Pekka Järvinen
- Mr Kimmo Leppo
- Ms Marja-Liisa Partanen
- Mr Juho Saari
- Mr Kari Välimäki

Ministry of Trade and Industry (MTI)

- Mr Kristian Tammivuori

National Agency for Medicines (NAM)

- Mr Hannes Wahlroos

Pharma Industry Finland (PIF)

- Mr Jarmo Lehtonen
- Ms Sirpa Rinta

Pharmaceuticals Pricing Board (PPB)

- Ms Ulla Kurkijärvi
- Ms Mareena Paldan
- Ms Sinikka Rajaniemi
- Mr Matti Toiviainen

ROHTO (Centre for Pharmacotherapy Development)

- Ms Taina Mäntyranta

The Association of Finnish Local and Regional Authorities

- Mr Rolf Eriksson
- Ms Liisa-Maria Voipio-Pulkki

The Association of Finnish Pharmacies (AFP)

- Mr Klaus Holttinen
- Mr Reijo Kärkkäinen

Vallila Health Centre

- Ms Seija Grönqvist
- Ms Kati Kobler



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### Cases

*Deutscher Apothekerverband vs. Doc Morris*, Case C-322/01, ECR I-14887, European Court of Justice, 2003.

*European Commission vs. Republic of Finland*, Case C-299/00, European Court of Justice, 2003.

### Decrees

Ministry of Social Affairs and Health. Annex to the Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price, on special reimbursement status for a medicinal product, and on the documentation to be attached to the application. Decree 1393/2003, Helsinki.



Ministry of Social Affairs and Health. Decree by the Ministry of Social Affairs and Health on applications for a reasonable wholesale price and reimbursement status of a medicinal product and on the documentation to be appended to the application. Decree 1111/2005, Helsinki.

Pharmaceuticals Pricing Board, Act 1151/2003; Decree 1377/2003, Helsinki.

### **Directives**

Council Directive 89/105/1988, Article 6, Subparagraphs 1 and 2.

Health systems are under continuous pressure to meet the demands of their populations. In Finland, one area currently under review is that of pharmaceutical policy. Following a request made by the Health Department, Ministry of Health and Social Affairs (MSAH), this report provides a policy review of the regulatory system of pharmaceutical policies in Finland. Our assessment suggests that despite the challenges within a very developed system of pharmaceutical regulation, there are practical options to improve transparency and pricing policies, to strengthen the institutional environment and to improve the development of pharmacotherapy practices. The purpose of this report is not to provide prescriptive solutions but to suggest a range of options for policy-makers to reflect on so as to assist them in the process of policy review.

This report offers a range of views from an international perspective and it is intended that this study might stimulate further debate on the continuing development of pharmaceutical policies.

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