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ÖBIG

COMMUNITY PHARMACY IN EUROPE

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ÖBIG

COMMUNITY PHARMACY IN EUROPE

Lessons from deregulation – case studies

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Foreword

It is a great pleasure for me to have opportunity of introducing this study on legislation in the pharmacy sector. The EESC is the EU Institution which represents organized civil society, and as its President and also because of my background, I am very interested in all issues related to liberal professions and particularly in research looking at regulation and the public interest.

I am convinced of the importance of organized civil society, and I think that liberal professions play a key role in civil society. I am convinced that the services provided by liberal professions have been and will continue to be essential for the proper functioning of our society.

In recent years, the EU Institutions have taken a great deal of interest in this sector. For example, the recent Communication from the European Commission entitled “Report on Competition in Professional Services”, the responses from the other institutions to this Communication, including the activities that the EESC has undertaken and is continuing to do on the subject, confirm that this sector is a key one to society and therefore a major contributor to the achievement of the Lisbon objectives.

At the end of 2003 the European Parliament adopted a Resolution on this subject. In that document the Parliament outlined very well the relation between competition in the areas of liberal professions and the need to ensure adequate regulation to protect the public interest. The European Parliament also clearly recognized the additional specificity of liberal professions active in the health sector, something which I think it is important to underline in the context of this study.

The study by the OBIG Institute highlights very well how the pharmacy sector, which is an integral part of healthcare systems, is an area in which, even though there are different models and different levels of regulation, the common objective is the protection of the public interest. This is achieved by ensuring convenient access to pharmacy services and thus contributing to a high level of public health protection. In addition, the study demonstrates that in the pharmacy sector the public payer (the National healthcare systems) and the private operators (in most case pharmacists) ensure effective and well-developed services throughout the national territories. Clearly, the study shows that adequate regulation is an additional guarantee to ensure good, effective, sustainable and accessible services.

The authors of the study have carried out exhaustive research including contacts with many stakeholders involved in the pharmacy sector, patient groups and national authorities and the development of a comprehensive questionnaire aiming to provide a balanced picture of the sector.

In my view, the key factor in analysing any area of professional services is to make sure that all aspects of the services and moreover the objectives that the service aims to ensure, are taken into account. It would be incomplete to base any analysis of such a complex sector only on merely economic data. This study is certainly an important step towards providing a comprehensive picture of a complex and essential sector like the pharmacy sector.

I am pleased to conclude that this study makes very interesting reading and offers very useful and up to date information. I would recommend it without reservation to those interested in getting to know more about how pharmacy services are organised and provided nowadays in several countries in Europe.

Anne-Marie Sigmund
President of the European Economic and Social Committee

Executive Summary

In the last few years, deregulation of public services has taken place in several Member States of the European Union. One of the sectors targeted is health care, and, among others, the pharmacy business. Pharmacy is, by tradition a strictly regulated sector, in order to guarantee high quality of and broad accessibility to pharmaceuticals. Typical regulations in the pharmacy sector concern the establishment of new pharmacies (often based on the assessment of the public's needs), ownership issues (pharmacies owned by independent pharmacists, prohibition of pharmacy chains), as well as the quality of the training of pharmacists and other staff working in community pharmacies.

The rationale behind deregulation in the pharmacy sector is the expectation that liberalisation will increase competition and thus succeed in lowering, or at least containing, (public) expenditure, while accessibility to and quality of pharmacy services will be, at least, kept stable or even be improved by the opening of new outlets. By now, scientific evidence has not been provided for the arguments in favour of deregulation especially in the pharmacy sector, as no detailed investigation has yet been carried out on this particular issue in Europe.

The Pharmaceutical Group of European Union (PGEU) commissioned the Vienna-based, independent research institute ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen/ Austrian Health Institute) to survey and analyse possible effects of deregulation in the pharmacy sector, with a special focus on the accessibility to, the quality of, and the expenditure of pharmacy services. Performance indicators of pharmacy services were developed, analysed and ranked, based on data gathered in selected European countries, analysed and ranked. In addition, to examine the assumption of cost-containment triggered by deregulation, the ÖBIG team performed a single-price comparison of OTC blockbusters.

The outcome of the analysis is this ÖBIG report “Community Pharmacy in Europe: lessons from deregulation - case studies”, submitted to the PGEU in February 2006.

Highlighting pharmacy deregulation in case studies

In order to study in detail the impact of deregulation for community pharmacies, three European countries, which have undergone liberalisation in the pharmacy sector, were selected for an in-depth investigation and analysis. After having collected the necessary data in a next step, they were subject to a cross-country comparison and benchmarking, comparing their performance to reference countries whose pharmacy sector is still highly regulated.

The three deregulated “case study” countries are Ireland, the Netherlands, and Norway.

The pharmacy sector in **Ireland** has always been a very liberal one, with quite a few regulations. One of the current challenges in drafting a new Pharmacy Act is to include modern “fitness-to-practice” rules, which, among others, will enable the Pharmaceutical Society of Ireland, a statutory body, to sanction pharmacists. As a general rule, in Ireland in principal any individual or legal person could own one or more pharmacies. In reality, pharmacy chains, often owned by pharmacists have started to be set up in the mid-1990s; all three Irish

wholesalers are involved in the pharmacy business. In 1996, needs-based establishment criteria for opening of pharmacies were introduce for the first time and were again revoked in 2002, leading to a rise of the number of pharmacies afterwards. In general, the provision with pharmacies, complemented by self-dispensing doctors, is rather good, compared to the other countries under survey. However, there are indications for a clustering of pharmacies in economically attractive urban places, whereas the satisfactory provision with dispensaries of prescription-only medicines in rural areas seems to be one of the challenges of the future.

In the **Netherlands**, the pharmacy sector has likewise been traditionally rather liberal. The sale of over-the-counter (OTC) products outside pharmacies has been allowed for more than a century, leading to a dichotomy between the dispensing of prescription-only medicines (POM) in Dutch community pharmacies and the sale of OTC products in drugstores. In the late 1990s, establishment and ownership rules, which had never been statutory, but determined by the Royal Dutch Pharmaceutical Society, were abolished. Since then, the increase in the number of pharmacies (especially in attractive urban places) as well as the rise of pharmacy chains has been observed. A major difference to pharmacies in other European countries concerns the composition of pharmacy personnel in the Netherlands. While Dutch pharmacies are, in general, well staffed, there is a comparatively low number of pharmacists per pharmacy, and pharmacy assistants, having received a secondary vocational education, are allowed to perform tasks, that are exclusively reserved to pharmacists in other countries (e. g. filling prescriptions or providing counselling to customers). The matter of qualified staff in Dutch pharmacies continues to be a burning issue: Under the new Pharmacy Act, which is currently drafted, pharmacists might be entitled to act as supervising pharmacists in more than one pharmacy, thus no longer guaranteeing the constant presence of a pharmacist in a pharmacy.

The Norwegian case is often quoted as the key example for deregulation of pharmacy services. Before liberalisation in 2001, the pharmacy sector in **Norway** was a very strictly regulated one, with a five-year state plan on the establishment of new pharmacies and the prohibition of multiple and non-pharmacist ownership. After the removal of the establishment rules in March 2001, there has been a sharp increase in the openings of new pharmacies. This development, on the one hand, is considered as a positive one because there was an under-supply of pharmacies before 2001, but, on the other hand, it has been, observed with concern due to an obvious trend for urban clustering. Even if, according to an agreement between the Norwegian Ministry of Health and pharmacy chains, no pharmacies have been closed in rural areas in the past few years, every second Norwegian municipality still has no pharmacy, as new pharmacies were mainly opened in municipalities where pharmacy services were already available. Another problem arises from the fact that the number of community pharmacists and other pharmacy staff could not keep track with the major increase in the number of pharmacies. Apart from this, vertical integration is the other major effect of the deregulation process in the Norwegian pharmacy sector. Within a surprisingly short period of time, pharmacy chains have been established, which are mainly owned by the three large European pharmaceutical wholesalers, thus dominating the market. Only four years after deregulation, four out of five pharmacies in Norway are part of a pharmacy chain owned by a wholesaler.

In addition to the increase in the number of pharmacies, Norway has also seen a considerable emergence of so-called LUA-shops (now around 6,000), which have been, since 2003, allowed to sell a small range of OTC blockbusters.

Besides the country-specific analysis of these three case study countries to identify possible changes arising from deregulation, their current pharmacy sectors were assessed in comparison to the ones of a control group. As reference countries **Austria**, **Finland** and **Spain** were chosen a reference countries, whereas France and Portugal acted as back-up countries, providing additional information if necessary.

These selected countries are characterised by several regulations in the pharmacy sector: They all have statutory establishment criteria as prerequisite for the opening of new pharmacies, providing for the ownership of community pharmacies only by pharmacists and prohibiting multiple ownership.

Urban clustering and accessibility concerns for rural areas

Accessibility is a key indicator for assessing pharmacy services in a country. It is mainly reflected not only in a sufficient number of POM-dispensaries reachable within reasonable time, but also in the range of products and services available.

Deregulation on establishment rules for pharmacies may lead, as evidenced in Norway after liberalisation, to a strong increase in the number of pharmacies. Within the group of the six countries surveyed, Norway, however, still lacks behind with regard to the pharmacy density (8,500 inhabitants per prescription-only medicines (POM) dispensary, The lowest ratio of inhabitants per POM-dispensary was found in Spain (2,050); followed by Ireland (3,000) and Austria (3,700). The development of the pharmacy density has been rather stable in Spain and Austria.

The removal of establishment rules for pharmacies usually leads to more pharmacies, but the new openings take place, for the most part, in attractive places, mainly city centres, as observed in the case study countries in this report. Besides the possible negative impact from a business perspective (excessive growth within a small area may damage the economic viability of the pharmacies), there are concerns from a public health perspective: With the focus on uncontrolled urban clustering, sparsely populated rural areas may be neglected.

Concerning the accessibility to pharmaceuticals, most of the surveyed countries (including the deregulated ones) provide for an immediate availability of frequently asked pharmaceuticals in their legislation or self-regulation. Among the countries studied, an immediate availability of pharmaceuticals is best guaranteed in Austria and Finland, followed by Spain and the Netherlands. This has also to be seen in connection with a high frequency of wholesale deliveries (on average three deliveries a day in Austria and Spain).

Market dominance resulting from vertical integration

In the regulated countries (Austria, Finland, and Spain), due to the regulations on ownership, every community pharmacy is owned by an independent pharmacist. In Ireland and in the

Netherlands, respectively 90% and 77% of the pharmacies respectively are owned by pharmacists, who in some cases co-operate and form pharmacy chains in response to the market dominance by other actors. This market power of (mainly) pharmaceutical wholesalers in the pharmacy sector is excessive in Norway, where big pharmaceutical wholesale companies bought many pharmacies within short time after deregulation, leaving only 19% of the pharmacies owned by pharmacists. In the meantime only 2% of all Norwegian pharmacies are not part of a pharmacy chain, while the respective numbers for Ireland and the Netherlands are about 25% and 70% respectively.

The Norwegian case evidences quite well that deregulation does not automatically lead to a boost in competition, because, without providing for safe-guards in the legal framework (e. g. excluding or limiting certain actors with regard to the ownership of community pharmacies), actors will utilise loop-holes to gain market dominance.

Another assumption is that the deregulation of community pharmacies may contribute to cost-containment, especially through a decrease of pharmaceutical prices. In this ÖBIG report the price development of four OTC blockbusters has been analysed from 1995 to 2005 (paracetamol tablets, ibuprofen tablets, diclofenac cream/gel and aciclovir cream/ointment) in the six countries under survey. The focus was put on OTC products, as in the prescription segment prices are usually determined by or negotiated with the state, while the development of free-priced OTC products could give an indication of the impact of deregulation on cost-containment. However, in none of the six countries clear price reductions for at least two of the OTC products selected could be observed, with Austria and Finland having the most stable price development, and Ireland and Norway showing the highest price fluctuations and growth rates respectively.

In addition, the three regulated countries (particularly in Finland) and the Netherlands had, in the last decade, lower growth rates in pharmaceutical expenditure compared to Ireland and Norway, whose runaway pharmaceutical expenditure needs to be seen in connection with the boosting economy of these countries.

Be aware of false expectations

Pharmacists are key health professionals, and community pharmacies in Europe play an important role in health care promotion and disease prevention, as patients do not only have their prescriptions screened and filled, but receive tailor-made preparations and pharmaceutical services (such as health checks or health related information, e. g. for Diabetes, Asthma or smoking cessation). Community pharmacists provide advice and counselling, and may, particularly in sparsely populated areas, even act as first contact point for patients.

The quality of pharmacy services in Europe is, in general, on a high level. This positive evaluation on the pharmacy sector is, according to the results gained in this survey, substantially true for all six countries analysed (Austria, Finland, Ireland, the Netherlands, Norway, and Spain).

However, when benchmarking the indicators on accessibility, quality, and expenditure, some countries (to a larger extent. the ones of the control group with a stricter regulatory framework) rank better than the others, whose performance is, nevertheless, still more than satisfactory. Every system – and thus, also the pharmacy sector – has its particularities, which reflect historical developments, cultural patterns and traditions. Therefore, the assessment of the pharmacy sector in this report was not limited to the impact of liberalisation in the deregulated countries, as each country's "policy culture" has been taken into account. For example, despite indications that tailor-made services may disappear after deregulation, the low relevance of magistral preparations in the deregulated countries under survey was contributed to traditional reasons, as these preparations have never played a major role in such countries.

The report "Community Pharmacy in Europe: lessons from deregulation - case studies" comes to the conclusion that deregulation in the pharmacy sector has not met the expectations, provided that these have explicitly been defined beforehand. In the three deregulated countries in this survey, liberalisation in the pharmacy system "happened" as one part of an overall deregulation process targeting several sectors like energy supply or telecommunications.

Assuming that increasing competition and cost-containment as the two key aims of deregulation, the research undertaken in this study could not provide any evidence that these goals have been achieved through deregulation of community pharmacies. On the contrary, unfavourable side-effects could be observed, such as extreme market power by other players dominating the pharmacy sector and therefore causing concern in relation to competition, or the uneven spread of new openings of pharmacies with disregard for rural areas. Thus, if deregulation is on the agenda for political reasons, modifications in the legislation should be well-prepared and include mechanisms, incentives and rules to prevent adverse effects for the citizens.

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AESGP	Association of the European Self-Medication Industry
AMP	Apotheken Monitoring program (Netherlands)
ASHP	American Society of Health System Pharmacists (USA)
AWBZ	Algemene Wet Bijzondere Ziektekosten (Netherlands)
BSc	Bachelor of Science
CBG	College ter Beoordeling van Geneesmiddelen (Netherlands)
cf.	confer
CTG	College voor tarieven in de gezondheidszorg (Netherlands)
CVZ	College voor Zorgverzekeringen (Netherlands)
DoHC	Department of Health and Children (Ireland)
DP	Drug Payment (Ireland)
DSW	Delfland, Schieland en Westland (Netherlands)
e.g.	Exempli gratia (= for example)
EEA	European Economic Area
EFP	Especialidades Farmaceuticas Publicitarias (Spain)
EMEA	European Medicines Agency
EU	European Union
FHI	Folkehelseinstituttet (Norway)
GDP	Gross Domestic Product
GMS	General Medical Services (Ireland)
GP	General practitioner
GPP	Good Pharmacy Practice
GSK	Glaxo Smith Kline
GVS	Geneesmiddelenvergoedingssysteem (Netherlands)
HE	Health expenditure
HPAI	Hospital Pharmacists Association of Ireland (Ireland)
HSE	Health Service Executive (Ireland)
HTD	High Tech Drugs (Ireland)
i.e.	id est
ICCPE	Irish Centre for Continuing Pharmaceutical Education (Ireland)
IGZ	Inspectie voor de gezondheidszorg (Netherlands)
IMB	Irish Medicines Board (Ireland)
inh.	Inhabitants

IPHA	Irish Pharmaceutical Healthcare Association (Ireland)
IPU	Irish Pharmaceutical Union (Ireland)
IWG	Interdepartementale Werkgroep Geneesmiddelendistributie (Netherlands)
KELA	Kanseläkelaitos (Finland)
km	kilometre
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Netherlands)
LTI	Long Term Illness (Ireland)
LUA	Legemidler Utenom Apotek (Norway)
mill.	millions
MSc.	Master of Science
n.a.	not available
NAF	Norges Apotekerforening (Norway)
NAM	National Agency for Medicines (Finland)
NAN	Nederlandse Apotheeknorm (Netherlands)
NHS	National Health Service (Ireland)
NIS	National Insurance Scheme (Norway)
NMD	Norsk Medisinaldepot (Norway)
NOK	Norwegian crowns
NoMA	Norwegian Medicines Agency (Norway)
NPCF	Nederlandse Patienten en Consumenten Federatie (Netherlands)
ÖAK	Österreichische Apothekerkammer (Austria)
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen – Austrian Health Institute
OECD	Organisation of Economic Co-operation and Development
OTC	Over-the-counter
PCRS	Primary Care Reimbursement Service (Ireland)
PGEU	Pharmaceutical Group of the European Union
ph.	pharmaceuticals
POM	Prescription-only medicines
PPP	Pharmacy purchase price
PRP	Pharmacy Retail Price
PSI	Pharmaceutical Society of Ireland (Ireland)
quo.	quoted
reg.	Regulation existing
SD	Self-dispensing

SFK	Stichting Farmaceutische Kentallen (Netherlands)
SM	Self-medication
STM	Sosiaali- ja Terveysministriö (Finland)
Tab.	tablet
UK	United Kingdom
VAT	Value Added Tax
VNA	Verenigde Nederlandse Apotheken (Netherlands)
vs.	versus
VWS	Volksgezondheid, Welzijn en Sport (Netherlands)
WGV	Wet op de Geneesmiddelenvoorziening (Netherlands)
ZFW	Ziekenfonds Wet (Netherlands)

1 Introduction

The Austrian Health Institute (Österreichisches Bundesinstitut für Gesundheitswesen, ÖBIG) was commissioned by the Pharmaceutical Group of the European Union (PGEU) to carry out a study on the pharmacy sector, with special regard to the effects of liberalisation in this segment. The project started in May 2005, and the report of the study "Community Pharmacy in Europe: lessons from deregulation - case studies" was submitted to the PGEU in February 2006.

1.1 Background

Pharmacists are key health professionals; They are responsible for checking and filling prescriptions and they are traditionally involved in the production of tailor-made preparations. In addition, with the growing importance of the OTC (over-the-counter) segment and of self-medication, they are increasingly acting as health advisers providing counselling to patients. Their product range thus covers not only pharmaceutical specialities but also intangible assets, such as various pharmaceutical services to the customers (like health promotion activities).

Due to the responsibility for assuring high quality, the pharmacist profession as well as the pharmacy sector in general are highly regulated in many European countries. Key areas of regulation concern the establishment of pharmacies (e.g. a needs assessment for new pharmacies) and ownership issues (e.g. limitation of ownership to pharmacists, and limits to the ownership of multiple pharmacies), as well as the qualification of pharmacists and other pharmacy staff.

In the last few years, together with the deregulation process in several other public sectors, the pharmacy sector was liberalised in some countries. In other Member States and at the EU level a discussion on the extent of (de-)regulation for liberal professions, among others pharmacists, has started.

A burning issue in this context are the possible consequences of deregulation of the pharmacy sector with regard to the fulfilment of the citizens' needs and public health.

1.2 Objective

The aim of this study "Community Pharmacy in Europe: lessons from deregulation - case studies" is to identify and analyse potential effects of deregulation in the field of community pharmacies.

The evaluation of the consequences of the liberalisation process in the pharmacy segment will be based on three pillars:

- accessibility
- quality, and
- expenditure.

The analysis is carried out on a country-specific macro-level from the perspective of public health and patients.

1.3 Methodology

To guarantee a smooth co-operation with the commissioner of the project, a contact group was set up, consisting of representatives of the PGEU Executive Committee and pharmacy experts with experience in research and analysis.

For analysing the impact of deregulation on community pharmacies, the following methodological approach was chosen: The situation in three deregulated countries (so-called case study countries) was surveyed and analysed in a comparative way with regard to the situation before and after the deregulation process, and with regard to three reference countries characterised by a larger extent of regulation.

Criteria applied for the selection of the case study countries were the following:

- European context
  The countries chosen should be situated in Europe, and should be either EU or EEA Member States.
- Deregulation process in several fields
  The case study countries should have undergone a deregulation process in the pharmacy sector. This reform would affect various regulatory areas, such as the establishment and ownership of pharmacies, rules for distribution and dispensing of pharmaceuticals (e. g. new actors allowed), the training and qualification of pharmacists and other pharmacy staff, and the availability of pharmaceuticals.
- Data availability on the change process
  The reform should have taken place only a few years ago, to ensure the availability of the necessary information on the situation before as well as after the reforms, enabling an analysis.
- Comparability of countries
  When selecting the countries the project team considered that both country groups should have similar characteristics, e.g. choosing one deregulated Nordic case study country should be accompanied by the selection of a Nordic control group country.

On the basis of these criteria, and in deliberation with the commissioner, the following de-regulated countries were selected:

- Ireland
- The Netherlands
- Norway

As reference countries (forming the so-called control group), the following regulated states were taken:

- Austria
- Finland
- Spain

The information and data for the case study countries were collected at first hand, in the course of the study visits to the countries. During these visits several personal interviews (8 in Ireland, 5 in the Netherlands, 8 in Norway) were undertaken, with representatives from competent authorities (e.g. the Ministry of Health, the reimbursement agency), pharmacists' representatives (e.g. pharmacists' associations, individual pharmacists), industry and pharmaceutical wholesale representatives, patients' organisations, and research institutes. The list of institutions directly contacted during the study visits is displayed in the Annex. The study visits lasted for 3-4 days and took place in August (Ireland, Netherlands) and September 2005 (Norway).

As key instrument of the survey the authors compiled a questionnaire, with questions mainly on the regulatory framework and for collecting data on the pharmacy sector (e.g. number of pharmacies and other dispensaries, number of community pharmacists and other pharmacy staff, number of pharmaceuticals, turnover, etc.). The questionnaire was presented to the contact group and then sent out to the six countries under survey (for a model questionnaire see Annex II). The questionnaire was also handed to Portugal, which - like France - kindly offered to act as a so-called back-up country.

Furthermore, the pillar "expenditure" of the evaluation is, among other indicators, based on a comparison of the price development of selected OTC medicines. Under consideration of various methods ÖBIG suggested to perform a single-price comparison of OTC blockbusters. Out of the 15 top-selling OTC products in each country ÖBIG, together with the contact group, identified four comparable substances (paracetamol tablets, ibuprofen tablets, diclofenac cream/gel and aciclovir cream/ointment); the comparison price being the pharmacy purchase price as information on this price level was available in all six selected countries. The period under investigation was 1995 till 2005, using the price level from 1 January each year. These price data were, if possible, gathered directly from contact institutions (pharmacy associations) in the six countries by differing between the most expensive and the least expensive product on the market. Of the four chosen substances diclofenac cream was found not being on the market or being classified as POM in Norway, Ireland and the Netherlands.

Based on the data collected, a number of indicators for accessibility, quality and expenditure were developed and assessed (cf. Table 1.1).

Table 1.1: The indicators, relating to the three pillars (accessibility, quality and expenditure), that were applied in this study

Accessibility	Quality	Expenditure
Provision with community pharmacies Accessibility of prescription-only medicines Accessibility of prescription-only medicines in rural areas Availability of pharmaceuticals Frequency of wholesale deliveries	Availability of pharmacists Professional independency of pharmacists Role of tailor-made products Focus on pharmaceuticals Relevance of pharmaceutical counselling Involvement in health promotion and prevention	Growth in pharmaceutical expenditure Development of OTC prices

1.4 Outline

The study report "Community Pharmacy in Europe: lessons from deregulation - case studies" is structured as follows:

- Country profiles on the case study countries (Chapter 2 to 4)

  The profiles on the selected deregulated countries follow the same structure: After a brief introduction of the healthcare and pharmacy system, the regulatory framework as well as current facts and figures, including important developments of the pharmacy sector are presented. The chapter on the pharmacy sector contains information on the dispensaries of pharmaceuticals, the regulations on the establishment of pharmacies, ownership rules and vertical and horizontal integration, the pharmacy staff, opening hours, and the range of products and services provided by pharmacies. A key part of these chapters is on market data, including the remuneration of pharmacies and sales data, as well as an analysis of the price development of four selected OTC products.

- Country profiles on the control group countries (Chapter 5)

  The profiles for the regulated countries of the control group are also written according to a homogenous structure, which follows the structure of the case study countries. The profiles on the control group countries also offer key information on the pharmacy sector, but are shorter, as they concentrate on facts and figures, and not so much on the background and analysis as the case study country profiles do.

- Benchmarking (Chapter 6)

  The benchmarking chapter is split into two parts: The first one provides comparative information on the relevant regulations in the six selected countries, the second part is an

analysis and a discussion of the indicators (benchmarks), as displayed in each country surveyed.

- Assessment (Chapter 7)

  After an introductory discussion of the role of the pharmacist, the results gained in this study are assessed: A comparative table provides information on the ranking of the pharmacy sector's performance in the six countries with regard to the three pillars (accessibility, quality and expenditure) defined for the evaluation of deregulation process in the field of community pharmacies. The study "Community Pharmacy in Europe: lessons from deregulation - case studies" closes with conclusions from the authors basing on the collected data and information.

2 Case study: Ireland

2.1 The healthcare system

In Ireland, the healthcare system is based on a National Health Service (NHS), mainly funded through taxation.

Organisation

Overall responsibility lies with the Department of Health and Children (DoHC) who governs healthcare policy and expenditure in Ireland. The structure of health services in Ireland has remained unchanged for over thirty years; however, recently, the Irish healthcare system has undergone a reform process.

Until 2004, healthcare was administered through ten regional health boards. At the beginning of 2005, this competence was shifted from the regional health boards to the newly founded Health Service Executive (HSE) who, as a single entity, now manages the health service. The aim of the reform was to reduce fragmentation.

The entire population is entitled to a core publicly funded service. Access to public health service is based on a means-tested system of eligibility comprising two categories:

- Category I:
  People with an income below a certain threshold and their dependants fall into category I. They are entitled to a wide range of free services (in-patient and out-patient services including drug therapy) under the so-called General Medical Services (GMS) scheme. The GMS scheme is also known as the medical card scheme and covers approximately 30 percent of the Irish population.
- Category II:
  The rest of population receives free in-patient treatment with a co-payment, and drug expenditure is reimbursed above a threshold under the Drug Payments (DP) scheme (cf. Section 2.2).

This eligibility structure forms the key feature of the Irish NHS. In addition, there is also a well developed private sector which can be accessed through insurance cover and/or direct payment. Even in the public health system there is, however, a mixture of public and private care.

Financing

Funding of the Irish National health system is mainly derived from taxation (75%), with private funding via insurance (accounting for 11%) and patient co-payments (the remainder).

In recent years, expenditure on healthcare has considerably increased (cf. Table 6.13). This rise in health expenditure coincided with increased economic prosperity. A response to the increasing health expenditure has been cost-containment which is, among others, reflected in the field of pharmaceuticals. However, on the EU average, the share of health expenditure on GDP is comparatively low.

On behalf of the health boards and the HSE respectively, the Primary Care Reimbursement Service (PCRS) has been making the payments to General Practitioners, pharmacists, dentists and optometrists/ophthalmologists with whom it has signed agreements.

2.2 The pharmaceutical system

The pharmaceutical system in Ireland is characterised by several actors and a range of Community Drug Schemes with different eligibility rules.

2.2.1 Framework

The Department of Health and Children is in charge of the overall pharmaceutical policy, whereas other statutory bodies such as the Irish Medicines Board (IMB), the HSE Primary Care Reimbursement Service (PCRS) and the Pharmaceutical Society of Ireland (PSI) fulfil concrete tasks in the field of licensing of pharmaceuticals (IMB), reimbursement (PCRS) and the licensing of pharmacists (PSI) respectively.

Beside the EMEA (European Medicines Agency) being the competent authority for the centralised registration of pharmaceuticals, the IMB is the relevant authority on national level for the registration of pharmaceuticals. In Ireland, there are nearly 5,000 pharmaceuticals (counted including different pharmaceutical forms, dosages and pack sizes) registered (cf. Table 2.2), which is a rather low number on EU average (ÖBIG 2001a). However, in Ireland, it is the usual picture of more pharmaceuticals being on the market (around 6,000) than licensed, as on behalf of doctors special pharmaceuticals for patients are ordered and imported individually (cf. Section 2.3.7).

The IMB is also in charge of the classification of pharmaceuticals according to their prescription status. The OTC market is rather small: in volume, less than 5 percent of the licensed pharmaceuticals are OTC (cf. Table 2.2).

In the 1990s, the Irish government has attracted a number of international research-based companies to establish in Ireland. The Irish pharmaceutical companies are mostly generic companies, which is only reflected in a minor extent in the generic market share: According to the Irish Pharmaceutical Union (IPU) 16 percent of items dispensed in Ireland are generic, totalling 5.7 percent of total cost of medicines.

While community pharmacies may occasionally obtain pharmaceuticals directly from manufacturers (generally amounting to approximately 8 percent of their supply), wholesalers are the predominant source of supply.

There are three principal full wholesalers, together holding more than 90 percent of the market:

- United Drug: The biggest wholesaler in Ireland, with a market share of around 44 percent. United Drug has three depots (in Dublin, Limerick, and Ballina).
- Cahill May Roberts: This wholesale company, owned by Celesio, has a market share in wholesale of 19-20 percent.
- Uniphar: This wholesaler is fully owned by community pharmacists (almost 40% of all retail pharmacists), it has a market share of about 30 percent.

Quite new in the Irish market is the parallel importer PCO who covers about 6 percent of the pharmaceutical wholesale.

In Ireland, there is a multi-channel distribution of pharmaceuticals, which means that there is no exclusivity for pharmaceuticals with regard to a special wholesaler. In reality, manufacturers use the wholesale companies not only for the wholesale business per se, but also for pre-wholesaling. Only GSK and Abbot have their own distribution schemes, they go directly to the community pharmacies - as do most of the Irish (generic) companies.

2.2.2 Reimbursement

In Ireland, reimbursement of pharmaceuticals is provided by the HSE Primary Care Reimbursement Service (PCRS) according the community drug schemes being in place, with the GMS scheme and the DP scheme representing the most important ones:

- GMS scheme:
  As explained above (cf. Section 2.1), people below an income threshold and their dependants fall under the General Medical Service (GMS) scheme and have free access to medicines, without any co-payment. Furthermore, since 1 July 2001, all residents over the age of 70 years, regardless of means, are also eligible under the GMS scheme.
  These medical cards holders account for about 30 percent of the population, nearly 70 percent of public pharmaceutical expenditure and 74 percent of all prescriptions.
- LTI scheme:
  The Long Term Illness (LTI) scheme entitles patients suffering from any of 15 specified chronic conditions (such as epilepsy, diabetes mellitus, multiple sclerosis, acute leukaemia, parkinsonism) to full reimbursement of pharmaceuticals.
  2.5 percent of the Irish population are registered under the LTI scheme; they account for 3 percent of the prescriptions and nearly 8 percent of public pharmaceutical expenditure.
- DP scheme:
  The Drug Payment (DP) scheme, introduced in July 1999, is applied to Irish residents not eligible under the GMS scheme. Under the DP scheme, individuals or families have to pay

a monthly co-payment up to € 85.- for prescribed pharmaceuticals (rate for the year 2005). Around 35 percent of the population avail of the DP scheme, which accounts for about 21 percent of the prescriptions and of public pharmaceutical expenditure.

- Other schemes:
  There are further schemes like the European Economic Area (EEA) scheme for visitors from other EU Member States and the High Tech Drugs (HTD) scheme, introduced in 1996, which facilitated the supply of certain high cost pharmaceuticals, e.g. those used in conjunction with chemotherapy, beta-interferon etc. by community pharmacies (previously these pharmaceuticals had been supplied primarily through hospitals).

Thus, only people eligible under the GMS or LTI scheme have full reimbursement of pharmaceuticals: this one third of the population accounts for about 70 percent of pharmaceutical expenditure.

2.2.3 Pricing

Pricing of pharmaceuticals supplied to the health service is outlined in an agreement between the industry association (Irish Pharmaceutical Healthcare Association, IPHA) and the Department of Health and Children. The agreement covers all medicines prescribed and reimbursable in the community drug schemes and all pharmaceuticals supplied to hospitals and health boards.

Under this agreement, Ireland links the pharmaceutical price by formula to those of 5 reference countries. The price at wholesale level (pharmacy purchase price, PPP) shall not exceed the lesser of the currency-adjusted wholesale price in the United Kingdom or the average of wholesale prices in Denmark, France, Germany Netherlands and the UK. If a product is not available in any of the reference countries, the Irish wholesale price is agreed between the DoHC and the manufacturer or importer. The choice of these five reference countries, being more or less high-price-countries, has been criticised for contributing to the rise in pharmaceutical expenditure (Barry et al. 2004, Tilson et al. 2004).

The current prize freeze agreement between IPHA and the DoHC commenced in 1993, it was renewed in 1997 and extended in 2001 until 2005. Currently (autumn 2005), there are negotiations concerning another renewal. Experts express their view to the authors' team that they do not expect a major change in pricing of pharmaceuticals in Ireland.

In Ireland, there is a linear wholesale margin of 15 percent on pharmaceuticals dispensed in the out-patient sector, except for high-tech medicines with a margin of 10%. The pharmacy margin depends under which community drug scheme is dispensed (cf. Section 2.4.2).

2.3 The pharmacy sector

2.3.1 Background

The pharmacy sector in Ireland is, from the point of view of the authors of this report, a rather liberal one: In comparison to other countries, there are few regulations. However, as evidenced in literature and in statements made to the authors during their study visit, this view is not fully shared: There are voices who consider pharmacies as “highly regulated” (see also OECD 2001), while other experts in Ireland share the viewpoint of the authors on the Irish pharmacy sector being rather liberal.

It is, however, generally agreed that some aspects of the pharmacy regulation need to be updated. A key ruling of the Pharmacy Act 1875 (the “Principal Act”) was that the Pharmaceutical Society of Ireland (PSI) was established as regulatory body to oversee pharmacies and pharmacists and to provide for a system of registration of pharmacists by the Society. The amendments to the Pharmacy Act 1875 in the course of the years were considered as substantially minor. In the last 10 to 15 years, there have, however, been changes in the status quo, e.g. the emerging of pharmacy chains since the mid-1990s.

Till the mid-1990s, there has never been a regulation on establishment nor on ownership of pharmacies in Ireland. In 1996, regulations on the establishment of pharmacies were introduced by the then Minister of Health and Children. These regulations specified the criteria and procedures under which the chief executive officer of the relevant health board was to decide on new Community Pharmacy Contractor Agreements for the provision of community pharmacy services. This regulation caused vivid discussion, and legal challenges were mounted by a number of parties. In 2002, the establishment criteria for pharmacies were revoked by the Minister of Health and Children.

The first years of the new millennium have seen a review of the regulatory framework for pharmacies in Ireland. In 2001, OECD published a study in which critical views on any existing restrictions were expressed (OECD 2001). In response to that report, the Minister for Health and Children established a High Level Group, the so-called Pharmacy Review Group, to examine pharmacy issues. The Pharmacy Review Group submitted its report in 2003. There were several recommendations, which require implementation in the drafting of two new Pharmacy Acts:

- The first Pharmacy Act, which is expected to come into act in 2006, will include the introduction of “Fitness to Practice” provisions, which will strengthen the statutory basis of the Pharmaceutical Society of Ireland (PSI) to ensure the highest standards are maintained in the pharmacy sector and that practising pharmacists have linguistic and forensic competence to practice, and the removal of the EU derogation on the “three-year rule”, i.e. pharmacists not trained in Ireland are not allowed to open a pharmacy less than three years old.
- The second Pharmacy Act, which shall come into force only after the first Act, is planned to give effect to most of the recommendations of the Pharmacy Review Group and will thus

define and regulate services, standards, inspection and licensing of pharmacies, as the current regulations dating back to Pharmacy Act 1875 are considered as out-of-date.

The Irish Pharmaceutical Union (IPU), the Pharmaceutical Society of Ireland (PSI) and the Hospital Pharmacists Association of Ireland (HPAI) would prefer that, instead of the two Acts, all planned changes are included in one new Pharmacy Act.

There are no plans to introduce regulations on the establishment/ownership of pharmacies.

2.3.2 Accessibility

In Ireland, pharmaceuticals are, in general, dispensed by pharmacies. Furthermore, there is dispensing of pharmaceuticals by

- Self-dispensing doctors in case that the nearest pharmacy is more than 3 miles (5 kilometres) away
- Drugstores and several other retail outlets (e.g. corner shops, petrol stations, supermarkets) for a very limited number of OTC medicines.

Table 2.1: Ireland – Number of pharmacies and other POM-dispensaries[1] 1990 - 2005

	1990	1995	2000	2001	2002	2003	2004	2005
Number of dispensaries								
Pharmacies	1,088	1,135	1,174	1,180	1,203	1,249	1,292	1,333
SD-doctors	273	227	221	179	136	148	156	143
Total	**1,361**	**1,362**	**1,395**	**1,359**	**1,339**	**1,397**	**1,448**	**1,476**
Inhabitants per dispensary								
Inh. per pharmacy	3,230	3,180	3,241	3,276	3,268	3,199	3,093	2,998
Inh. per POM-dispensary	**2,582**	**2,650**	**2,728**	**2,845**	**2,937**	**2,860**	**2,760**	**2,707**

POM = prescription-only medicines, SD = self-dispensing, Inh. = Inhabitants, n.a. = not available

[1] Only dispensaries which are allowed to dispense prescription-only medicines are included, data on 1 January.

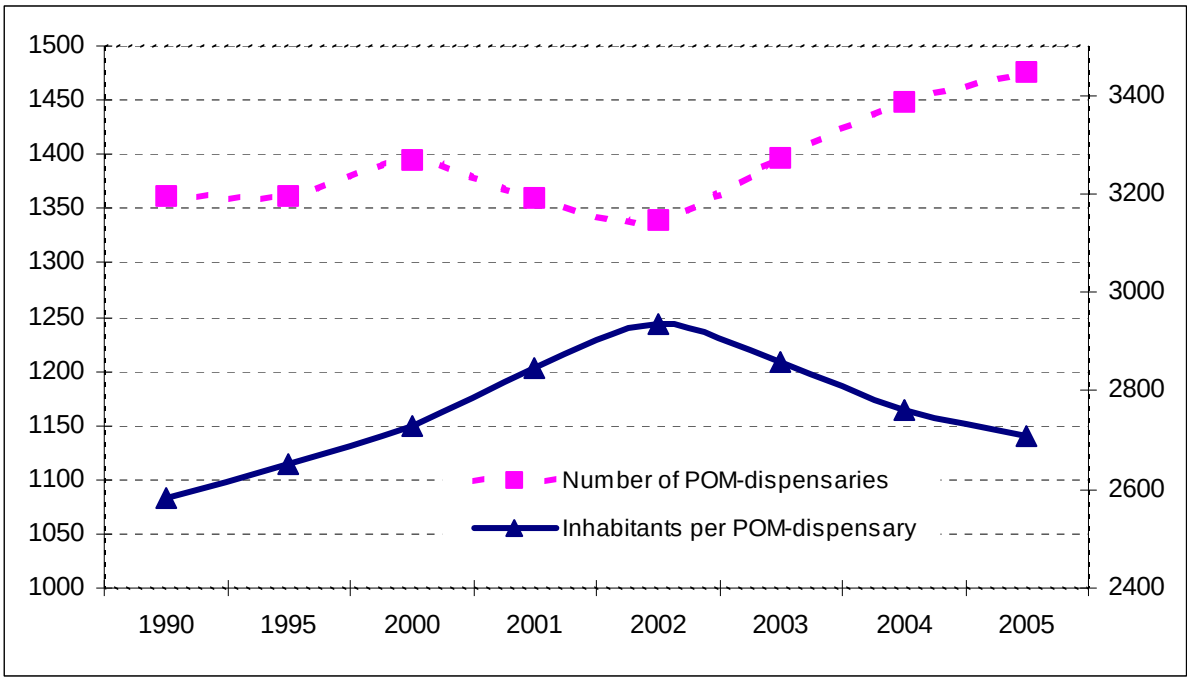
Source: data gathering by ÖBIG

In Ireland, there are 1,333 pharmacies in 2005, which corresponds to nearly 3,000 inhabitants per pharmacy. Furthermore, there are around 140 self-dispensing doctors, their number having declined since the 1990s (cf. Table 2.1). The provision of the population with pharmacy service has, since 2002, improved (cf. Figure 2.1:).

Since 2000, the number of openings of pharmacies has increased. There were 17 and 16 openings respectively in the year 2000 and 2001 and 26 in the year 2002. In 2003 and 2004 more than 30 pharmacies were opened; and in the first half of 2005 alone more than 50 pharmacies. The number of closed pharmacies is difficult to track, as it is - even for the pharmacists association - not always clear if a pharmacy was really shut down or was rather

taken over by a new owner. From 2002 on, the annual number of pharmacies closed is considered to be less than 5.

Figure 2.1: Ireland – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM-dispensary 1990 - 2005



POM = prescription-only medicines

Source: data gathering by ÖBIG

Concerning the geographic distribution of pharmacies, there is no data available. However, there is data on the opening of new pharmacies, which demonstrates that from 2003 on, considerably more pharmacies (more than 25) were established in urban areas (defined as places with more than 3,000 inhabitants per km^2) than in rural areas (less than 10 per year). In 2002, this discrepancy was not as obvious (16 openings in urban areas versus 10 openings in rural areas), while in the year before revocation of the establishment rules more pharmacies were opened in rural areas than in towns. The trend of the last years confirms concerns expressed by some interview partners that there seems to be a clustering of pharmacies in attractive places (city centres).

Nearly all pharmacies (except for around 50) have a contract with the reimbursement authority, as this HSE contract secures the viability of pharmacies (cf. Section 2.4.3).

2.3.3 Establishment of pharmacies

Ireland has for a long time been a country without any rules on the establishment of pharmacies, so there were no geographic and/or demographic provisions regulating the settlement of pharmacies.

In 1996, statutory regulations on the establishment of pharmacies were introduced. These regulations specified the criteria and procedures for the conclusion of a new Community Pharmacy Contractor Agreement between the regional health board and the pharmacy (cf. Section 2.2.2). The criterion of "definite public health need" was taken as basis for the decision on serving a new pharmacy with a contract. Essentially, "definite public health need" was defined as:

- a ratio of pharmacies to population in the proposed catchment area of
  - 1 to 4,000 in the case of urban and large towns (with population exceeding 3,000), and
  - 1 to 2,500 in the case of other locations; and
- the "distance between the premises in respect of which the community pharmacy contractor agreement is sought and the nearest contracting community pharmacy measured door to door by the shortest lawful access route" is
  - 250 metres in the case of urban areas including towns, and
  - 5 kilometres in rural areas; and
- the "new pharmacy will not have an averse impact on the viability of existing community pharmacies in the area, to the extent it will affect the quality of pharmacy services being provided by them".

Thus, the "definite public need" was made up of a mixture of demographic, geographic, and viability criteria. It was agreed that these ratios would allow for an increase in the number of pharmacies, which, in fact, only happened to a minor extent. The rationale behind the 250 metres distance requirement was to reduce the tendency for clustering of pharmacies in towns, thus giving a better spread of outlets. These establishment rules were accompanied by other conditions such on the accessibility ("free and direct access to the public road at all times", certain requirements on opening hours), equipment, facilities, staffing, quality which have to be met by the applicants for a community pharmacy contract.

The rules on establishment of pharmacies in the 1996 regulations were designed to have no effect on the existing Community Pharmacy Contract Agreement holders. Shortly after the introduction of these rules, they were harshly criticised by different stakeholders, among them the Competition Authority. Legal challenges against the 1996 Contractor Regulations were initiated (by a pharmacy chain and by an applicant who had been refused a contract), which, however, never led to a decision.

Besides, there was an OECD report (OECD 2001) on regulatory regimes, among them the pharmacy sector, in Ireland, published in November 2001, which criticised the establishment rules for pharmacies and recommended their elimination. In reaction to the OECD report, Ireland set up a High Level Pharmacy Group to examine the Irish pharmacy sector. In the course of the review a consultancy company provided a report to the Pharmacy Review

Group in August 2002 (INDECON 2002), including a survey among community pharmacists. Concerning the establishment rules, 60 percent of the respondents expressed themselves in favour of maintaining the establishment rules, however, with a major variation between contractor pharmacists (80 percent in favour) and employee pharmacists (35 percent).

In January 2002, the Department of Health and Children decided to revoke the 1996 Contractors Regulations on the establishment rules. At that time, the Pharmacy Review Group had just started to work.

Since then, there have been no establishment rules for pharmacies in Ireland. The final report of the Pharmacy Review Group included the recommendation: “Health boards should identify, through a needs assessment, any areas with a significant pharmacy needs (including areas served by dispensing doctors) which the market has not filled and is unlikely to do so.” (Pharmacy Review Group 2003).

In the Pharmacy Acts which are, at the time of this report, being drafted, there will be no establishment rules included. According to the policy-makers interviewed by ÖBIG, there are currently no plans for the future to introduce establishment rules.

2.3.4 Ownership of pharmacies

In principal, in Ireland any individual or legal person may own one or more pharmacies (multiple ownership allowed), but for quality assurance in each pharmacy a full pharmacist has to be in charge as supervising pharmacist. The only rules concerning the ownership of pharmacies, which date back from 1962, state that four separate entities are entitled to own a pharmacy: A pharmacist or partnership of pharmacists, a legal representative of a deceased pharmacist at the time of his/her death, a trustee of a pharmacist in practice who is adjusted bankrupt or becomes of unsound mind, and a corporate body. Apart from this there is one other small restriction on the ownership of pharmacies, in that physicians may not hold a contract for a pharmacy if they have their practice in the same area. This restriction, however, can easily be bypassed, for example by a family member purchasing a pharmacy. Trading of pharmacies is allowed as there is no licence attached to a pharmacy.

In addition, the 1985 EU Directive on the Mutual Recognition of Qualifications in Pharmacy (Directive 85/433/EEC) was implemented in Ireland (and in six other EU Member States, among which Austria, the Netherlands and Spain), which means that a pharmacist who is professionally trained in another EU or EEA country is not allowed to manage or supervise a pharmacy in Ireland that is “less than three years old”. This means that pharmacists not trained in Ireland could only open a new pharmacy if he/she employed an Irish qualified pharmacist for the first three years. In the last years, this derogation caused a lot of discussion, as due to a shortage of training posts, many Irish citizens were trained as pharmacists outside Ireland (mostly in UK), and when they returned to Ireland, they were also not entitled to own, manage or supervise a new pharmacy. This “three-year-rule” was reviewed by the Pharmacy Review Group who recommended “to continue until a Pharmacy Act is in place,

and then be discontinued" (Pharmacy Review Group 2003). So the rule is expected to be abolished in the year 2006.

In the course of the last 20 years, the ownership pattern in the pharmacy sector has changed: While in 1985, 60 percent of the pharmacies were owned by independent pharmacists, 27 percent by companies owned by pharmacists and 5 percent by companies owned by non-pharmacists (other ownership forms as partnerships disregarded), the relevant percentage rates changed to 44 percent (independent pharmacists), 44 percent (companies owned by pharmacists) and 9 percent (companies owned by non-pharmacists) in 1993 and 24 percent (independent pharmacists), 64 percent (companies owned by pharmacists) and 10 percent (companies owned by non-pharmacists) in 2001. Thus, the share of pharmacies owned by companies (pharmacists-owned and non-pharmacists owned companies) has risen from 33 percent in 1985 to 74 percent in 2001 (Pharmacy Review Group 2003).

Concerning vertical (wholesale-retail) integration, United Drugs is the only one of the three wholesalers who does not own pharmacies. However, it runs the so-called Catalyst service providing advice and finance to pharmacists who want to buy or sell pharmacies. Cahill May Roberts bought the Unicare pharmacy chain in 2001, and after further acquisitions it now owns 56 pharmacies. Uniphar buys community pharmacies and "sells" them to pharmacists on a quota of 20 percent, with the pharmacists remaining as employees and shareholders of the pharmacy. The pharmacists have the option to purchase the pharmacy over a period of 12 years. As this is rather a young scheme (in act for about 5 years), it still has to be evaluated.

As these figures show, companies owned by pharmacists are a common phenomenon and wholesalers are also involved in the ownership of pharmacies. As described in Section 2.2.1, two of three wholesalers own pharmacies: Cahill May Roberts (Celesio) runs 56 pharmacies (Unicare chain), and Uniphar operates a joint-venture scheme allowing pharmacists to buy into a pharmacy over 12 years. The biggest wholesaler on the Irish pharmaceutical market, United Drug, is, by running the above described Catalyst service, also involved in the pharmacy business, but does not own pharmacies.

As multiple ownership has always been allowed, especially since the mid-1990s pharmacy chains have become a reality in the Irish pharmacy sector. The biggest chain (covering 56 pharmacies) is owned by the wholesale company Cahill May Roberts (Celesio), followed by the Boots the Chemists chain with 32 pharmacies. The Mc Sweeney group (24 pharmacies), Hickey (19 pharmacies) and McCabe (15 pharmacies) are further pharmacy chains, formed by Irish pharmacists. According to the Irish Pharmaceutical Union (IPU), there are nearly 460 chain pharmacies in 2005 compared to 168 in 1995. Nearly 40 percent of all pharmacy owners have two or more pharmacies.

2.3.5 Pharmacy staff

Pharmacy workforce in Ireland consists of full pharmacists, qualified assistants, pharmacy technicians and any other staff. The total number of pharmacy staff is not available. The IPU estimates that employed pharmacists work, on average, 1 to 2 years at the same pharmacy.

The prerequisite for being a full pharmacist is a five years university degree including one year practice, followed by a licence exam to prove forensic competency. For a long time, pharmacy courses were only provided by the Trinity College in Dublin, which offers about 70 places per year. As there was excess of applications, many Irish students went to the UK or to other countries for training. The overseas training of Irish pharmacy students had again consequences for opening a new pharmacy ("three-year-rule", cf. Section 2.3.4). Meanwhile, two other universities (University College Cork and Royal College of Surgeons of Ireland in Dublin) have started to offer pharmacy courses; the first graduates will finish in 2006.

Before registering as a pharmacist, graduates have to complete one year of practical training under the supervision of a tutor pharmacist. At least six months of this training must be spent in a hospital or retail pharmacy.

Pharmacists have to register with the Pharmaceutical Society of Ireland (PSI) which is the statutory body for pharmacists. However, there are no statutory possibilities for the PSI to sanction misbehaviour of pharmacists. This shortcoming is aimed to be changed by the introduction of "fitness-to-practice" rules in the planned Pharmacy Act. At the moment, there are 3,546 pharmacists registered.

Every pharmacy must be managed by a supervising pharmacist (cf. Section 2.3.4).

Another group of staff in a pharmacy are known as "qualified assistants" or "assistants to pharmaceutical chemists". These are allowed to dispense pharmaceuticals in the temporary absence of a pharmacist. The training for this group, which lasted 3 years, is no longer offered. At the moment, there are about 580 qualified assistants left in Ireland.

A further type of staff are pharmacy technicians who do not have a right to dispense pharmaceuticals. Their training lasts 2 years, ending with a certificate, plus a practice training of 100 days.

Apart from tutors (pharmacists who supervise graduates during their one-year practice training) who must at least spend 30 hours a year on training, there is no compulsory continuous education for pharmacists or any of the other staff group. However, IPU and the Pharmaceutical Society of Ireland encourage pharmacists in continuous education. In addition to a master program in Community Pharmacy (2 year part-time course) offered by the Trinity University in Dublin and the University College Cork, there is special training for pharmacists provided by the Irish Centre for Continuing Pharmaceutical Education (ICCPE). The ICCPE, funded by the DoHC, was set up on request of the IPU during the 1996 regulations. If there are enough places available, training is also open to qualified assistants and pharmacy technicians. In 2004, 960 pharmacists (some may be counted more times if attending more courses) attended continuous training, and in spring 2005 1,237 pharmacists.

Concerning the liability of pharmacists, the pharmacy is, under the terms of the Community Pharmacy Contractor Agreement, obliged to have Professional Indemnity Insurance which covers all staff who work in the pharmacy.

2.3.6 Opening hours

In Ireland, opening hours of pharmacies are not regulated by law, but they are subject to the contract between the pharmacy and the HSE. The supervising pharmacist must state the hours of opening as an appendix to the contract.

A pharmacy is then obliged to maintain these hours of business (the contract opening hours are minimum hours, further opening is possible). Any changes to these hours must be notified and agreed with the Health Service Executive (HSE). The opening hours indicated must be “reasonable”, a typical contract would state the following hours:

- On weekdays (Monday to Friday): from 9 am to 6 pm
- On Saturday: from 9 am to 6 pm

In addition, some pharmacies open a few hours on Sunday, even though this is not part of the contract.

There are no national night duties or Sunday requirements. Local arrangements which usually involve the pharmacists on stand-by duty as part of a rota system via a mobile phone and responding to call outs. This is provided on a voluntary basis in most locations.

In Ireland, no 24-hours pharmacies (defined as pharmacies open and accessible to the public for 24 hours per day, 7 days per week) are known.

2.3.7 Products

The following categories of products are sold in pharmacies:

- Prescription-only medicines (POM)

  Pharmacies have the monopoly to provide prescription-only medicines, which account for more than 95 percent of the registered pharmaceuticals and for 61 percent of the pharmacy turnover. Prescription-only medicines are mainly dispensed to consumers through the Drug Community Schemes (cf. Section 2.2.2); thus, a contract with the HSE Primary Care Reimbursement Service is essential for the viability of a pharmacy.

- OTC medicines

  OTC medicines account for 20 percent of the turnover of a pharmacy. Hereby, it has to be distinguished between pharmacy-only OTC medicines which may only be sold in pharmacies and other OTC medicines listed for “general sale”, which are also sold in any type of retail outlet. Selected products are meant to be used for minor pain and cold symptom relief. However, some interviewed experts doubted that these products are really only for

minor relief. Shortly before the study visit by the ÖBIG team, ibuprofen was legalised to be sold in any retail outlet.

- Non-pharmaceutical products

  There are around 40,400 non-pharmaceutical products on the market (cf. Table 2.2). These products (cosmetics, toiletries, and sundries) may be sold in any retail outlet. In Irish pharmacies, as the study visit team evidenced, these products fill a lot of space in the premises of a pharmacy. Therefore, several Irish pharmacies (especially in big towns) do not look like pharmacies in continental European countries, but resemble "normal" retail stores. According to some of the interview partners, this also explains why Irish pharmacies are seen as "any other shop" and why pharmacists are considered as "shopkeepers". The non-pharmaceutical turnover accounts for about 19 percent of the pharmacy turnover.

Table 2.2: Ireland – Number of pharmaceuticals

Pharmaceuticals[1]	2000	2001	2002	2003	2004	2005
Registered ph.	4,873	4,908	4,836	3,935	4,883	4,992
Ph. on the market	5,158	5,272	5,513	4,544	5,796	6,071
POM	3,904	4,002	4,129	4,185	4,539	4,876
Reimbursable ph.	3,070	3,125	3,045	2,822	2,819	3,085
Non-pharmaceutical products on the market	29,869	32,820	36,107	39,087	39,270	40,435

ph. = pharmaceuticals, POM = prescription-only medicines

[1] Data per 1 January. Pharmaceuticals for human use, excluding magistral or officina formula, counted including different pharmaceutical forms, dosages, pack sizes.

Source: data gathering by ÖBIG

There are no regulations on the availability of pharmaceuticals in the market. On average, pharmacies receive at least once a day - and in case of emergencies twice a day - deliveries by wholesalers. However, the second delivery in the afternoon is not standard. Customers receive, on average, a pharmaceutical within 12 hours (half a day) and at least in one day.

In Ireland, there is the unusual situation with more pharmaceuticals on the market than registered. Ireland is a small market, and if a special unregistered pharmaceutical is needed, then it is possible to import and supply it on behalf of the prescribing physicians for the patient in need. Pharmacies are essentially involved in the supply of those pharmaceuticals.

2.3.8 Quality of pharmacy services

In Ireland, prescription by generic name is possible; however, generic substitution is not allowed and it is not expected to be introduced in near future. In general, generic use is considered as low in Ireland.

There has been discussion on the possibility of prescribing by pharmacists (like in the UK). The Irish Pharmaceutical Union (IPU) would welcome this initiative, but so far the Department of Health and Children has not indicated their position on this matter. Nurses have recently been given prescribing rights in Ireland.

A task in which pharmacies are usually involved in several countries is the manufacturing of magistral preparations. However, in Ireland, the manufacturing of pharmaceuticals in a pharmacy has no tradition, and most of the pharmacies do not have a laboratory. Nonetheless, both the PSI guidelines and the contract with the HSE do say that a pharmacy is obliged to have the equipment, such as scales, to prepare pharmaceuticals.

A standard piece of equipment in a pharmacy is the computer; 99 percent of the Irish pharmacies are considered as computerised.

Clause 9 of the 1996 Pharmacy Regulations sets out the professional duties of pharmacists. These include the provision of general advice to individuals on prescription medicines, including the promotion of compliance, reviewing prescribed medicines and screening for potential drug therapy problems. The provision of other pharmaceutical services to the customers, such as blood pressure and cholesterol measurement, is only just starting in Ireland. According to the interview partners, these services are particularly provided by chain pharmacies and urban pharmacies, which, in reaction to competition, start with new services. Many Irish pharmacies do not have a separate place for counselling but they are starting to refurnish their outlets.

With the introduction of the methadone substitution treatment scheme, methadone is given through some community pharmacies, while this was previously done by hospitals. Pharmacies receive extra remuneration for this service.

The new trends are, as said, in particular true for urban pharmacies; whereas in rural areas pharmacies have a more traditional role. According to a survey pharmacists, especially in rural areas, are often seen as the first contact point in health care. Contrarily, some of the interview partners in Ireland mentioned to the study visit team that in urban areas pharmacies are often considered by the general public as “any other retail shop”. Unfortunately, there are no consumer satisfaction studies, which would allow for further information on the role of the pharmacies. According to the Irish patient association, complaints regarding pharmacists are rare compared to other providers in health care.

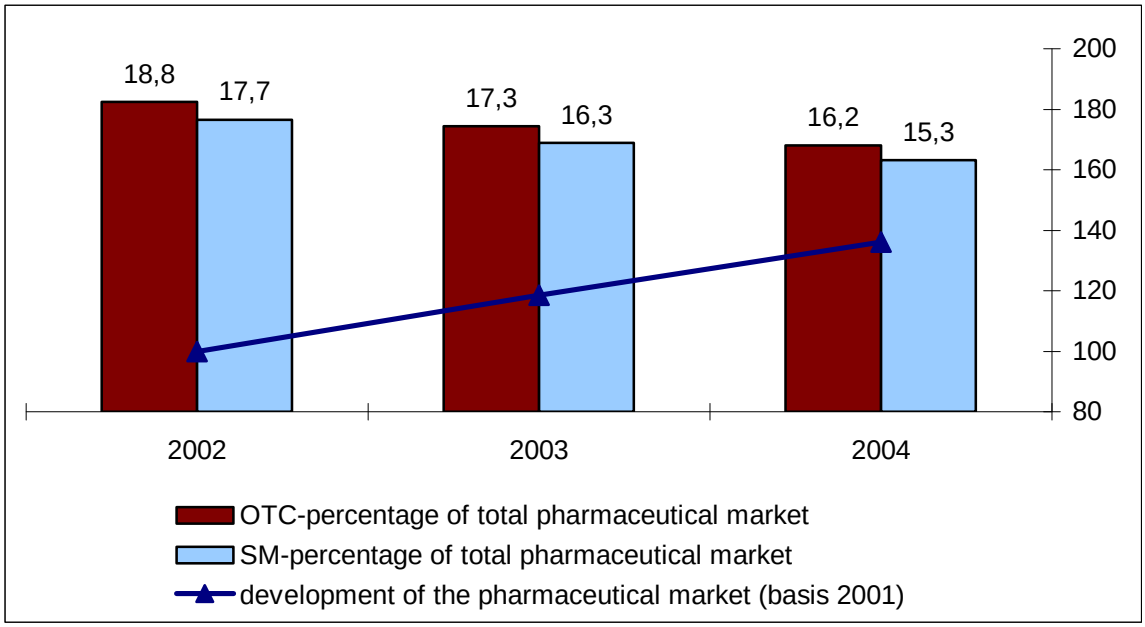
2.4 Market data

2.4.1 Pharmaceutical expenditure

Pharmaceutical expenditure in Ireland according to OECD data amounted to € 1,180 million in 2003, equivalent to 11.6 percent of total expenditure on health.

Figure 2.2 shows a tremendous increase in the pharmaceutical market capitalisation at consumer price level of 40 percent during the last three years (2001-2004: plus 60%). Nonetheless the market growth happened mostly in the reimbursement sector, the share of self-medication dropping from 18.8 percent to 15.3 percent during the last three years.

Figure 2.2: Ireland – Development of pharmaceutical market 2002 - 2004



OTC = over-the-counter, SM = self-medication

Source: AESGP 2003-2005, data gathering by ÖBIG

2.4.2 Remuneration of pharmacies

As stated in section 2.2.3, the remuneration of pharmacies depends on the community drug scheme under which a pharmaceutical is dispensed. For the GMS scheme the pharmacy retail price is determined from the wholesale price plus a fixed dispensing fee (currently amounting to € 2.98). The DP and LTI pharmacy retail price comprises the wholesale price plus a 50 percent mark-up and a dispensing fee of € 2.59. For OTC medicines, because of competition rules, there are no recommended retail selling prices. Pharmacies typically apply a margin between 25 percent and 33 percent.

Therefore, payments to pharmacists is much greater under the DP scheme as compared to the GMS scheme; and the study visit team noticed that there is much discussion on that 50 percent mark-up.

2.4.3 Sales

According to the IPU the average turnover per pharmacy was € 1.43 million in 2003, a rise of more than 50 percent since 2000. The sales are estimated to be split into 61 percent turnover on prescription-only medicines, 20 percent OTC medicines and 19 percent on non-pharmaceutical products.

2.4.4 Price development

Recent reports on the Irish health care system highlight its increasing expenditure on prescription-only medicines (cf. Figure 2.2), which represents more a rise in consumption than in prices as there has been a price freeze on prescription-only medicines since 1993. The prices of reimbursable pharmaceuticals (mostly POM) are interlinked to those in five Northern EU Member states, thereof United Kingdom and Germany (cf. Section 2.2.3).

In terms of OTC, the situation is - as Figure 2.3 shows - somewhat different. The selected products from top-selling OTC substances ibuprofen, paracetamol and aciclovir cream (diclofenac gel/cream not being marketed as OTC in Ireland) show a continuous rise during the end of the 1990s and a drop in their prices especially in the last years.

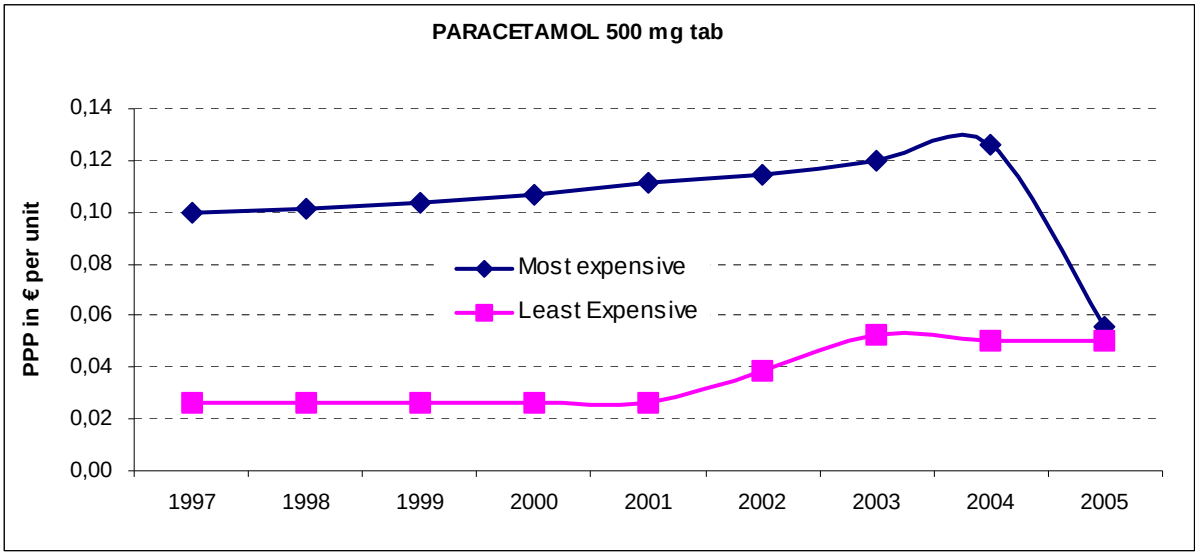
The price development of the current most expensive 500 mg **paracetamol** preparation 'Paralief' by Clonmel, which used to be the cheapest on the market in 1997 and 1998 (24-tablet pack price: € 0.63), is of special interest: In total the price of 'Paralief' has doubled since 1997, but during this period the price for a 24-tablet pack has dropped from € 1.33 in spring 2005 to € 1.26 in September 2005.

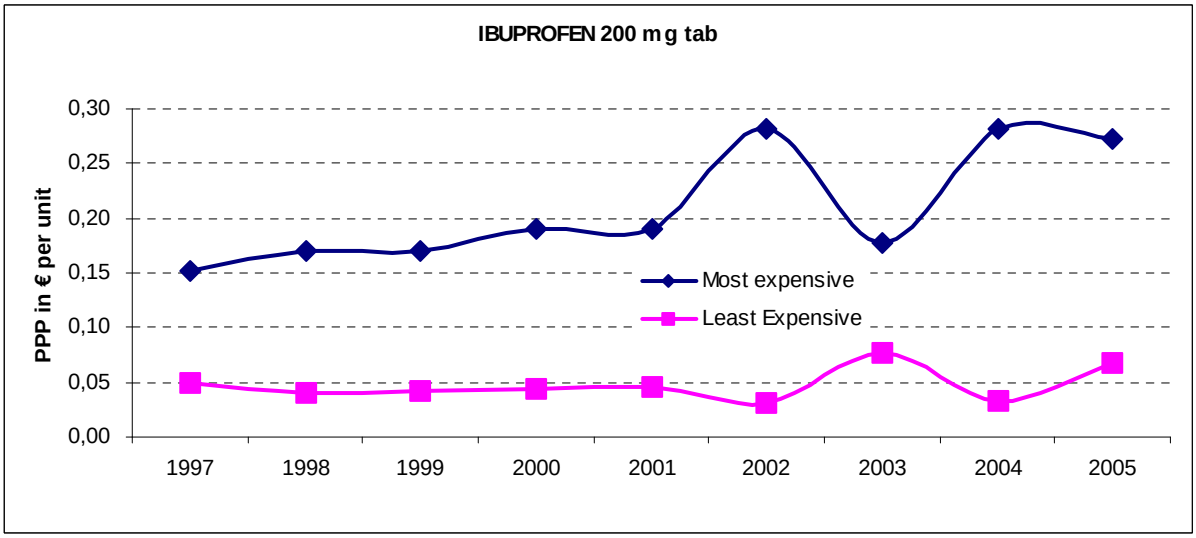
The average annual growth rate of paracetamol prices in general was minus 4.0 percent for the most expensive one (if only considering the years 1997-2004 it would be: + 3.4%), and plus 9.7 percent for the least expensive one ('Paratabs' by Pinewood).

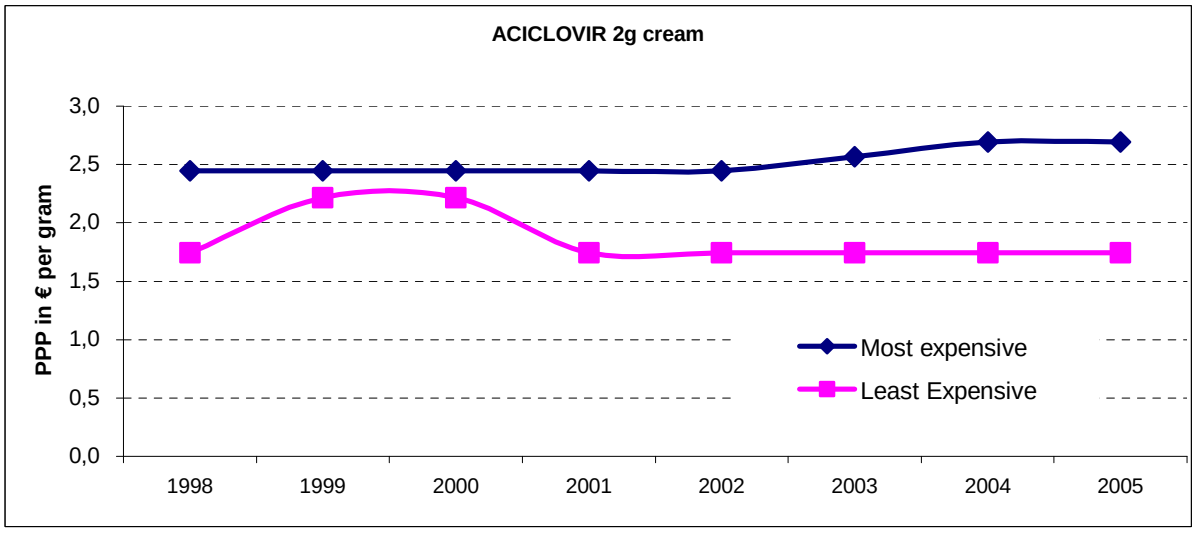
Ibuprofen products encountered rather strong fluctuations, the most expensive OTC being 'Nurofen' by Boots Healthcare. In total the price of 'Nurofen' has increased by 79 percent since 1997 and the price of the cheapest one by 39%.

Contrary to the other products, the price development of **aciclovir** preparations has been very stable during the last decade, the most expensive one being the original brand 'Zovirax' (in a dosing pump) by GSK. The average annual growth rate was +2.5 percent for Zovirax and +0.8 percent for the Bayer 'Soothlip' cream.

Figure 2.3: Ireland – Price development of selected OTC blockbusters 1997 - 2005







PPP = pharmacy purchase price, tab = tablet

Source: national sources, data gathering by ÖBIG

3 Case-study: Netherlands

3.1 The healthcare system

The Dutch health care system is characterised by continuous debate and discussion about its structure and reform. Some reforms have helped prepare the way for the new basic health insurance scheme, which will be implemented on 1 January 2006. In reviewing the reforms of the last decade, the shift of responsibility for purchasing care from government to insurers can be observed as a consistent trend. Secondly there has been a trend towards more competition among care providers. Thirdly, there has been a move towards combinations of market and non-market elements in health care.

Organisation

The Ministry of Health, Welfare and Sport (Ministerie van VWS) and local authorities are jointly responsible for the provision of public health care. The Ministry established the social health insurance schemes under the Sickness Funds Act (Ziekenfonds Wet, ZFW) and the Exceptional Medicines Act (Algemene Wet Bijzondere Ziektekosten, AWBZ), which came into force respectively in 1964 and in 1968.
The Dutch health care system is based on three compartments of insurance, governed by different bodies:

1. a national health insurance under the AWBZ for exceptional medical expenses associated with long-term care or high-cost treatment. With very few exceptions everyone living in the Netherlands is covered by the AWBZ.
2. compulsory sickness funds for persons with less than a certain income, and private, mostly voluntary health insurance. This compartment comprises “normal medical care”, such as care provided by general practitioners, pharmaceutical care and hospital transportation. These normal medical expenses are covered by a variety of insurance arrangements, and the most important of these is the one governed by the ZFW, which covers 63 percent of the population. Private health insurance covers 30 percent of the population.
3. voluntary supplementary health insurance, which includes care which is considered less necessary, such as additional dental care, prostheses, hearing aids, etc.

People with an income below a certain threshold are compulsorily insured under the Sickness Funds Act. Since 2002 these people are free to choose their own sickness fund and are allowed to change to another fund once per year. In 2002 there were 22 sickness funds, under the control of the Health Care Insurance Board (College voor Zorgverzekeringen, CVZ). On 1 January 2006 a new act will come into force, which will replace the public and private health insurance systems with one basic insurance package.

A new system for enhancing professional standards and quality control was introduced in 2001. The country’s three inspectorates monitor and enhance the quality of health care. Of

these, the Health Care Inspectorate (Inspectie voor de gezondheidszorg, IGZ) is the most important.

Public health is organised through municipal or district services, with supervision and monitoring at regional and national level by the IGZ. Primary health care is provided mainly by family physicians (GPs) who act as gatekeepers in the system. Prescription rates by GPs are relatively low, with prescriptions given in about 66 percent of the cases, compared to 75 - 95 percent in other European countries.

Financing

Health care is largely funded (88%) through a system of public and private insurance schemes, with taxes accounting for only 5.6 percent. Out-of-pocket payments cover approximately 6 percent of health expenditure, and supplementary insurances (the third compartment) comprise 3 percent of health expenditure (in 2002). The cost of insurance is covered by percentage and/or flat-rate contributions of employed persons, government grants, and private sector contributions. Sickness funds are subject to a so-called “double budgeting system”. On one side, each sickness fund receives a budget from the CVZ. The difference between the allocated budget and the expenditure has to be covered by the flat-rate contributions which each fund determines by itself. On the other side, sickness funds negotiate budgets, as well as quality, quantity and, to some extent, prices of services with providers.

According to OECD health expenditure in the Netherlands has risen by 8.1 percent in 2003 as compared to 2002. Compared to 1995 total health expenditure has increased by 75.4 percent (7.3 percent per year on average) and health expenditure per inhabitant has increased by 67.2 percent (6.6 percent per year on average). As a response to the increasing health expenditure several cost-containment measures, among others in the field of pharmaceuticals, have been implemented during the past years.

3.2 The pharmaceutical system

3.2.1 Framework

The Ministry of Health, Welfare and Sport is in charge of the overall pharmaceutical policy. Other statutory bodies are the Medicines Evaluation Board (College ter Beoordeling van geneesmiddelen, CBG), the Health Care Insurance Board (College voor Zorgverzekeringen, CVZ), the Health Care Tariff Board (College voor tarieven in de gezondheidszorg, CTG) and the Royal Dutch Pharmaceutical Society (Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie, KNMP). Health insurance funds are in the process of assuming a greater role. For example, the insurance funds are no longer obliged to contract pharmacies and are increasingly tendering contracts for the distribution of pharmaceuticals and for pharmaceutical care. In accordance with the Pharmaceutical Supply Act (Wet op de Geneesmiddelenvoorziening, WGV), pharmaceuticals may only enter the market once the

Medicines Evaluation Board has registered a positive assessment of their quality, safety and effectiveness. The Health Care Insurance Board provides the Ministry of Health, Welfare and Sport with advice considering the reimbursement of medicines. The Health Care Tariff Board consists of independent experts, advised by representatives of doctors, pharmacists and insurance funds, and sets the dispensing fees for pharmacists, which will be further discussed under Section 4.4.2.

Manufacturers and importers mainly deliver the pharmaceuticals to wholesalers, who take care of the supply to pharmacies and drugstores. The distribution of pharmaceuticals by wholesalers is multi-channel.

3.2.2 Reimbursement

Once a pharmaceutical is licensed the Ministry of Health, Welfare and Sport determines whether it will be included in the reimbursement system (Geneesmiddelenvergoedingssysteem, GVS) or not. This decision is based on the advice from the Health Care Insurance Board. Reimbursed products are listed on a positive list, which is divided into the following three categories:

- Annex 1A: Therapeutically interchangeable products reimbursed according to a reference price system.
- Annex 1B: Unique products (not reimbursed according to the reference price system, no reimbursement limit exists)
- Annex 2: Medicines only reimbursed under specific circumstances, for example if prescribed by a specialist, if administered within a specialised health care centre (e.g. for cancer treatment), or after approval of the health insurance.

Only products listed in Annex 1A of the positive list require patient co-payments if the product is priced above the maximum reimbursement level. Since January 2005, submission of economic evaluations is mandatory when applying for the reimbursement of Annex 1B products.

Reimbursement is based on the average price of pharmaceuticals with a comparable effect (reference price system). If the price of a pharmaceutical is higher than the group average, the consumer has to pay the difference. Reimbursement prices have not been recalculated since 1999.

Until January 2004 OTC medicines that had been prescribed for chronic use were reimbursed. Nowadays almost all OTC medicines, even if prescribed by a physician, are not reimbursable.

Health insurances may restrict the range of reimbursable pharmaceuticals by deciding that they will only compensate the costs for one “preferred” (mostly generic) pharmaceutical. Only on sufficient medical grounds, health insurances will reimburse other pharmaceuticals.

3.2.3 Pricing

All prescription-only medicines dispensed by pharmacies are subject to the Medicinal Product Prices Act (Wet Geneesmiddelenprijzen). Since 1996 the Medicinal Product Prices Act has fixed the maximum wholesale price of all reimbursed medicines as the average wholesale price of comparable products in four European countries. Maximum prices are revised every six months. Free pricing is allowed for OTC medicines.

Moreover, the government also stimulates more competitive pricing in order to keep prices as low as possible. In February 2004 a covenant was agreed between the Ministry of Health, Welfare and Sports, the Royal Dutch Pharmaceutical Society (KNMP) and the Health Care Insurance Board. It was decided that the prices consumers and health insurance companies must pay for generic prescription medicines will decrease to an average of 40 percent below the level of the list prices from the manufacturers involved on 1 January 2004. In addition, pharmacists and insurance companies committed themselves to make optimum use of the availability of cheaper (generic) medicines.

3.3 The pharmacy sector

3.3.1 Background

In 1994 the Interdepartmental Working Group for Distribution of Pharmaceuticals (Interdepartementale Werkgroep Geneesmiddelendistributie, IWG) reviewed the legislation for the pharmaceutical sector. As a result they published a number of recommendations regarding the revoking and adjustment of laws, in order to increase competition in the sector. As a precondition they stated that the quality of the distribution of pharmaceuticals should not decrease.
According to the recommendations of the Working Group, the following changes were implemented in the law on the distribution of pharmaceuticals:

- The legal requirements regarding the opening hours, and the equipment (e.g. for preparation of magistral formulae) of pharmacies were abolished (1996).
- The prohibition of pharmacists being employed by non-pharmacists was abolished (1999).
- The prohibition of hospital-pharmacies selling pharmaceuticals to out-patients was changed, in that pharmacies in outpatient clinics (“polyclinic pharmacies”) were allowed to act as community pharmacies (2000).

The government is currently discussing the removal of article 19 of the Pharmacy Act, which says that a pharmacist is allowed to work in only one pharmacy. Thus in the future pharmacists might be allowed to be supervisor in more than one pharmacy, so that pharmacies will not always have a pharmacist present.

3.3.2 Accessibility

In the Netherlands prescription-only medicines are mostly sold in pharmacies. Furthermore, there is dispensing of pharmaceuticals by

- Self dispensing doctors in areas where the distance to the closest pharmacy is more than 4.5 kilometres.
- Polyclinic pharmacies: Since 1 April 2000 hospitals are also allowed to run pharmacies in out-patient clinics, which may dispense pharmaceuticals also to non-patients.
- Drugstores, which have been allowed to sell non-prescription medicines for a long time already (since approximately 1850). Nowadays more than 80 percent of OTC medicines are sold through approximately 3,961 drugstores or drugstore departments within supermarkets. Prescription-only medicines are not allowed to be dispensed through drugstores. The dispensing of OTC medicines in a drugstore requires that the manager or a staff member has a special drugstore license.
- Other OTC outlets, which can be located in groceries, supermarket, or on camping sites. If the distance to the nearest pharmacy, dispensing doctor or drugstore is three kilometres or more, a special license for the dispensing of a restricted range of OTC medicines can be granted. In 2001, the Netherlands counted 760 of these types of OTC outlets. The government is currently discussing the retail of non-prescription medicines by outlets other than drugstores and pharmacists, e.g. in gas stations, without requiring special licenses.
- Internet pharmacies, which are also allowed to dispense prescription-only medicines in the Netherlands. Currently there are four internet pharmacies active in the Netherlands.

Table 3.1: Netherlands – Number of pharmacies and other POM-dispensaries[1] 1995 - 2005

	1995	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Number of dispensing outlets							
Community pharmacies	1,513	1,588	1,602	1,629	1,654	1,697	1,732
Including:							
Polyclinic pharmacies[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	10[3]
SD-doctors	665	644	636	636	606	593	586
Internet pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	4
Total	**2,178**	**2,232**	**2,238**	**2,265**	**2,260**	**2,290**	**2,322**
Inhabitants per dispensary							
Inh. per pharmacy	10,217	10,029	10,016	9,913	9,810	9,561	9,368
Inh. per dispensary	**7,098**	**7,135**	**7,170**	**7,130**	**7,179**	**7,085**	**7,000**

POM = prescription-only medicines, Inh. = Inhabitants, SD = self-dispensing, n.a. = not available

1 Only dispensaries which are allowed to dispense prescription-only medicines are included, data on 1 January.

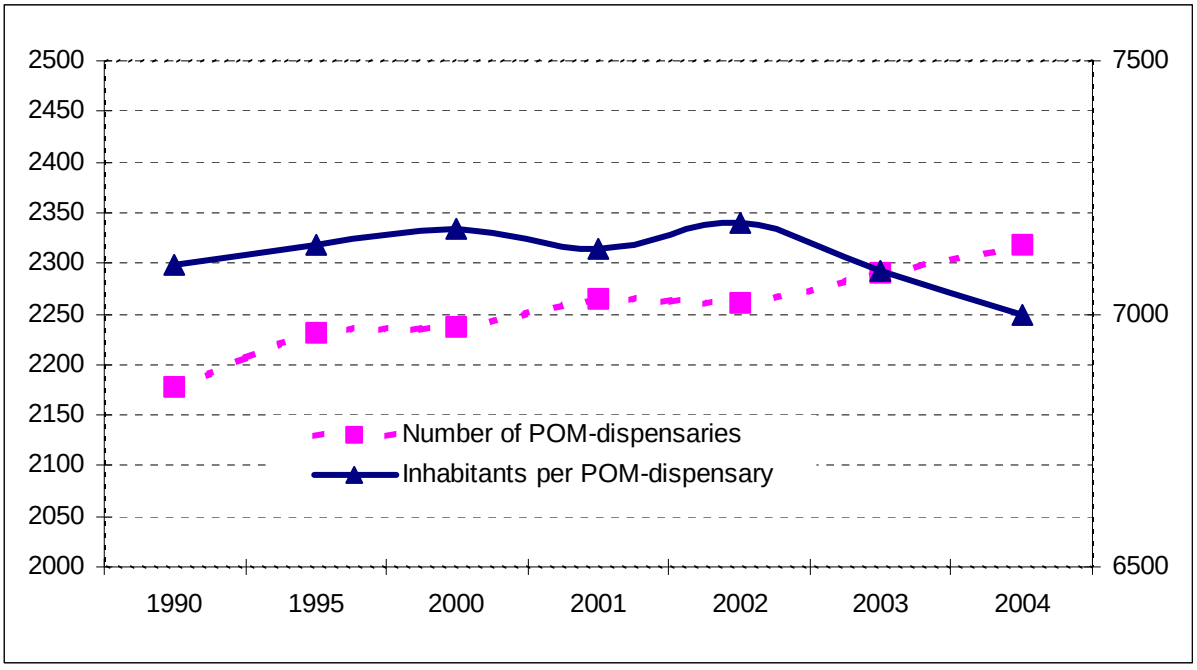
2 Pharmacies in out-patient clinics, which may dispense pharmaceuticals to the general public.

3 Estimation, no exact numbers available.

Source: data gathering by ÖBIG

Table 3.1 and Figure 3.1 display the development in the number of dispensaries for prescription-only medicines (POM) and the number of inhabitants per POM dispensary. In the Netherlands the number of inhabitants per POM dispensary is high compared to most other European countries. Currently each POM dispensary has to provide on average 7,000 inhabitants with pharmaceuticals. Whereas the last ten years have shown an increase in the number of pharmacies, the number of self-dispensing doctors went down (cf. Table 3.1). Due to this development and because of a growing population the ratio of inhabitants per POM dispensary has only slightly decreased between 1995 and 2005 (cf. Figure 3.1).

Figure 3.1: Netherlands – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM-dispensary 1990 - 2005



POM = prescription-only medicines

Source: data gathering by ÖBIG

Since the year 2000 30 to 40 new pharmacies have opened per year, with an exception in 2003, when 50 new pharmacies opened. The number of closures per year has been reasonably constant (approximately 6 to 10 closures), but shows a peak in 2000 (21 closures) due to the fact that the pharmacy chain Boots closed all of its 12 recently opened pharmacies. Boots decided to leave the Dutch market as its concept (drugstore-like pharmacies) was not accepted by the Dutch consumers, and because they were not able to find enough qualified personnel willing to work for them.

Of the 483 Dutch municipalities 73 did not have a community pharmacy in 2004. This is often compensated through dispensing by family physicians. According to statutory regulations a family physician can get a license to dispense medicines if the distance to the nearest pharmacy is at least 4.5 kilometres. In 2004 347,220 (2.1%) Dutch citizens did not live within 4.5 kilometres of the nearest pharmacy or dispensing doctor. These residents were mainly living

in the northern part and in the south-western part (Zeeland) of the Netherlands, which are the less densely populated areas. The percentage of people living within 4.5 kilometres of a pharmacy or dispensing doctor has not increased significantly since 2001, indicating that the newly established pharmacies are mainly situated in the areas where pharmacies or dispensing doctors have already existed before.

3.3.3 Establishment of pharmacies

There have never been statutory geographic or demographic restrictions to the establishment of pharmacies in the Netherlands. However, the Royal Dutch Pharmaceutical Society (KNMP) applied its own establishment policy and accompanying sanctions. For example the KNMP would reject the registration of a new pharmacy if it was to be established next to an existing pharmacy. The aim of this establishment policy was to ensure a minimum number of clients per pharmacy.

Due to a number of legal pronouncements, the KNMP has since 1987 no longer been allowed to apply sanctions in their establishment policy. Whereas, from then on, the advise of the KNMP was not compelling, the rules were still in many cases copied into the contracts between the pharmacies and the health insurance companies. Since 1 January 1998 the application of restrictions to the establishment of pharmacies is forbidden by the Law on Competition (Mededingingswet). Before that, the establishment policy of the KNMP was already often disregarded by pharmacists who were not a member of the KNMP.

Since 1992 health insurance funds are no longer obliged to contract each pharmacy. They are merely obliged to make sure that health care is well organised for the insured people. This development has led to health insurance funds defining requirements for pharmacies and being involved in the choice of the location of a pharmacy (i.e. not too close to an existing contracted pharmacy). Since 1998 people have been free to choose their own health insurance provider. These are often local health insurance funds. If people move to another area they prefer to stay with their old health insurance fund. This could cause problems as local health insurance funds tend to have only contracts with local pharmacies, thus not in the new neighbourhood of the people that have moved.

If the distance to the nearest pharmacy is at least 4.5 kilometres the Ministry of Health, Welfare and Sport can grant a family physician a license to dispense medicines from, in order to compensate for the absence of a pharmacy. Drugstores, which want to sell OTC medicines also have to apply for licences at the Ministry of Health, Welfare and Sport. Selling of OTC medicines in drugstores is only allowed if supervised by a qualified employee. In case the distance to the nearest OTC outlet (drugstore or pharmacy) is more than 3 kilometres, a drugstore does not need to have a qualified employee to receive a “special licence” for the selling of OTC medicines.

3.3.4 Ownership of pharmacies

There are no state licenses required to own a pharmacy, but in order to run a pharmacy profitably contracts with health insurance funds are necessary. These contracts can not be traded or transferred. Until 1992, health insurance funds used to be obliged to contract any pharmacy.

In the Netherlands multiple ownership was not allowed until 1987. This has led to the development of (a few) pharmacy chains already in the early 1990s. Until 1999 the owner of a pharmacy had to be a pharmacist. Only in a few occasions foundations or sickness funds were allowed to own pharmacies. Since 1999 it has been possible for non-pharmacists to own pharmacies and employ pharmacists for supervision of the pharmacy practices. This has led to an increase in the number of newly established pharmacies and in the number and size of pharmacy chains. The owners of the pharmacy chains are mainly wholesale companies (OPG, Brocacef (Phoenix), Alliance Unichem and Celesio). In addition drugstore chains and one of the health insurance funds are starting to employ pharmacists, and open pharmacies. The British pharmacy/drugstore chain Boots opened in 1999 in total 12 pharmacies. One year later however Boots had to close all their pharmacies because they were not viable and they were not able to find enough qualified personnel willing to work for them. Currently 511 (29.5%) community pharmacies are, wholly or partly owned by pharmacy chains, which are owned by non-pharmacists (cf. Table 3.2). In addition, 37 (2.1%) pharmacies are part of one of the two pharmacy chains (Prickartz and Thio Pharma) owned by pharmacists. With the liberalisation of the ownership of pharmacies, the prices of pharmacies have risen considerably, making it increasingly difficult for independent pharmacists to buy their own pharmacy. Pharmacies are increasingly joining co-operations of pharmacies. One example of such a co-operation is “kring apotheken” in which app. 270 pharmacies have joined.

Table 3.2: Netherlands – Pharmacy chains 2005

Pharmacy Chain	Owner	Owner type	Number of pharmacies [1]
Mediveen-Groep	OPG	wholesaler	207
Farmassure-Groep	Brocacef, Phoenix	wholesaler	70
De Vier Vijzels	Alliance Unichem	wholesaler	65
Lloyds apotheken	Celesio	wholesaler	38
Apotheken in Overdracht	Regifarm	wholesaler	37
VNA	VNA	foundation	80
Etos	Etos	drugstore chain	5
DA	DA, Dynadro	drugstore chain	4
DSW	DSW	health insurance fund	5
Prikartz	-	pharmacist	21
Thio Pharma	-	pharmacist	16
		Total:	**548**

DSW = Delfland, Schieland en Westland, VNA = Verenigde Nederlandse Apotheken

[1] Wholly or partly owned by the pharmacy chain, on 1 January 2005.

Source: data gathering by ÖBIG

3.3.5 Pharmacy staff

The professional staff of Dutch pharmacies consists of pharmacists, pharmacy assistants and other personnel (e.g. administrative, cleaning). The university education for pharmacists is according to the EU directive 2005/36/EC and takes six years. During the university education students choose to become a hospital pharmacist or a community pharmacist. In every community pharmacy there always needs to be a responsible pharmacist present. This rule might fall with the new Pharmacy Act, which is expected to come into force in 2006. Abolishment of the rule will allow pharmacists to supervise more than one pharmacy at a time. During the absence of a pharmacist, medicines will be dispensed by pharmacy assistants, who have always been allowed to perform many of the tasks of the pharmacist, such as the manufacturing of pharmaceuticals, the filling of prescriptions and counselling. The required secondary education for pharmacy assistants takes four years.

All practicing pharmacists are obliged to gather a minimum of 30 training-points per five years. One training-point stands for one hour of continuous training. Pharmacy assistant are also obliged to continuously keep their knowledge up to date by means of courses. Trainings and courses are provided by professional associations, universities and sometimes by industry. All trainings and courses must be accredited by the KNMP.

Concerning the liability of the pharmacy staff the pharmacist is always responsible, as long as the pharmacy assistants follow the rules defined by the pharmacist.

Table 3.3: Netherlands – Staff working in community pharmacies 1990 - 2005

Pharmacy staff[1]	**1990**	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Pharmacists [2]	1,970	2,188	2,472	2,611	2,636	2,670	2,681	2,734
Pharmacy assistants [3]	8,310[4]	10,630	12,189	12,600	13,023	13,563	14,133	14,641
Other pharmacy personnel	857[4]	1,983	2,549	3,080	3,845	4,497	4,909	5,057
Total	**9,167[4]**	**14,801**	**14,738**	**15,680**	**19,504**	**20,730**	**21,723**	**22,432**

[1] Data per 1 January, staff counted per head, working in community pharmacies.

[2] Trained according to EU Directive 2005/36/EC (30 September 2005).

[3] With the right to dispense pharmaceuticals under supervision of a pharmacist.

[4] Pharmacy assistants and other pharmacy personnel employed for less than one third of the regular working hours were not counted in 1990. .

Source: data gathering by ÖBIG.

As table 3.3 shows, the total number of practicing community pharmacists has increased by 9 percent over the past years. Whereas the number of pharmacies has also increased (10%), the number of pharmacists per pharmacy has been reasonably constant (Approximately 1.6) since 2000. The number of other employees per pharmacy has increased from 9.3 in 2000 to 11.4 persons in 2005. However, many of the pharmacy assistants (72%) work part time. In 2004, the fulltime equivalent (40 hours per week) of the number of assistants per pharmacy was 6, compared to 8.3 when counted by head.

3.3.6 Opening hours

The statutory requirements regarding the opening hours of pharmacies were abandoned in 1996. Since then pharmacies are allowed to be open outside normal shop-hours. Nonetheless, typical opening hours are on weekdays (Monday to Friday) from 9 am to 6 pm. Most pharmacies are closed on Saturdays and on Sundays.

According to the Dutch Pharmacy Standard (Nederlandse Apotheek Norm, NAN), and as required by the health insurance funds, pharmacies must ensure 24 hour delivery of pharmaceuticals to their customers. In order to do so pharmacies join groups and provide service outside the normal opening hours on a rotation basis. In this case each pharmacy has to make sure that its customers are aware of which pharmacy will be available at night or in the weekend. In addition several so-called service-pharmacies ("Dienstapotheken") have been set up, which are only opened during evenings, nights and in weekends. Personnel for these pharmacies consists of a pool of pharmacy employees (i.e. pharmacists and assistants) from regular pharmacies in the neighbourhood. Pharmacy services provided outside normal opening hours are always based on stand-by duty. A recent study on the quality of the service delivered by the service pharmacies conducted by the Health Care Inspectorate (IGZ) concluded that the service pharmacies do not have enough insight into the history of their customers regarding the previous and current use of pharmaceuticals. Apart from that quality of service was found to be sufficient.

3.3.7 Products

Products sold in pharmacies fall into one of the following categories:

- Prescription-only medicines (POM)
  POM are mainly sold through pharmacies and to a lesser extent through self dispensing doctors, policlinic pharmacies and internet pharmacies. Currently approximately 11,440 POM (counted including different pharmaceutical forms (e.g. tablets) and dosages) are registered, of which 9,960 are on the market. Of these 9,960 POM that are on the market, 99.6 percent is reimbursed and 36 percent are generics.
- OTC medicines
  OTC medicines or non-prescription medicines account for 9 percent of the pharmacies' turnover. Pharmacies account for only 15 percent of the total turnover of OTC medicines. The largest share of OTC medicines are sold through drugstores.
- Non-pharmaceutical products
  A relatively small part of the pharmacies' turnover (5%) is made on non-pharmaceuticals. Non-pharmaceutical products sold through pharmacies are almost all medical devices (e. g. band aids, dressings). Currently approximately 9,400 different types of medical devices are sold through pharmacies.

Since 1996 there have been no regulations on the minimum amount and types of pharmaceuticals that a pharmacy must have on stock. Pharmacies are thus allowed to specialise e.g. for specific disease classes. Examples of such initiatives are a pharmacy within an outpatient clinic for rheumatic patients and a pharmacy for diabetes patients. Up till now not many pharmacies have specialised but it is expected that this will happen increasingly in the future. In general pharmacies are delivered twice a day by wholesalers.

3.3.8 Quality of pharmacy services

Not every pharmacy is equipped to manufacture pharmaceuticals, as this is not longer required by law. There are a few central pharmacies that manufacture pharmaceuticals for other pharmacies. The contract with the health insurance says that the pharmacy must take care that manufactured pharmaceuticals can be delivered. The share of pharmacy-manufactured pharmaceuticals has been reasonably stable since 2001. In 2004 the number of pharmacy manufactured pharmaceuticals was 6.3 million, which is a decrease of 3.8 percent compared to 2003. Currently, of every 20 dispensed reimbursable medicines one (5 percent) is pharmacy manufactured. Generic substitution by pharmacists is only allowed if the physician has prescribed the active substance and not the brand name of a pharmaceutical. In 2005, 46.6 percent of all filled prescriptions were generics.

In 1998 the KNMP signed an agreement with the Ministry of Health, Welfare and Sport which says that the KNMP will help to improve the quality and the efficiency of pharmaceutical care. Several projects have resulted from this agreement, for example to improve counselling of customers for specific medicines. Also as a result of the agreement the Dutch patients' and consumers' federation (Nederlandse Patiënten en Consumenten Federatie, NPCF) received in 2000 from the KNMP a subsidy for a project called "Apotheken door clienten bekeken" ("Pharmacies through the eyes of the customers"). Within this project a questionnaire was developed which pharmacies can use to assess their quality of service as perceived by their customers. The assessment will then lead to possible improvements of their services. Such assessments of customer satisfaction are also offered by the Pharmacies Monitoring Program (Apotheken Monitoring Program, AMP). In addition the AMP offers services such as mystery guest shoppers, assessment of employee satisfaction, organisation scans and advice, and a congress called "landelijke kwaliteitsdag apotheken" ("national day for quality in pharmacies"). Both the quality assessment of the NPCF and of the AMP are voluntary for pharmacies.

The shift from the insurances' obligation to the insurances' right to contract has led to increased requirements for pharmacies set by the insurers. For example insurers increasingly require that a pharmacy is certified according to the standards set by the foundation for harmonisation of quality assessment. Certification, for example, requires that pharmacy personnel is sufficiently trained and that pharmacies assess customer satisfaction on a regular basis. In addition, since 2002 the law on Quality of Health Care Institutions (Kwaliteitswet Zorginstellingen) provides that each year, pharmacies have to hand over to the health insurances their plans and aims for the coming year concerning the assurance of the quality of their services. The Dutch Pharmacy Standard (Nederlandse Apotheek Norm,

NAN), which includes guidelines for example concerning the manufacturing of pharmaceuticals by pharmacists or the home delivery of medicines, is also often part of the contracts between insurers and pharmacies. The Dutch Pharmacy Standard, which has been developed by the KNMP, indicates for community pharmacies what is meant by good quality services under the law on Quality in Health Care Institutions. According to the guidelines pharmacy services must be of a high level, effective, efficient and patient centred and should meet the needs of the patients. The Dutch Pharmacy Standard is also used by the Health Care Inspectorate (IGZ) or, in extreme cases, by the court to test the procedures of pharmacists, e.g. in case of problems or adverse incidents.

Published customer satisfaction studies show that in general pharmacy customers are satisfied and think highly of pharmacists. The results of the 2005 national Healthcare Monitor indicate that 74 percent of the Dutch population has a lot of confidence in their pharmacist, and that 93 percent thinks of a pharmacist as an expert. A survey among 600 people living in the east part of the Netherlands in 2005 revealed that, of the people that visit a pharmacy at least four times per year, 72 percent gives a positive judgement and 9 percent gives a very positive judgement of their pharmacist. Also, 94 percent of the respondents in this study found their pharmacist reliable. A study from the University of Utrecht in 2005 concluded that often customers are not aware of the qualification of pharmacists, of the information they can provide, and of the possibility of having a personal consultation with the pharmacist in case they feel they do not have enough privacy at the counter. A study in 2002 showed that customers are in general satisfied with the accessibility of pharmacies. Nonetheless, customers felt that the accessibility of pharmacies outside regular opening hours, the information they received regarding possible side effects of medicines and the amount of pharmaceuticals the pharmacy has on stock could be improved.

3.4 Market data

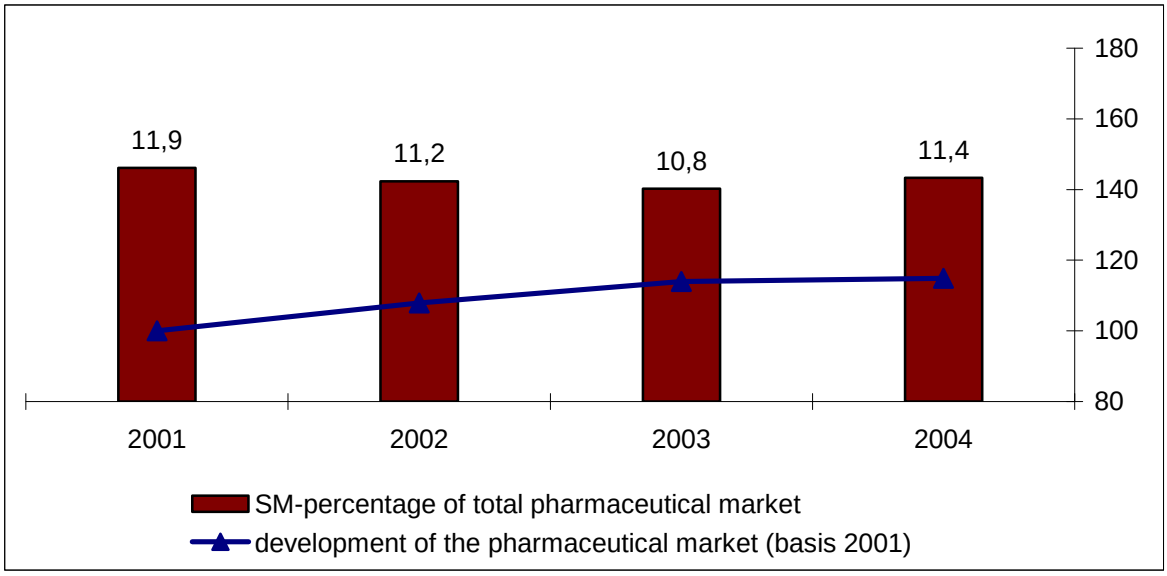
3.4.1 Pharmaceutical expenditure

According to OECD, total pharmaceutical expenditure in the Netherlands amounted to € 5,099 million in 2003, which is 11.4 percent of total health expenditure. In 2004 the Dutch authorities have reported a 2.5 percent (€ 100 million) decrease in the expenditure on medicines sold through community pharmacies.

This decrease was on the one hand due to the removal of a number of pharmaceuticals from the positive list, and on the other hand due to the lowering of the prices of generics by, on average, 40 percent. The cut on generics prices was part of the 2004 covenant between the Ministry of Health, Welfare and Sport, the KNMP, Dutch health insurances and the Association of the Dutch Generic Medicines Industry. It is for the first time in many years that pharmaceutical expenditure has shown a decrease instead of an increase. The largest growth (10.6%) in pharmaceutical expenditure was in 2000/2001.

The self-medication (OTC) market in the Netherlands accounts steadily for about 11-12 percent of the total pharmaceutical expenditure (cf. Figure 3.2). Parallel import reached its peak in the mid-nineties, and decreased after 1996. Between 1996 and 2003 parallel imported pharmaceuticals accounted for 13 to 15 percent of the total expenditure on prescription-only medicines. In 2004 this share increased slightly and amounted to 16.3 percent.

Figure 3.2: Netherlands – Development of the pharmaceutical market at consumer price level, 2001 - 2004



SM = self-medication (OTC)

Source: data gathering by ÖBIG.

3.4.2 Remuneration of pharmacies

In the Netherlands pharmacies receive a fixed fee per filled prescription. This fee is regardless of the price and the quantity of the dispensed pharmaceutical. Depending on the situation and the kind of medicine, there is however a limit to the quantity supplied: for 15, 30 or 90 days.

As of 1 January 2003, the Health Care Tariff Board (CTG) determined the pharmacy fee to be € 6.10. The CTG applies annually an index-related adjustment of the pharmacy fees. Both in 2004 and in 2005 the pharmacy fee did not change. The dispensing fee may not be charged by self-dispensing doctors or if a general practitioner manages the pharmacy.

Since 1991 a large part of the pharmacies' remuneration is formed by discounts given by the manufacturers or wholesalers. Since the exceeding of the pharmaceutical budget has become an annually recurring problem, the Ministry of Health, Welfare and Sport introduced a claw back rule in 1998.

According to the claw back rule pharmacies are currently obliged to grant patients and health insurance companies a 6.82 percent discount on the list prices issued by the pharmaceutical manufacturers, with a maximum of € 6.80 per dispensed pharmaceutical.

3.4.3 Sales

In 2004, the turnover of the average Dutch pharmacy decreased by 4.7 percent to € 2.3 million. The cause of this decrease has been explained under Section 3.4.1. The main source of the pharmacy turnover is the fixed fee per prescription (€ 424,000 on average). The average profit on the selling of non-prescription medicines has decreased from 2003 to 2004 by 40 percent to € 25,000.

Sales of pharmacies are estimated to be split into 86 percent turnover on prescription-only medicines, 9 percent on OTC medicines and 5 percent on non-pharmaceutical products (mainly medical devices).

Table 3.4: Netherlands – Pharmacy turnover 2000 - 2004

	2000	2001	2002	2003	2004
Prescriptions filled (mill.)	121.3	127.1	130.3	136.6	127.8
Total pharmacy turnover (mill.)	€ 3,105	€ 3,447	€ 3,730	€ 4,017	€ 3,907
Average pharmacy turnover (mill)	€ 1.9	€ 2.1	€ 2.3	€ 2.4	€ 2.3
Share of turnover for different product groups					
Pharmaceuticals	95 %	95 %	95 %	95 %	95 %
OTC	12 %	12 %	12 %	10 %	9 %
Non-pharmaceuticals	5 %	5 %	5 %	5 %	5 %

mill. = in millions, OTC = over-the-counter

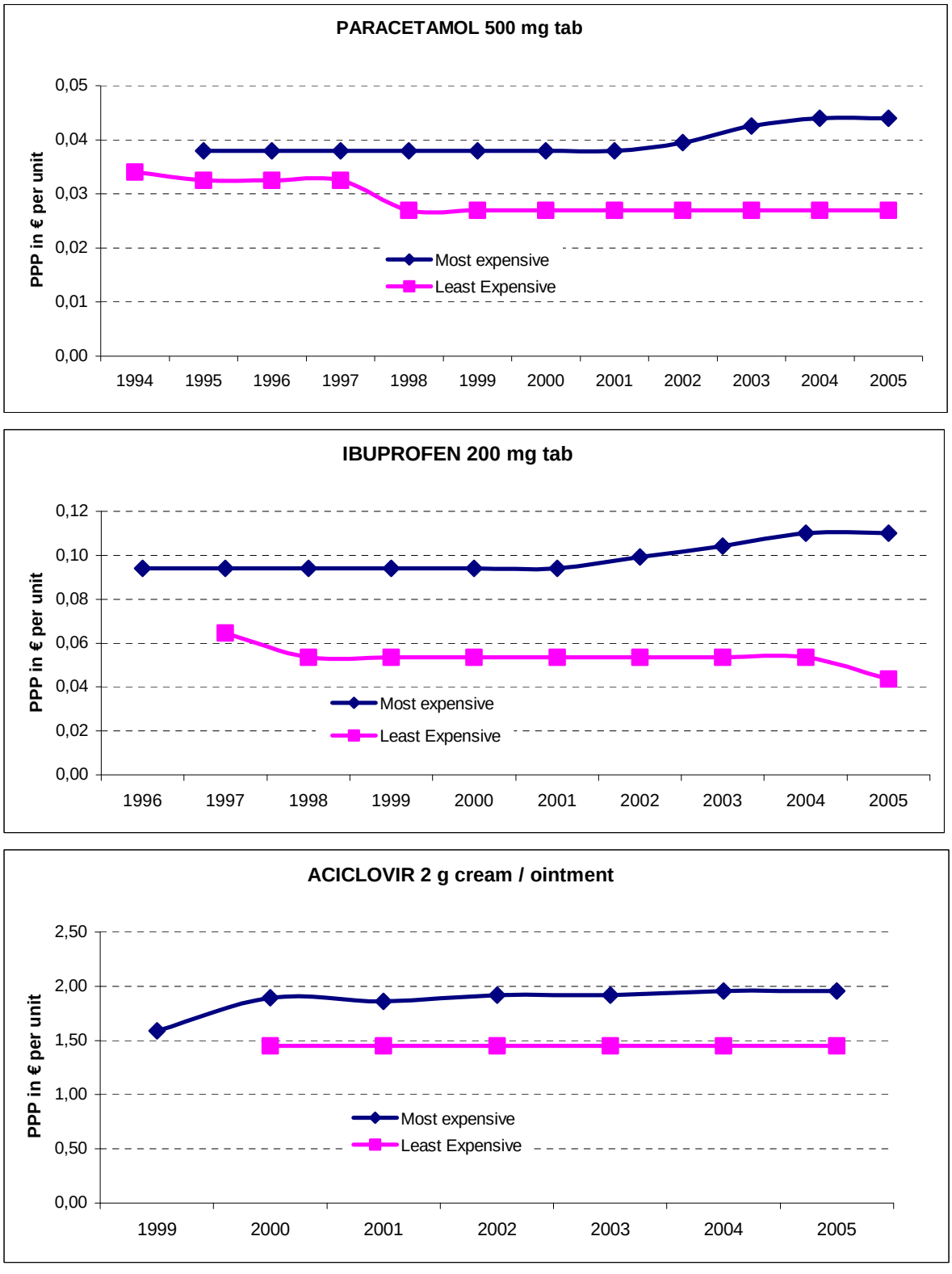
Source: data gathering by ÖBIG

3.4.4 Price development

Considering the above described price cuts and the vivid OTC-competition in the Netherlands (as there are many wholesalers and besides pharmacies, other OTC-dispensing units on the market) OTC prices remained rather stable throughout the years.

Figure 3.3 shows in detail the price development of selected OTC-blockbuster substances (ibuprofen, paracetamol and aciclovir cream, diclofenac gel/cream not being marketed as OTC in the Netherlands). It does not seem that deregulation activities have influenced OTC-prices in a noticeable way, i.e. not leading to considerable reductions.

Figure 3.3: Netherlands – price development of selected OTC blockbusters 1995 - 2005



PPP = pharmacy purchase price, tab = tablet

Source: data gathering by ÖBIG

The average annual growth rate of **paracetamol** prices amounted to plus 1.5 percent for the most expensive product by Bayer, whereas the price of the least expensive paracetamol tablet by ratiopharm held a stable price during the last seven years. Ratiopharm prices were reduced by 17 percent in 1998.

In terms of **ibuprofen** 200 mg the most expensive product continuously on the market, is still the Boots manufactured 'Nurofen', even if the British pharmacy chain closed all their dispensing outlets by 2001. The price had an average annual growth rate of 1.8 percent, whereas the price of the cheapest product (by ratiopharm) dropped by almost 19 percent from 2004 to 2005.

The cheapest **aciclovir ointment/cream** product is manufactured by Katwijk and on the market since 2001. There were no price changes since then. The current most expensive aciclovir cream 'MP Koortslip' by Sandoz has also kept its price almost stable since 2001.

4 Case-study: Norway

4.1 The healthcare system

The Norwegian health care system is founded on the principles of universal access to health care services, political decentralisation and free choice of provider.

Organisation

The health care system in Norway has three main levels, which relate to the country's three political tiers: the central state, 19 counties and 435 municipalities. The central state level is responsible for regulating and supervising services. At this level there are three national bodies overseeing the health care system: The Ministry of Health and Social Affairs (Helse- og omsorgsdepartementet), the National Institute of Public Health (Folkehelseinstituttet, FHI), and the National Board of Health (Helsetilsynet). In 1974 the country was divided into five health regions. In each of these regions a Regional Health Committee was established. In 2000 each region became required to submit strategic plans to the Ministry showing how they aim to fulfil national health policy.

At county level, County Councils are responsible for the financing, planning and provision of specialised care. The country's 435 municipalities are responsible for the provision and financing of primary health care and social services. In 1986, municipalities were given the authority to prioritise health services. It was assumed that this autonomy would lead to a better serving of the local needs. Nevertheless, there are still large elements of centralised planning, such as broad guidelines for priority setting, and regional health plans have to be authorised by the Ministry.

All residents in Norway are compulsorily insured under the National Insurance Scheme (NIS). Attempts to provide complementary voluntary health insurance have not been successful. The role of private insurance in Norway is very limited.

During the 1990s a broad range of reforms was discussed and approved in Norway. Major pieces of legislation, concerning e.g. patients' rights, regional planning of health care services, hospital financing and pricing of pharmaceuticals, were passed.

Financing

The Norwegian health care system's most important feature is the predominance of tax-funded public provision together with limited out-of-pocket payments (about 10%). The NIS finances approximately 15 percent of total public health expenditure (comprehending mainly pharmaceuticals, fees of private doctors and transportation). The remainder is financed by the Counties and the State.

During the past ten years, health expenditure in Norway has more than doubled. This large growth coincided with an increased economic prosperity. As in other European countries the Norwegian government has responded to the increase in health expenditure by implementing cost-containment measures. Nevertheless, the share of health expenditure from the GDP (10.3 percent in 2003) is higher than in most other countries in Europe.

4.2 The pharmaceutical system

4.2.1 Framework

The main authority which supervises all activities related to the pharmaceutical sector is the Norwegian Ministry of Health and Social Affairs. Through the control of a subordinated agency, the Norwegian Medicines Agency (Statens legemiddelverk, NoMA), the entrance of new drugs on the Norwegian market is regulated. This authority is also involved in price setting mechanisms of pharmaceuticals. The Norwegian Board of Health, which distributes licenses for medicines production and trade, has overall supervision on the distribution of medicines from the manufacturer to the patient.

There are basically three major stakeholders in the distribution chain of pharmaceuticals: the pharmaceutical industry / importers, wholesalers and pharmacies. The structure of the pharmacy and wholesale system has changed substantially after the new Pharmacy Act which came into force in 2001. From being a market with a few wholesalers and many independent pharmacies, the business is now dominated by three players that own both wholesale and pharmacies. The vertical and horizontal integration in the wholesale and pharmacy sector will be further discussed in Section 4.3.4. There are currently no wholesalers that do not have a pharmacy chain incorporated. In theory the wholesale system in Norway is multi-channel, but in practice pharmacies get nearly all their products from the wholesaler who owns them. Since there are so few players, the Norwegian pharmacy and wholesaler market can be characterised as an oligopoly, i.e. what one pharmacy business does will have significant impact on how the other pharmacy businesses behave. The owners of the Norwegian wholesale - pharmacy chains are all international companies.

4.2.2 Reimbursement

Pharmaceuticals are classified into three categories: Besides non-prescription medicines, which are fully paid for by the patient, there are prescription medicines, which are either fully covered by the Norwegian National Insurance Scheme (“Blue prescriptions”) or fully paid for by the patient (“White prescriptions”). All persons who are either residents or working as employees in Norway are compulsorily insured. The National Insurance Scheme, administered by the National Insurance Administration (Trygdeetaten), offers reimbursement for certain medicines to patients suffering from chronic illnesses, according to a list of diagnoses with a set of criteria the patients have to meet. For each diagnosis there is a corresponding list of reimbursable medicines, the “Blue list”. The NoMA decides on the inclusion of medi-

cines in the reimbursement list. The list of diagnoses can only be expanded by the Norwegian parliament. Applications for reimbursement of medicines for indications outside the list of diagnoses are also assessed by the NoMA.

Within the National Insurance Scheme co-payments are required from most patients, except those receiving minimum old-age or disability pension, and children below 7 years of age. The co-payment threshold in 2005 is 36 percent of sales value, but no more than 490 Norwegian crowns (€ 58). If the patient's total combined co-payment (e.g. on medicines, visits to physicians and psychotherapy) exceeds 1,585 Norwegian crowns (€ 189) before the end of the calendar year, then the patient will receive a "free card" and does not have to pay any further co-payments during the rest of the calendar year.

4.2.3 Pricing

The NoMA controls the maximum prices of prescription medicines in the pharmacies (pharmacy retail price) by 1. setting maximum purchase prices for pharmacies (pharmacy purchase price, PPP) and 2. setting the maximum pharmacy margins.

The pharmacy profit consists of a percentage mark-up based on the wholesale price and a fixed amount per package. The manufacturer selling price, and thus the wholesale margin, is not restricted. Since 2000 the PPP is set to be the average of the three lowest market prices for the medicines in nine European countries (Sweden, Finland, Denmark, Germany, UK, the Netherlands, Austria, Belgium and Ireland). To determine the maximum amount refunded by the National Insurance Administration, therapeutically interchangeable medicines are grouped. The NoMA fixes one price per group, differentiating by large and small packages.

On 1 January 2005 a new pricing system for generic medicines was introduced. In the new price system, medicines for which the patent has expired and which are listed on the NoMA's exchange list get reduced reimbursement prices. The reimbursement price reductions are stepped.

There is no control on the pricing of non-prescription (OTC) medicines in Norway. The pharmacy decides its own prices and thereby its margins for non-prescription medicines.

4.3 The pharmacy sector

4.3.1 Background

Before 2001, the pharmacy sector in Norway was subject to strict regulation. The Norwegian Board of Health used to determine the establishment of new pharmacies, and Norway had a relatively low number of pharmacies compared to other European countries.

On March 2001 a new Pharmacy Act came into force. The authorities' goals were to increase accessibility and service, make the pharmacy trade more efficient and bring sales prices of pharmaceuticals down. The act entailed changes especially with regard to two key issues:

1. Free establishment of pharmacies and free ownership in pharmacy trade: The new act sets no limits on the number or location of pharmacies and puts no competency requirements on the ownership of pharmacies.
2. Access to generic substitution at pharmacies: Pharmacists may dispense bio-equivalent products (generics) instead of the original (brand) prescribed by a doctor without prior consent of the doctor.

At the same time, the quality standards for pharmacies were tightened and focussed more on what a pharmacy should look like. The new act allows for a broader use of market mechanisms than before. Through generic substitution, the authorities have provided for increased competition between pharmaceuticals. The liberalisation in the pharmacy sector was part of a larger political trend towards deregulation, e.g. following liberalisation in energy supply and telecommunications.

4.3.2 Accessibility

Medicines are mainly distributed by pharmacies, which must be run by pharmacists (MSc.). In addition, medicines are also allowed to be dispensed through:

- Branch pharmacies (Filial Apotek), which may only be opened by pharmacies. These branch pharmacies are established, if a pharmacy is considered necessary in a region, but no pharmacist can be found to run the pharmacy. Branch pharmacies are run by prescriptionists (BSc.). In this case the pharmacist in the main pharmacy, to which the branch pharmacy belongs, is responsible.
- Hospital pharmacies, which are allowed to dispense pharmaceuticals to out-patients.
- Pharmacy outlets, which can be established by pharmacies in order to compensate the absence of pharmacies in an area. The NoMA decides on the establishment of medicine outlets. A pharmacy outlet has the right to sell and deliver only non-prescription medicines. These pharmacy outlets do not have an independent right to fill prescriptions, but are affiliated to a pharmacy that exercises this right. Most of the pharmacy outlets are located in

grocery shops. In 2005 there are approximately 1,240 pharmacy outlets in Norway, about half of the pharmacies in Norway have pharmacy outlets. Self-service is not allowed.

- LUA ("medicines outside pharmacies") outlets, which have been allowed to sell a very limited range of OTC medicines since 1 November 2003. The list of medicines that can be sold outside pharmacies currently covers about 50 OTC products. The NoMA has defined a minimum list of medicines which may be sold by the LUA-shops. In reality, 10 to 15 blockbusters are sold through LUA-outlets. By 1 January 2005 there were almost 5,700 LUA outlets in Norway.

Table 4.1: Norway – Number of pharmacies and other POM-dispensaries[1] 1990 - 2005

	1990	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Number of dispensaries								
Community pharmacies	320	346	392	397	461	502	520	535
Of which:								
Branch pharmacies	n.a.	69	105	92	119	125	126	138
Hospital pharmacies	19	27	27	28	28	30	30	30
Total	**320**	**346**	**392**	**397**	**461**	**502**	**520**	**535**
Inhabitants per dispensary								
Inh. per dispensary	**13,253**	**12,598**	**11,457**	**11,370**	**9,844**	**9,094**	**8,779**	**8,533**

POM = prescription-only medicines, Inh. = inhabitants, n.a. = not available

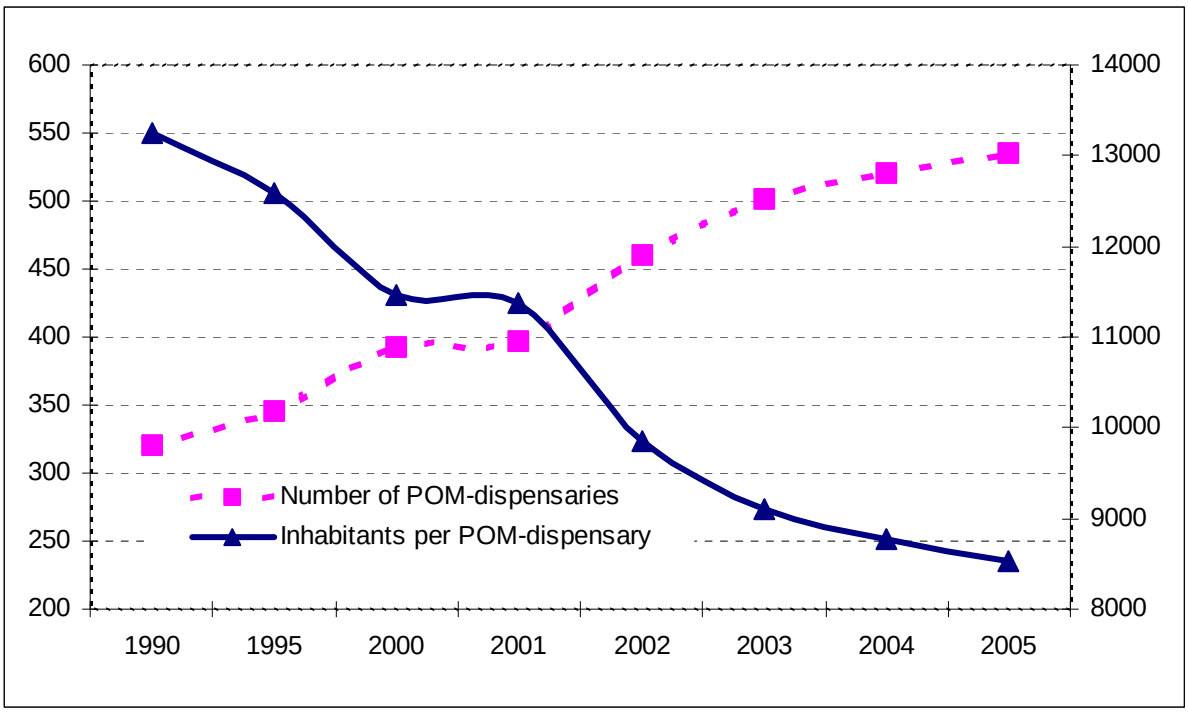
[1] Per 1 January, only outlets that are allowed to dispense prescription-only medicines.

Source: data gathering by ÖBIG

On 1 January 2005 there were 535 pharmacies in Norway, which is an increase of 35 percent compared to 2001. The largest number of new openings was seen in 2001 when 65 new pharmacies were established. In 2004, 16 new pharmacies were opened. In comparison, between 1990 and 2000 the number of pharmacies increased by 72.

The number of closures of pharmacies since 2001 is limited (1 to 9 per year) and mostly concerns pharmacies that had been established after the new Act came into force. The number of inhabitants per pharmacy has fallen sharply from 11,370 in 2001 to 8,533 in 2005. Nevertheless, Norway still has a relatively low pharmacy coverage compared to most European countries.

Figure 4.1: Norway – Number of prescription-only medicines (POM) dispensaries and number of inhabitants POM dispensary 1990 - 2005



POM = prescription-only medicines

Source: data gathering by ÖBIG

4.3.3 Establishment

Under the old Pharmacy Act, the location and number of pharmacies were decided by the Norwegian Board of Health. The Board made a “pharmacy plan” for five years onward. With the new Pharmacy Act dating from 1 March 2001 geographic and demographic criteria were abolished and establishment of pharmacies is no longer determined by the Board. Nevertheless, there are still some restrictions on the establishment of new pharmacies, in that municipalities’ zoning plans may predefine which buildings are to be used for business and restrict the establishment of pharmacies to these buildings. It is however interesting, that the official committee that has investigated the pros and cons of different competitive policies before the drafting of the new pharmacy law, did not recommend to allow vertical integration (Anell 2005). The rationale for the Ministry of Health to allow it was that vertical integration would create more powerful purchasers that are able to better negotiate discounts with manufacturers.

The establishment of pharmacies in rural areas is not particularly stimulated by the government. Nevertheless, in the rural, scarcely populated areas, no pharmacy has closed since the pharmacy reform. One reason for this is that the Ministry of Health and Care Services has agreed with the pharmacy chains that, if a pharmacy in a rural area (which was opened before 2001) is about to close, one of the pharmacy chains will take over this pharmacy or will establish a new pharmacy in the same area. Since the new act this agreement has been applied three times; three pharmacies were closed and reopened. The main part of the new

establishments has been in densely populated urban areas, especially in Oslo and the surrounding area. As of 1 January 2005, 199 of the 434 municipalities in Norway do not have a pharmacy, which is 9 less than before the pharmacy reform.

4.3.4 Ownership

Before the new Pharmacy Act came into force in 2001, only pharmacists were allowed to own pharmacies, and pharmacists had to apply for the ownership of a pharmacy if one was to be established. Decisions on the awarding of the ownership of a pharmacy were often not transparent enough. The new Pharmacy Act from 2001 states that pharmacy business requires two licences for each pharmacy. First a licence to own a pharmacy ("apotekkonsesjon") and second a licence to run the pharmacy ("driftskonsesjon"). Under the new act ownership of pharmacies by other legal entities than certified pharmacists, except by pharmaceutical manufacturers and prescribers (i.e. doctors), is allowed. The only boundary for corporate pharmacies is that no pharmacy chain is allowed to own more than 40 percent of all pharmacies. The role of the government under the new act is limited to issuing licences for running a pharmacy. All pharmacies must be run by a pharmacist.

Together with the deregulation of the establishment for pharmacies, the liberalisation of the ownership led to a large increase in the establishment of new pharmacies in Norway. In addition, many pharmacy owning pharmacists decided to sell their pharmacy for a lot of money to one of the wholesalers. The pharmaceutical market in Norway has become very much integrated, both horizontally and vertically: horizontally because many retailers are now owned by the same player, and vertically in that retailers and wholesalers now have the same owners.

Currently, the vertically integrated wholesale - pharmacy enterprises are Apokjeden / Apotek1, NMD (Norsk Medisinaldepot) / Vitusapotek, and Holtung / Alliance UniChem. The pharmacies have various forms of associations with the chains, from purchasing agreements and part ownership to being wholly owned by the chains. Table 4.2 displays the distribution of the 402 pharmacies that are for 100 percent owned by the pharmacy chains. Of the remaining pharmacies about 50 percent have perhaps partly-ownership contracts with chains and are loosely connected in an independent chain called "Ditt Apotek", and 35 percent have an agreement with a chain, mostly Apokjeden, but are not owned by it. Currently there are 13 pharmacies (2.4% of all pharmacies) left which are totally independent.

Table 4.2: Norway – Distribution of pharmacies entirely owned by pharmacy chains 2005

Pharmacy Chain	Wholesaler	Owner	Number of pharmacies[1]
Apotek[1]	Apokjeden Distribusjon AS	Tamro, Phoenix	172
Alliance Apotekene	Holtung AS	Alliance Unichem Plc	116
Vitusapotek	NMD Grossisthandel AS	Celesio, Franz Haniel & Cie GmbH	114
		Total:	**402**

[1] Entirely owned by the pharmacy chain, on 1 June 2005.

Source: data gathering by ÖBIG

4.3.5 Pharmacy staff

The professional staff in pharmacies consists of a pharmacy manager (“apoteker”), employed pharmacists ("provisor”), prescriptionists (“reseptar”), pharmacy technicians and sometimes nurses. Pharmacy managers are pharmacists who have a license to run a pharmacy, whereas employed pharmacists (“provisors”) work in a pharmacy which is run by a pharmacy manager. The pharmacy managers have the formal responsibility for errors or negligence conducted in the pharmacy. The pharmacy owner is obliged to have insurance arrangements for the pharmacy manager.

Prescriptionists, which form a special group of pharmacy professionals in Nordic countries, are entitled run branch pharmacies and pharmacy outlets. Prescriptionists are thus allowed to fill prescriptions. The required university education of prescriptionists (BSc.) takes three years, which is two years less than that of pharmacists (MSc.).

According to the Health Personnel Act the employer has the obligation to provide for and to organise necessary updating of the pharmacy staff’s competence. Minimum numbers of training hours or training schemes are not defined. Follow-up courses for the up-grading of the knowledge of pharmacy personnel are provided by the pharmacy chains, by the Norwegian Pharmacy Association (Norges Apotekerforening, NAF) and by external institutions such as the University of Oslo, which has a department for pharmaceutical up-grading called VETT. On average, each year 970 pharmacists attend these courses.

Table 4.3: Norway – Staff working in community pharmacies 1995 - 2005

Pharmacy staff[1]	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Pharmacists [2]	730	859	890	866	883	909	949
Of which:							
Pharmacy managers	277	287	305	342	377	394	397
Prescriptionists	771	882	894	903	962	1,010	1,056
Other pharmacy personnel	n.a.	4,288	4,404	4,456	4,456	4,330	4,144
Of which:							
Pharmacy technicians/ assistants	3,383[3]	4,071	4,087	4,153	4,133	4,016	3,976
Total	**n.a.**	**6,029**	**6,188**	**6,225**	**6,301**	**6,249**	**6,149**

n.a. = not available

1 Data per 1 January, staff counted per head, working in community pharmacies.

2 Trained according to EU Directive 2005/36/EC (30 September 2005).

3 Only technicians working more than 13 hours per week are counted.

Source: data gathering by ÖBIG

Looking at the development of pharmacy personnel we see that since 2001 the number of pharmacists has increased by 6.6 percent, whereas the number of pharmacies has grown by

35 percent since 2001. This implies a decrease in the number of pharmacists per pharmacy. In fact, in 2000 on average 2.2 pharmacists were working in a pharmacy, whereas the number of pharmacists per pharmacy on 1 January 2005 was 1.8.

In total the number of staff per pharmacy decreased from 15.5 in 2000 to 11.5 in 2005. This reduction has at least partly been compensated by an increased efficiency; purchasing routes are more coordinated and that some tasks (e.g. administration) have been taken over by the central chain offices.

4.3.6 Opening hours

According to the new Pharmacy Act, pharmacies should open for a minimum of 35 hours per week and they must be open on all weekdays and Saturdays. Under the old statutory provisions pharmacies were obliged to open for a minimum of 40 hours per week. Nevertheless, the reduction in the required minimum number of opening hours has not led to a reduction in actual opening hours. Contrarily, since 2001 the average number of opening hours has increased by approximately 2 hours. Currently the average opening hours of pharmacies are from 9 am to 6 pm on weekdays and from 9 am to 4 pm on Saturdays. In addition, pharmacies located in shopping centres have the same opening hours as the other shops there, which means that they are often open until 8 pm.

There is currently one pharmacy that provides full service 24 hours a day. This 24-hours pharmacy is located in Oslo. In case of an emergency most people visit the emergency ward of a hospital and receive medication there.

4.3.7 Products

Marketing authorisations for pharmaceuticals are either given on a central European level, by the European Medicines Agency (2,110 registered on 1 January 2005, counted including different pack sizes), or on a national level, by the Norwegian Medicines Agency (3,705 registered on 1 January 2005, counted including different strengths and forms).

Of the total of the registered pharmaceuticals, approximately 55 percent are available on the market (cf. Table 4.4). Of the about 5,800 pharmaceuticals on the market approximately 150 products (counted including different forms and strengths) are OTC, the rest of the pharmaceuticals are prescription-only medicines (POM).

Table 4.4: Norway – Number of pharmaceuticals 2001 - 2005

Pharmaceuticals[1]	2001	2002	2003	2004	2005
Registered pharmaceuticals[2]	3,178	3,732	4,411	5,002	5,815
Pharmaceuticals on the market[2]	2,722	2,759	3,044	3,092	3,247
Reimbursable pharmaceuticals[3]	n.a.	n.a.	n.a.	n.a.	2,571[4]

n.a. = not available

1 Data per 1 January. Pharmaceuticals for human and veterinarian use, excluding magistral or officina formula, herbal products and parallel import.

2 National market authorisations (Norwegian Medicines Agency) are counted including different strengths and forms, Centralised marketing authorisations (European Medicines Agency) are counted including different pack sizes.

3 Counted including different pack sizes.

4 Data from 28 October 2005.

Source: data gathering by ÖBIG

There are no statutory provisions defining the minimum range of medicines which pharmacies must have on stock. Pharmacies are required to have in stock all medicines which are regularly asked for (this may differ per pharmacy) and to be able to deliver medicines to the customers within 24 hours. Many pharmacies have implemented direct dispensing, which means that the prescription is dispensed directly (i.e. within the same visit). Before 2001, patients often had to wait several hours for their prescription to be filled. Waiting times for patients have thus decreased since the new Pharmacy Act. In addition, during the last few years a number of pharmacies have been equipped to accommodate self-services zones for health-related merchandise and non-prescription pharmaceuticals. There are no figures available for the development of waiting times and self-services in pharmacies over the past ten years.

On average pharmacies receive deliveries from wholesalers four times per week, in rural areas many pharmacies receive less than four deliveries.

Non-pharmaceuticals sold through pharmacies are, besides medical devices (e.g. band aids and dressings), skin care products. For the selling of non-pharmaceuticals by pharmacies, the approval of the NoMA is required. The general rule is that to be sold in a pharmacy products must be considered as health-promoting or health-related (e.g. sun-protection glasses). In addition, the share of the pharmacy turnover of non-pharmaceuticals may not exceed 15 percent.

4.3.8 Quality of pharmacy services

During the last decade various reforms tried to encourage the prescribing of generics. With the Pharmacy Act 2001 generic substitution was introduced at the pharmacy level. Pharmacies are now allowed to substitute another, equivalent pharmaceutical for the one that is indicated on a prescription. A doctor can proactively state that substitution is not allowed. In

addition, pharmaceuticals may only be substituted if they are on a substitution list which is compiled by the NoMA.

Not all pharmacies are equipped for the manufacturing of medicines. If not, then they have an agreement with another pharmacy that does have the necessary equipment and a laboratory.

Increasingly pharmacies are offering their customers additional services such as blood pressure measurement. A relatively new trend is that pharmacy chains offer their customers the opportunity to become a member. Members of a pharmacy chain for example receive discounts on services such as blood pressure measurement. However, with regard to the core activities of pharmacies, such as filling prescriptions and counselling, the non-members must receive the same services as the members. Pharmacies are thus not allowed to offer discounts on medicines only to their members.

In 2003 the Norwegian company "Econ Analyse AS" evaluated the new Norwegian Pharmacy Act on behalf of the Norwegian government. According to this report some pharmacists fear that the quality of pharmacy services has deteriorated due to an increase in workload. The pharmacists' opportunity to provide patients with professional advice is perceived by many pharmacists to have reduced. Over half of the interviewed pharmacists believed that the advice given on POM is not sufficient. The customers of the pharmacies appear to be satisfied with the advice they receive, and they do not feel that this has changed since the new Act came into force. It must be considered however that customers might not be able to recall in much detail the situation before the new Pharmacy Act. The Econ report also states that the extent of incorrect dispensing does not appear to have increased.

Pharmacy chains take care of the assurance of the quality of services provided by the pharmacies, for example by means of the following:

- Mystery shoppers, who visit the pharmacies and for example assess the delivery time and the way they are treated
- Benchmarking between pharmacies
- Organizing competitions between the pharmacies, which for example lead to the awarding of the title “Best pharmacy of the year”.

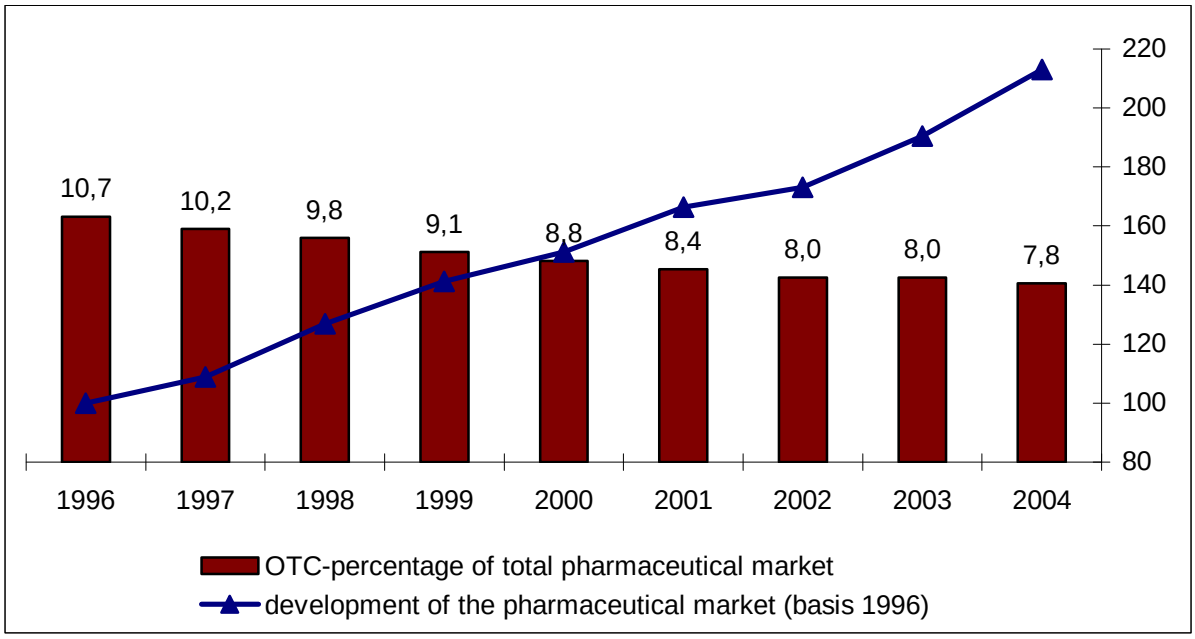
4.4 Market data

4.4.1 Pharmaceutical expenditure

In 2003 the total pharmaceutical expenditure in Norway was € 1,688 million, which amounts to 9.4 percent of the total health expenditure.

Figure 4.2 shows that the pharmaceutical market at the pharmacy purchase level has more than doubled in the past ten years. However, pharmaceutical expenditure as a share of the GDP has in general been stable.

Figure 4.2: Norway – Development of pharmaceutical market 1996 - 2004



OTC = over-the-counter

Source: AESGP 1995-2004, data gathering by ÖBIG

The government finances more than two thirds of the medicine consumption in Norway. Most of this is paid through the ordinary reimbursement system ("the blue prescription scheme"). The remaining third is distributed between non-prescription medicines, patient co-payments and non-reimbursable prescription medicines ("white prescriptions"). This split has been relatively stable in recent years.

4.4.2 Remuneration of pharmacies

The pharmacies' gross profit margin is defined as the percentage share of the pharmacies' selling price (excluding value added tax) which is not used for purchasing pharmaceuticals. The maximum pharmacy mark up for prescription-only medicines is currently:

- 8% for the first 200 NOK (€ 23.90)
- 5% for the amount above 200 NOK, and
- a fixed sum of 21.50 NOK (€ 2.50) per package.

In addition there are special fees for medicines without marketing authorisation and for narcotic drugs. If the product is potentially addicting, a special handling routine is required, and an additional 10 NOK (€ 1.20) may be charged by the pharmacy.

4.4.3 Sales

In 2004, approximately 25 million prescriptions were filled by pharmacies and pharmacies had a total turnover of € 2,172 million. The growth of the total pharmacy turnover was particularly large in 2003 and 2004 because, due to stabilisation and the high value of the Norwegian crown, the price referencing system “imported” higher prices for medicines in Norway. The increase in the average turnover (+2.3% 2003-2004) has been lower than that in the total turnover (+5.7% 2003-2004), due to the growth in the number of pharmacies. The average turnover per pharmacy was € 4.2 million in 2004.

Pharmacy sales in 2004 can be split into 76.7 percent turnover on prescription-only medicines, 9.6 percent on OTC medicines and 13.7 percent on non-pharmaceutical products. There was a decline in sales of non-prescription medicines from 2003 to 2004, mostly because certain OTC medicines were allowed to be sold outside pharmacies from November 2003. The sales of these OTC medicines in community pharmacies fell by 18.1 percent. According to latest NAF data pharmacy sales of paracetamol even dropped by 30.1 percent and ibuprofen sales by 16.7 percent since the establishment of LUA-shops.

4.4.4 Price development

Surprisingly the share of OTC on the pharmaceutical market is declining constantly (cf. Figure 4.2) although OTC may, since the year 2003 be sold outside pharmacies and pharmacy outlets (starting with nicotine replacement products like e.g. 'Nicorette' in January and followed by about 20-25 other products in November 2003). One reason might be the enormous increase in the prices of reimbursable products which led to several cost-containment measures in the last decade.

No comprehensive analysis, like in the other five countries surveyed, was possible for Norway, as price data for the selected four OTC products could be only provided for the years 2003 and 2004 due to a change in pharmacy statistics from 1 January 2003.

The already mentioned ECON report, published in October 2004, reported rather high growth rates of the prices of various OTC, among those ibuprofen, paracetamol, 'Nicorette' and fungicides from 1999 to 2004. The growth rates of nine compared OTC substances ranged between 10 and 45 percent, compared to an overall rise of the general consumer price index of 8 percent. The ECON report characterises the rise in OTC prices as substantial.

The authors of the ECON report conclude that if it seems that the Pharmacy Act from 2001 did not trigger price increases in the OTC market, it also clearly did not lower them. Still, it was observed, that community pharmacies seemed not to compete with each other on the basis of the discounts or lower prices. A final assessment concerning the impact of the establishment of LUA-shops on OTC prices is not yet possible because of the short observation period.

5 Control group countries

5.1 Austria

In Austria, there are several statutory regulations on the pharmacy sector (e.g. Pharmacy Act, The Regulation on the Operation of Pharmacies and the Law on Prescription Control). In the year 2002, the responsibility of the competent authorities for the pharmacy sector shifted from the federal and provincial level to the regional authorities (Bezirkverwaltungsbehörden).

5.1.1 Accessibility

Pharmaceuticals in Austria are mainly sold through community pharmacies. In addition, medicines may be dispensed through:

- Branch pharmacies, which practice under the supervision of a (main) community pharmacy. Every community pharmacy is allowed to operate one branch pharmacy.
- Self-dispensing doctors, who are allowed to dispense both prescription-only and over-the-counter (OTC) medicines, in municipalities without a pharmacy. Self-dispensing doctors are allowed to provide pharmaceuticals only to their own patients.
- Drugstores, which are allowed to sell a very restricted range of non-pharmacy OTC medicines.

In Austria, self-dispensing doctors play an important role, as they constitute nearly half of all POM dispensaries, which is reflected in the quantitative figures (cf. Table 5.1). On 1 January 2005, there were 1,172 community pharmacies (of which 19 branch pharmacies) and 992 self-dispensing doctors in Austria. This corresponds to one prescription-only medicines (POM) dispensary per 3,720 inhabitants.

When classifying pharmaceuticals in Austria, OTC medicines are divided into pharmacy-only OTC medicines, which may only be sold in pharmacies, and non-pharmacy OTC medicines (mostly vitamin preparations and antiacids), which may also be sold outside pharmacies (e.g. in drugstores).

Table 5.1: Austria – Number of pharmacies and other POM-dispensaries 1990 - 2005

Dispensaries[1]	1990	1995	2000	2001	2002	2003	2004	2005
Number of dispensaries								
Community pharmacies	950	1,004	1,086	1,112	1,126	1,141	1,162	1,172
Of which:								
Branch pharmacies	12	14	20	21	21	19	20	19
SD-doctors	947	983	987	998	982	993	989	992
Total	**1,909**	**2,001**	**2,093**	**2,131**	**2,129**	**2,153**	**2,171**	**2,183**
Inhabitants per dispensary								
Inh. per pharmacy	7,981	7,807	7,244	7,099	7,048	7,001	6,871	6,819
Inh. per POM-dispensary	**4,022**	**3,972**	**3,828**	**3,774**	**3,797**	**3,772**	**3,741**	**3,720**

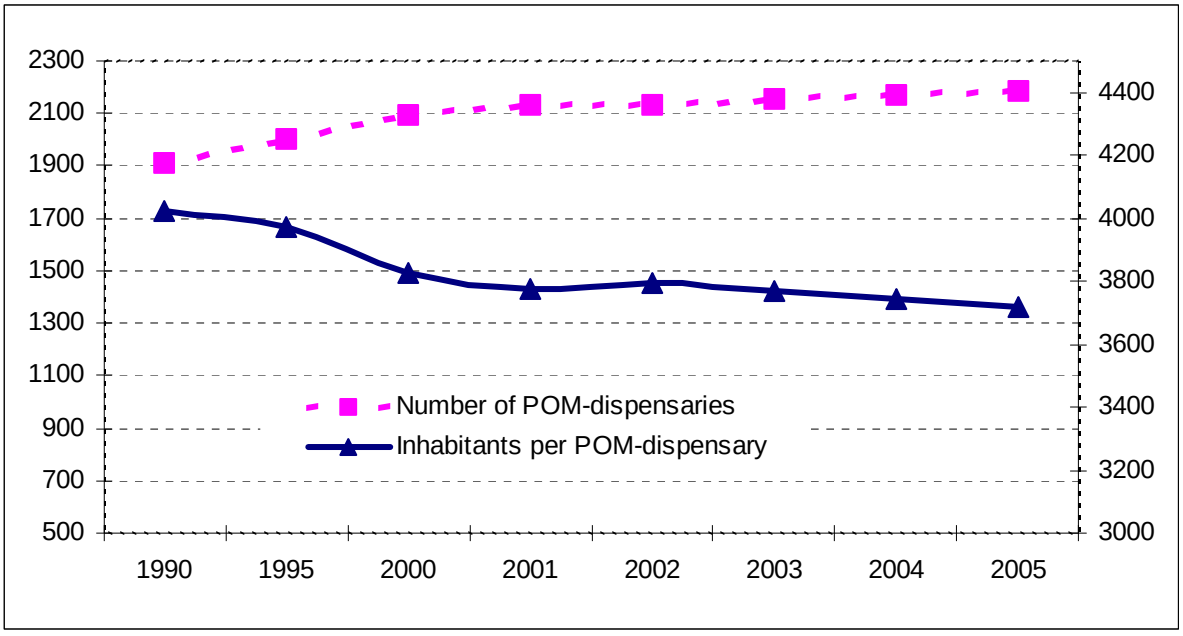
POM = prescription-only medicines, SD = self-dispensing, Inh. = Inhabitants

[1] Only dispensaries which are allowed to dispense prescription-only medicines are included, data on 1 January.

Source: data gathering by ÖBIG

As Table 5.1 shows, the total number of pharmacies and of self-dispensing doctors has been reasonably stable since 2000. Only two pharmacies have closed down and 10 - 26 pharmacies have opened per year. Since 1995, the ratio of inhabitants per pharmacy has decreased by 300.

Figure 5.1: Austria – Number of POM-dispensaries and number of inhabitants per POM-dispensary 1990 - 2005



POM = prescription-only medicines

Source: data gathering by ÖBIG

When looking at the allocation of community pharmacies throughout Austria we see that more than half of the community pharmacies are situated in rural areas and small towns. 365 pharmacies are situated in communities with up to 6,000 inhabitants, 234 in communities with more than 6,000 and less than 20,000 inhabitants, and 573 in communities with more than 20,000 inhabitants (of these 295 are located in Vienna). Over the past ten years, the largest increase in the number of pharmacies (65 new pharmacies) could be observed in smaller communities that did not have a pharmacy before. In towns outside the provincial capitals that were already equipped with pharmacies 52 new pharmacies have been opened, and in provincial capitals 56 new pharmacies were opened within the last 10 years. Thus, in general, new pharmacies are set up mainly in rural areas and small towns.

The role of drugstores in the retail of pharmaceuticals used to be negligible, as the government used to be restrictive in granting licences for the selling of medicines outside pharmacies. However, during the past few years there has been an increase in the number of OTC selling drugstores and there has been pressure from drugstore-chains for further liberalisation of the sector (i.e. drugstores want to be allowed to sell more pharmaceutical products).

5.1.2 Establishment of pharmacies

The establishment of a new pharmacy in Austria requires the authorisation by regional authorities, which is granted provided the pharmacy fulfilled statutory prerequisites as defined in the Austrian Pharmacy Act (Apothekengesetz).

There was a change in the regulations on the establishment of pharmacies in March 1998. Currently, the establishment of a new pharmacy requires

- that a general practitioner has its practice within the same municipality, and
- that a need for a new pharmacy is proven, which is expressed by geographic and demographic criteria.

These criteria are described in more detail in Table 5.2. One of the criteria states that the number of inhabitants who continue to be supplied by existing pharmacies should not drop below 5,500. Before 1998, it was also required that the newly established pharmacy would serve a minimum of 5,500 inhabitants. This rule was abolished in order to allow the opening of pharmacies in shopping centres.

Another criterion for the establishment of a new pharmacy is the space available in the premises. The Regulation on the Operation of Pharmacies defines a minimum size of 143 m^2 for the premises of a pharmacy which must cover different rooms within a pharmacy, such as the material stock room, the sales office, and a laboratory. In practice the size of a pharmacy is on average about 200 m^2, of which one quarter is used to serve customers.

Every community pharmacy is allowed to open a maximum of one branch pharmacy, provided that the distance to the nearest pharmacy is more than four kilometres. This branch pharmacy is under the supervision of the (main) pharmacy.

In a municipality without a pharmacy a general practitioner is entitled to receive a license for the dispensing of pharmaceuticals. An amendment of the Pharmacy Act in 1998 stated that a self-dispensing doctor could lose the license for dispensing medicines in case a new pharmacy opened within a distance of four kilometres. Due to protests by Austrian physicians this regulation was changed in December 2000: A transitional period of ten years was determined, and only self-dispensing doctors who received their license after 1 June 1998 have to stop the dispensing of pharmaceuticals as soon as a new pharmacy establishes within four kilometres.

According to a survey undertaken by the Austrian Chamber of Pharmacists, the average distance between two pharmacies in Austria is estimated to be 3.5 kilometres (median: 996 metres), and it takes on average 5.9 minutes (median: 3 minutes) to get from one pharmacy to the next one.

Table 5.2: Austria – Establishment rules for community pharmacies in 2005

Reg.	Provision	Criteria for establishment of new pharmacies	
Yes	Statutory provision in a federal law	Geographic	• The minimal distance between the new pharmacy and the nearest existing pharmacy should be at least 500 metres
		Demographic	• The number of persons who continue to be supplied by adjoining pharmacies should not drop below 5,500, as a result of the establishing of a new pharmacy. • If there is a dispensing doctor within 4 kilometres, 5,500 persons must be supplied by the new pharmacy.
		Other	• A physician must have his permanent practice within the community. • Minimal room requirements

Reg. = regulation existing

Source: data gathering by ÖBIG

5.1.3 Ownership of pharmacies

The right to own a pharmacy in Austria is statutorily reserved to pharmacists, with a university degree, trained according to EU Directive 2005/36/EC. Further prerequisites for owning a pharmacy are a management permit (at least five years of working experience in a pharmacy), full legal capacity, reliability, physical fitness and a good state of health, and excellent knowledge of the German language.

Co-ownership is allowed in Austria in so far as community pharmacies may be owned by partnerships. However, the licensee and managing pharmacist must own more than half of the shares in that partnership and has the exclusive power of management and representation of the partnership.

Apart from running at maximum one branch pharmacy under the supervision of the main pharmacy (cf. Section 5.1.2), it is forbidden to own more than one pharmacy (multiple ownership is not allowed).

Table 5.3: Austria – Ownership regulation on pharmacies in 2005

Ownership	Reg.	Content
Entity of pharmacy ownership	Yes	Only pharmacists are allowed to own a pharmacy. In case of multiple owners per pharmacy, at least one owner must be a pharmacist.
Number of pharmacy owners	Yes	Plurality of pharmacists as owners of a pharmacy is allowed (so-called co-holders).
Trade in pharmacy licenses	Yes	Not allowed
Multiple ownership	Yes	No multiple ownership allowed, but a pharmacist may open one branch pharmacy, which practices under the supervision of a main pharmacy

Reg. = regulation existing

Source: data gathering by ÖBIG

5.1.4 Pharmacy staff

Nearly 13,000 people work in community pharmacies in Austria (cf. Table 5.4), which is equivalent to an average staff of 10.9 persons per pharmacy.

More than one third of pharmacy staff are pharmacists, corresponding to 5.8 pharmacists per 10,000 inhabitants. Pharmacists in Austria have received a 5.5 years university education, according to the EU Directive 2005/36/EC, including one year of practice training. Of the around 4,600 community pharmacists, nearly 1,300 are independent (thus acting as the owner of the pharmacy), whereas the remaining 3,400 pharmacists are employed. Thus, on average, there are four pharmacists per pharmacy, of which three work as employed pharmacists. In total, the number of community pharmacists has risen by nearly 50 percent since 1990, while the increase in the number of pharmacies was significantly lower (by 23%) during this time, indicating that the pharmacies in Austria have become better provided with pharmacists. Looking at the number of pharmacists on the basis of full-time equivalents (40 hours per week), there are on average 3.2 pharmacists per pharmacy.

Of the other pharmacy staff (around 8,200 people in total), 55 percent have received a specific vocational training, while 45 percent are employees without any vocational training or other, non-pharmacy specific vocational training. In this group, also further supporting staff (cleaners, etc.) is included. The vocational training for pharmacy assistants in Austria may last two or three years (depending on the type of assistant), and around 80 percent of the training is provided in the pharmacy.

Table 5.4: Austria – Staff working in community pharmacies 1990 - 2005

Pharmacy staff[1]	1990	1995	2000	2001	2002	2003	2004	2005
Pharmacists[2]	3,215	3,792	4,211	4,311	4,356	4,467	4,623	4,746
Other pharmacy personnel	4,879	5,837	6,590	6,929	7,371	7,792	8,208	n.a.
Of which								
Pharmacy assistants	2,115	2,743	3,549	3,826	4,094	43,76	4,521	n.a.
Total of pharmacy staff	8,094	9,629	10,801	11,240	11,727	12,259	12,831	n.a.

n.a. = not available

1 Per 1 January, counted per head.

2 Trained according to Directive 2005/36/EC (September 2005).

Source: data gathering by ÖBIG

Continuous training and education of pharmacists is not obligatory, but encouraged by the Austrian Chamber of Pharmacists (Österreichische Apothekerkammer, ÖAK) and by the Austrian Pharmacists' Association (Österreichischer Apothekerverband). Each year professional associations and the pharmaceutical industry offer more than 100 training courses for pharmacists, which are attended by more than 8,000 pharmacists. On average a pharmacist spends 30 hours per year on education and training, which is equivalent to two courses per year.

5.1.5 Opening hours

Opening hours of pharmacies are not regulated by a federal law, but by regional authorities. On average, pharmacies in Austria are open:

- On weekdays (Monday to Friday): from 8 am to 12 am, and from 2 pm to 6 pm
- On Saturday: from 8 am to 12 am

Increasingly pharmacies, especially those in Vienna, are also open the whole day, without a break at 12 am.

During the nights (from 6 pm to 8 am) and on Sundays pharmacies offer, on a rotation basis, stand-by duties. During these stand-by duties a pharmacist is present, but customers may not enter the pharmacy. Instead, service is provided through a window. Information on the pharmacies providing the stand-by night / weekend services is displayed outside all pharmacies. Throughout Austria, there are, on average each day, approximately 380 pharmacies providing 24 hours stand-by services. On average, 157 pharmacies provide stand-by duty 24 hours a day, 7 days per week. However, there are no pharmacies that provide full (walk-in) service for 24 hours every day.

5.1.6 Quality of pharmacy services

A total of 11,400 pharmaceuticals are currently registered in Austria (counting different pharmaceutical forms and dosages, but excluding different pack sizes). Of these, 9,116 (80%) are prescription-only medicines. Currently, about 5,200 pharmaceuticals, counted including different pack sizes, are reimbursable (i.e. they are included in the Austrian positive list). The number of reimbursable medicines has increased substantially on 1 January 2005, when the new reimbursement scheme for pharmaceuticals ("Erstattungskodex") was introduced. However, most of the pharmaceuticals that have been added to the list of reimbursable medicines can only be prescribed under very specific circumstances (for example only by a specialist, rather than a general practitioner). In Austria, only approximately 60 percent of the registered pharmaceuticals are on the market.

According to the Regulation on the Operation of Pharmacies, the amount of pharmaceuticals that is held on stock in a pharmacy should correspond to “the common customer needs”, and a community pharmacy must ensure immediate availability of frequently asked medicines. In fact, a survey has shown that 96 percent of the customers have their prescription filled within the first visit. On average a pharmacy has 80 - 90 percent of the pharmaceuticals available on the market on stock, which amounts to about 5,500 different pharmaceuticals.

Pharmacies in Austria are, in general, delivered three times per day by the pharmaceutical wholesale. In case of emergencies, immediate delivery, even for one package, is possible (e.g. by taxi).

A study conducted in 2004 has shown that 64.6 percent of all conversations between customers and pharmacists take four to ten minutes and 32.3 percent of all conversations take three minutes or less.

With regard to non-pharmaceutical products sold by pharmacies, there are restrictions in force. Non-pharmaceuticals should be “health-related”, and their amount and the way in which they are presented should not influence the typical “looks” of a pharmacy.

Generic substitution by pharmacists is not allowed in Austria, i.e. generics may only be dispensed if a physician has prescribed them explicitly. Tailor-made magistral preparations (i.e. those produced in the pharmacy) do play an important role in Austria, where every pharmacy is equipped with a laboratory. In terms of value, magistral preparations constitute 2.4 percent of the pharmacies’ turnover to the debit of the health insurance. All pharmacies are equipped with a computer, to enable electronic billing of prescriptions, which is obligatory since 2005.

Table 5.5: Austria – Number of pharmaceuticals 1995 - 2005

Pharmaceuticals[1]	1995	2000	2001	2002	2003	2004	2005
Registered ph.[2]	7,034	10,294	10,619	10,512	10,954	11,147	11,407
Including:							
POM[2]	5,545	8,116	8,298	8,255	8,648	8,887	9,116
Reimbursable ph.[3]	n.a.	n.a.	n.a.	n.a.	n.a.	4,518[4]	5,184
∅ number of packages on stock per pharmacy[5]	n.a.	14,000	15,000	15,300	15,800	16,300	n.a.

ph. = pharmaceuticals, POM = prescription-only medicines, ∅ = average, n.a. = not available

1 Per 1 January. Pharmaceuticals for human use, excluding magistral or officinal formula.

2 Counted including different pharmaceutical forms and dosages, excluding different pack sizes.

3 Counted including different pharmaceutical forms, dosages, and pack sizes.

4 Data on 31 December 2004.

5 Counted including different pharmaceutical forms, dosages, and pack sizes. These figures correspond to 5,500 pharmaceuticals (counted including different pharmaceutical forms and dosages, excluding different pack sizes).

Source: data gathering by ÖBIG

The core task of pharmacies in Austria is definitely the dispensing of medicines. Nevertheless, there are a number of other pharmaceutical services commonly provided by pharmacies, such as screening (e.g. blood pressure measurement, weight checks, vision tests), collecting and disposing of expired pharmaceuticals, participation in health campaigns and special health-related programs (e.g. for asthma or diabetes patients). Furthermore pharmacies offer services like the control of private emergency medicines or give general health advice.

Table 5.6: Austria – Pharmacy services in 2005

Pharmacy services	Provision
Availability of pharmaceuticals	- Immediate availability of frequently asked pharmaceuticals
Generic substitution	- Not allowed
Magistral preparations	- Magistral preparations play an important role - All pharmacies have a laboratory to manufacture preparations
Computerisation	- 100 % (all pharmacies) - Electronic billing of prescriptions has been obligatory since 2005

Source: data gathering by ÖBIG

5.1.7 Market data

Since 1996 the Austrian pharmaceutical market increased by almost 60 percent (cf. Figure 5.2). The pharmaceutical expenditure amounted to € 2.878 million (€ 354 per inhabitant) in 2003, a rise of 9.2 percent compared to the year 2002.

The total pharmacy turnover in 2004 was € 2,396 million, which amounts to about € 1.7 million per pharmacy on average. Compared to 2003 the total pharmacy turnover increased in 2004 by 4.7 percent.

The pharmacy margins on pharmaceuticals at the expense of the social insurance are regulated through a regressive margin scheme. In 1995, 1997 and 2004 the pharmacy margins were lowered. In 2004, the aggregate pharmacy margin amounted to 28.2 percent. The Federation of Austrian Social Insurance Institutions and the Pharmacists' Association have agreed that from 1 January 2000 pharmacies pay a Solidarity Contribution of 13 percent of their individual increase in turnover compared to the previous year to the social insurance. In addition, a further rebate (2.5%) was introduced payable by pharmacies whose turnover from the sale of reimbursable drugs lies above the nationwide mean.

Table 5.7: Austria – Pharmacy turnover 1990 - 2004

	1990	1995	2000	2001	2002	2003	2004
Prescriptions filled[1] (mill.)	35.8	41.1	44.4	43.7	43.7	45.2	45.7
Pharmacy turnover (mill.)	€ 893	€ 1,330	€ 1,892	€ 1,995	€ 2,126	€ 2,289	€ 2,396
Of which:							
Turnover of pharmaceuticals	91.0%	91.7%	91.5%	91.6%	91.0%	90.9%	90.8%
Turnover of OTC	23.5%	22.4%	20.0%	20.4%	19.9%	20.0%	20.3%
Turnover of non-pharmaceuticals	9.0%	8.3%	8.5%	8.4%	9.0%	9.1%	9.2%

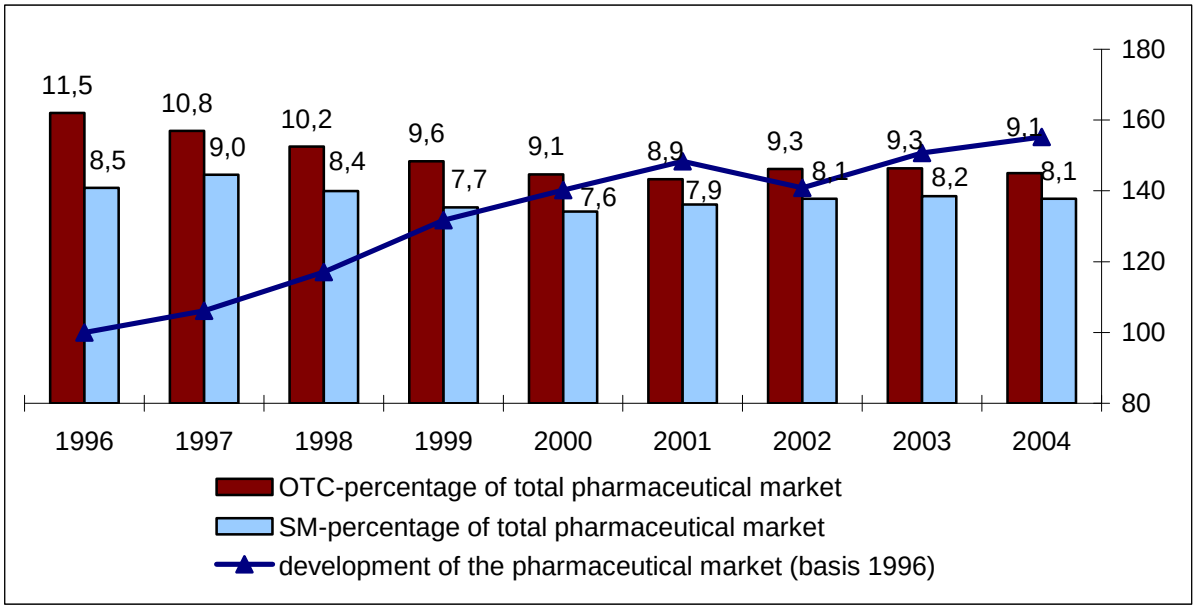
mill. = in millions, OTC = over-the-counter

[1] Only prescriptions to the debit of health insurance.

Source: data gathering by ÖBIG

The largest part (90.8%) of a pharmacy's turnover is generated by pharmaceuticals. OTC medicines accounted for 20.3 percent in 2004, which is three percentage points less compared to 1995. This is probably partly due to an increase in the sale of OTC medicines through drugstores in the past years. The share of non-pharmaceutical products in the total pharmacies' turnover and in the total pharmaceutical market has been stable (around 9% and around 8% respectively) the past ten years.

Figure 5.2: Austria – Development of pharmaceutical market 1996 - 2004



Source: AESGP 1996 – 2004, data gathering by ÖBIG

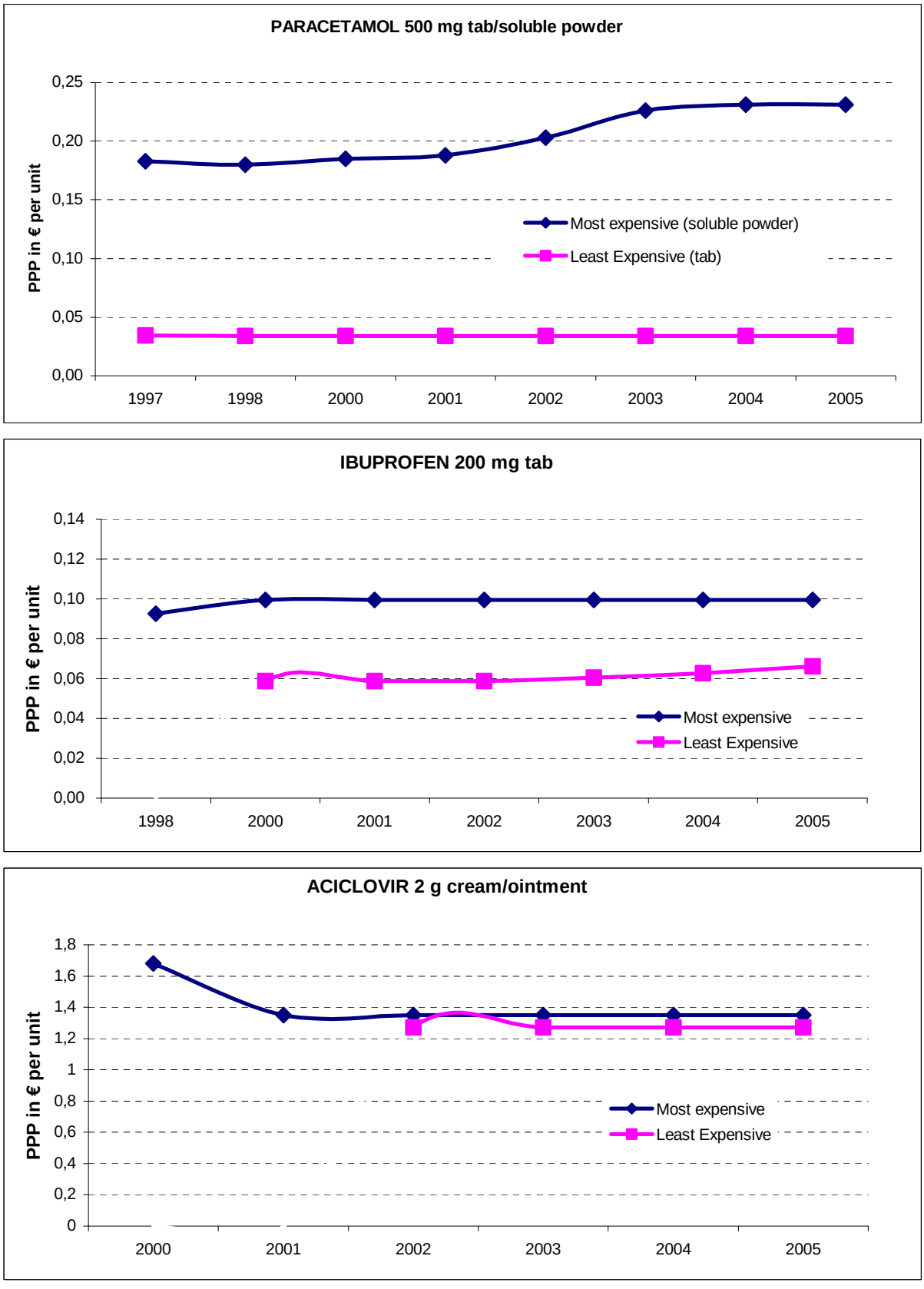
Price development

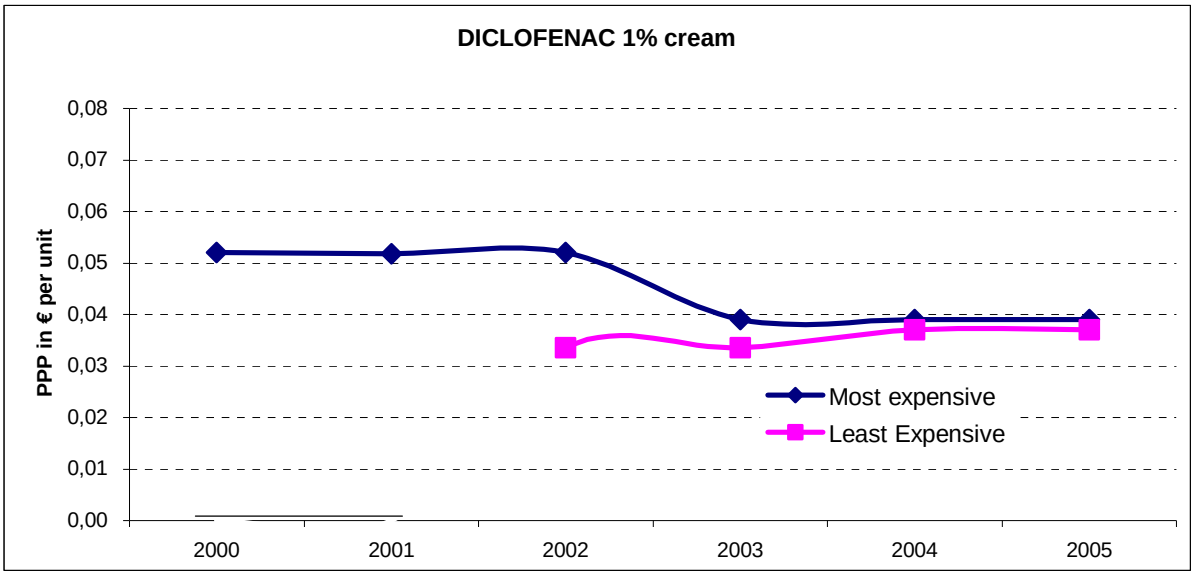
The overall price level in terms of gross pharmacy retail price is relatively high in Austria, which is mainly due to the fact that in contrary to other countries the full VAT rate of 20% is applied to pharmaceuticals. In general the prices of many pharmaceuticals dropped during the last ten years because of several margin cuts and the introduction of an additional obligatory rebate in favour of social insurance. Whereas the latter is only relevant for reimbursable products, above mentioned margin cuts also affected OTC as all pharmaceutical products are regulated via statutory wholesale and pharmacy margins in Austria.

In the light of this changes the prices of OTC medicines remained relatively stable in Austria, as figure 5.3 illustrates. The strongest price change in the last five years could be observed at **diclofenac** cream preparations, where the price of the most expensive one, 'Algefit Gel' by Strallhofer dropped by 25 percent between 2002 and 2003. Since 2003 the price of both the most expensive and the cheapest product hast remained relatively stable.

Both, diclofenac and aciclovir, are only on the market as OTC for about 5 years, therefore the comparison period is shorter than with the other products. Shortly after the POM-to-OTC switch the price of 'Herpomed' by S. Med (most expensive **aciclovir** cream) plunged by almost 20 percent and remained exactly at this level ever since.

Figure 5.3: Austria – Price development of selected OTC blockbusters 1997[1] - 2005





PPP = pharmacy purchase price, tab = tablet
[1] or latest available year

Source: national sources, data gathering by ÖBIG

The largest price difference between the least and the most expensive product showed **paracetamol** with a price deviation of € 0.20 per unit. The price of the most expensive paracetamol preparation rose in average by 3.5 percent annually since 1998, whereas the price of the lowest dropped in average by only 0.3 percent. However this difference is biased by the different pack sizes of the two compared products (20 vs. 50 unit-pack) and the fact, that the most expensive product 'Vicetamol' by Gebro Pharm comes in the pharmaceutical form of a soluble powder whereas the least expensive one, 'Mexalen' by Merckle are tablets.

The price of the most expensive **ibuprofen** tablet by Merz and Co. did not change since the year 2000 whereas the price of the least expensive paracetamol tablet ('Ibumetin' by Nycomed) showed a moderate annual growth of 2.4%.

5.2 Finland

The responsibility for organizing health care lies with the approximately 440 municipalities. These can either provide health care services independently or together with neighbouring municipalities in joint municipal boards which maintain a joint health centre. A municipality can also buy in health care services from other municipalities, non-governmental organisations or the private sector. The Finnish Ministry of Social Affairs and Health (Sosiaali - ja terveysministeriö, STM) is in charge of planning and supervising, e.g. formulation health care targets and guidelines and also decides on health care subsidies.

The Finnish health care system is mixed, as health care is tax funded but provided by local authorities with a partial subsidy from the state. One of the major players is the Finnish Social Insurance Association (Kansaneläkelaitos, KELA) which is also responsible for the reimbursement of pharmaceuticals. All Finnish residents are insured under a national health insurance scheme.

5.2.1 Accessibility

Pharmaceuticals in Finland are mainly dispensed through (private or branch) pharmacies. With the authorisation of the National Agency for Medicines (Lääkelaitos, NAM), the owner of a private pharmacy may also keep a branch pharmacy in an area that does not have sufficient operating basis for an independent pharmacy due to a small number of inhabitants, but for guaranteeing accessibility to pharmaceuticals a pharmacy service is required. The NAM may authorise a licensed pharmacist to keep up to a maximum of three branch pharmacies. Branch pharmacies are allowed to run by so-called prescriptionists (cf. Section 5.2.4), under the supervision of the pharmacy to which they belong. A branch pharmacy can only be turned into a private community pharmacy by the decision of the NAM. This prevents the formation of pharmacy chains, which are not allowed in Finland.

In areas where there is no pharmacy or branch pharmacy and where transport connections to the nearest pharmacy are restricted, pharmacy owners may keep a so-called medicine chest, on the basis of authorisation granted by the NAM. These medicine chests are for example located in post offices or groceries. Only a limited selection of non-prescription medicines (OTC) may be sold from a licensed medicine chest, under the supervision of a pharmacy. Medicine chests are run by laymen, which means that only written information may be provided to the customers. If customers need information in addition to the instruction leaflet they must make a telephone call to the pharmacy. Today there are approximately 160 medicine chests in Finland. Over the past 15 years the number of medicine chests has decreased. Due to an increase in the number of branch pharmacies and due to the migration of people from the urban areas to the cities, fewer medicine chests were necessary.

The dispensing of pharmaceuticals through other outlets, such as drugstores, is not allowed in Finland.

Table 5.8: Finland – Number of pharmacies and other POM dispensaries[1] 1990 - 2005

	1990	1995	2000	2001	2002	2003	2004	2005
Number of POM dispensary[1]								
Pharmacies	741	783	794	796	797	799	800	802
Of which:								
Private pharmacies	578	581	589	593	595	597	600	603
Branch pharmacies[2]	162	201	203	201	200	200	198	197
University pharmacies	1	1	2	2	2	2	2	2
Total	**741**	**783**	**794**	**796**	**797**	**799**	**800**	**802**
Inhabitants per POM dispensary								
Inh. per pharmacy	**6,729**	**6,524**	**6,519**	**6,518**	**6,526**	**6,533**	**6,525**	**6,509**

POM = prescription-only medicines, inh. = Inhabitants

[1] Only dispensaries which are allowed to dispense prescription-only medicines are included, data on 1 January.

[2] Operating under supervision of a private pharmacy.

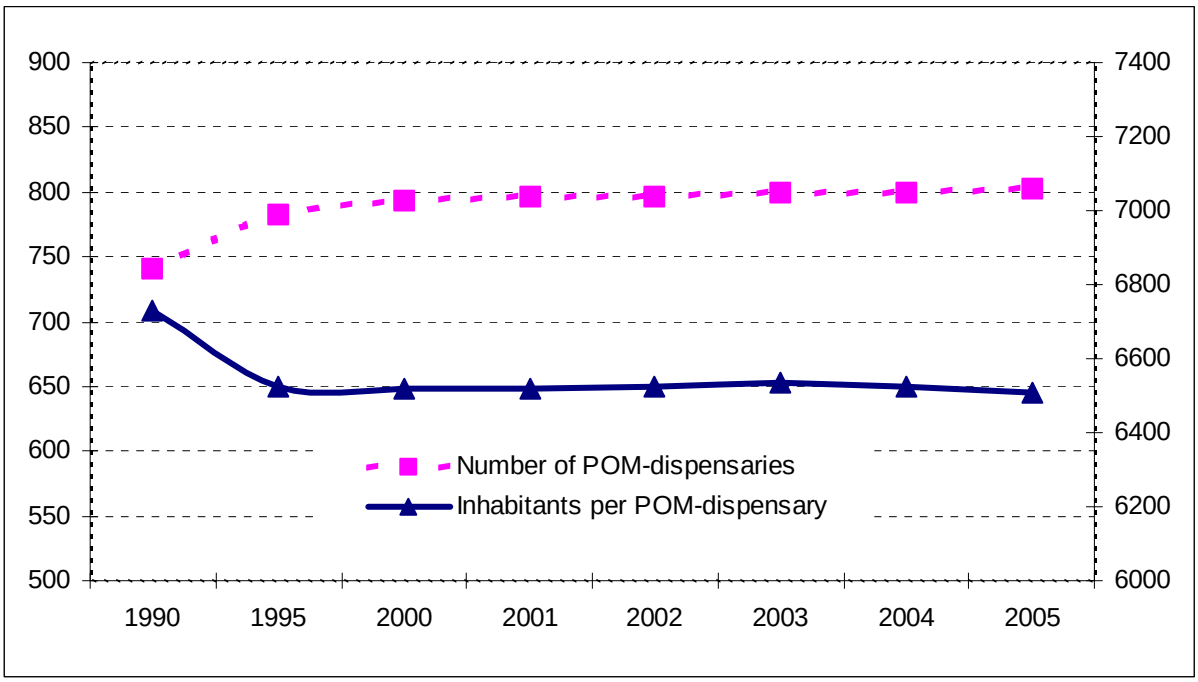
Source: data gathering by ÖBIG

The number of pharmacies in Finland has not changed very much over the past years. It is noticeable that during the last 15 years no pharmacy was closed in Finland. As Table 5.8 shows, Finland currently has 802 pharmacies, of which 197 are branch pharmacies and two are university pharmacies. On average a Finnish pharmacy serves 6,509 inhabitants (cf. Figure 5.4).

A report in 2004 showed that nearly 99 percent of the Finns live in a municipality with at least one pharmacy. Only 42 municipalities out of a total of 444 municipalities in Finland do not have a pharmacy, whereas a total of 200 municipalities do not have a health centre. Thus, some municipalities do have a pharmacy, whereas there is no health centre.

Of the 42 municipalities without a pharmacy, 16 are on the archipelago or in the very north of Finland. In those municipalities without a pharmacy, access to medicines has been ensured by means of local arrangements, like home deliveries of pharmaceuticals.

Figure 5.4: Finland – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM-dispensary 1990 - 2005



POM = prescription-only medicines

Source: data gathering by ÖBIG

5.2.2 Establishment of pharmacies

A community pharmacy licence is granted for a pharmacist to run a pharmacy in a specific catchment area, usually a municipality. There may be several of these areas within one municipality. Since the mid 1990s, it is possible that two or more pharmacies are established within one area, and pharmacies can be established freely, for example next to another pharmacy, within the area for which they have received a licence. The NAM may decide to establish a new pharmacy in an area if required, with regard to the availability of pharmaceuticals, and after having heard and considered the views of the respective municipality. When a pharmacy licence becomes vacant, the NAM announces that it can be applied for, and grants the licence to the best qualified applicant.

5.2.3 Ownership of pharmacies

A pharmacy licence may only be granted to EEA (European Economic Area) citizens, who are a licensed Master of Science in Pharmacy. The licence expires at the age of 67. A pharmacy licence cannot be sold or leased out.

Table 5.9: Finland – Establishment and ownership rules for community pharmacies 2005

Establishment / Ownership	Reg.	Content
Establishment of pharmacies	Yes	A community pharmacy licence is granted for a pharmacist to run a pharmacy in specific municipality or a part of it. The National Agency for Medicines may decide to establish a new pharmacy in a municipality if required for the accessibility to pharmaceuticals and after having considered the views of the respective municipality.
Entity of pharmacy ownership	Yes	Only pharmacists are allowed to own a pharmacy
Trade in pharmacy licenses	Yes	Not allowed
Multiple ownership	Yes	Multiple ownership of private pharmacies is not allowed. Private pharmacies are allowed to have a maximum of three branch pharmacies.

Reg. = regulation existing

Source: data gathering by ÖBIG

5.2.4 Pharmacy staff

On average, there are per pharmacy 1.7 pharmacists, 4.6 prescriptionists and 3.2 pharmacy technicians / assistants in Finland. Some of the pharmacy technicians / assistants (approximately 19 percent) are allowed to dispense OTC medicines. The number of pharmacists has steadily grown since the beginning of the 1990s, i.e. since the year 2000 by more than 16 percent.

The required university education for pharmacists takes 5 to 6 years, and results in a Master of Science degree. The university education for prescriptionists takes only three years, and gives prescriptionists the degree of Bachelor of Science. Prescriptionists are allowed to perform a lot of the same tasks as pharmacists, i.e. they may dispense prescription medicines without direct supervision of a pharmacist. Nevertheless, the pharmacist remains responsible for defining working procedures and in case of malpractice.

Continuous education is mandatory for pharmacists and encouraged by the Association of Finnish Pharmacies. Training and/or further education are provided by universities, professional organisations and other institutions. Professional training programs, organised by the Association of Finnish Pharmacies (Suomen Apteekkarilitto), focus on care of asthma, diabetes and coronary heart disease patients. The Pharmaceutical Learning Centre organises several programmes and courses every year. Professional Development programmes are also arranged for pharmacists. On average 70 percent of the pharmacists attend education and/or training per year. On average a pharmacist spends two days per year on education and training.

Table 5.10: Finland – Staff working in community pharmacies 1990 - 2005

Pharmacy staff[1]	1990	1995	2000	2001	2002	2003	2004	2005
Pharmacists (MSc.)[2]	1,045	1,085	1,182	1,226	1,297	1,315	1,345	1,374
Of which								
pharmacy owners	n.a.	n.a.	572	575	584	578	576	580
Prescriptionists (BSc.)	3,045	3,190	3,281	3,332	3,405	3,339	3,548	3,659
Other pharmacy staff	2,142	2,053	2,082	2,087	2,313	2,415	2,572	2,751
Of which:								
Technicians /assistants with right to dispense[3]	602	536	538	536	543	534	534	533
Technicians /assistants without right to dispense	1,541	1,488	1,443	1,537	1,726	1,805	1,896	1,994
Total of pharmacy staff	6,834	6,864	7,083	7,181	7,558	7,603	7,999	8,317

MSc. = Master of Science, BSc. = Bachelor of Science, n.a. = not available

1 Data per 1 January, staff counted per head, working in community pharmacies.

2 According to directive 2005/36/EC (September 2005).

3 Only allowed to dispense non-prescription medicines.

Source: data gathering by ÖBIG

5.2.5 Opening hours

Regulations regarding the opening hours of pharmacies were abolished in the 1990s. According to the current Medicines Act the opening hours of pharmacies and branch pharmacies must ensure the immediate availability of frequently asked pharmaceuticals.

Pharmacy owners must notify the opening hours to the local authorities. Average opening hours are:

- On weekdays (Monday to Friday): from 8:30 am to 6 pm
- On Saturdays: from 9 am to 3 pm
- On Sundays: from 10:30 am to 4 pm

In urban areas pharmacies often keep open outside these hours. During late evening duties access to the sales office is restricted and the number of staff is reduced. There is one 24-hours pharmacy located in Helsinki. Furthermore, there are no duties after midnight. During these hours emergency medicines are dispensed in health centres and out-patient clinics. The next morning patients get such prescriptions filled in the normal way.

5.2.6 Quality of pharmacy services

Currently there are 6,078 pharmaceuticals (including different pharmaceutical forms and strengths) registered in Finland, thereof 93 percent are prescription-only medicines (POM). Approximately 60 percent of the registered pharmaceuticals are actually on the market. According to the Medicines Act the amount of pharmaceuticals, the equipment and supplies for administering pharmaceuticals, and the dressings kept by a community pharmacy must correspond to the usual customer needs. The generic share of the market is estimated to be about 44 percent in terms of volume.

On average pharmacies are delivered by wholesalers five times per week. Of all pharmacy customers 98.7 percent receive their pharmaceuticals immediately and 98.9 percent within the same day.

Table 5.11: Finland – Number of pharmaceuticals 1990 - 2005

Pharmaceuticals [1]	**1990**	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Registered ph.	3,259	3,360	4,210	4,385	4,610	4,907	5,330	6,078
Of which								
Ph. on the market	> 90%	n.a.	94%.	n.a.	n.a.	72%	n.a.	60%
POM	82%	82%	87%	n.a.	n.a.	n.a.	n.a.	93%

ph. = pharmaceuticals, POM = prescription-only medicines, n.a. = not available

[1] Data per 1 January. Pharmaceuticals for human use, excluding magistral preparations/ officina formula, counted including different pharmaceutical forms and strengths.

Source: data gathering by ÖBIG

Since 1 April 2003 regulations oblige pharmacies to offer customers a cheaper substitute (generic or parallel import) if a doctor has prescribed a more expensive medicine beyond a pre-determined price corridor. The customer or the doctor may refuse the substitution. However, the doctor must act on good medical reasons for refusing and document his/her decision.

Table 5.12: Finland – Pharmacy services in 2005

Pharmacy services	Provision
Availability of pharmaceuticals	- Pharmaceuticals on stock must meet the usual customer needs in the area - Delivery time to patients: immediate delivery - 5 deliveries per week by wholesalers
Generic substitution	- Since 1 April 2003 regulations oblige pharmacies to offer the customer a cheaper substitute if a doctor has prescribed a medicine beyond pre-determined price corridor - Pharmacies are obliged to offer their customers generics
Magistral preparations	- Make up a small share (1%) of prescribed medicines - 100% of pharmacies are equipped with a laboratory to manufacture pharmaceuticals
Computerisation	- 100% of all pharmacies are equipped with a computer

Source: data gathering by ÖBIG

Every pharmacy has a laboratory or a place to manufacture pharmaceuticals. Nevertheless, the preparation of medicines in pharmacies has decreased in recent years. In 2003 pharmacy produced powders, capsules, tablets, ointments and liquids, made up approximately 1 percent of all prescribed medicines.

During the past 20 years Finnish pharmacies have started to bring some of their non-prescription products from behind the pharmacy counter to place them in the customer area. In case pharmaceuticals are presented in the customer area, it is required that a person with a pharmaceutical education on university level (i.e. either a pharmacist or a prescriptionist) is present in this area, to provide the customers with advice and to take the pharmaceuticals from the shelves. There is thus no self-service allowed for pharmaceuticals which are presented in the customer area.

Health promotion is an important part of the pharmacy services offered in Finland, and national health campaigns (e.g. on smoking, diabetes, hypertension and obesity) have been instituted in pharmacies since 1988. With regard to screening (such as blood pressure measurement), Finnish authorities only allow pharmacies to be involved to a limited extent.

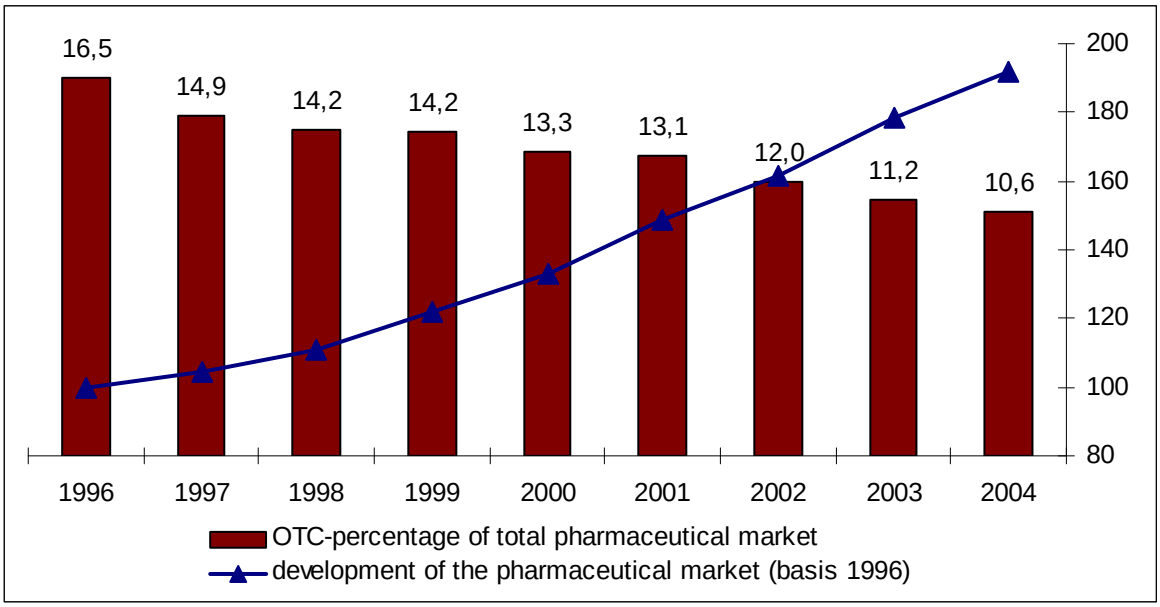
The Association of Finnish Pharmacies is keen to ensure that medicines are not considered by consumers as ordinary items of commerce, and it made a recommendation that a pharmacy should not resemble a supermarket or any other self-service outlet.

A customer survey by Taloustutkimus Oy in 2004 showed that Finnish customers are satisfied with the services of their community pharmacies. Of all customers surveyed, 83 percent were extremely satisfied with the friendliness of the staff, 81 percent with the willingness to be of service, 80 percent with the location of the pharmacies and 77 percent with the competence of the staff.

5.2.7 Market data

Pharmaceutical expenditure in Finland according to OECD data amounted to € 1,707 million in 2003, a rise of about 26.3 percent compared to the year 2000. In general the pharmaceutical market has almost doubled since 1996 as Figure 5.5 shows. According to an OECD report on health expenditure in Finland, which was published in 2005, 40 percent of the total increase in pharmaceutical expenditure in Finland between 2000 and 2004 is attributed to only ten new pharmaceutical products (OECD 2005).

Figure 5.5: Finland – Development of pharmaceutical market 1996-2004



Source: AESGP 1995-2005, data gathering by ÖBIG

The total annual gross turnover in community pharmacies (including VAT) in Finland was almost € 2 billion in 2004, thereof more then 90 percent were from human medicines. The annual gross turnover of OTC medicines was approximately € 270 million, equivalent to 13.5 percent of the total sales of medicines. On average, a Finnish pharmacy has an annual turnover of around € 2.9 million. The turnover of pharmacies is displayed in detail in Table 5.13.

Among self-care pharmaceuticals anti-inflammatory medicines had the highest share of OTC sales with 24.8 percent.

In 2004 the aggregate turnover of all pharmacies in Finland rose by 7.4 percent (2002-2003: 6.5%) compared to the previous year and the number of prescriptions delivered increased by 2.3 percent (2003-2004: 3.5%).

Table 5.13: Finland – Pharmacy turnover 1990 - 2004

	1990	1995	1999	2000	2001	2002	2003	2004
Prescriptions filled (mill.)	29.5	29.3	35.2	36.7	37.8	38.5	39.9	40.8
Total pharmacy turnover (mill.)	€ 615	€ 888	€ 1,335	€ 1,446	€ 1,591	€ 1,744	€ 1,857	€ 1,995
Share of turnover for different product groups								
Pharmaceuticals	n.a.	n.a.	95%	96 %	95%	95%	95%	95%
OTC	n.a.	n.a.	17%	16%	15%	14%	14%	14%
Turnover of non-pharmaceuticals	n.a.	n.a.	5%	4%	5%	5%	5%	5%

mill. = in millions, OTC = over-the-counter, n.a. = not available

Source: data gathering by ÖBIG

Pharmacies are remunerated via a regressive mark-up scheme based on the so-called "approved" wholesale or pharmacy purchase price (PPP). Due to this fact, the increase in the total pharmacy turnover does not reflect the profitability of the pharmacies. Depending on their sales private community pharmacies have to pay a pharmacy fee to the state, which was on average 7 percent in 2004, ranging from 6 to 11 percent. Based on an evaluation of the National Agency for Medicines, the Finnish government proposed in 2004 to abolish the pharmacy fee in several steps. The Association of Pharmacies opposed to this intention, because the pharmacy fee allows for subsidies to pharmacies in rural areas, which otherwise might be closed due to lower profitability, thus the abolishment of the pharmacy fee could threaten the accessibility to medicines. The Finnish government has postponed further measures so far.

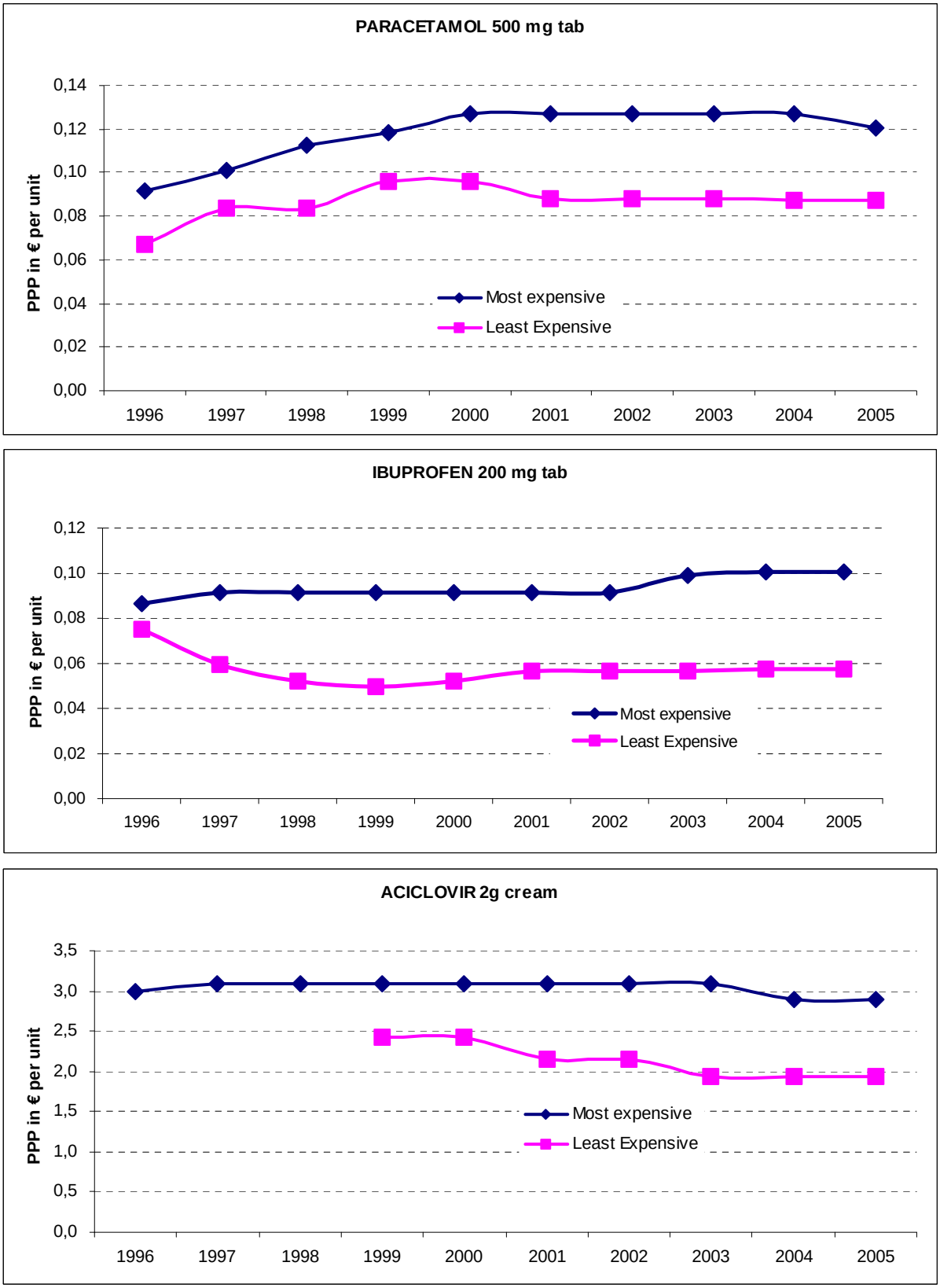
Price development

According to the Finnish Pharmaceutical Information Centre wholesale prices of prescription medicines have dropped during the past five years. In 2004, the average decrease compared to 2003 was minus 2.1 percent. Currently, pharmaceutical prices in Finland in general are 5.6 percent lower than in 1998. One reason for the decline is the introduction of a generic substitution regime, which came into force in April 2003.

In contrary to POM the wholesale prices of freely priced OTC medicines continued their slight up-ward trend and rose by 3.1 percent in 2004 (2002-2003: + 2.1%, 2000-2001: + 1.9%). This trend is not exactly reflected in the price development of three OTC blockbusters as illustrated in Figure 5.6. Whereas the prices of the most expensive paracetamol and ibuprofen rose on average by 3 percent and 1.5 percent annually since 1996, the price of aciclovir cream has dropped in the same period.

The price per unit of the most expensive paracetamol product, 'Panadol' by GSK, and that of the cheapest on the market, 'Paramax Rap' by Vitabalans, differs by € 0.034 (2005) whereas this price difference for ibuprofen ('Burana' by Orion vs. 'Ibumax' by Vitabalans) is € 0.043. The price of 'Burana' is almost double the price 'Ibumax'.

Figure 5.6: Finland – Price development of selected OTC blockbusters 1996 - 2005



PPP = pharmacy purchase price, tab = tablet

Source: national sources, data gathering by ÖBIG

5.3 Spain

In Spain, some competences which were previously in the hands of the Central Government have been transferred to the Autonomous Communities. This also regards the field of health-care, and is reflected in the pharmacy sector. While the Central Government is in charge of the general coordination of health care and pharmaceutical care and of matters related to pharmaceuticals, such as registration, each Autonomous Community is competent to organise its health care system, including the planning of the pharmacy system.

5.3.1 Accessibility

In Spain, community pharmacies are the only health establishments authorised to dispense prescription-only medicines (POM) and over-the-counter (OTC) medicines (Especialidades Farmaceuticas Publicitarias) to the general public.

Table 5.14: Spain – Number of pharmacies [1] 1991- 2005

	1991	1995	2000	2001	2002	2003	2004	2005
Number of dispensaries								
Pharmacies	**17,896**	**18,593**	**19,439**	**19,641**	**19,766**	**20,098**	**20,348**	**20,461**
Inhabitants per dispensary								
Inh. per pharmacy	**2,176**	**2,116**	**2,066**	**2,068**	**2,084**	**2,083**	**2,058**	**2,047**

Inh. = Inhabitants

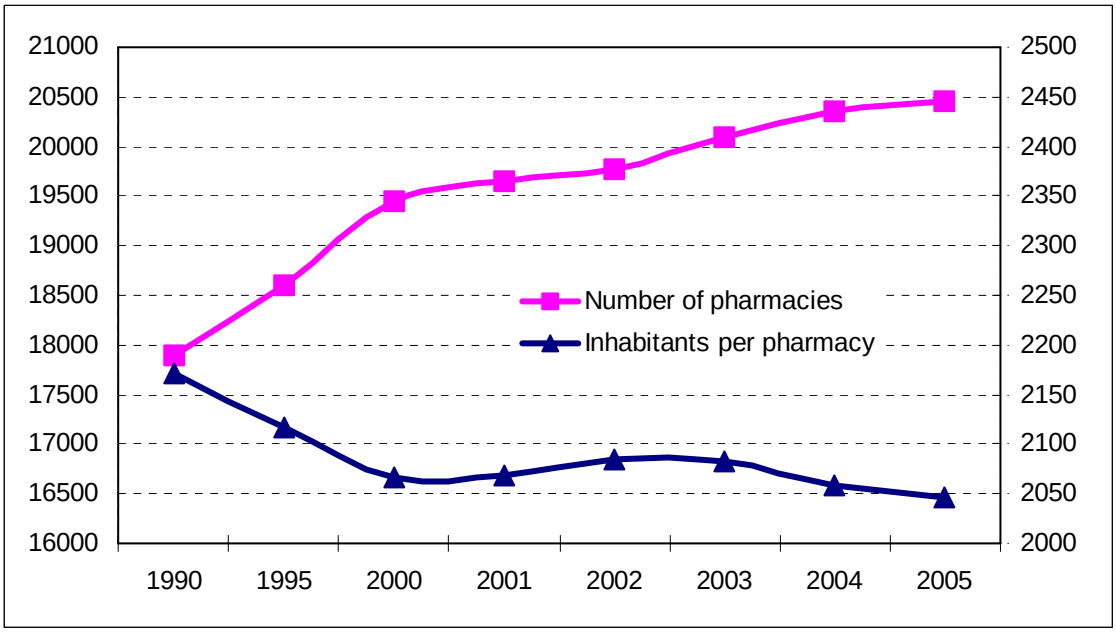
[1] Data per 1 January.

Source: data gathering by ÖBIG

In 2005 there are around 20,500 community pharmacies, which corresponds to one pharmacy per 2,047 inhabitants. In the last 15 years, there have been no closures of pharmacies; instead, 150 to 300 pharmacies were opened each year. Nevertheless, due to the population growth the ratio of inhabitants per pharmacy has not changed significantly as Figure 5.7 shows, although compared to the end of 1990 one pharmacy now serves 2,050 Spaniards instead of almost 2,200.

78 percent of the community pharmacies in Spain (15,973 pharmacies per 1 January 2004 and 15,896 per 1 January 2005) are situated in areas defined as urban (settlements with more than 5,000 inhabitants).

Figure 5.7: Spain – Number of pharmacies and number of inhabitants per pharmacy 1990 – 2005



Source: data gathering by ÖBIG

5.3.2 Establishment of pharmacies

In Spain, there exist rules concerning the opening of new pharmacies, which take into account geographic and demographic criteria and the spread of the population, in order to guarantee the accessibility of the services. These rules are based on an central law. Each autonomous community has adapted the criteria for establishment to its own geographic and demographic conditions. Due to these regional adaptations, especially those in the rural or mountainous areas where the number of inhabitants served by a pharmacy is in general relatively low, the average number of inhabitants per pharmacy is lower than the minimum of 2,800 which was laid down in the central law, as can be seen in Table 5.14.

Table 5.15: Spain – Establishment rules for community pharmacies in 2005

Reg.	Provision	Criteria for establishment of new pharmacies	
Yes	Statutory provision in a central law (Regulation 16/97) Adjustment by each Autonomous Community in their own regulation	Geographic	• Minimum distance of 250 metres to next pharmacy (central law) • Minimum distance of 250 metres to next pharmacy in most Autonomous Communities. Special specifications in some Autonomous Communities (e.g. Baleares and Canarias: 1,000 metres in tourist areas; Andalucia: 500 metres in rural and in areas in expansion) • In some Autonomous Communities there also exist regulations on the distance between a pharmacy and a health centre
		Demographic	• In general minimum number of 2,800 inhabitants per pharmacy (according to central law) • Adjustment of criteria by each autonomous community, taking into account several characteristics such as urban areas, rural areas, mountainous areas, tourist areas

Reg. = regulation existing

Source: data gathering by ÖBIG

Navarra is one of the 17 Autonomous Communities of Spain. In 2000, the Navarra Law on Pharmaceutical Care established demographic and geographic criteria for the opening of pharmacies. The current Navarra law allows the opening of a new community pharmacy for every 700 inhabitants and the minimum distance between community pharmacies has been reduced to 150 metres. The number of community pharmacies in Navarra has increased from 308 in 2000 to 531 in 2004. Before 2000, the average number of new community pharmacies opening each year was around 2. With the new legislation, in almost three years time, an average of 80 community pharmacies were opening each year. Eight community pharmacies that were established in rural areas have closed down since 2000. The owners of these pharmacies have moved to more densely populated areas where the needs of the population were already covered by existing pharmacies, leaving the small localities without pharmaceutical coverage.

5.3.3 Ownership of pharmacies

Only pharmacists are allowed to own a pharmacy in Spain. Thus, market strategies as vertical integration by wholesalers are unknown in Spain. There are no affiliate pharmacies or pharmacy chains, as multiple ownership is not allowed. Information on the ownership rules for pharmacies are summed up in Table 5.16.

Table 5.16: Spain – Ownership regulation on pharmacies in 2005

Ownership	Reg.	Content
Entity of pharmacy ownership	Yes	Only pharmacists are allowed to own a pharmacy
Number of pharmacy owners	Yes	Plurality of pharmacists as owners of a pharmacy is allowed (so-called co-holders)
Trade in pharmacy licenses	Yes	Allowed, but only to other pharmacists and after running the pharmacy for at least 3 years
Multiple ownership	Yes	Not allowed

Reg. = regulation existing

Source: data gathering by ÖBIG

5.3.4 Pharmacy staff

In Spain, 35,579 pharmacists out of a total of 54,700 active pharmacists are working in community pharmacies. More than 60 percent of the pharmacists, who are active in community pharmacies, are the owners of such a pharmacy; the others work as employed pharmacists. Another interesting fact is that two thirds of all pharmacists are female.

The prerequisite for being a pharmacist is five years university training offered in 14 pharmacy faculties in Spain, followed by six months of practice training.

Community pharmacies in Spain are rather small. On average, 3.3 persons work in a pharmacy, of which 1.8 are pharmacists. Further pharmacy staff include pharmacy technicians with a two years vocational training plus three months practice. The exact number of pharmacy technicians is not available. These pharmacy technicians are not allowed to dispense pharmaceuticals, not even under the supervision of the pharmacist, thus granting that every dispensed pharmaceuticals has gone through the hands of a pharmacist.

Table 5.17: Spain – Staff working in community pharmacies 2000 - 2004

Pharmacy staff[1]	2000	2001	2003	2004
Pharmacists[2]	28,863	31,778	33,385	35,579
Other pharmacy staff[3]	23,017	23,731	32,335	n.a.
Total of pharmacy staff	**52,017**	**55,509**	**65,720**	**n.a.**

n.a. = not available

1 Data per 1 January, staff counted per head, working in community pharmacies.

2 Educated according to EU Directive 2005/36/EC (30 September 2005).

3 Including pharmacy technicians.

Source: data gathering by ÖBIG

Concerning further education of pharmacists, there are several pharmacy specialisations, which provide pharmacists with the official title of “specialist pharmacist”. Specialisations which do not require hospital training are radiopharmacy, analysis and control of medicines and drugs, and additionally industrial and galenic pharmacy.

Continuous education is not compulsory by law, neither for pharmacists nor for other pharmacy staff. However, the law on health professions (44/2003), which was introduced in 2003, considers continuous education as a right as well as an obligation for health professionals. This law, asking health professionals for engaging in continuous education, is seen as a signal that the health authorities are, for the first time, pushing for continuous education.

Continuous education is also encouraged by the General Spanish Council of Pharmacists, which, besides pharmacist colleges, the pharmaceutical industry, wholesalers, universities, health administrations, etc. offers programs and courses. The General Spanish Council of Pharmacists developed a National plan for continuous education, covering more than 22,000 pharmacists. According to a study carried out by the General Spanish Council of Pharmacists, from 1996 to 2003 an increase has been observed in pharmacies receiving education (from 10,840 to 11,565), in courses per pharmacy (from 2.6 to 3.2), in courses taken by pharmacists (from 2.7 to 3.5) and in people trained (from 50,000 in 1996 to 69,000 to 2003). With an increase in the length of courses in that time period, the education per pharmacy had also risen (from 100 to 178 hours).

5.3.5 Opening hours

In Spain, the framework for opening hours is regulated by a central law, stating that community pharmacies are basically free to provide their services, but they have to comply with the official schedule and rules on night and holiday service duty laid down by the Autonomous Communities, in order to guarantee the continuity of care.

In each Autonomous Community, there are regulations to guarantee continuous provision with pharmacy services, which are considered as minimum rules. Pharmacies with opening hours exceeding the minimum regulation should communicate these wider opening hours in advance to the relevant authority of the Autonomous Community, and they are asked to stick to the enlarged opening hours indicated. The timetable and the night- and holiday duties of a pharmacy, and of other pharmacies in its neighbourhood, are made public through a note at the entrance.

Therefore, typical opening hours for community pharmacies cannot be provided. Some regulations allow for openings of 24 hours. For example, the regulation in the Autonomous Community of Andalusia offers two models of extended opening hours: either from Monday to Saturday from 9:30 am to 22 pm or for 24 hours on all days a week. The regulation for Madrid implies the obligation for assigned stand-by services for all pharmacies.

Night service may be organised on a stand-by duty basis, but may also be provided by pharmacies open for 24 hours every day. 15 percent of all pharmacies in Spain are 24-hours pharmacies.

5.3.6 Quality of pharmacy services

In Spain, there are nearly 12,000 pharmaceuticals (counted including different pharmaceutical forms, dosages, and pack sizes) registered. Of the registered pharmaceuticals, 85 percent are prescription-only medicines. 80 percent of all registered pharmaceuticals are reimbursable. The share of prescription-only medicines and reimbursable medicines has risen in the past five years.

A key task of pharmacies in Spain is filling prescriptions. In total, nearly one billion prescriptions were filled in Spain in 2004, which amounted to 48,000 prescriptions dispensed per pharmacy. The number of prescriptions filled has risen by 26 percent in the last 10 years. One reason for this comparably high number is that in Spain, in contrary to other European countries, physicians may only write one item on a prescription.

The typical classification of pharmaceuticals in Spain is into “Farmaceuticas eticas”, which cover most prescription-only medicines, and “Especialidades Farmaceuticas Publicitarias” (EFP), for which advertising to the public is permitted.

Table 5.18: Spain – Number of pharmaceuticals 2000 - 2005

Pharmaceuticals[1]	2000	2001	2002	2003	2004	2005
Registered ph.	11,806	11,094	12,775	11,137	11,157	11,783
POM	9,226	9,403	10,181	9,056	9,119	10,074
Reimbursable ph.	8,922	8,756	9,580	8,348	8,474	9,569
Farmaceuticas eticas	10,565	9,856	11,522	9,985	9,453	10,144
EFP	1,241	1,238	1,253	1,152	1,163	1,127
Generics	580	857	1,211	1,669	1,675	2,202
Non-pharmaceutical products on the market	29,597	29,151	28,899	25,460	25,842	26,546

EFP = Especialidades Farmaceuticas Publicitarias, ph. = pharmaceuticals, POM = prescription-only medicines

[1] Data per 1 January. Pharmaceuticals for human use, excluding magistral or officina formula, counted including different pharmaceutical forms, dosages, pack sizes.

Source: data gathering by ÖBIG

One of the services which pharmacies in Spain offer is generic substitution, which is compulsory by law. The introduction of generic substitution came into force after some years of preparation, as there had not been enough generics on the market, which is a prerequisite for generic substitution. The share of generics has considerably increased in the last five years (from 5 percent of all registered pharmaceuticals in 2000 to nearly 20 percent today).

Spain is among those countries with regulations on the availability of pharmaceuticals. There is a central law stating that pharmacies are obliged to provide a compulsory stock of pharmaceuticals; in addition, some Autonomous Communities have their own regulation. The compulsory stock is considered as minimum. From the region of Navarra, as explained before, it is reported that some pharmacies just stock pharmaceuticals according to the

statutory minimum, which poses in some cases a problem of under-supply in the sense that the variety of the products offered is very small.

Usually patients get a pharmaceutical in pharmacy immediately (i.e. direct dispensing). If it happens to be not available, the mean delivery time is within three hours, as pharmacies receive 2 to 4 deliveries per day by the pharmaceutical wholesale.

A typical service offered by pharmacies in Spain is the manufacturing of pharmacy-produced pharmaceuticals (magistral preparations). All pharmacies in Spain have a laboratory section to manufacture pharmaceuticals.

Table 5.19: Spain – Pharmacy services in 2005

Pharmacy services	Provision
Availability of pharmaceuticals	- Regulation on availability (central law plus regulation in Autonomous Communities): compulsory stock of pharmaceuticals - Delivery time to patients: immediate delivery, maximum 3 hours - 2 - 4 deliveries per day by wholesalers
Generic substitution	- Obligatory generic substitution by law - A generic could be substituted by another generic; an original product should be substituted by a generic whenever possible - Generic substitution is encouraged by the government (reference price system: difference between reference price and pharmacy retail price of a more expensive brand would have to be paid by patient) - No financial remuneration / incentives for generic substitution for pharmacists
Magistral preparations	- Important pharmacy service - 100% of pharmacies are equipped with a laboratory to manufacture pharmaceuticals
Computerisation	- 96% of all pharmacies are equipped with a computer

Source: data gathering by ÖBIG

Besides pharmaceuticals, there are around 26,500 non-pharmaceutical products on the market, which are also offered in pharmacies and account for approximately 13 percent of the pharmacy turnover.

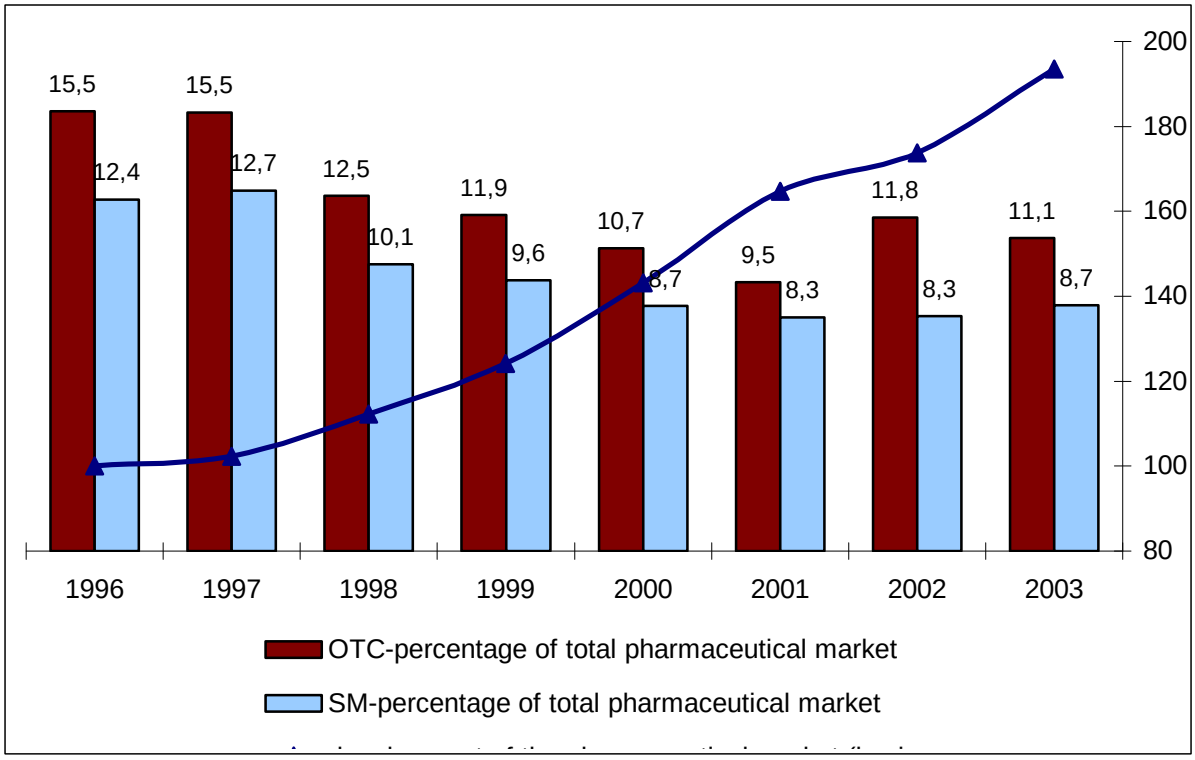
Besides providing additional pharmacy services, such as blood pressure measurements and diabetes test, community pharmacies should, according to the Spanish law, collaborate in health programs initiated by regional public authorities. As consequence of its decentralised structure, the campaigns are sometimes managed by regional colleges representing pharmacists or by Consejo General de Colegios Oficiales that at national level coordinates the campaign in collaboration with the regional and local colleges. Examples of these are campaigns on HIV/AIDS and a program aiming to correct the dietary habits of the population and to promote a healthy life-style and a healthy diet, called Plenufar. This campaign, which started in the year 1992, was initially targeted to housewives as the person responsible of the dietary habits of a family. The next (3rd) phase of the Plenufar campaign will address elderly people.

5.3.7 Market data

Pharmaceutical expenditure in Spain according to OECD data amounted to about € 12.5 billion in 2003, a rise of 29.2 percent compared to the year 2000. In general the pharmaceutical market has almost doubled since 1996 as Figure 5.8 shows. A law, which came into force in May 2000, established at national level the so called pay back (Rappel), which is a measure to balance the pharmaceutical expenditure. The pay back is an established scheme whereby pharmacies with significant turnover have to make discounts to the social health system. The higher the turnover, the bigger the discount. In the region of Navarra, the "rappel" is progressively decreasing every year making the cost containment strategy inefficient, whereas in the rest of the Spain the "rappel" has increased, supporting the cost containment measures.

On average, a pharmacy in Spain had in 2004 an annual turnover of around € 745,000.- (including OTC medicines and non-pharmaceuticals). The average pharmacy turnover has more than doubled in the last 10 years. In the region of Navarra, however, the existing pharmacies are suffering from the large increase in the opening of new pharmacies and their income is now 20 percent less than what it used to be before 2000. Those pharmacies are struggling to keep their staff and an adequate supply of medicines.

Figure 5.8: Spain – Development of pharmaceutical market 1996 - 2003



Source: AESGP 1995 – 2004, data gathering by ÖBIG

10 to 15 years ago, the sales of pharmacies in Spain solely consisted of pharmaceuticals; meanwhile the share of non-pharmaceutical of total pharmacy turnover has reached about

13 percent. The core business is still on prescription-only medicines, the OTC sales account for only 4 percent of pharmacy turnover.

Remuneration of pharmacies is statutorily regulated: The pharmacy retail price is determined from the (also statutorily regulated) wholesale price plus a regressive pharmacy mark-up scheme. The average pharmacy margin in 2003 was approximately 25 percent.

Price development

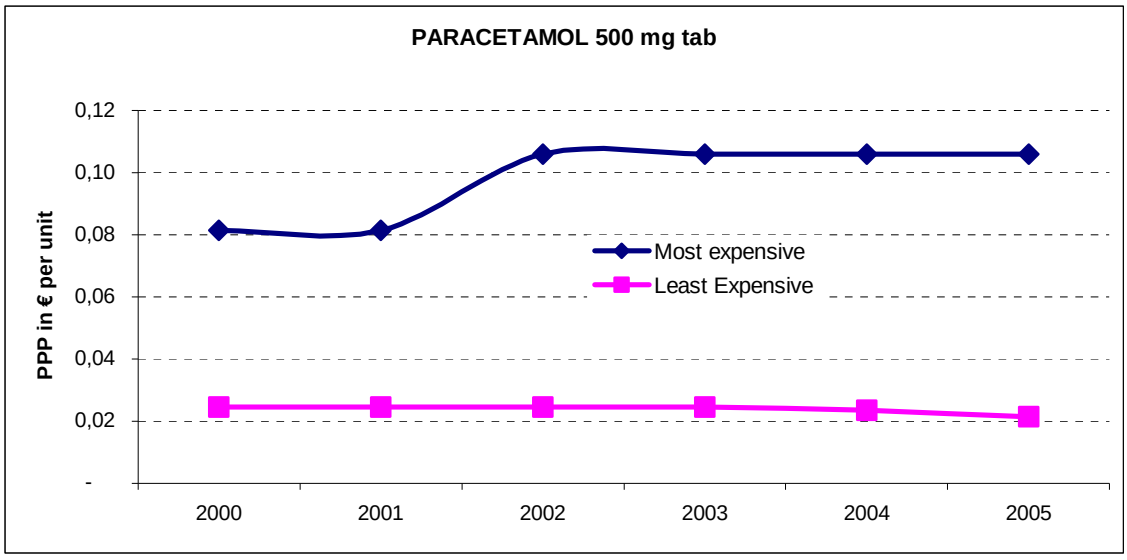
After a period of a rather steady pricing situation as well as for prescription-only medicines and OTC medicines the Spanish government revised the current pharmacy margins. In March 2005 prices of pharmaceuticals not included in the reference pricing system with an ex-factory price higher than € 2.- were cut by 4.2 percent. An additional 2 percent price reduction is expected for March 2006.

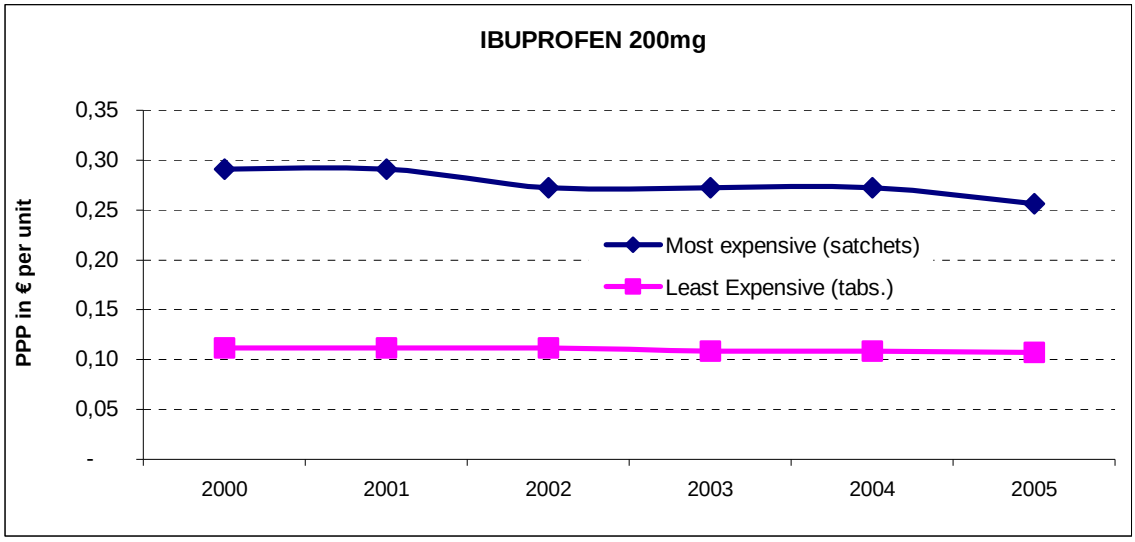
Figure 5.9 shows the development of selected blockbuster OTC products in Spain. Compared to other countries the price differences between the most expensive product of a kind and the least expensive one are, e.g. in the case of **diclofenac** cream, almost neglect able. The 60 gram pack of 'Voltaren' by Novartis costs only about 2 percent more than its competitor 'Dolotren' by Faes.

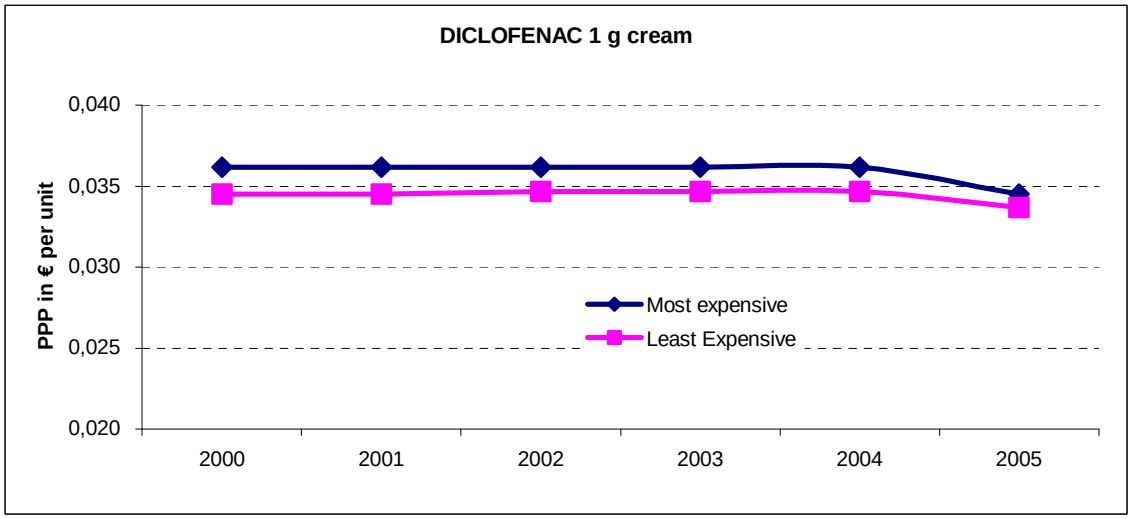
Aciclovir encountered rather strong fluctuations, the most expensive OTC currently being 'Bel Labial' cream.

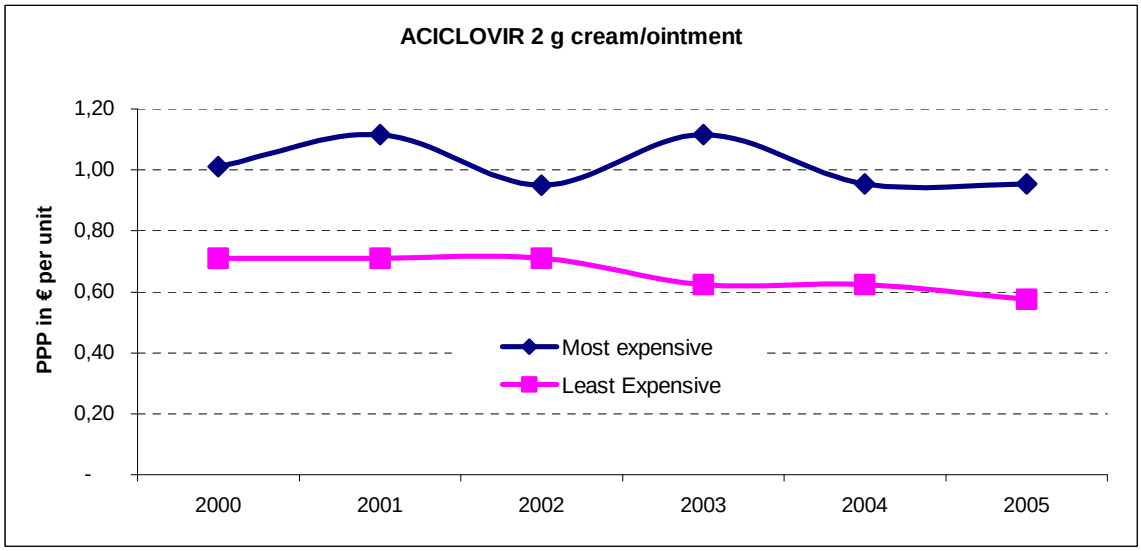
In case of **paracetamol** the gross pharmacy retail price of the most expensive OTC is € 0.13 per tablet (20 tab-pack: € 2.62) above the price of the cheapest one on the market.

Figure 5.9: Spain – Price development of selected OTC blockbusters 1997 - 2005









PPP = pharmacy purchase price, tab = tablet

Source: national sources, data gathering by ÖBIG

6 Benchmarking

In this chapter, the key findings of the six country profiles are presented and analysed. Of the six countries, Ireland, the Netherlands and Norway (cf. Chapters 2 to 4) are considered to be “deregulated countries”, whereas Austria, Finland and Spain (cf. Chapter 5) are viewed as "regulated countries". This benchmarking chapter is divided into two main sections: In Section 6.1 and its subsections, information is given on the relevant regulations in the pharmacy sector. In Section 6.2, based on facts and figures, benchmarks (comparative indicators) are developed and assessed, based on collected facts and figures.

6.1 Regulatory framework

This section starts with a general overview of the selected countries, offering a framework to better understand the pharmacy system in each country. Key topics are, among others, actors entitled to dispense pharmaceuticals, establishment and ownership rules for pharmacies, as well as the regulations relating to the qualification of pharmacists and other pharmacy staff.

6.1.1 Background

The countries selected differ not only with regard to the pharmacy sector (more or less regulated), but also with regard to their size and population, as well as the organisation of health care in general (cf. Table 6.1).

Table 6.1: Benchmarking – Key data on the countries selected

Country	Inh. (in mill.)	Size (in km^2)	Organisation	Inh. / physicians (2003)	Acute care beds / 1,000 inh. (2003)	Prescriptions / inh. (2004)
IRL	3.996	70,280	NHS	389	3.0	11.8
NL	16.225	41,526	Mixed system	319	3.2[1]	8.5
N	4.565	324,000	Mixed system	323	3.1	5.4
A	8.121	83,858	SI	296	6.0	9.3
FIN	5.220	338,145	Mixed system	378	2.3	7.6
E	41.874	504,788	NHS	309	3.1	23.6[2]

Inh. = Inhabitants, mill. = millions, NHS = National Health Service, SI = Social Insurance

[1] 2002 instead of 2003.

[2] In Spain contrary to the other countries listed above, only one item per prescription is allowed except in cases of systemic antibiotics, multidose insulin, growth hormones, hospital prescribed medicines and narcotics where up to four items per prescription are allowed.

Source: data gathering by ÖBIG

Organisation of health care in Ireland and Spain is based on a National Health Service (NHS), while Austria organises its health care within the framework of a Social Insurance system. The Norwegian health care system is mainly funded by tax (although all residents are insured under the National Insurance system), and responsibility for the provision of services is decentralised in five health regions. The central government is in charge of regulating and supervising services. In the Netherlands the health care system consists of a combined system of public and private health insurance. Statutory health insurance is obligatory for persons whose income does not exceed a certain amount/limit (insurance obligation); persons with higher income, as well as self-employed persons, may opt for private health insurance. In Finland, there is a mixed system as healthcare is tax funded but provided by local authorities with a partial subsidy from the state. All Finnish residents are also insured under a national health insurance scheme, which covers for example medicines in out-patient care.

Whereas the countries differ markedly in size, the differences in the numbers of inhabitants per physician are relatively small. Looking at the number of beds per 1,000 inhabitants, we see that one country, Austria, still provides a relatively large number of acute care beds.

An indicator for pharmaceutical consumption is the average number of prescriptions per inhabitant: Table 6.1 shows large differences between the countries. Whereas in Spain the average number of prescriptions per inhabitant in 2004 amounted to 23.6, it was only 5.4 for Norwegian inhabitants. Both among the deregulated and the regulated countries, there are states with a relatively high number of prescriptions per inhabitant and one with a relatively low number. The number of prescriptions per inhabitant depends among others on the number of items allowed per prescription, which some countries define. For example, in Spain only one item per prescription is allowed, whereas in Portugal a maximum of four items per prescription is allowed. In Austria there is no limit on the number of items per prescription, but a prescription contains on average two items. In addition, when considering the number of prescriptions per inhabitant for each country, one has to keep in mind that the sizes of the packages might differ. For example, in the Netherlands, depending on the situation and the kind of medicine, the quantity supplied can be for a maximum of 15, 30 or 90 days, while patients in Finland receive pharmaceuticals for a maximum of three months.

Ireland and the Netherlands can be considered in general, and in particular with regard to health care, as liberal countries. In these countries regulations have never existed for certain areas or existed only to a limited extent, and the organisation and provision of community services has, for a long time, been left to the private sector. The health care sector in the third case study country, Norway, used to be relatively strongly regulated, but has undergone a number of reforms that have resulted in deregulation alongside the liberalisation of other services of general interest like gas, energy and telecommunications in the past 15 years. The three control group countries (Austria, Finland and Spain) can, on the contrary, be considered as rather regulated countries in terms of health care. Concerning the provision of health care in Spain, it is important to mention that the National Health Service has undergone a process of regionalisation, whereby health care competencies have been transferred to the Autonomous Communities, that is also reflected in the pharmacy sector.

6.1.2 Dispensing of pharmaceuticals

Besides the countries observed in this study, pharmacies are the main dispensaries, and in most cases the sole dispensaries, for prescription-only medicines (POM) across all other EU countries. Also in the six countries selected for this study pharmacies are the key actors in the dispensing of pharmaceuticals, in particular POM, with some exceptions, such as Austria, where especially in rural areas dispensing doctors have an important role. Self-dispensing doctors also exist in Ireland and the Netherlands, where their role is of less importance compared to Austria. The ratio of self-dispensing doctors and pharmacies in Austria is approximately 0.85 (cf. Section 5.2), whereas in Ireland and the Netherlands these are 0.11 and 0.33 respectively.

Table 6.2: Benchmarking – Key dispensaries of pharmaceuticals in 2005.

Country	Dispensaries for POM & OTC medicines		Dispensaries for OTC medicines only
	Main dispensaries	Others dispensaries	
IRL	Pharmacies	SD-doctors	Drugstores[1] Other retail shops[1]
NL	Pharmacies	SD-doctors Pharmacies in out-patient clinics “Policlinic pharmacies” Internet pharmacies	Drugstores Other shops with special licence[1,2]
N	Pharmacies	Branch pharmacies Hospital pharmacies	Pharmacy outlets[2] LUA-shops[1,2]
A	Pharmacies	Branch pharmacies SD-doctors	Drugstores[1]
FIN	Pharmacies[3]	Branch pharmacies	Pharmacy outlets[1,4]
E	Pharmacies	-	-

POM = prescription-only medicines, OTC = over-the-counter, SD-doctors = Self dispensing doctors, LUA = Medicines Outside Pharmacies (Norway)

1 Only a very limited number of OTC medicines may be sold.

2 Located in, for example, post offices or groceries.

3 Including 2 university pharmacies.

4 Also called “medicine chests”.

Source: data gathering by ÖBIG

In some countries hospital pharmacies are allowed to act as community pharmacies, i.e. they are accessible for and serve the general public. Of the countries selected, this is true for Norway. In the Netherlands, only hospital pharmacies in out-patient clinics (policlinics) are accessible to the general public and are therefore also considered as community pharmacies, while ordinary Dutch hospital pharmacies only serve in-patients.

In Norway, Austria and Finland, pharmacies may run a limited number (at max. one in Austria and three in Finland) of branch pharmacies, that are supervised by the "main-pharmacy" and are legally considered as part of the main pharmacy.

All of the countries examined allow some medicines to be made available outside of pharmacies. Only Spain reserves this task for pharmacists. However, it should be noted, that Spain is also the country with the highest provision of pharmacies (cf. Section 6.2.1).

Table 6.3: Benchmarking – Supervision of dispensaries of pharmaceuticals in 2005

Country	Branch pharmacies or pharmacy outlets supervised by main pharmacies		Other outlets not supervised by pharmacies	
	POM & OTC	Only OTC	POM & OTC	Only OTC
IRL	No	No	No	Yes
NL	No	No	No	Yes
N	Yes	Yes	No	Yes
A	Yes	No	No	Yes
FIN	Yes	Yes	No	No
E	No	No	No	No

POM = prescription-only medicines, OTC = Over the counter

Source: data gathering by ÖBIG

In the Netherlands OTC medicines are mainly dispensed through certified drugstores rather than pharmacies. The full range of OTC products may be sold by certified drugstores, whereas shops with special licenses are only allowed to dispense a restricted range of OTC products. The so-called pharmacy outlets in Norway and the "medicine chests" in Finland practise under the supervision of a pharmacy, whereas other outlets selling OTC medicines, such as drugstores in the Netherlands and Ireland and LUA-shops in Norway, are not supervised by a pharmacist. These stores, which practice without supervision of a pharmacy, mainly exist in the deregulated countries and in Austria. However, Austrian and Irish drugstores only have a narrow range of OTC medicines for self-medication. In Norway, pharmacy outlets have the full OTC range, while LUA-shops only have a very restricted list of max. 50 OTC products (in reality 10-15 blockbusters). In Norway, there is also a distinction concerning the handling of OTC medicines: Self-service for OTC medicines is allowed in pharmacies, while in pharmacy outlets and LUA-shops self-service for these products is not allowed.

From the public health perspective, it is important to notice that OTC outlets, which are not supervised by a pharmacy, are often run by laymen (except the certified drugstores in the Netherlands) who are not qualified and/or not allowed to provide counselling on the pharmaceuticals that they sell.

6.1.3 Establishment of pharmacies

In the context of the establishment of pharmacies, it is worth noting that the directive on the mutual recognition of professional qualifications (Directive 2005/36/EC), which governs, among other aspects the professional title of a pharmacist, specifically states that the geographic distribution of pharmacies is a Member State's responsibility. The vast majority of EU Member States have implemented systems to regulate accessibility to pharmacy services, i.e. establishment criteria. However, very often the criteria differ between countries. Differences in types and combinations of establishment criteria for pharmacies can also be found between the six selected countries analysed in this study.

While in the three regulated countries strict statutory establishment rules (including e.g. a needs assessment) are applied, there are currently no such rules in Ireland, the Netherlands and Norway. In Norway, regulations for the establishment of pharmacies were abolished with the deregulation process in March 2001. Before 2001, the National Board of Health developed, in deliberation with community authorities, a plan for the establishment of new pharmacies for five years forward. According to the plan, if a new pharmacy was to be established, pharmacists could apply for ownership. Establishment rules in Ireland, which had been introduced in 1996, were revoked in 2002. They included geographic and demographic criteria, and the requirement of not affecting the viability of existing pharmacies. The Netherlands have never had statutory regulations for the establishment of pharmacies. Until 1998 the Dutch pharmacists association (KNMP) applied its own establishment policy for pharmacies, which was often disregarded by non-members. Even though there are no statutory requirements concerning the establishment of a pharmacy in the Netherlands, establishment can still be prevented by local authorities if it does not fit into a municipality's zoning plan.

The establishment rules in the regulated countries take into consideration the pharmaceutical needs of the local population. In Austria and Spain there are specific geographic and demographic criteria, with different adjusted criteria in the Spanish regions (cf. Table 6.4). Furthermore the establishment of a pharmacy in Austria can also be prevented by local authorities if the pharmacy to be opened does not suit the local zoning plan.

In Finland, like in other Nordic countries (i.e. Denmark), there are no pre-defined geographic or demographic criteria. However, here the opening of new pharmacies is subject to a licensing system which is regulated by the National Agency of Medicines (NAM). The NAM bases its decisions on the needs of each municipality and grants the licence following a system of merit between pharmacists applying for vacant licences. Most EU Member States (for example France, Italy and Portugal) have also defined geographic and demographic criteria to ensure a good coverage of pharmacy service throughout the country (ÖBIG1998, ÖBIG 2001).

Table 6.4: Benchmarking – Establishment rules for community pharmacies in 2005

Coun-try	Regulation			Criteria for establishment of new pharmacies	
	Y/N	**Level**	**Provision**	**Geographic**	**Demographic**
IRL	No[1]	-[1]	-[1]	-[1]	-[1]
NL	No	-	-	-	-
N	No[2]	-	-	-	-
A	Yes	National	Statutory	Minimum distance of 500 metres to next pharmacy	Minimum of 5,500 persons must continue to be supplied by adjoining pharmacy
FIN	Yes	National	Statutory	License granted if required with regard to availability of pharmacies in a specific (part of a) municipality, no strict criteria.	
E	Yes	National & regional[3]	Statutory	Minimum distance of 250 metres to next pharmacy	Minimum number of 2,800 inhabitants

[1] From 1996 to 2001: establishment rules defined geographic criteria (1 pharmacy per 4,000 inhabitants in urban areas and per 2,500 inhabitants in rural areas) and demographic criteria (minimum distance between pharmacies of 250 metres in urban areas and 5 kilometres in rural areas), and required that the viability of existing pharmacies was not harmed by the establishment of new ones.

[2] Before 2001 location and number of pharmacies were decided by the Norwegian Board of Health. The Board made a "pharmacy plan" for 5 years forward.

[3] Basically, there are criteria for establishment, as stated in the table, written in a central law. On the regional level, the Autonomous Communities have adjusted these criteria for their own peculiarities (cf. Section 6.3).

Source: data gathering by ÖBIG

6.1.4 Ownership of pharmacies

Concerning the ownership rules for pharmacies, there are also differences in the types of rules between the regulated countries and the deregulated countries. In this context it is important to recall that the EU Directive 2005/36/EC on the recognition of professional qualifications allows Member States to prohibit the engaging of commercial companies in the distribution of medicines to the public.

In the three regulated countries analysed in this report (Austria, Finland and Spain) only pharmacists, trained according to the EU Directive 2005/36/EC, are entitled to own a pharmacy. This is not the case in the three deregulated countries: Here any individual and legal person may own a pharmacy. Yet, these countries put in place a number of legal instruments to regulate the management and supervision of a pharmacy. For example, in all six observed countries at least one supervising pharmacist must always be present in a pharmacy during opening hours. It should be noted, however that this regulation is currently under discussion in the Netherlands, and such obligation might be lifted in the new Dutch Pharmacy Act.

Table 6.5: Benchmarking – Ownership regulation on pharmacies in 2005

Country	Ownership structure of pharmacies		Multiple ownership		Trade in pharmacy licences
	Only pharmacists	Other groups allowed	Allowed	Specifications	
IRL	No	Any individual or legal person, except prescribers (i.e. doctors) with a practice in the same area	Yes	No limitation on number of pharmacies in a chain	Allowed
NL	No	Any individual or legal person	Yes	No limitation on number of pharmacies in a chain	Not allowed [1]
N	No	Any individual or legal person, except prescribers (i.e. doctors) and manufacturers	Yes	Limitation on number of pharmacies in a chain (40% max.)	- [2]
A	Yes	-	No	No multiple ownership allowed, but a pharmacy may run one branch pharmacy	Not allowed
FIN	Yes	-	No	No multiple ownership allowed, but a pharmacy may run max. 3 branch pharmacies	Not allowed
E	Yes	-	No	-	Allowed [3]

max. = maximum

[1] No licenses, but agreements with insurances. Trade in agreements is not allowed.

[2] Not applicable. There are two types of licenses: 1) a license to own a pharmacy and 2) a licence to run a pharmacy. The licenses have no trading value.

[3] Allowed to sell to other pharmacists after running the pharmacy for at least 3 years.

Source: data gathering by ÖBIG

In addition, in Ireland and in Norway there are limitations with regard to the ownership of pharmacies, designed to prevent a conflict of interests. In these countries, doctors, as they act as prescribers, are not allowed to own a pharmacy (in Ireland this is limited to the area in which a doctor practises). In Norway, manufacturers are also not entitled to own a pharmacy whereas wholesalers are. Consequently, there is a strong involvement of the pharmaceutical wholesalers in the pharmacy sectors in Ireland, the Netherlands and Norway (cf. Table 6.11).

Another regulation, derived from the derogation according to the 1985 EU Directive on the recognition of qualifications in pharmacy (Directive 85/433/EEC consolidated by Directive 2005/36/EC), stated that a pharmacist who was professionally trained in another EU or EEA country was not allowed to own, manage or supervise a pharmacy less than three years old. This derogation, has been adopted by seven Member States, among which Ireland, the Netherlands, Austria and Spain.

In the vast majority of the countries selected pharmacies can be owned both individually or in a partnership. In Austria in case of co-ownership the managing pharmacist (licensee) must own more than half of the shares in that partnership.

With regard to multiple ownership, i.e. the same legal person owning more than one pharmacy, the distinction between the two groups of countries is also obvious: In the three regulated countries multiple ownership, and thus the forming of pharmacy chains, is forbidden (with Austria allowing for one branch pharmacy per community pharmacy and Finland a maximum of three branch pharmacies per community pharmacy).

In Ireland, the Netherlands and Norway multiple ownership is allowed and also very common. In the Netherlands multiple ownership was not allowed for members of the Dutch pharmacy association (KNMP) until 1987. In Norway, where multiple ownership of pharmacies has always been allowed in the form of branch pharmacies, there was a large growth in pharmacy chains immediately after deregulation took place in March 2001, such that now there are only about 13 independent pharmacies left (cf. Section 6.2.2).

A consequence of multiple ownership is the emergence of pharmacy chains, which are increasingly penetrating the Irish, the Dutch and the Norwegian markets. In some cases, when multiple ownership is allowed, additional rules have been put in place to maintain fair competition. For instance, in Norway, to prevent one of the chains holding too much market power, one pharmacy chain can not control more than 40 percent of the pharmacies operating in the country.

Further information on the consequences of the liberalisation of the ownership with particular regard to vertical and horizontal integration is provided in Section 6.2.2.

6.1.5 Pharmacy staff

The staff in a pharmacy consists of pharmacists (independent and/or employed), sometimes of other academically trained staff (prescriptionists, in a few Nordic countries), of pharmacy technicians and/or assistants as well as other personnel. Their qualification and consequently their competencies differ.

In all the six countries examined, as well as in all EU Member States, the key person in a pharmacy is, of course, the pharmacist. All six countries selected require that pharmacies must be owned and/or supervised by a pharmacist. The pharmacist is responsible for the other pharmacy staff and for quality of the services provided in the pharmacy. Such pharmacist is also legally responsible for all activities carried out in the pharmacy. In all the countries included in the analysis, the pharmacist is legally obliged to be present in the pharmacy during opening hours.

In all the six countries pharmacists must have received a university education, according to EU Directive 2005/36/EC which entered into force on 7 September 2005, and which consolidated existing Directives dating from 1985 (85/432/EEC and 85/433/EEC). These legal texts set minimum common requirements at a European level for pharmacy curricula including: duration (a minimum of five years), the content of the studies and the in-service training period. In line with Directive 2005/36/EC, the duration of the university education for pharmacists goes from five years (Ireland, Spain, Norway), to five and a half years (Austria and Finland), and six years in the Netherlands.

Table 6.6: Benchmarking – Requirements for the qualification of pharmacy staff in 2005

Coun-try	Qualification	Duration of qualification		Continuous education required
		Total (years) [1]	Practice training	
Pharmacists				
IRL	Pharmacists[2]	5	1 year	No[3]
NL	Pharmacists[2]	6	6 months	Yes
N	Pharmacists[2] (MSc)	5	6 months	No[4]
A	Pharmacists[2]	5.5	1 year	No[5]
FIN	Pharmacists[2] (MSc)	5 - 6	6 months	Yes
E	Pharmacists[2]	5	6 months	No[6]
Other academically trained staff				
N	Prescriptionists (BSc)	3	6 months	n.a.
FIN	Prescriptionists (BSc)	3	6 months	Yes
Pharmacy technicians / assistants with the right to dispense pharmaceuticals under the supervision of a pharmacist				
IRL	Special course for "Qualified assistants" [7]	3	n.a.	No
NL	Secondary vocational education	4	n.a.	Yes
N	-	-	-	-
A	-	-	-	-
FIN	-	-	-	-
E	-	-	-	-
Pharmacy technicians / assistants without the right to dispense pharmaceuticals				
IRL	Special vocational course with certificate	2	100 days	No
NL	-	-	-	-
N	Secondary school at advanced level	3	n.a.	No
A	Vocational education	2 - 3	80% of total education period	No
FIN	Secondary vocational education	3	n.a.	No
E	Vocational education	2	3 months	No

n.a. = not available

1 The time spent on practice training is included in the total duration of the qualification.

2 According to Directive 2005/36/EC, as of 30 September 2005.

3 Except for tutors supervising graduate pharmacists during their practice training.

4 However, according to the Health Personnel Act, the employer has an obligation to provide for and to organise necessary updating of the pharmacy staff's competence.

5 Approx. 30 hours of voluntary vocational training per year.

6 No obligation by law, but commitment to continuous education written in Act on health professionals.

7 Qualified assistants are temporarily allowed to dispense medicines, for example if the pharmacist is ill. The training is no longer offered.

Source: data gathering by ÖBIG

There are significant differences in the composition and qualification of the pharmacy staff, others than pharmacists, in the six countries selected. In Norway and in Finland so-called “prescriptionists”, who have received a university education for three years, are working in pharmacies. Prescriptionists, who are entitled to dispense prescription-only medicines, generally do so under the supervision of a pharmacist. They can also provide counselling to customers. In the event that no pharmacist is available to run a branch pharmacy, prescriptionists can also take up this responsibility.

The duration of the qualification required for pharmacy assistants or technicians goes from two to four years in the chosen countries. The qualification is reflected in the competencies of pharmacy assistants. Whereas in Austria pharmacy assistants who have undertaken a two year apprenticeship have only limited competencies, pharmacy assistants in the Netherlands are, for example, entitled to make compound pharmaceuticals, to fill prescriptions and to provide counselling and advice to customers. Nevertheless, as long as these assistants practice according to the guidelines and the rules set by the pharmacist, the pharmacist is responsible for their actions. Until a few years ago Ireland also trained pharmacy assistants with the right to dispense pharmaceuticals for a “short period” (e.g. in case of illness of the pharmacist). These “qualified assistants” or “assistants to pharmaceutical chemists” are allowed to supervise a pharmacy in the event of the pharmacist being ill or on holiday. Except for Ireland and the Netherlands none of the countries examined in this study have pharmacy assistants who are allowed to dispense prescription medicines.

All analysed countries require practical training for pharmacy students, prescriptionists and assistants/ technicians. In all countries selected continuous education and training for practicing pharmacists is provided, e.g. by universities and pharmacist associations. The regular participation in continuous training is a deontological obligation for pharmacists in all six countries selected and also in the broader European context. However, only a few countries have made it a legal requirement: among the countries examined in this study, only the Netherlands and Finland. In addition, recently Spain (and outside the scope of this study also Portugal and Italy) has implemented a system of linking the pharmacy licence to continuous professional development activities. Continuous education for pharmacy assistants is only obligatory in the Netherlands.

Having examined the composition and level of qualification of pharmacy staff in the countries selected, it appears that there is a higher level of pharmacist supervision can be found in the regulated countries.

6.2 Analysis

In Section 6.1 the relevant regulations in the pharmacy sector of the three deregulated countries and the three regulated countries were presented. In this Section, a number of comparative indicators (benchmarks) will be provided and discussed.

6.2.1 Accessibility

Provision of the population with pharmacies

In each of the six countries studied, pharmaceuticals are mainly dispensed trough community pharmacies. Table 6.7 shows that the density of community pharmacies differs considerably, covering a range from 2,047 inhabitants per pharmacy in Spain to 9,368 inhabitants per pharmacy in the Netherlands. In Section 6.1.2, we have stated that, in Ireland, the Netherlands and Austria, prescription-only medicines (POM) are not only dispensed in community pharmacies but also by self-dispensing doctors. When considering the provision of all POM dispensaries, which includes community pharmacies and self-dispensing doctors, the differences between the examined countries are still large and the number of inhabitants per POM dispensary remains relatively high in the Netherlands and in Norway (cf. Table 6.7).

Table 6.7: Benchmarking – Density of pharmacies, and density of pharmacies and other POM dispensaries in 1995 and 2005

Country	Community pharmacies[1]			Community pharmacies and other POM dispensaries[2]		
	Inh./pharmacy		Change in %	Inh./POM dispensary		Change in %
	1995	2005	1995-2005	1995	2005	1995-2005
IRL	3,180	2,998	17.4%	2,650	2,707	8.3%
NL	10,217	9,368	14.5%	7,089	7,000	6.4%
N	12,589	8,533	54.6%	12,589	8,533	54.6%
A	7,807	6,819	16.7%	3,972[2]	3,720	9.1%[3]
FIN	6,524	6,509	2.4%	6,524	6,509	2.4%
E	2,116	2,047[4]	10.1%	2,116	2,047[4]	10.1%

inh. = inhabitants, POM = prescription-only medicines, Note: Data on pharmacies and dispensaries per 1 January

[1] Including branch pharmacies (N, A, FIN), university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies (N).

[2] Including branch pharmacies (N, A, FIN), university pharmacies (FIN), policlinic pharmacies (NL), hospital pharmacies acting as community pharmacies (N), and self-dispensing doctors (IRL, NL, A).

[3] Year 1996 instead of year 1995.

[4] Year 2004 instead of year 2005.

Source: data gathering by ÖBIG

The number of inhabitants per POM dispensary is a key benchmark for the evaluation of the pharmacy sector. From the patients' perspective, easy accessibility and a good provision of pharmacies and other POM dispensaries is strongly desirable. However, it should be noted that it is important to find a good balance between convenient accessibility of pharmaceutical services and the sustainability of the services. A very low number of inhabitants served per pharmacy, is likely to put pressure on the sustainability of the pharmacy through, for example, a reduction of the capacity of the pharmacy to invest (e.g. in stock and/or in additional personnel). A pharmacy that does not have the adequate stock causes inconvenience to

patients, as it leads to additional visits to the pharmacy in order to obtain the prescribed medications.

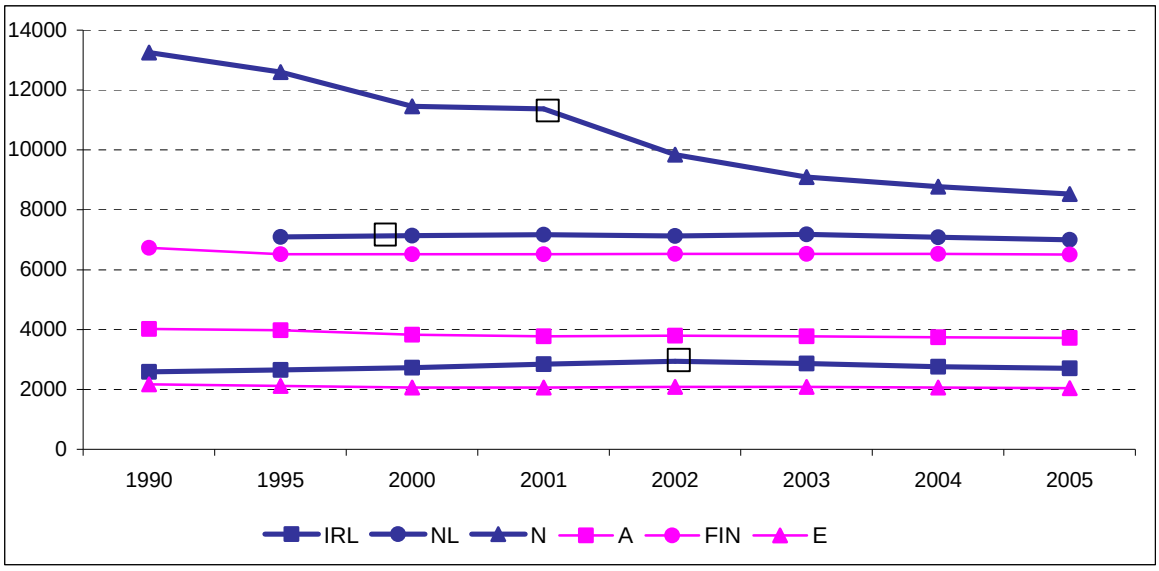
For example, in the Spanish region of Navarra, which is the only region in Spain that has relaxed controls on the establishment of pharmacies, newly established pharmacies have opened only in urban areas, leading to a very high density of pharmacies in those areas. This has lead to the fact that currently pharmacies in these urban areas work on a very tight margin of stock, with many pharmacies just stocking pharmaceuticals according to the statutory minimum, which has already caused problems of under-supply. To prevent this situation from occurring when rules on the establishment of pharmacies have been removed, some European countries (not examined in this survey) have decided to re-introduce rules. For instance, the Belgian government introduced a moratorium on the establishment of new pharmacies in 1994; the Greek government introduced restrictions on the opening of new pharmacies in 1997; and in Estonia; new rules to limit the number of new pharmacies were implemented on 1 January 2006 (Scrip 2005).

Other challenges are faced by countries where the number of inhabitants per POM dispensary is low. For instance, in the case of a high number of inhabitants per pharmacy it is essential to ensure that sufficient personnel is available not only to cope with the work load and to prevent work overload, but also to make sure that pharmaceuticals are regularly delivered by wholesalers so that products are available in sufficient numbers. These issues will be analysed in the following subsections.

Figure 6.1 illustrates that there has been an increase or a stabilisation in the density of POM dispensaries during the past ten years in all analysed countries, except in Ireland. In Ireland the density of POM dispensaries decreased in the second half of the 1990s, when establishment rules were in force, although several community pharmacies opened every year, e.g. in 1999 25 pharmacies, many of them in rural and disadvantaged areas (cf. Section 2.3.2). After the liberalisation in 2002, when the POM-density was at the lowest level (2,937 inhabitants per POM dispensary) – due to a declining number of SD-doctors in line with a population growth - the density of POM dispensaries started to increase again through the opening of new pharmacies, the vast majority of which were in economically attractive urban areas (see below for further details).

In the majority of the six examined countries, the number of pharmacies or other POM dispensaries has developed in a rather stable way during the last 15 years: Though in the Netherlands and Austria the number of pharmacies has increased, the number of other actors entitled to dispense pharmaceuticals (e.g. self-dispensing doctors) has decreased in the past years, which resulted in only a minor increase in the number of POM dispensaries. In Spain, even if the number of pharmacies has grown considerably, the overall pharmacy density has been quite stable, like in the other two regulated countries. This can be attributed to the establishment criteria. If the number of POM dispensaries in a specific country has not increased substantially, this may be seen as an indication that the existing number of pharmacies meets the needs of the population.

Figure 6.1: Benchmarking – Development of the number of inhabitants per pharmacy or other POM dispensary[1] 1990 - 2005



POM = prescription-only medicines, ☐ = year in which ownership and establishment of pharmacies were liberalised. (Ireland: 2002, Netherlands: 1999, Norway: 2001)

Note: Data on pharmacies and dispensaries per 1 January

[1] i.e. POM dispensaries including branch pharmacies (N, A, FIN), including self-dispensing doctors (IRL, NL, A), university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies (N)

Source: data gathering by ÖBIG

The largest decrease in the number of inhabitants per dispensary can be seen in Norway, mainly due to a sudden sharp growth in the number of pharmacies after March 2001, when the establishment and ownership rules were abolished. A similar effect was, however to a lesser extent, observed in the other two countries (Ireland and the Netherlands) after deregulation took place in the pharmacy sector. However, it should be noted, that especially in Norway the situation before the change in legislation in relation to accessibility was rather problematic, as there was only one pharmacy per 11,000 inhabitants, the EU-average being about 3,500 inhabitants per pharmacy.

In terms of analysis we have considered branch pharmacies in Norway, Austria and Finland as regular community pharmacies, because they offer the same range of services and fulfil public health duties. Nevertheless, it is important to note that branch pharmacies in Norway and Finland may also be run by prescriptionists.

In addition, when considering the number of pharmacies in a country, it is also important to look at the allocation throughout the country. Even if the development of pharmacies in a country looks stable or if the density of pharmacies has improved from an overall perspective, a closer look might reveal that the spread of pharmacies has shifted from rural to urban areas. Although hard data on the spread of pharmacies could not be obtained for all six

countries selected, Table 6.8 provides a general view of the regional allocation of pharmacies.

Based on the data available for the countries selected we have found indications for clustering of pharmacies in urban areas in all three deregulated countries. In Ireland, for instance, openings of new pharmacies after deregulation have been observed primarily in bigger cities, and, particularly, in town centres, where pharmacies have been set up very close to each other (see below). Indications of pharmacy clustering in urban areas in the three regulated countries have not been found.

With the clustering of pharmacies in economically attractive urban areas, there is concern of inadequate provision of pharmacies in the rural areas. For example, even though more than 130 new pharmacies have been established in Norway since the liberalisation act of March 2001, only 9 of them were opened in municipalities without a pharmacy or a branch pharmacy. In the summer of 2005, pharmacy services were still not available in 199 out of 434 municipalities (46%). This is in clear contrast to the situation in other countries, such as, for example, Austria where each municipality has at least one pharmacy or a self-dispensing doctor, and Finland which holds a comparable number of municipalities (444) of which only 42 (9.5%) are without a pharmacy. Besides Austria, Ireland and the Netherlands also allow self-dispensing doctors in sparsely populated areas, to compensate for the absence of POM dispensaries. As a result, 97 percent of the Dutch population lives within a maximum distance of 4.5 kilometres to the nearest POM dispensary. The remaining 3 percent live in less densely populated areas. When interpreting these data, one should keep in mind that there are great differences between the population density in the Netherlands and, for example, in Nordic countries like Norway and Finland. In the latter two countries the less densely populated, or “rural” areas are far more extensive.

None of the three deregulated countries have defined minimal distances between pharmacies. As a result the distance between pharmacies may be very small. In two of the regulated countries, Austria and Spain, regulations on the distance between pharmacies do exist, in Spain being adapted to the particular characteristics of the regions (e.g. population density). In Finland, the National Agency for Medicines determines the number of pharmacies within each area, but there are no regulations on the distance between pharmacies within one area.

Table 6.8: Benchmarking – Accessibility of pharmacies in 2005

Country	Regional spread of pharmacies		Distance to pharmacies	Opening and closures
	Clustering in urban areas	Other comments		
IRL	Yes	• In areas without pharmacies, POM are dispensed by SD-doctors	• No rules for distance to nearest pharmacy • Very close distances between pharmacies in some (urban) places • Average distance between pharmacies is estimated to be less than 5 kilometres	• Increasing number of new openings, mainly in urban areas, especially. in the last few years • 15-35 openings per year (2000-2004) • Closures of 1-5 pharmacies annually in the last few years
NL	Yes	• In areas without pharmacies, POM are dispensed by SD-doctors	• No rules for distance to nearest pharmacy • 97% of population within 4.5 kilometres of nearest pharmacy or SD-doctor	• Increasing number of openings since 1999 • ~35 openings per year, since 1999
N	Yes	• Gentlemen's agreement prevents closure of pharmacies in rural areas • 199 out of 434 (46%) municipalities without a pharmacy	• No rules for distance to nearest pharmacy	• Large increase in number of new openings in 2001, mainly in urban areas • Almost no closures since 2001
A	No	• More than half of pharmacies situated in rural areas and small towns [1] • In past years 38% of new pharmacies opened in communities without a pharmacy, currently no municipalities without POM dispensary • In areas without pharmacies, POM are dispensed by SD-doctors	• Rules for distance to nearest pharmacy exist • The average distance to the nearest pharmacy is 3.5 (median: 996 metres) kilometres in all areas. Average travelling time to the nearest pharmacy is 5.9 minutes (median: 3 minutes).	• Increase in number of new openings last years
FIN	No	• 42 of 444 (9.5%) municipalities are without a pharmacy, whereas 200 do not have a health centre. Of the 42, 16 are in rural area • In 2004 99% of population lived in a municipality with at least one pharmacy	• Number of pharmacies within each area is predetermined • No rules for distance between pharmacies within one area	• Since 1990 increase in number of branch pharmacies and decrease in number of medicines outlets (medicine chests) • Few openings and closings of pharmacies in the past ten years
E	No	• Geographic and demographic criteria by the Autonomous Communities consider the specific peculiarities of the regions • Pharmacy is often the only health service provider in a rural municipality	• Rules for distance to nearest pharmacy are regionally adapted • In some regions distance between pharmacies is also specified	• No closures of pharmacies in the last 15 years • 100-200 pharmacies on average opened per year

POM = prescription-only medicines, SD-doctor = self-dispensing doctor

[1] Rural areas and small towns are defined as municipalities with less than 20,000 inhabitants.

Source: data gathering by ÖBIG

Availability of pharmaceuticals

Next to the accessibility of pharmacies, it is also important to look at the extent to which pharmacies are able to dispense the required pharmaceuticals in an acceptable time span to the patient, which is shown in Table 6.9.

Table 6.9: Benchmarking – Availability of pharmaceuticals in 2005

Country	Legislation or self-regulation		Deliveries by / to pharmacies	
	Y/N	Content	Ø delivery time to patients	Frequency by WS
IRL	No	-	Within 1 day	1 - 2 deliveries / day
NL	Yes [1]	Immediate availability of frequently asked pharmaceuticals, others within 24 hours	Immediately	1 - 2 deliveries / day
N	Yes	Immediate availability of frequently asked pharmaceuticals, others within 24 hours	Immediately	4 deliveries / week
A	Yes	Immediate availability of frequently asked pharmaceuticals	Immediately	3 deliveries / day
FIN	Yes	Immediate availability of frequently asked pharmaceuticals	Immediately	5 deliveries / week
E	Yes [2]	Compulsory minimum stock	Immediately, max. 3 hours	2 - 4 deliveries / day

Y/N = Yes/No, WS = pharmaceutical wholesale

[1] According to the Dutch Pharmacy Standard (Nederlandse Apotheeknorm, NAN).

[2] Regulation on compulsory stock in central law, plus separate regulations in some Autonomous Communities.

Source: data gathering by ÖBIG

In five of the analysed countries (three “regulated” and two “deregulated” countries) legislation or self-regulation guarantees immediate availability of frequently asked pharmaceuticals. In Ireland there are neither statutory regulations nor self-regulation to guarantee the immediate availability of pharmaceuticals. As a consequence, patients in Ireland may have to wait up to one day for their medication. Since 1996, Dutch pharmacies are no longer statutorily obliged to have all frequently asked pharmaceuticals in stock. Pharmacies are allowed to specialise, for example in specific patient groups (e.g. diabetes patients). So far, very few pharmacies have specialised. The Dutch Pharmacy Standard (Nederlandse Apotheeknorm, NAN) does, however, require immediate availability of frequently asked pharmaceuticals, others within 24 hours. As health insurances funds require adherence to this NAN guideline, most pharmacies do so.

In Norway the waiting time for pharmacy customers was one of the greatest problems for a long time, as a few years ago it was common that customers of Norwegian pharmacies had to wait several hours for their prescription to be filled. The recent introduction of “direct dispensing”, which means that the prescription is dispensed directly while the patient waits, has contributed to decrease this waiting time considerably.

The only country among those compared, that has defined a minimum stock for pharmacies on a statutory basis is Spain. But there is concern that if the statutory minimum is considered as sufficient, as it is in some regions (in particular the example of Navarra) pharmacies may reduce their stock to this minimum, which can cause an under-supply of medicines in these pharmacies. Austria and Spain are the only countries of the five with legislation or self-regulation on the immediate availability of frequently asked pharmaceuticals, that usually receive deliveries from wholesalers more than twice a day. In several regulated European countries (such as the control group country Austria, but also in Germany and France), additional emergency deliveries of pharmaceuticals within one hour (e.g. by taxi), even for one package, are commonly provided by wholesalers. On the contrary, in Ireland, there are usually one or two deliveries per day by wholesalers to pharmacies, of which the second (afternoon) delivery is not standard.

Opening hours

The availability of pharmaceuticals is also determined by opening hours of POM dispensaries. In all six countries selected some sort of regulation on the opening hours of pharmacies exists, but on different levels: Usually it is not written in national law, but regulated on a regional or community level (like in Austria), or it is defined in agreements with the reimbursement authority (Ireland) or the health insurance funds (the Netherlands). In Finland, the pharmacists may choose opening hours freely, but must report them to the authorities; before 1995 the authorities had to approve the opening hours.

Regulations on opening hours usually include minimum opening hours, during which the pharmacies are required to stay open. Pharmacies have to stick at least to these opening hours. In addition, for example in Ireland, some pharmacies do open for one or two hours on Sundays. This is however on a voluntary basis, and not written in the agreement with the reimbursement authority. In Norway the minimum required number of opening hours has decreased from 40 to 35 hours per week due to the deregulation. Nevertheless, the actual opening hours have increased by, on average, two hours per week.

When comparing the average opening hours on weekdays there are no large differences between the six countries. In most of the countries selected pharmacies are open from Monday to Friday, from 8 or 9 am in the morning to about 6 pm in the evening. The opening hours of pharmacies have to be seen in the context of general opening hours of shops in a country. Pharmacies in shopping centres in, for example, Norway and Finland have longer opening hours (until 8 pm), as the other shops in the shopping centre also stay open in the evening. In the six countries selected, pharmacies have limited opening hours at weekends; they are usually open to the public only on Saturday mornings, and not on Sundays, except in Finland, Spain (partly) and Ireland (partly). Other countries do provide stand-by duty during the weekends, mostly on a rota basis.

Two countries, Norway and Finland, have one pharmacy, which is open and provides full service for 24 hours a day. In Spain, where there are regional regulations concerning the opening hours of pharmacies, 15 percent of all pharmacies provide a 24 hours full service. To ensure 24 hours accessibility to, at least, restricted pharmacy services, pharmacies in the

three deregulated countries, Austria and Spain co-operate on a regional level, thus offering night (and weekend) services on a rota basis. Of the countries providing these rotation shifts, Austria and Spain are the only countries where there is always a pharmacist available during night and weekend duties, whereas in other countries, e.g. in Ireland or the Netherlands, it is common that pharmacists on stand-by duty are reachable via (mobile) phones.

6.2.2 Quality

The quality of health services should be measured by using several dimensions impacting the improvement of the citizen's health and quality of life. Pharmacy services are no exception to this.

As proxy indicators of the quality of pharmacy services, the availability of professional pharmacy staff, the extend of integration in the pharmacy sectors, and the range of products and services offered through community pharmacies were used.

Pharmacy staff

The quality of services is, to a great extent, determined by the pharmacy staff and their qualification. The key person in a pharmacy is the pharmacist, who is responsible for the dispensing of the pharmaceuticals. The six countries show large differences in the number of pharmacists per 10,000 inhabitants (Table 6.10 and Figure 6.2).

Table 6.10: Benchmarking – Pharmacy staff in 2005

Country	Overall country level		In a pharmacy	
	Pharmacists[1] per 10,000 inhabitants	Pharmacists[1] / non-pharmacists	Staff per pharmacy	Pharmacists[1] per pharmacy
	2005[2]	2005[2]	2005[2]	2005[2]
IRL	8.9	n.a.	n.a.	2.7
NL	1.7	0.1	13.0	1.6
N	2.1	0.2	11.5	1.8
A	5.8	0.6[3]	10.9[3]	4.0
FIN	2.6	0.2	10.4	1.7
E	8.5[3]	1.0[4]	3.3[4]	1.8[3]

n.a. = not available

1 According to the Directive 2005/36/EC as of 30 September 2005.

2 Or latest year available.

3 Year 2004 instead of 2005.

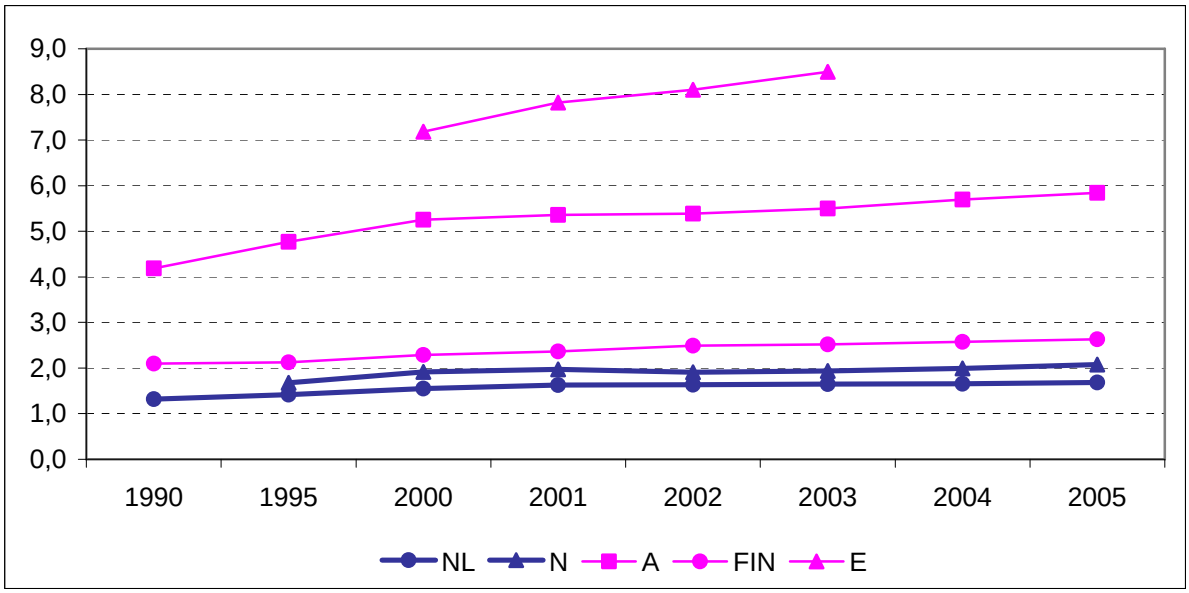
4 Year 2003 instead of 2005.

Source: data gathering by ÖBIG

Whereas in the Netherlands there are only 1.7 pharmacists per 10,000 inhabitants, there are more than eight in Ireland and Spain. Norway and the Netherlands have fewer pharmacists per 10,000 inhabitants than the three regulated countries. However, in these two countries, and in Finland, a large part of the pharmacist's tasks is also performed by so-called prescriptionists (in Norway and in Finland) or by pharmacy assistants (in the Netherlands). Nevertheless, it should be noted that prescriptionists and the Dutch pharmacy assistants have received less training than pharmacists (cf. Table 6.6).

In Norway we can see a sharp decrease in the number of pharmacists per pharmacy and in the number of staff per pharmacy. This decrease started in 2001 and is due to the large increase in the number of pharmacies with the number of pharmacists being relatively stable. In 2003 the number of pharmacists per pharmacy in Norway stabilised, but the number of staff per pharmacy continued to decrease.

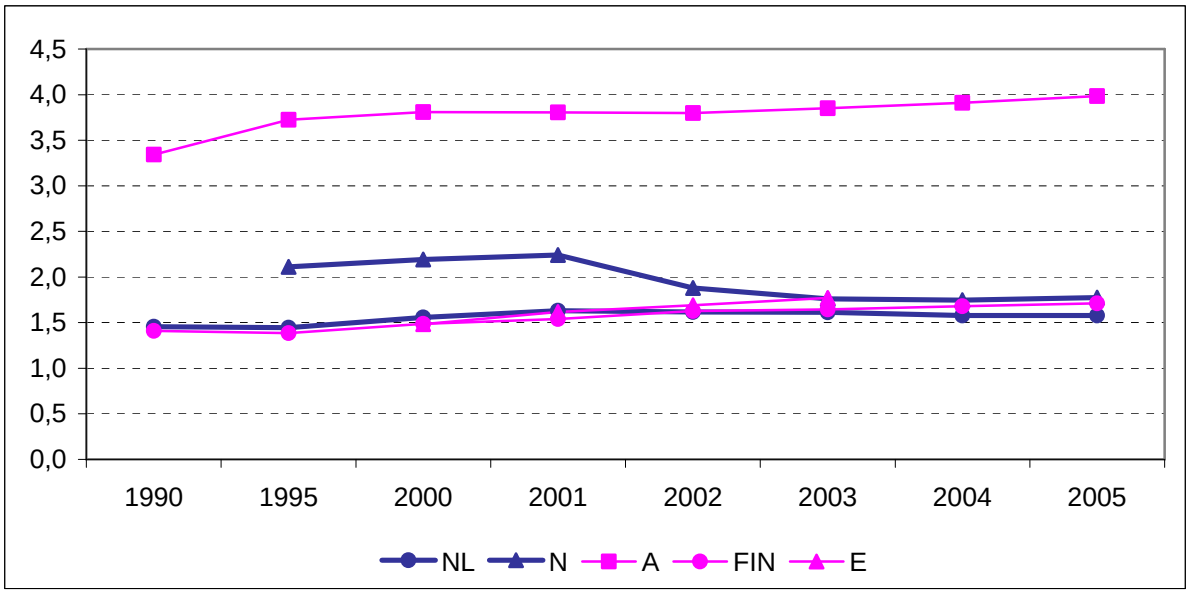
Figure 6.2: Benchmarking – Pharmacy staff: number of pharmacists per 10.000 inhabitants 1990 - 2005



Source: data gathering by ÖBIG

The number of staff per pharmacy in the Netherlands has increased in recent years, mainly due to a large increase in the number of pharmacy assistants. A relatively large part of pharmacy staff in the Netherlands consists of the pharmacy assistants who have the right to dispense medicines. This is also reflected in the low ratio of pharmacists per non-pharmacists.

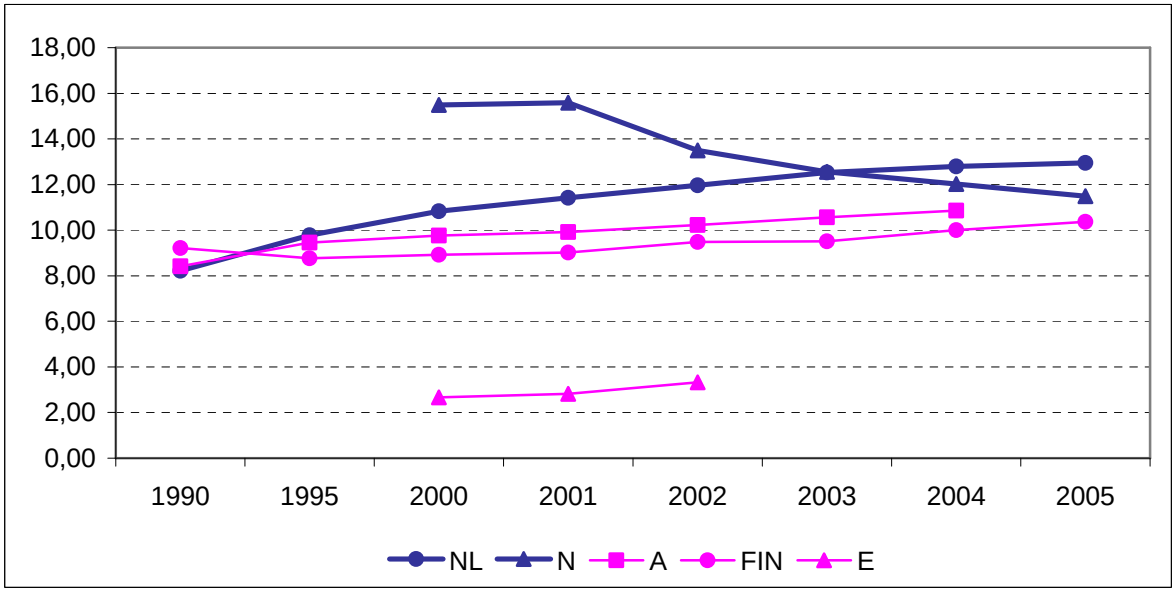
Figure 6.3: Benchmarking – Pharmacy staff: number of pharmacists per pharmacy 1990-2005



Source: data gathering by ÖBIG

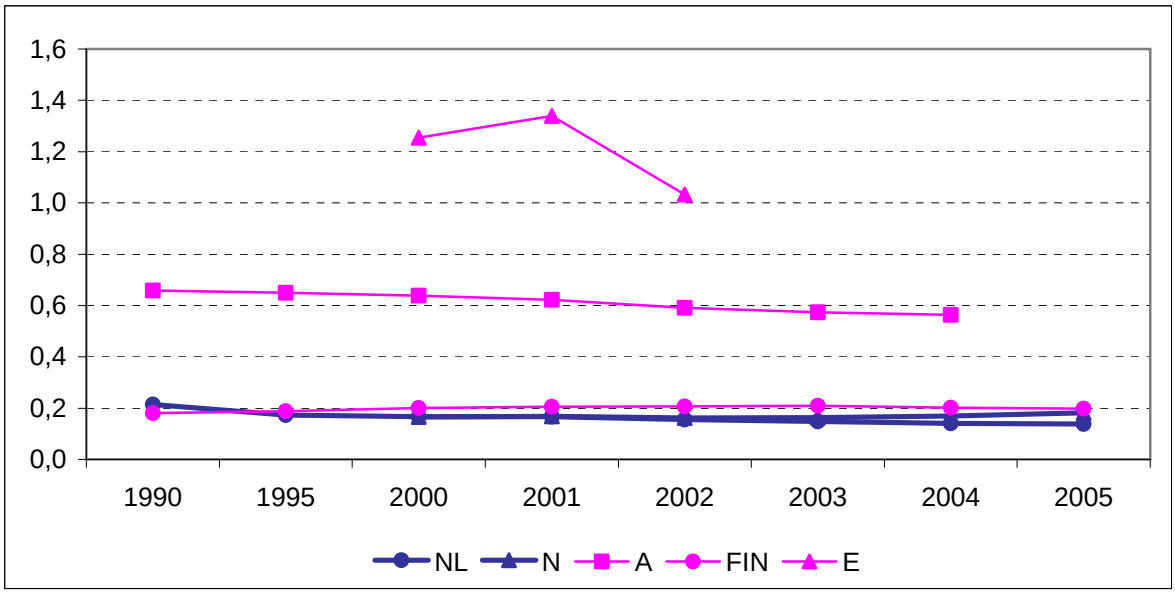
Currently, Norway still has the second highest number of staff per pharmacy, after the Netherlands, which is consistent with the relatively large number of inhabitants that the pharmacies in these countries have to serve (cf. Table 6.7).

Figure 6.4: Benchmarking – Pharmacy staff: staff per pharmacy 1990-2005



Source: data gathering by ÖBIG

Figure 6.5: Benchmarking – Pharmacy staff: Number of pharmacists per non-pharmacists 1990-2005



Source: data gathering by ÖBIG

In Ireland it is often hard to find a pharmacist to run a pharmacy. There used to be very limited places for pharmacy students as only one university (Trinity College in Dublin) offered pharmacy education. A few years ago two other Irish universities started to offer pharmacy education. There have been no pharmacy graduates from these two universities as yet, the first students will finish their studies within the next year. In addition, the abolishment of the "three-year-rule" with the new Pharmacy Act, which is expected to come into force in 2006, will allow pharmacists who have received their degree in other EU countries to open, own or supervise a new pharmacy in Ireland. Experts to whom the authors have spoken expect that this development could lead to a further increase in the number of pharmacies.

Due to a shortage of trained pharmacists, the fluctuation of pharmacy personnel in Ireland and in Norway is relatively high. In Ireland, employed pharmacists stay up to 1 or 2 years in one pharmacy, whereas in Finland a pharmacist stays for 5 to 10 years. In Norway the strong demand for pharmacists due to the large increase in the number of pharmacies also results in high wages and in the recruiting of pharmacists from neighbouring and Baltic countries.

Integration trends

The liberalisation of the ownership of pharmacies has led to major consequences in all three deregulated countries. Pharmacies in these three countries have integrated both horizontally, by forming pharmacy chains, and vertically, as pharmacies are being owned by other actors, such as pharmaceutical wholesalers.

As can be seen in Table 6.11, the biggest change occurred in Norway, where currently already 81 percent of pharmacies are owned by one of the three big wholesalers on the market, whereas only 19 percent of all pharmacies are still owned by pharmacists. Of this 19

percent only 13 pharmacies (2.4%) are completely independent, while the others have some sort of contractual agreement with wholesalers or other pharmacies. When analysing the pharmacy reform in Norway, several experts considered the vertical integration the most important change (Anell 2005).

Table 6.11: Benchmarking – Vertical and horizontal integration in the pharmacy sector

Country	Ownership of pharmacies	% pharmacies owned by pharmacists	Pharmacy chains	% pharmacies not part of a chain
IRL	- Change in ownership in the course of the last 20 years - Corporations formed by pharmacists gained importance: 64% of pharmacies owned by companies in ownership of pharmacists (2001) - Vertical integration: 2 out of the 3 full-line wholesalers own pharmacies. Third one runs an advisory service for selling/ purchasing pharmacies	- 90% (2001)	- Start of pharmacy chains in the mid-1990s - 460 chain pharmacies in 2005 compared to around 170 in 1995 - Clustering of chain pharmacies in Dublin and other big towns - 40 percent of all pharmacy owners have two or more pharmacies	- 24% (2001)
NL	- Foundations and sickness funds have long been allowed to own pharmacies under certain conditions, and did so - Change in ownership ever since supervising pharmacists are allowed to be employed - Wholesalers increasingly buy or partly own pharmacies. - Currently also drugstore chains are establishing pharmacies	- 70%[1]	- Few chains already existed in the early 1990s (owned by foundations or sickness funds)	- 68%
N	- Wholesalers immediately started buying after implementation of new pharmacy act in March 2001 - Currently all three wholesalers own pharmacy chains - Many of the remaining independent pharmacies are partly owned by wholesalers	- 19%[1]	- 80.6% of pharmacies are part of a pharmacy - wholesale chain - 10% of pharmacies have partly-ownership contracts with chains and are loosely connected in an independent chain: “Ditt Apotek” - 7% of the pharmacies have an agreement with a chain, but are not owned by it	- 2%
A	- Pharmacies are exclusively owned by independent pharmacists	- 100%	- A maximum of 1 branch pharmacy is allowed	- 100% [2]
FIN	- Pharmacies are exclusively owned by independent pharmacists	- 100%	- A maximum of 3 branch pharmacies is allowed	- 100% [2]
E	- Pharmacies are exclusively owned by independent pharmacists	- 100%	- No pharmacy affiliates or chains (multiple ownership not allowed)	- 100%

[1] Including pharmacies that are partly owned by a pharmacist and partly by a pharmacy-wholesale chain.

[2] Pharmacies with up to three branch pharmacies under the supervision of a pharmacy are not considered as a pharmacy chain.

Source: data gathering by ÖBIG

This share of 19 percent of the pharmacies being owned by pharmacists in Norway is drastic, even compared to the other deregulated countries (cf. Table 6.11): 70 percent of pharmacies are owned by pharmacists in the Netherlands and 90 percent in Ireland (still almost amounting to the 95 percent from 20 years ago, when the process of changes in ownership regulations started). In the countries of the control group, as regulation forbids vertical integration, all pharmacies are owned by pharmacists.

Pharmacies in deregulated countries can also be partly owned by non-pharmacists. For example, in Norway pharmacists who own a pharmacy themselves may have an agreement with a wholesaler that after her/his retirement, the pharmacy will entirely belong to the wholesaler. In Ireland, under the arrangement provided by one of the three large wholesalers, pharmacists are offered the opportunity to purchase a pharmacy over a period of 12 years. In this scenario, the pharmacist owns an increasing part of the pharmacy, but remains employee, for this period of time.

Whereas pharmacy chains are not allowed in the regulated countries, their emergence and growth have been observed during the last decade in the three deregulated countries selected in this study. In the Netherlands, pharmacy chains have existed for longer, but since it has become easier for non-pharmacists to own a pharmacy, and since members of the Dutch Pharmacy Association (KNMP) are allowed to own several pharmacies, the number and size of pharmacy chains have increased. The current pharmacy chains in the Netherlands continuously aim to grow and include further pharmacies. At the moment, more than 30 percent of all Dutch pharmacies are part of a pharmacy chain.

There are still further Dutch pharmacy chains coming into existence, whereas in Norway the number of pharmacy chains has stabilised. Currently there are three large pharmacy chains in Norway. Together these pharmacy chains own such a large part of the pharmacies that is impossible for other pharmacy chains to enter the market. However, there are nearly no independent pharmacies (2 percent) left which have not been incorporated into a chain. The three pharmacy chains in Norway thus are very strong actors in the Norwegian pharmaceutical sector. To prevent one of the chains holding too much market power, pharmacy chains in Norway are not allowed control more than 40 percent of the pharmacies operating in the country.

Pharmacy chains in Ireland (and the Netherlands) have not yet become as powerful as the three chains owned by wholesalers in Norway. This may be due to the fact that in Ireland and the Netherlands, as a response to multiple ownership, pharmacists started to co-operate and formed their own chains. Nevertheless, in Ireland currently only 24 percent of the pharmacies are owned by independent pharmacists and thus not part of a pharmacy chain, while this percentage amounted to 44 percent in 1993 and to 60 percent in 1985.

Pharmacy services

When analysing the quality of pharmacies across the countries, we have to take a closer look at the range of products and services provided. Considering the fact that there is no straightforward method for measuring the quality of pharmacy services, we have used some proxies

that were considered adequate. With regard to these, there appear to be differences in the quality of pharmacy services between the two groups of countries surveyed in this study.

This clear distinction between the deregulated and the regulated countries is, for instance, seen in the manufacturing of pharmaceuticals in a pharmacy. In the regulated countries almost all pharmacies have a laboratory allowing them to produce, on their own, selected pharmaceuticals, mostly dermatological preparations. This is consistent with the fact that in two of these three countries pharmaceutical preparations, which are specifically tailored to the patients needs, are relatively important. In all three deregulated countries, however, only a few pharmacies are equipped with a laboratory. In order to ensure the availability of pharmacy-manufactured medicines, in Norway and the Netherlands, pharmacies that do not have a laboratory need to enter agreements with other pharmacies that deliver them with these products.

Non-pharmaceutical products play only a small role in all three regulated countries and in the Netherlands (also with regard to the turnover, cf. Table 6.15). In these countries the pharmacies' focus is more on pharmaceuticals. Both in Ireland and in Norway much of the pharmacies' business is made on non-pharmaceutical products, such as skin care products. In Norway, some pharmacies even have a separate counter for non-pharmaceutical products. The selling of non-pharmaceutical products by Norwegian pharmacies is subject to restrictions: The products must aim to retain or improve the health of people, and may not account for a more than 15 percent of a pharmacy's turnover. Restrictions on non-pharmaceuticals are also in force in Austria, where non-pharmaceuticals sold by pharmacies must be related to health in general, and must be presented in such an extent that it will not influence the "looks" of the pharmacy (a pharmacy may not look like a drugstore).

On the other hand, in Ireland the selling of non-pharmaceutical products by pharmacies is something that the customers have always been used to. Irish customers expect to find a large range of non-pharmaceutical products in a pharmacy. Pharmacies in Ireland, especially chain pharmacies in cities, resemble more other shops ("supermarket-like stores"), with their wide range of non-pharmaceutical products such as cameras, sun glasses, boots, post cards and similar products. The opposite is the case for the Netherlands, where customers do not appreciate and accept the selling of many types of non-pharmaceutical products, such as bathing products, by pharmacies. In the Netherlands, these products are mainly sold through drugstores (cf. Section 6.1.2).

Table 6.12: Benchmarking – Quality of pharmacy services

Country	Equipped with laboratory[1]	Products		Pharmaceutical services
		Individual magistral preparations	Non-pharmaceuticals	Other services
IRL	A few	Rarely produced	High percentage of turnover Customers expect to find several non-pharmaceutical items in pharmacies	Health checks[2,3]
NL	A few[4]	Rarely produced 5 percent of reimbursed medicines	Small role for non-pharmaceuticals Comparatively low percentage of turnover	Checking of measuring devices Health campaigns
N	A few[4]	Rarely produced, some pharmacies specialised	Relatively high percentage of turnover Share of pharmacy turnover may not exceed 15%	Health checks[2] (just starting) Membership for customers
A	100%	Rarely produced In terms of value 2.5% of annual turnover	Restrictions on amount of non-pharmaceuticals in pharmacies	Health checks[2] Health campaigns
FIN	100%	1% of prescribed medicines	Small role for non-pharmaceuticals Comparatively low percentage of turnover	Health checks[2] (limited) Health campaigns Dose dispensing
E	100%	Play an important role	Relatively high percentage of turnover Comparatively low percentage of turnover	Health checks[2] Health campaigns

1 Percentage of pharmacies with a laboratory or a place to manufacturer pharmaceuticals.

2 Including diagnostic tests, e.g. blood pressure, cholesterol measurement

3 Just starting, mainly offered by pharmacies in towns and chain pharmacies

4 Some pharmacies are specialised in manufacturing pharmaceuticals. Other pharmacies have agreements with these specialised pharmacies.

Source: data gathering by ÖBIG

Besides the range of products offered in pharmacies, pharmaceutical services are a typical contribution for health care provided by pharmacies. These pharmaceutical services range from typical services, such as interaction checks and disposal of expired pharmaceuticals, to other services, such as blood pressure checks, dose dispensing for elderly people and complete health care promotion programs, e.g. for smoking cessation or diabetes prevention. There are indications, as our interviews with health care stakeholders in the countries analysed have revealed, that in regulated countries pharmacies usually offer a broader range of these other pharmaceutical services.

Health checks are offered by pharmacists in Ireland, Norway, Austria, Spain and Finland. Health checks include for example diagnostic tests, such as blood pressure and cholesterol measurement, and weight checking. Ireland and Norway have just started to offer such

health checks. In addition, pharmacy chains in Norway have started to offer their customers a membership, with which they receive for example discounts on health checks, but not on regular pharmacy services (thus not on medicines or counselling). In the Netherlands these types of services are not offered by pharmacies, but rather by general practitioners and health centres. Dutch pharmacies do offer customers a regular check of their measuring instruments, such as instruments for measuring blood pressure or glucose level at home. Pharmacies in Austria, Finland, Spain and the Netherlands are also regularly involved in special health care promotion programs. In addition, the Association of Finnish Pharmacies issues three times a year a customer magazine Terveydeksi ("For Your Health"), which provides up-to-date information on medicines, management of illnesses and health promotion.

6.2.3 Expenditure

Health expenditure

Health expenditure in all six countries has risen in the past ten years (cf. Table 6.13). The largest rise can be seen in Ireland and in Norway, where health expenditure has more than doubled. In both these countries the large increase in health expenditure coincided with growing economic prosperity. Please note that, when comparing financial data from other countries with that of Norway, the development of the exchange rate of the Norwegian Crown (NOK) in terms of the Euro, which was favourable for Euro-Countries, must be taken into account.

Table 6.13: Benchmarking – Health expenditure in 2003 and development

Country	Health expenditure				Public health expenditure			
	Year 1995		Year 2003		Year 1995		Year 2003	
	€ / inh.	% GDP	€ / inh.	% GDP	in €	% HE	in €	% HE
IRL	991	6.8%	2,493	7.4%	709	71.6%	1,944	78%
NL	1,644	8,4%	2,748	9.8%	1,168	71.0%	1,714	62.4%
N	2,036	7,9%	4,208	10.3%	1,715	84.2%	3,524	83.7%
A	1,868	8,5%	2,099	7.5%	1,302	69.7%	1,419	67.6%
FIN	1,400	7.5%	2,044	7.4%	1,058	75.6%	1,565	76.5%
E	846	7.6%	1,366	7.7%	611	72.2%	972	71.2%

% GDP = in percentage of Gross Domestic Product, % HE = in percentage of health expenditure

Source: data gathering by ÖBIG

In all three deregulated countries the increase in health expenditure was larger than that of the Gross Domestic Product (GDP). Whereas in the regulated countries the share of the GDP spent on health care decreased (Austria) or stayed approximately the same (Finland and Spain). In addition, in 2003 all three deregulated countries spent more on health care per inhabitant than the regulated countries, the highest being Norway with € 4,208 per inhabitant.

There are no structural differences between the deregulated and the regulated countries regarding the share of public health expenditure. In general, no major influence of the pharmacy system on the pharmaceutical expenditure could be observed, as although the share of public health expenditure in Norway is rather high, it is relatively low in the Netherlands.

Pharmaceutical expenditure

Considering the pharmaceutical expenditure we see in table 6.14 that the three regulated countries spent a larger share of the health expenditure on pharmaceuticals in 2003. In addition, whereas the share of the pharmaceutical expenditure has increased between 1995 and 2003 in the regulated countries, it has been rather stable in the three deregulated countries. Nevertheless, we see that in Ireland and in Norway the growth rate of the pharmaceutical expenditure per inhabitant between 1995 and 2003 is higher than that in the regulated countries. This indicates that liberalisation of the pharmacy sector, and increasing competition in the pharmacy sector, does not necessarily lead to a containment of the expenditure on pharmaceuticals. We will further discuss this below, under “sales and price development”.

Table 6.14: Benchmarking – Pharmaceutical expenditure in 2003 and development

Country	Pharmaceutical expenditure (PE) / inhabitant					Public PE
	Year 1995		Year 2003		Growth rate	Year 2003
	in €	% HE	in €	% HE	95-03	% PE
IRL	103	10.4%	295	11.8%	186.4%	86.2%
NL	181	11.0%	314	11.4%	73.5%	57.4%
N	183	9.0%	372[1]	9.4%[1]	103.3% [1]	58.6%[1]
A	197	10.6%	354	16.9%	79.7%	70.2%
FIN	197	14.1%	327	16.0%	66.0%	53.7%
E	163	19.2%	298	21.8%	82.8%	73.5%

% HE = in percentage of health expenditure, PE = pharmaceutical expenditure, % PE = in percentage of total pharmaceutical expenditure

[1] Year 2002 instead of 2003.

Source: data gathering by ÖBIG

It is noticeable that the share of public pharmaceutical expenditure on total pharmaceutical expenditure in Finland (approximately 54%) and Norway (approximately 59%) is much lower than the respective share on public expenditure on total health expenditure (Finland: 76.5%, Norway: about 84%). The reason for that is the pharmaceutical reimbursement system in these two countries: In Norway only pharmaceuticals prescribed with a "blue prescription" are paid almost fully by the National Insurance Scheme and in Finland the general reimbursement level of pharmaceuticals is 50 percent (for severe and chronic diseases up to 100%).

In the other four countries almost all POM are more or less fully reimbursed, especially in Ireland. This is reflected in the highest share of public pharmaceutical expenditure on total pharmaceutical expenditure.

Sales

The turnover of pharmacies can be roughly divided into two categories: turnover made on pharmaceuticals and turnover made on non-pharmaceutical products, such as medical devices, and beauty products. In general, the focus of pharmacies in all six countries is on the dispensing of pharmaceuticals. In two of the deregulated countries, Ireland and Norway, the share of the turnover that results from the selling of non-pharmaceuticals is greater than in the most of the regulated countries. Although in these two countries non-pharmaceuticals are an important source of income for the pharmacies, this is not the case in the Netherlands and in the regulated countries.

As mentioned previously under “pharmacy services”, the Irish population makes very much use of the pharmacy when buying for example bathing products. In Norway non-pharmaceutical products are mainly skin care products. To avoid that non-pharmaceuticals take the overhand and to maintain the typical looks of the pharmacies the percentage of a pharmacy’s turnover made on non-pharmaceuticals may not exceed 15 percent in Norway. As we see from Table 6.15 the Norwegian pharmacies are on average near their legal limit concerning the share of non-pharmaceuticals. As in Norway, Austrian pharmacies must also restrict the share of non-pharmaceutical products in order to maintain the typical looks of a pharmacy. However, in Austria no specific limit is defined.

The share of non-pharmaceuticals sold through pharmacies is partly determined by the traditional background. For example in the Netherlands people are not used to pharmacies selling for example bathing and beauty products, and thus will not buy them there. This has been an important cause of the fruitless attempt of the British pharmacy chain Boots to enter the Dutch pharmacy market.

Another clear result of the analysis shows that the turnover of OTC medicines in pharmacies is likely to drop when OTC be also sold in other dispensing outlets: Since the establishment of LUA-shops in Norway pharmacy sales of paracetamol dropped by 30.1 percent and ibuprofen sales by 16.7 percent.

Table 6.15: Benchmarking – Pharmacy turnover in 2004

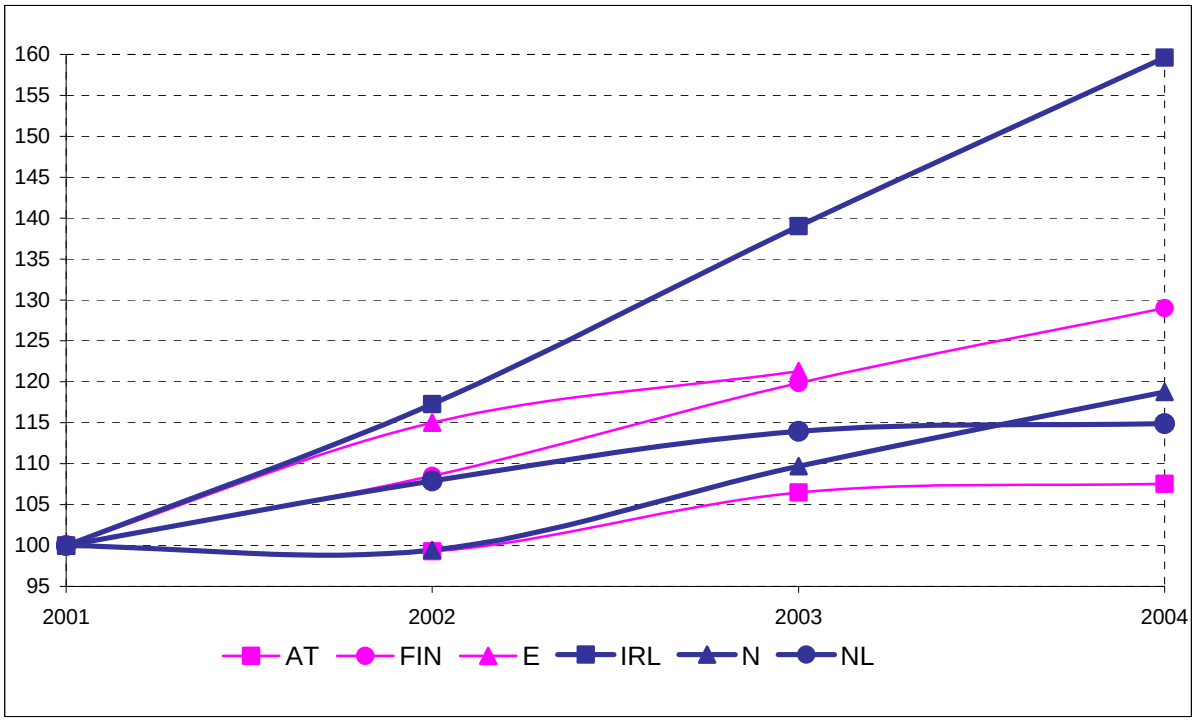
Country	Turnover of products in % of pharmacy turnover	
	Pharmaceuticals	Non-Pharmaceuticals
IRL	81 %	19 %
NL	95 %	5 %
N	86 %	14 %
A	91 %	9 %
FIN	95 %	5 %
E	83 %	13 %

Source: data gathering by ÖBIG

Besides the pharmaceutical market capitalisation, which is quite different in the six analysed countries (Spain being the biggest market), the average market growth also varies considerably: Whereas the total market rose between 2001 and 2004 by 60 percent in Ireland, the growth in Austria was rather moderate with only 8 percent (cf. Figure 6.6).

In Ireland the market growth is on the one hand based on the prospering economy and on the other hand on changed pharmaceutical consumption habits. The prices of POM in Ireland remained rather stable as there is a price freeze on prescription-only medicines since 1993.

Figure 6.6: Benchmarking – Development of pharmaceutical market in deregulated countries versus regulated countries (basis 2001)



Source: AESGP 2001-2004, data gathering by ÖBIG

In terms of OTC the highest growth rate could be observed in Spain, whereas the growth rate in Austria and Finland (plus 5% respective 8%, 2001-2004) was comparable low.

Price comparison

One of the arguments quoted in favour of liberalisation is that due to deregulation the overall price level decreases, which, in the field of health care, would benefit the patients and the health care systems struggling to contain health expenditure.

As prices of POM, especially if they are reimbursable, are directly (via statutory pricing) or indirectly (via price agreements or reimbursement criteria) controlled/monitored by the state the price development of OTC medicines is more likely to show the impact of deregulation on out-of-pocket pharmaceutical spending.

A cross-country comparison of three OTC blockbusters (paracetamol 500 mg tabs, ibuprofen 200 mg tabs and aciclovir 2 g (50 mg/g) cream/ointment) on pharmacy purchase price level is shown in Figures 6.7, 6.8 and 6.9.

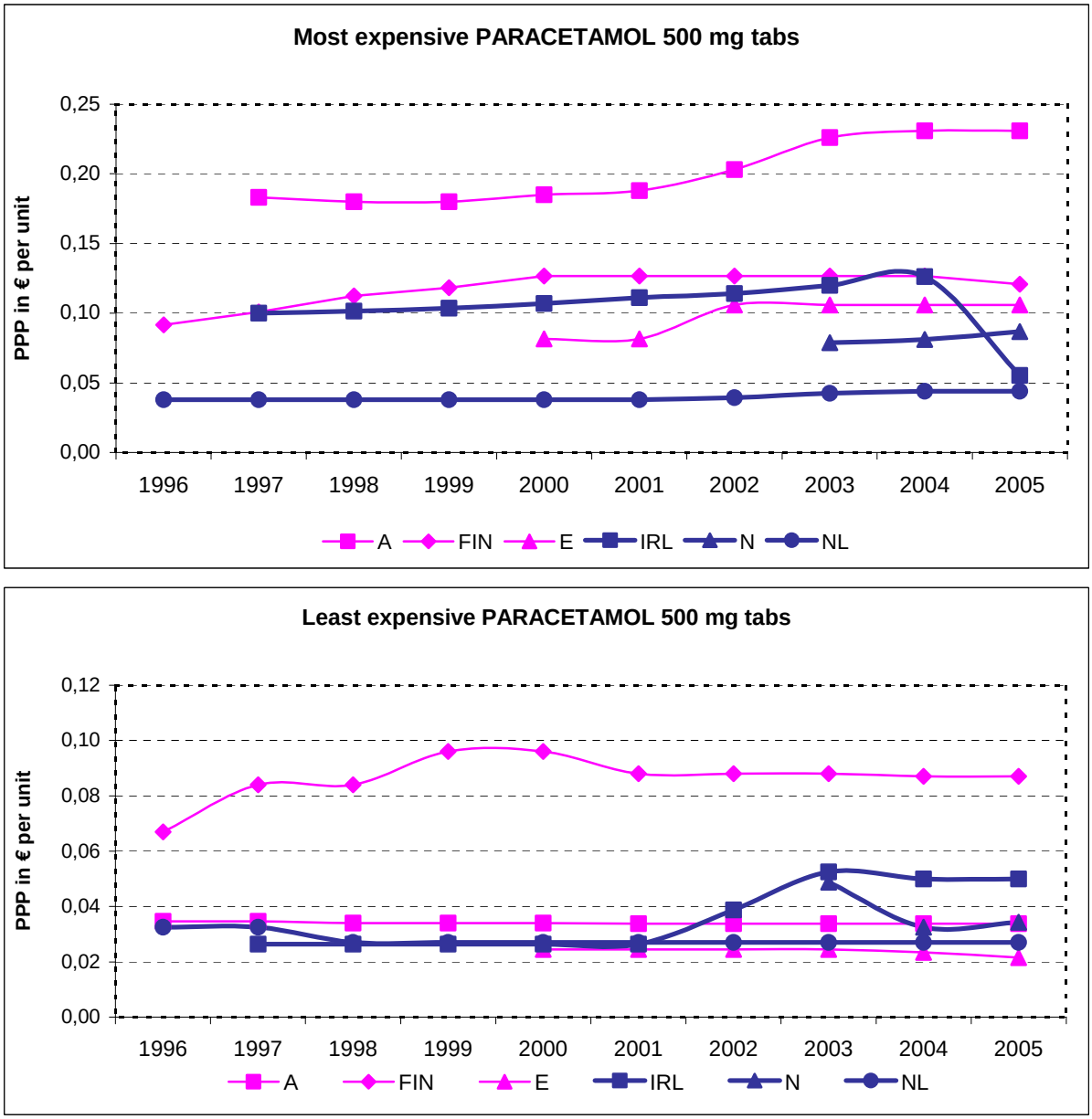
With the exception of Ireland and Finland, the prices of the respective most expensive paracetamol tabs rose in all countries on average by 3 to 6 percent during the last five years. The absolute price per unit in Euro is not exactly comparable, as in Austria the most expensive OTC on the market containing 500 mg paracetamol is 'Vicetamol' effervescent powder.

Looking at the least expensive paracetamol OTC we see that since 2000 its price has gone down in all countries except Ireland, where it rose by 15.7 percent. This is quite interesting as according to reports published by the European Commission deregulation would be expected to lead to price reductions and not rises. In addition, several interview partners observed that after de-listings the prices of such de-listed products tend to rise.

The price of ibuprofen in Ireland is also characterised by fluctuations, showing a peak in 2002 for the most expensive product on the market, accompanied by an all time low of the least expensive 200 mg ibuprofen tablets by Clonmel. It is noticeable, that the prices of the most expensive OTC ibuprofen rose by approximately 13.4 percent in Ireland and by approximately 3.2 percent in the Netherlands between the years 2000 and 2005. Contrarily, in the regulated countries its price went down (Spain) or at least remained stable (Austria, Finland), cf. Figure 6.8.

The highest price variation between the most costly and the least expensive product can be observed in Ireland (price difference: € 0.20 per tab), whereas the smal lest difference is currently found in Norway and Austria.

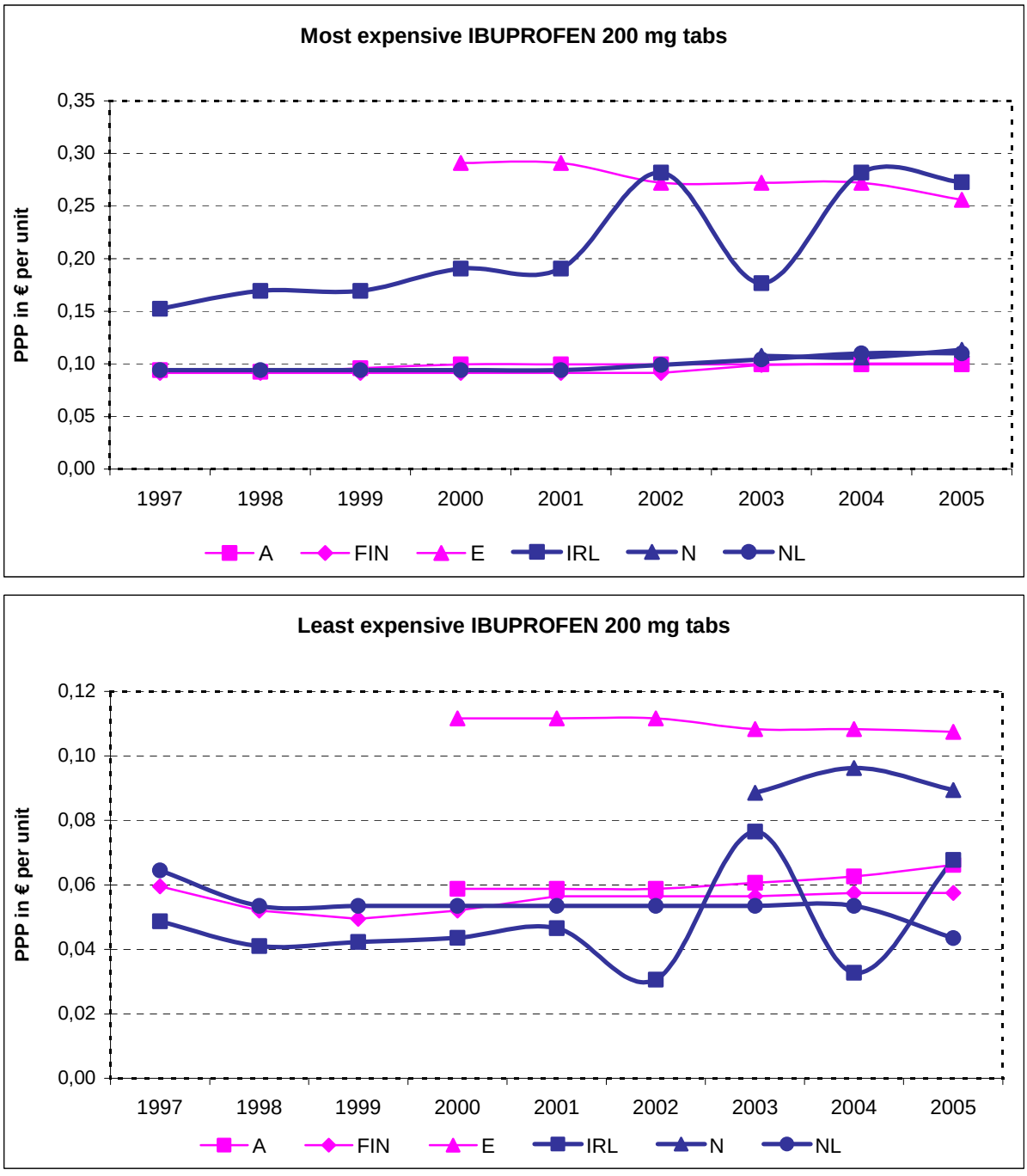
Figure 6.7: Benchmarking – Price development of paracetamol in case study countries versus control group countries 1996 - 2005



Note: In Austria, the most expensive product is effervescent powder (1999 = estimation)

Source: data gathering by ÖBIG

Figure 6.8: Benchmarking – Price development of ibuprofen in case study countries versus control group countries 1996 - 2005



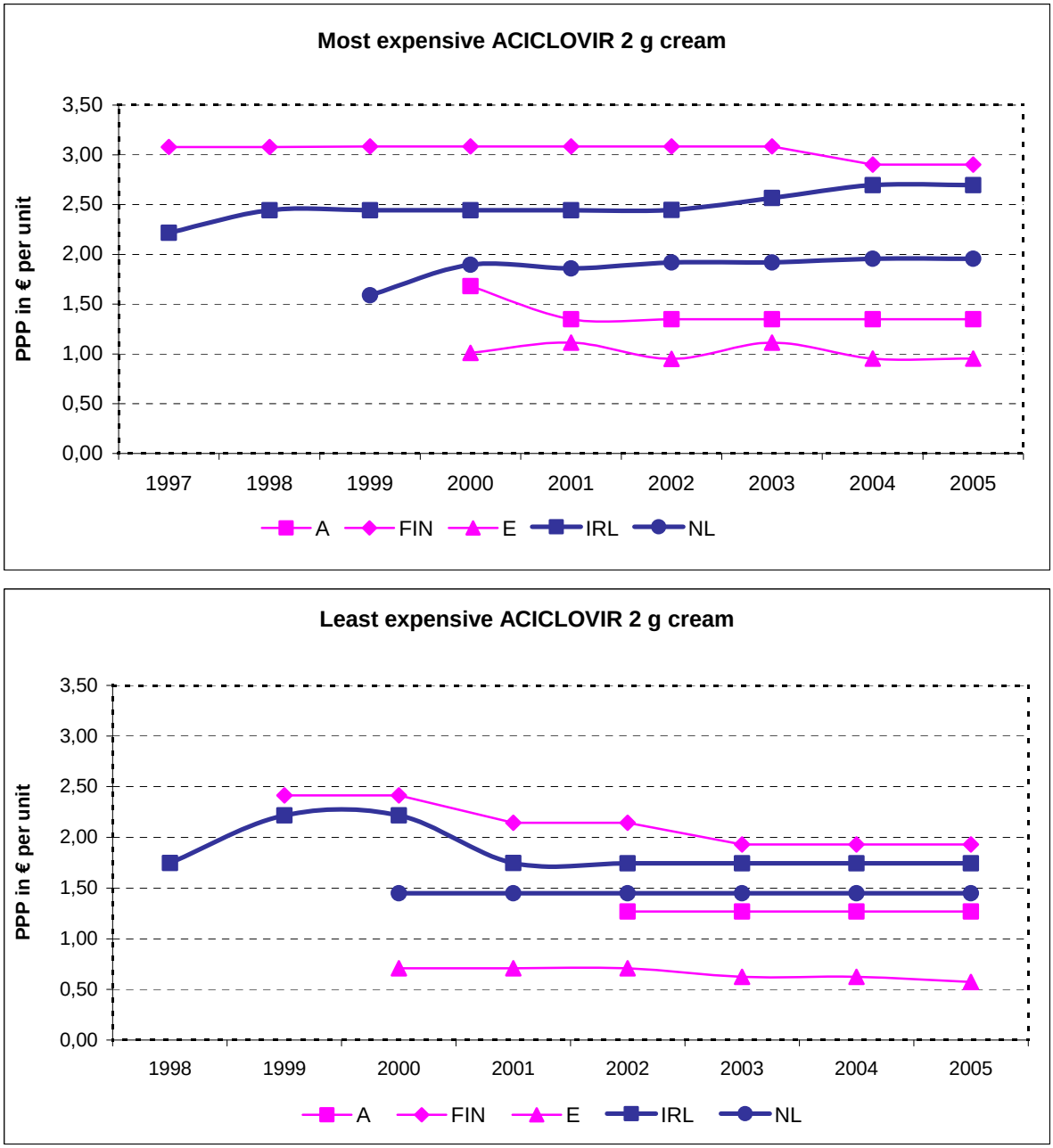
Austria: 1999 = estimation

Source: data gathering by ÖBIG

Aciclovir price development is characterised by an overall price reduction from 2000 to 2005, ranging from about minus 4.0 % in Ireland, Spain in Finland (although in the latter from a comparatively high level) for the least expensive product, to a price increase in Ireland by

2.0 % for the most expensive aciclovir cream on the market. Again Figure 6.9 reveals that the growth rates in regulated countries are below those of the deregulated countries.

Figure 6.9: Benchmarking – Price development of aciclovir in case study countries versus control group countries 1996 - 2005



Source: data gathering by ÖBIG

In Norway no comprehensive analysis was possible for the OTC under survey as the observation period was too short, but a Norwegian governmental report published in October 2004 also reported rather high growth rates for various OTC substances, among those ibuprofen, paracetamol and fungicides.

7 Assessment

7.1 Role of community pharmacists

The pharmacist is one of the key health professionals. As health care in general and pharmaceuticals in particular are considered a unique good for which special care and knowledge are required, the education and training of pharmacists in the European Union is covered by profession-specific Directives designed to guarantee good quality of care and service provided (cf. section 6.1.5). Furthermore, pharmacists practise within strict codes of ethics and professional standards. One key document to mention within this context is “Good Pharmacy Practice (GPP) in community and hospital pharmacy settings”, which provides standards for pharmacy service. The document was developed by the International Pharmaceutical Federation and adopted and incorporated in a WHO document (WHO 1996). PGEU also adapted this document to the European context and incorporated it as key European standard.

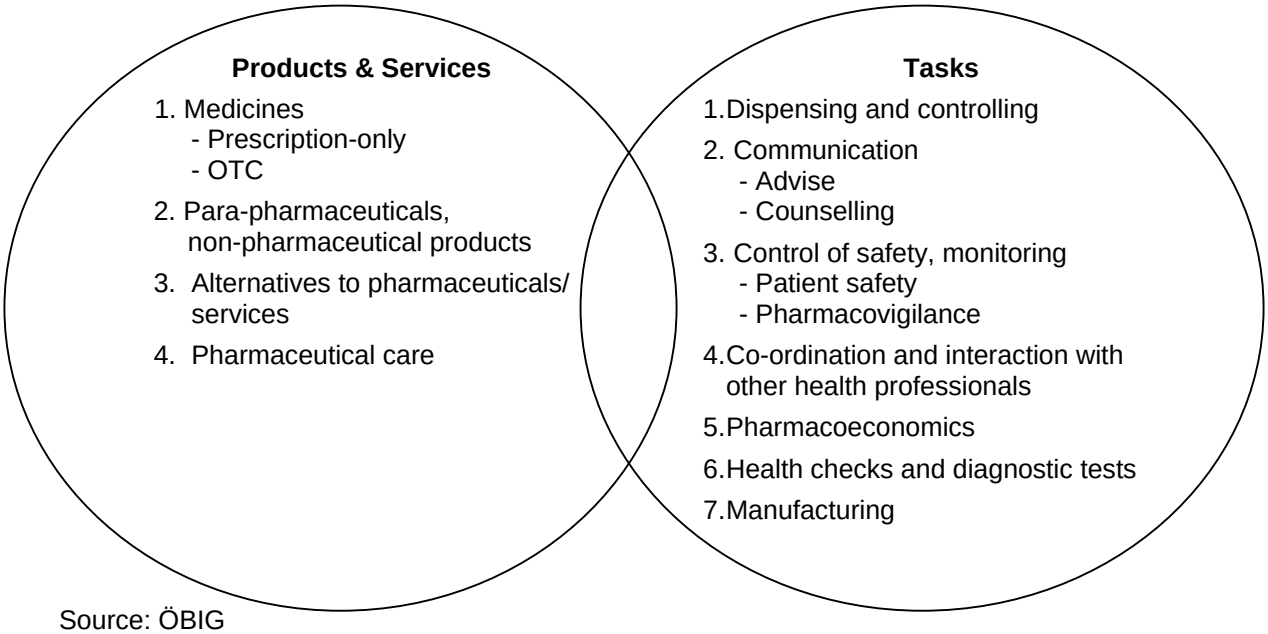
Professionals trained as pharmacists are active in several fields, such as the pharmaceutical industry or wholesale, clinical laboratories and hospitals, but mainly in community pharmacies.

In community pharmacies, pharmacists play an important role as health professionals in the prevention and treatment of illnesses. It is a fact that the role of pharmacists, especially that of community pharmacists, has been changing over the past decades, as “the pharmacist is no longer just a supplier of medicines and a concocter of medicinal products, but also a team member involved in the provision of health care” (WHO 1998).

This quotation refers to the core task of community pharmacists which is the dispensing of, mainly prescription-only, pharmaceuticals. Filling and control of prescriptions is still an important activity and requires in-depth expertise on the pharmaceuticals dispensed as well as knowledge on the patients and communication with other health professionals. The activities of a pharmacist require the surveillance of the pharmaceuticals dispensed with the purpose to avoid dangerous interactions and negative side-effects. Thus, the filling of prescriptions very much involves good communication with, and information to, the patients.

The other traditional task of community pharmacists quoted in the WHO document concerns the manufacturing of pharmaceuticals which is still today of much importance in several countries, as it enables patients to receive tailor-made preparations for her/his purpose. This activity also reflects the role of community pharmacists in their interaction with the patients and their needs on the one hand, and with the prescribers on the other.

Figure 7.1: Assessment – Responsibilities of community pharmacies



Source: ÖBIG

These two examples of, more traditional, activities have made evident that providing health information and advise is a key responsibility of community pharmacies. This is not only true for prescribed medication (e.g. it is known that in the treatment of chronic diseases no more than 50 percent of the patients, left on their own, take pharmaceuticals as intended by the prescribers, see Haynes 1999), but advise and counselling have particularly gained relevance with the increasing importance of self-medication and self-care.

In this function as an adviser in public health, a community pharmacist is asked to initiate a dialogue in order to obtain sufficient detailed information on the condition of the patient and her/his needs. Based on this "screening", the pharmacist will then pass on relevant information (e.g. how to take the medication, safety issues). When advising, a pharmacist has to take care that a self-medication product does not interact negatively with any prescribed pharmaceuticals which the patient takes, and that self-care does not lead to negative effects for the patient. Thus, a community pharmacist must not only have good knowledge on pharmaceuticals, but should also be trained in communication techniques as well as in screening for specific conditions and diseases of the patients.

The authors of this report have developed an illustrative overview in Figure 7.1, which sums up the key activities performed by community pharmacists. The pharmacist's tasks are interlinked with the "products" which they provide. These are, in the first place, pharmaceuticals (prescription-only medicines and OTC products), complemented by para-pharmaceuticals and non-pharmaceutical products such as medical devices, on which pharmacists are also required to give information and advice. Further "products" in community pharmacies are services in pharmaceutical care, where pharmaceutical care is defined as "the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life" (ASHP 1993). Pharmaceutical services, ranging from health checks and diagnostic tests (like blood pressure and cholesterol measur-

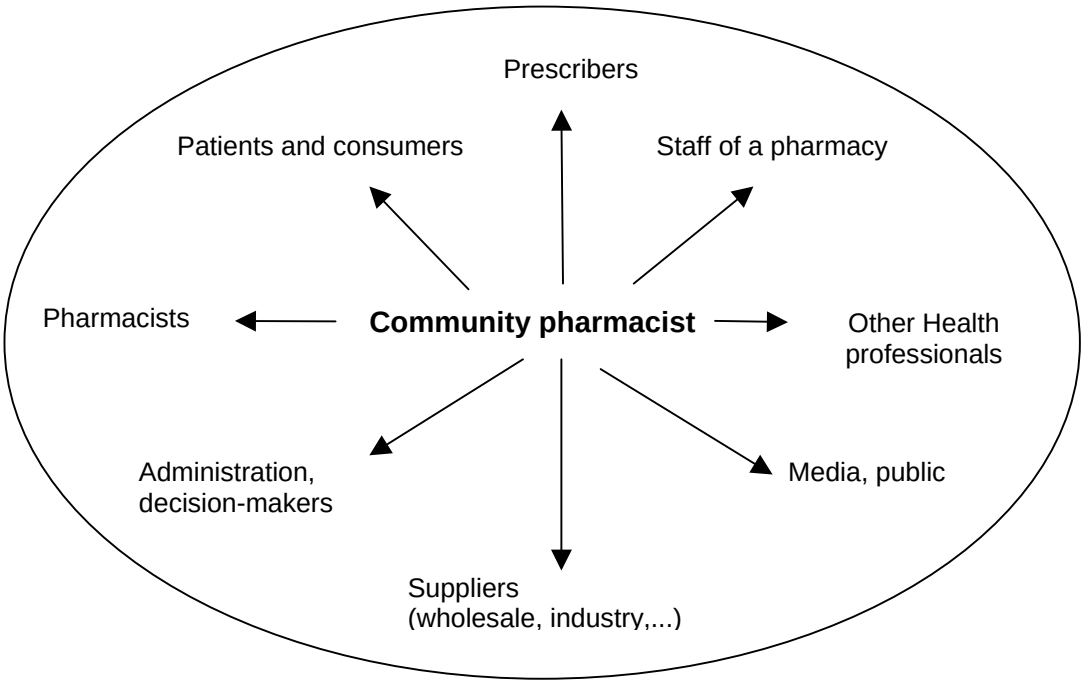
ing) to promotion programs (e.g. smoking cessation, diabetes prevention) and disease management, are offered by pharmacies in several countries (cf. Section 6.2.2) and highlight again the role of community pharmacists in public health, with regard to prevention and promotion.

The importance of health information provided in community pharmacies is also supported by statistics saying that one of four consumers who visit a pharmacy "only" ask for health advice and do not buy any pharmaceuticals (Consejo General de Colegios Oficiales de Farmaceuticos España 2003). In addition, surveys have shown, that the pharmacist ranks among the most trusted health professionals and is highly recognized for his reliability and professionalism (TNS Gallup 2003, Newcom 2005).

In this context, it should also be reminded that community pharmacies are often, in particular in rural areas, the first point of contact with regard to health related issues, which was also mentioned in the authors' interviews with health care stakeholders. Patients come to "their" community pharmacist with specialized questions and with clear expectations on advice and help.

On the other hand it can also happen that the public sees the pharmacist from a different perspective – more as a specialized shop-keeper, instead of a health professional. However, it seems that this different public impression of pharmacists is related to a large range of non-pharmaceutical products being offered by the pharmacies.

Figure 7.2: Assessment – Interaction of community pharmacists



Source: ÖBIG

As discussed and shown in Figure 7.1, co-ordination and interaction with other health professionals is a key activity of community pharmacists. This is, of course, not restricted to advising and counselling patients. Contact to the prescribing physicians may be necessary in several cases, like in medicines management programs where, for example, the compliance of patients is monitored. Furthermore, as high quality medicines' supplier, community pharmacists have to keep good and regular contacts to their suppliers in the distribution chain.

There are thus various interactions of community pharmacists, which are displayed in Figure 7.2. Reaching the end of this section, one further role of community pharmacists should still be mentioned. To keep up-to-date and ensure a high quality of pharmacy services, an independent pharmacist owning a community pharmacy must actively encourage and motivate her/his staff (employed pharmacists and other personnel) and must take care that their services also correspond to the high-level standards of practice.

7.2 Evaluation of pharmacy services

7.2.1 Country-specific assessment

The country profiles presented in chapters 2 to 5 provide an elaborate discussion on the changes and developments that have taken place in each of the six countries, for example with regard to pharmacy regulations, provision of community pharmacies and pharmaceutical expenditure. A summary of the main changes, and of the analysis of the developments and the current situation in the pharmacy sectors is presented in table 7.1.

The pharmacy sector in Ireland appears to be a rather liberal one, as there are few regulations. The regulations that do exist are mostly laid down in the Community Pharmacy Contractor Agreement. For example, Clause 9 of this agreement describes the professional duties of pharmacists. Until the mid-1990s, there had never been a regulation on establishment nor on ownership of pharmacies in Ireland. In 1996, regulations on the establishment of pharmacies were introduced by the then Minister of Health and Children. In 2002, these establishment criteria were revoked.

In general, the density of POM dispensaries (mainly pharmacies, but also self-dispensing doctors) in Ireland is good compared to other countries. There has been a decrease of the number of inhabitants per POM-dispensary since 2002, but the number still has not reached the level of 1990. However, there are indications that pharmacies tend to cluster in the more attractive urban areas. The real consequences of this clustering can not be seen yet, but an important issue for the coming years will be to assure a sufficient pharmaceutical coverage in the rural areas of Ireland.

The removal of the derogation, according to which pharmacists who have received their degree outside of Ireland are not allowed to manage a pharmacy which is less than three years old, and the increase in the number of places for pharmacy students are expected to lead to an increase in the number of pharmacists able supervise (new) pharmacies in Ireland.

Like Ireland, the Dutch pharmacy sector has always been rather liberal. As an example, the selling of OTC medicines outside pharmacies was already allowed in the 19th century. Statutory establishment rules for pharmacies never existed, instead the Royal Dutch Pharmaceutical Society (KNMP) applied its own establishment policy and accompanying sanctions. Since 1998 the application of restrictions to the establishment of pharmacies is no longer allowed. Nevertheless, there is still some influence on the establishment of new pharmacies through the health insurances, who have the right to choose whether to contract a pharmacy or not, and through community zoning plans. The health insurances' right to contract also enables them to define requirements for pharmacies, which mostly include the Dutch Pharmacy Standard.

Like in Ireland, POM in the Netherlands are also dispensed by self-dispensing doctors in some rural areas. The number of inhabitants per POM dispensary (pharmacies, self-dispensing doctors and polyclinic pharmacies) is relatively high, compared to other European countries. In addition, pharmacies are more likely to establish in urban areas than in rural areas.

Both in Ireland and in the Netherlands the main challenge for the pharmacy sector currently lies in the drafting of a new Pharmacy Act. In Ireland the „three-year-rule" (derogation) will be removed, fitness-to-practice rules will be introduced and the Pharmaceutical Society of Ireland will receive a stronger statutory basis and the possibility of sanctioning pharmacists. The discussions about the formulation of the new Pharmacy Act in the Netherlands mainly consider the abolishment of the regulation which says that a pharmacist always needs to be present in a pharmacy. This might mean that in the future pharmacies do not need to have a pharmacist present at all time.

In Norway, the pharmacy sector used to be one of the most regulated sectors until March 2001. The Norwegian Board of Health used to decide on the establishment of new pharmacies, and Norway had a relatively high number of inhabitants per pharmacy compared to other European countries.

On March 2001 a new Pharmacy Act came into force, which introduced a free establishment of pharmacies and allowed non-pharmacists to own pharmacies. In addition, under the new Act the quality standards for pharmacies were tightened and focussed more on what a pharmacy should look like.

As a consequence of the removal of the establishment rules, the number of pharmacies in Norway increased drastically, by 35 percent, between 2001 and 2005. Nevertheless, the number of inhabitants per POM dispensary in Norway is still relatively high. In addition, like in Ireland and the Netherlands, new pharmacies tend to cluster in urban areas. Due to the sharp increase in the number of pharmacies in Norway, the number of pharmacists and other personnel per pharmacy has decreased since 2001. A shortage of pharmacists and other personnel might become a problem if the number of pharmacies continues to increase. In a report published by ECON, pharmacists said to believe that the increasing work pressure, which is largely due to the lower number of staff per pharmacy, has led to a decrease in the quality of the information provided to the patients. The patients however, believe that the level of information is equally high to that before 2001.

As part of the liberalisation process, a range of OTC medicines have since 2003 been allowed to be sold outside pharmacies, in so-called 'LUA shops'. In the past years the number of these LUA shops has risen to nearly 6,000, reducing the turnover of pharmacies with OTC that may be sold also in LUA shops by 25-30 percent. Besides the improvement in the accessibility of medicine dispensaries in Norway, another positive development of the past years is the decrease in the time that a patient has to wait for his/her prescription to be filled.

In all three deregulated countries it is now possible for non-pharmacists to own pharmacies, and multiple ownership (more than one pharmacy per owner) is allowed, which has led to the development of pharmacy chains and to pharmacies (or pharmacy chains) being owned by other actors in the pharmaceutical distribution system. In Norway, the share of pharmacies owned by one the pharmacy-wholesale chains is particularly large (81%). Even though the Government has set a limit, which means that a pharmacy chain is not allowed to incorporate more than 40 percent of all pharmacies, there are only three large pharmacy – wholesale chains on the Norwegian market, which thus have relatively much power.

In Austria, Finland and Spain, which all have defined criteria for the establishment of new pharmacies, the density of POM dispensaries has been rather stable the past ten years. The ownership of pharmacies in these countries is restricted to pharmacist and multiple ownership of pharmacies is not allowed. Consequently, we do not see horizontal nor vertical integration in the pharmacy sectors.

The major challenges for the pharmacy sectors of Finland and Austria come from the increasing pressure from drugstore-owners, who either want to receive licences for the dispensing of OTC products, or want to increase the range of OTC products which they are allowed to dispense. Furthermore, for the near future no drastic legal changes are expected in the pharmacy sectors in the regulated countries at a national level. Nevertheless, developments on a EU level, towards liberalisation might influence the pharmacy sector in the regulated countries.

Table 7.1: Assessment – Highlights on the selected countries

Country	Key changes	Analysis
Case study countries		
Ireland	• Introduction of establishment rules in 1996 • Revocation of establishment rules in 2002 • "Three-year-rule" (EU derogation): pharmacists trained outside Ireland are not allowed to own, supervise or manage a pharmacy less than 3 years old (i.e. no openings of new pharmacies allowed) – is expected to fall with new Pharmacy Act • Apart from "three-year-rule", any individual or legal person may, in principal, own one or more pharmacies (multiple ownership allowed) • New Pharmacy Act with "fitness-to-practice"-rules under preparation	• Liberal environment (not due to deregulation, but historical development) • Good standing of pharmacists, but nevertheless considered as normal shop-keepers by public • Starting of pharmacy chains in the mid-1990-ties, often owned by pharmacists • Clustering of pharmacies in attractive places (big cities) • Shortage of training posts for pharmacists till some years ago, many UK-trained pharmacists, high fluctuation • Pharmaceutical care projects are just starting (namely pharmacies in cities) • Wholesalers involved in pharmacy business
Netherlands	• Multiple ownership is allowed since 1987 • Since 1992 insurance companies are no longer obliged to contract each pharmacy • Interdepartmental Working Group for Distribution of Pharmaceuticals (1994): recommendations regarding the revoking and adjustment of laws, in order to increase marketing • In 1996 the requirements for opening hours and equipment of pharmacies were abolished • Since 1998 the Royal Dutch Pharmaceutical Society is no longer allowed to apply establishment criteria • Since 1999 also non-pharmacists can own pharmacies • Currently under dicussion that, under the new Pharmacy Act, pharmacists may be supervising pharmacists in more than one pharmacy	• Liberal environment (not due to deregulation, but historical development) • Increasing role for social insurance funds. Insurances formulate requirements • Never known statutory restrictions on establishment and multiple ownership: Policy determined by Royal Dutch Pharmaceutical Society • OTC market deregulated at least since 1850 • Since 1987 forming of pharmacy chains, since 1999 partly integrated in wholesale • Many pharmacy tasks performed by pharmacy assistants

Table continued: Assessment – Highlights on the selected countries

Country	Key changes	Analysis
Case study countries		
Norway	• On March 2001 a new Pharmacy Act came into force • With the new Pharmacy Act: - the limits on the establishment of new pharmacies were abolished and it became possible also for non-pharmacists to own pharmacies. - Pharmacists are allowed to substitution generics - the minimum standards for pharmacies were tightened and focussed more on what a pharmacy should look like • Since 2003 OTC products may also be sold in “LUA“ (medicines outside pharmacies) shops	• Since 2001 there has been a drastic increase in number of pharmacies, especially in urban areas • With the establishment of many new pharmacies the number of pharmacists and other personnel per pharmacy has decreased • Three large pharmacy chains have established, pharmacists have sold pharmacies to chains for a lot of money • Vertical integration in the pharmacy sector, in that the pharmacy chains are being owned by (international) wholesaler companies • Large increase in the number of LUA-shops, decrease in the turnover of OTC products in pharmacies • Observed improvement in quality of pharmacy services (increased provision with community pharmacy and decreased waiting times)

Table continued: Assessment – Highlights on the selected countries

Country	Key changes	Analysis
Control group countries		
Austria	• In 1998 change in the regulations on the establishment of new pharmacies (fall of one criterion; there are still geographic and demographic criteria for the establishment) • In 2002 shift of responsibility to regional authorities • On 1 January 2005 a new reimbursement scheme for pharmaceuticals was introduced	• Self-dispensing doctors play an important role, especially in rural areas. • No major changes in number of pharmacies, staff, etc. • No vertical and horizontal integration due to regulatory framework on ownership rules, all pharmacies owned by an independent pharmacist • Drugstores want to play an increasing role in dispensing of OTC products • Decreasing role of OTC in pharmacies, low importance of non-pharmaceutical products for pharmacy business
Finland	• Generic substitution allowed since 1 April 2003 • Deregulation of opening hours of pharmacies in the 1990s • Deregulation of territorial monopoly for pharmacies in the 1990s	• No major changes in number of pharmacies, no closures of pharmacies • Increase in the number of staff • Relatively high importance of OTC for pharmacy business, small role for non-pharmaceutical products
Spain	• Regionalisation of the National Health Service, shifting of competences to the Autonomous Communities, also with consequences for the pharmacy sector • Thus, basic framework on national level, with specific regional rules: adjusted criteria for the establishment rules, opening hours, etc.	• Small pharmacies, low number of staff, thus high ratio of pharmacist per non-pharmacists in the staff of a pharmacy • Good provision with pharmacies • No major changes in number of pharmacies, staff, etc. • No vertical and horizontal integration due to regulatory framework on ownership rules, all pharmacies owned by independent pharmacist • Filling of prescriptions continues to be a core task of community pharmacies, high importance of pharmacy-manufactured pharmaceuticals and non-pharmaceutical products, comparatively low significance of OTC for pharmacy business

Source: ÖBIG

7.2.2 Cross-country assessment

The objective of this study is to analyse the effects of deregulation of the pharmacy sector on the accessibility of pharmaceuticals, the quality of pharmacy services and pharmaceutical expenditure. The indicators developed for these three pillars were analysed in more detail in Section 6.2. In Table 7.2 the results of this benchmarking analysis are presented on an aggregated level. The indicators that were analysed in section 6.2 were reduced to a total of 13 benchmarks, clustered according to the three pillars: Accessibility (5), Quality (6) and Expenditure (2). In the following table the countries under survey are awarded one, two, three or four asterisks for each indicator, indicating their performance with regard to the other countries studied. The number of asterisks gives an indication of the ranking of the performance of a country with regard to the indicator in question, when compared to the other countries studied, where four asterisks (∗∗∗∗) indicate that none of the other countries studied performed better and one asterisk (∗) does not imply that the country in question is performing badly.

Table 7.2: Assessment – Evaluation of community pharmacy services with regard to accessibility, quality and expenditure

Benchmarks of evaluation	Case study			Control group		
	IRL	NL	N	A	FIN	E
Accessibility indicators						
Good provision with community pharmacies	***	*	*	**	**	****
Good accessibility of prescription-only medicines	****	**	*	***	**	****
Good accessibility of prescription-only medicines in rural areas, through community pharmacies	**	**	**	***	***	****
Immediate availability of pharmaceuticals	**	***	***	****	****	****
High frequency of wholesale deliveries	***	***	*	****	**	****
Quality indicators						
Good availability of pharmaceutical expertise	***	**	**	****	**	****
Professional independency of pharmacists	**	**	*	****	****	****
Important role of tailor-made products (magistral preparations)	*	**	*	****	***	****
Focus on pharmaceuticals	**	****	**	***	****	**
Relevance of pharmaceutical counselling	**	***	**	***	***	****
Involvement in health promotion & disease prevention	***	***	***	***	****	***
Expenditure indicators						
Moderate growth in total pharmaceutical expenditure	*	***	*	***	****	***
Stable development of OTC prices	*	***	*	****	***	****

OTC = over-the-counter

Note: The number of asterisks (1 *; 2 **, 3 *** or 4 ****) gives an indication of the ranking of the performance of a country, with regard to the indicator in question, when compared to the other countries studied.

Source: ÖBIG

Accessibility

As an indicator for the **provision with community pharmacies** we used 'the number of inhabitants per pharmacy' (including branch pharmacies in Norway, Austria and Finland). Among the examined countries the lowest number of inhabitants per pharmacy can currently be found in Spain (2,047), followed by Ireland (2,998). Among the studied countries, the Netherlands and Norway have a relatively high number of inhabitants per pharmacy (cf. Table 6.7).

As mentioned previously, in three of the countries studied (Ireland, the Netherlands and Austria) prescription-only medicines may also be dispensed through self-dispensing doctors. These have, besides the community pharmacies, also been included in the assessment of the **accessibility of prescription-only medicines**, by using 'the number of inhabitants per pharmacy or other POM-dispensary' as an indicator (cf. Table 6.7). Due to this, the accessibility of prescription-only medicines in Ireland comes close to that of Spain. Especially in Austria and, to a lesser extent, in the Netherlands self-dispensing doctors play an important role in the accessibility to POM: In Austria the number of inhabitants per pharmacy or other POM-dispensary (3,720) is almost half of the number of inhabitants per pharmacy (6,819). Norway still has a relatively low pharmacy density compared to the other countries studied.

Good accessibility of prescription-only medicines does, however, not automatically guarantee an even distribution of pharmacies or other POM dispensaries throughout the country. Unfortunately, we have no consistent hard indicator for the **accessibility of prescription-only medicines in rural areas** due to the lacking of the exact numbers of pharmacies and other POM-dispensaries in rural and in urban areas. However, the information we were able to collect indicates that in the deregulated countries, especially in Ireland, but also in the Netherlands and in Norway, pharmacies tend to cluster in the, economically more attractive, urban areas. In Norway, most openings of new pharmacies in the past four years took place in municipalities where pharmacy services were already available, whereas still 199 out of 434 municipalities do not have a community pharmacy. On the contrary, in Finland only 42 of 444 municipalities are without a pharmacy, while 200 municipalities do not have a health centre. Nevertheless, due to an agreement between the Ministry of Health and the pharmacy chains in Norway, no pharmacies have been closed in rural areas in the past years. In the Netherlands there are relatively small rural areas, but still a lower provision of pharmacies and self-dispensing doctors is seen in some sparsely populated areas. In the three regulated countries, establishment rules, that are regionally adapted, especially those in Spain, take care of smoothing disparities between rural and urban areas concerning the provision of POM dispensaries.

To ensure the **immediate availability of pharmaceuticals**, Austrian and Finnish pharmacies follow the statutory regulations, requiring that all frequently asked pharmaceuticals are immediately available to customers. In Spain a required minimum stock has statutorily been defined, and all pharmacies satisfy these requirements. Nevertheless, it should be noted that in the Autonomous Community of Navarra, which makes up only a very small part of Spain, some pharmacies tend to reduce their stock to the absolute minimum, which may cause an under-supply of medicines in these pharmacies. This situation arises from the fact that such pharmacies face the competition of the new pharmacies that opened up in the same areas

after the liberalisation of the pharmacy establishment rules took place in Navarra. Statutory regulations on the pharmacies' stock are also in force in Norway, but in fact it does happen that products are out-of-stock. Regulations on the immediate availability of pharmaceuticals in the Netherlands are not statutory, but laid down in the contracts between the pharmacies and the health insurance funds. These contractual regulations are generally followed. On a statutory level pharmacies are allowed to specialize, e.g. for specific patient groups, but hardly any pharmacy has done so thus far. In Ireland, there are no regulations in order to guarantee the immediate availability of pharmaceuticals.

Concerning the **frequency of wholesale deliveries** Austria (3 times per day) and Spain (2 to 4 times per day) take the lead. Furthermore, emergency deliveries of pharmaceuticals within one hour (e.g. by taxi), even for one package, are common in Austria. In Ireland and in the Netherlands, wholesalers deliver 1 to 2 times per day, but the second (afternoon) delivery is not standard. The lowest frequency of wholesale deliveries can be found in Finland (5 times per week) and in Norway (4 times per week).

Quality

When assessing the **availability of pharmaceutical expertise** in community pharmacies, a number of different aspects have to be taken into account. First of all, in Austria, and in Ireland, a relatively high number of pharmacists per community pharmacy can be found (cf. Table 6.10). In all other countries the number of pharmacists per pharmacy ranges is approximately equal. It needs to be considered, however, that in the Netherlands, Norway and Finland other personnel (pharmacy assistants in the Netherlands, and academically trained prescriptionists in Norway and Finland) are allowed to perform many of the tasks of a pharmacist, which is reflected in a relatively low ratio of pharmacists per non-pharmacists. The opposite is the case in Spain: While the number of pharmacists per pharmacy is almost equal to that in the Netherlands, Norway and Finland, the ratio of pharmacists per non-pharmacists is higher than that in the other countries observed. Actually, in general the average number of staff per pharmacy in Spain is relatively low, but as we have seen, also the average number of inhabitants served per pharmacy in Spain is low compared to the other countries observed. The relatively low number of inhabitants per pharmacy, which was also the case Ireland, is reflected in a high number of pharmacists per 10,000 inhabitants, which amounts to 8.5 in Spain and 8.9 in Ireland. In all other countries studied the number of pharmacists per 10,000 inhabitants is much lower. If we combine both the number of pharmacists per pharmacy, the ratio of pharmacists per non-pharmacists and the number of pharmacists per 10,000 inhabitants (cf. Table 6.10) we can conclude that availability of pharmaceutical expertise from pharmacists in community pharmacies is best guaranteed in Austria and in Spain, followed by Ireland, Finland and, lastly, the Netherlands and Norway.

The **professional independency of pharmacists** from other players in the pharmaceutical market implies that their practices are not driven by e.g. turnover targets or promotions of selected products, which have been enforced by superiors other than national bodies such as the governments or the national pharmacy associations. In the three regulated countries observed in this study, community pharmacies are exclusively owned by individual pharmacists. Consequently, in these three countries pharmacists are likely to have a high level of

professional independency. On the other hand in the three deregulated countries, also non-pharmacists may own pharmacies, and pharmacy-owners are allowed to have more than one pharmacy (multiple ownership). This has contributed to the formation of pharmacy chains owned by non-pharmacists, mainly pharmaceutical wholesalers, in all three deregulated countries. Especially in Norway the share of pharmacies in sole ownership of individual pharmacists is currently very low (cf. Table 6.11). In addition, 75% of the Norwegian pharmacists reported that the conflict between professional and commercial interests has become greater the past years (Anell 2005). In Ireland and in the Netherlands, a reasonably high share of the pharmacies is still owned by independent pharmacists.

The importance of **the role of tailor-made products (magistral preparations)** differs considerably between the two groups of countries. In the Austria and in Spain the manufacturing of pharmaceuticals within the pharmacy is by tradition an important pharmacy service, that is reflected in the fact that all pharmacies in these countries are equipped with a laboratory to prepare tailor-made pharmaceuticals. Also in Finland, each pharmacy is able to prepare pharmaceuticals. Nevertheless, tailor-made pharmaceuticals in Finland make up only a very small part of the total number of prescribed medicines. In the deregulated countries, the manufacturing of pharmaceuticals within the pharmacy plays a much smaller role. In Ireland, where the manufacturing of pharmaceuticals within the pharmacy has never been a tradition, only a few pharmacies are equipped with a laboratory. In the Netherlands and in Norway pharmacies without a laboratory have their magistral formulae prepared by one of the few pharmacies that do have the necessary equipment.

In general, one can say that pharmacies in all countries **focus on pharmaceuticals**. However, differences can be observed, as in some countries the focus on the dispensing of pharmaceuticals is somewhat low and the importance of non-pharmaceutical products is somewhat higher than in others. Of the countries observed, pharmacies in Finland and in the Netherlands appear to have the greatest focus on pharmaceuticals compared to the others, followed by Austria. In these three countries a relatively small amount and range of non-pharmaceutical products are sold through pharmacies, and non-pharmaceutical products account for a relatively small share of the pharmacies' turnover (cf. Table 6.15). This can either be attributed to the fact that the law restricts the selling of non-pharmaceutical products through pharmacies, or that customers are simply not used to buying items like bathing and skin care products in a pharmacy. In Ireland, on the other hand, people are used to find and buy in a pharmacy a large range of non-pharmaceutical products, like for example newspapers and bathing products, in a pharmacy. Consequently, non-pharmaceutical products make up a large share of the Irish pharmacies' turnover. In Spain and in Norway, the share of non-pharmaceuticals in the pharmacies' sales is also quite large. In Spain this indicates the role of pharmacies as often sole health care provider in a community. However, it should also be kept in mind that the total turnover of the average Spanish pharmacy is considerably lower than that of pharmacies in the other countries. In general, it is possible that lower turnovers on pharmaceuticals, e.g. caused by margin cuts, form an incentive for pharmacies to increase the sales of non-pharmaceutical products. In Norway, like in Austria, the selling of non-pharmaceutical products in pharmacies is restricted in the sense that non-pharmaceuticals should be health-related and should not affect the typical looks of a phar-

macy. In addition, in Norway the share of non-pharmaceuticals in a pharmacy's turnover is restricted to 15 percent.

Pharmaceutical counselling plays an important role in community pharmacies of all six countries under survey. When assessing their relevance, it should be taken into consideration that counselling may also be provided by prescriptionists in Norway and in Finland, and by (qualified) pharmacy assistants in Ireland and the Netherlands. These professional groups have had less training and education compared to pharmacists. According to the Norwegian Econ report (cf. Section 4.3.8) some pharmacists feel that the time spent on pharmaceutical counselling per patient has reduced since the deregulation (Econ Analyse AS 2004). In addition, pharmacies in Norway are allowed to be dispense OTC medicines through self-service. In Norway and in Finland pharmaceuticals are also sold through so-called "pharmacy outlets" and "medicine chests". These outlets are under the supervision of a pharmacy, but they are run by people who have neither the competencies nor the right to provide advice and counselling. It should be mentioned that the number of medicine chests in Finland is relatively low and decreasing. Furthermore, Ireland, the Netherlands, Norway and Austria (OTC) pharmaceuticals are also allowed to be sold in drugstores and other outlets (e.g. LUA shops in Norway) which are not supervised by a pharmacist and can not provide counselling to their customers. In the Netherlands however, the managers (or other staff members) of the drugstores must have a special drugstore diploma in order to be allowed to sell OTC medicines. This diploma implies that the person in question has the necessary expertise to provide advice and counselling on the use of OTC medicines.

As seen in Section 7.1 community pharmacies are actively **involved in health promotion and prevention**. In the three regulated countries analysed, this is reflected in the fact that pharmacies are participating in health campaigns and providing pharmaceutical services such as health checks and diagnostic tests. In Finland the Association of Pharmacies publishes and distributes a magazine, providing information on pharmaceuticals and health promotion. In the Netherlands, pharmacies are also involved in national health campaigns, but they do not offer their customers health checks. Pharmacies in Ireland (predominantly those in urban areas) and in Norway are just starting with the provision of pharmaceutical services such as blood pressure measurement. In Spain, for example, community pharmacies collaborate in health programs initiated by regional public authorities like the Plenufar campaign, aiming at correcting the dietary habits of the population and promoting a healthy life-style and a healthy diet.

Expenditure

As in other European countries, the pharmaceutical expenditure in all six countries highlighted in this study has increased, which can be explained, among other reasons, by the introduction of new expensive pharmaceutical products and by the ageing population. A relatively **moderate growth in total pharmaceutical expenditure** of 66 percent over the last eight years was observed in Finland. In the other two regulated countries and in the Netherlands the growth rates in pharmaceutical expenditure were somewhat higher, but still not excessive. In Ireland and Norway the growth in pharmaceutical expenditure has been significant; pharmaceutical expenditure has (more than) doubled during the past ten years. In

any case these results indicate that deregulation is not, by definition, an effective measure for cost-containment.

One further aspect to be considered is the development of OTC-prices, which was analysed on the basis of a price comparison for four selected OTC blockbusters and, if available, other local price development reports. For Norway, the necessary data could only be gathered for the past two years, thus not allowing for a price comparison before and after deregulation in 2001. From a public health perspective, price reductions or at least a **stable development of OTC prices** are being considered favourable. This leads to the following assessment: Among the six countries compared, Ireland showed the highest price fluctuations and a governmental document reported rather high growth rates for ibuprofen and paracetamol in Norway. In none of the six countries clear price reductions for at least two of the selected OTC could be observed. Aciclovir, which in some countries (e.g. Austria) was switched from Rx to OTC only in the late 1990s, showed the most continuous price development.

In general, the rankings presented in the Table 7.2 indicate that, with regard to the first pillar ('accessibility'), the regulated countries perform somewhat better than the deregulated countries, as community pharmacies and other POM dispensaries in these countries are not only sufficient in number, but they are also evenly spread throughout the country, and the availability of pharmaceuticals is more guaranteed. With regard to the second pillar ('quality'), especially the differences between the regulated and the deregulated countries concerning the professional independence of pharmacists and the importance of the role of tailor-made services are particularly striking. Regarding the importance of the role of pharmaceuticals, there are differences between the countries studied, but these are not according to the division between regulated and deregulated countries.

In relation to the indicators selected, the rankings show that the quality of pharmacy services in the three regulated countries is likely to be superior to that in the three deregulated countries. With regard to the third pillar ('expenditure'), it appears that in the three regulated countries surveyed and the Netherlands the growth in pharmaceutical expenditure was more moderate, and that in the regulated countries the prices of OTC medicines tend to be more stable.

7.3 Conclusions

Based on the analysis of the situation in the case study countries (Ireland, the Netherlands and Norway) and the comparison of the case study countries with the three control group countries (Austria, Finland and Spain) we have drawn the following conclusions.

Consequences of deregulation on the ownership of pharmacies

Total freedom in ownership of pharmacies (i.e. non-pharmacists allowed to own pharmacies) leads most likely to **vertical integration** in the pharmacy sector. In this case, the ownership of pharmacies shifts from pharmacists to other actors within the pharmaceutical distribution system, which very often seem to be, besides pharmacists, wholesalers. This is likely to put

a restriction on the professional freedom of pharmacists, in that, as employees, they have to follow the objectives of their superiors, which might include turnover targets and strict regulations on ordering, processing and "promoting" selected products. In addition, vertical integration in the pharmacy sector can also cause other problems.

Firstly, vertical integration can become a threat if it leads to a **conflict of interests**. To avoid this, most countries have decided not to allow doctors and manufacturers of pharmaceuticals to own pharmacies.

Secondly, the penetration of large companies into the pharmacy sector can make it very **difficult for independent pharmacists to buy pharmacies** themselves, as companies are willing and able to pay large amounts of money for pharmacies.

In addition, a change in ownership rules for pharmacies will cause a split between the ownership and the professional responsibility, which can create uncertainty with regard to **liability** in case of misconduct or negligence in a pharmacy. Clear legislation is needed in order to prevent this situation from happening.

Allowing multiple ownership of pharmacies results in the formation of **pharmacy chains.** Pharmacies in these chains are being owned by the holder of the chain, and supervised by one or more pharmacists. Some pharmacy chains give to supervising pharmacists the opportunity to partly own the pharmacy.

This horizontal integration can **decrease the pharmacists' professional freedom** and lead to a **higher fluctuation** of personnel. The independence of the profession and the continuous presence of the pharmacist in the community pharmacy is an important factor to create a personal and strong relationship with patients that will result in a higher level of compliance with the prescribed treatment and further safety for patients.

In combination with vertical integration, horizontal integration can become a threat if (one of the) actors in the pharmaceutical distribution system becomes very large and gains too much market power, i.e. leading to **oligopoly or monopoly situations**, still with still high barriers for market entry. This needs to be prevented by putting limits to the growth of pharmacy chains. For example, in Norway the number of pharmacies in a pharmacy chain is restricted to 40 percent of all Norwegian pharmacies.

Consequences of deregulation on the establishment of pharmacies

Removal of criteria for the establishment of new pharmacies leads to a growth of the number of newly established pharmacies and thus, most likely, to an **increase of the pharmacy density.** The extent of the increase depends on the situation before the liberalisation. The growth in the number of pharmacies will be larger if the provision of pharmacies was formerly relatively low, as it occurred in Norway.

Still, in a liberal pharmacy sector, without establishment criteria for pharmacies and with increased competition, the growing number of community pharmacies does not imply improved accessibility for all inhabitants, because newly established pharmacies tend to **clus-**

ter in urban areas at the expense of the less densely populated rural areas, and some existing pharmacies choose to **leave the rural areas** and move to economically more attractive urban areas. This way, deregulation can lead to a relatively bad provision of pharmacy services in rural areas, compared to the larger cities in country.

However, one should realize that, besides an improved accessibility of pharmacies, a growing number of community pharmacies can also have negative impacts.

For example, excessive growth of the number of pharmacies in a region can **damage the economic viability of individual pharmacies**, which in turn might lead to a reduced variety of available pharmaceuticals in pharmacies and customers having to visit multiple pharmacies in order to get their prescriptions filled. Furthermore, the quality of the services provided may be affected in a negative way.

In addition, due to the growing number of pharmacies, in combination with increased competition in the pharmacy sector the **number of pharmacists and other pharmacy staff per pharmacy will decrease,** as the available pharmacy personnel needs to be spread over more pharmacies and pharmacy owners try to keep the costs for personnel as low as possible. A smaller number of staff per pharmacy can lead to an increase of the workload for pharmacy personnel, especially pharmacists, and possibly also to a lower quality of the services provided. It has been observed that the **overall work satisfaction of pharmacy staff is lessening** in some deregulated countries, as they experience a much higher workload and somehow have been cut in their former total freedom of choice of products to dispense and sell.

Thus it seems, that regulation leads to higher involvement in professional practice and that deregulation leads to increased relevance of reaching business targets, thus leading to a reduction of (expensive) pharmacy staff and services, which is more or less true for all analysed countries.

False expectations

Apart from these possible consequences of deregulation in the pharmacy sector, the analysis of the three chosen deregulated countries has also shown that deregulation does not always lead to what was intended to be accomplished through deregulation.

Apparently, liberalisation of the pharmacy sector **does not necessarily lead to more competition**, as can be seen in Norway, where there are currently only three large pharmacy-wholesale chains that own, together, more than 80 percent of all pharmacies practically leaving no chance for other new pharmacies to enter the market. As mentioned previously, precautions need to be taken in order to prevent this scenario from happening.

Deregulation **does not necessarily reduce the price of OTC medicines,** as these are more connected to the statutory framework than to the pharmacy system. Thus, liberalisation of the pharmacy sector alone will not decrease the prices of pharmaceuticals.

In general, liberalisation and increased competition in the pharmacy sector do **not guarantee cost-containment** in the pharmaceutical sector. Obviously, there are more factors, apart from the financial stimulation (induced by increased competition) of pharmacists to dispense cheaper pharmaceuticals.

General conclusions

Besides the possible consequences and the false expectations of deregulation, conclusions on a more general level can also be drawn.

First of all, it is apparent that **historical developments, traditions and culture have a large influence** on the way how issues are regulated and how systems are organised in a country, which is reflected in the health care and pharmacy policy. Several EU Member States have seen deregulation initiatives with regard to public services in the course of the last 10 to 15 years, often due to pressure by European authorities. Deregulation focused on several sectors (like telecommunication or energy supply), of which the health care and pharmacy sector were "just" further areas being deregulated.

This deregulation process "by chance" and the historical background of the underlying system, makes it difficult to link some developments to specific deregulation initiatives. For example, there are indications that liberalisation and increased competition in the pharmacy sector leads to pharmacies focussing more on the blockbusters at the costs of specific tailor-made services. However, in the deregulated countries that were analysed in this report, these customized services seem to have never played a large role in the pharmacy sector. Thus the observed differences with regard to the preparations of magistral formulae are also likely to be the result of different historical backgrounds.

Based on the benchmarking analysis of the pharmaceutical sectors in the six examined countries, we can state that, with regard to the **accessibility of pharmaceutical services, the regulated countries perform quite better than the deregulated countries**, as community pharmacies and other POM dispensaries in these countries are not only sufficient in number, but they are also evenly spread throughout the country.

The **quality of services offered by pharmacies seems to be sufficient in all countries surveyed**. Nonetheless, the benchmarking analysis has provided indications that the quality of the pharmaceutical services in countries where the pharmacy sector is regulated is somewhat superior to that in countries with a liberalised pharmacy sector, with regard to the extent to which the dispensing of pharmaceuticals in pharmacies, and especially in other medicines dispensaries, is supervised by pharmacists, and with regard to the participation of pharmacies in public health tasks. Concerning the pharmaceutical expenditure in the six countries, the **growth in pharmaceutical expenditure was more moderate and the prices of OTC medicines tended to be more stable in the regulated countries**.

In general, the analysis of the developments in the deregulated countries have made clear that **reforms need to be well-prepared in order to have the impact envisaged** and that possible negative consequences must be tackled. A good example of this is the Norwegian agreement which prevents the closure of pharmacies in rural areas. In preparation of any

reform (deregulation initiatives or any other), the consequences should be assessed thoroughly, and side-effects and loop-holes for some of the actors affected should be anticipated. In addition, it should be evaluated whether the situation in a country justifies liberalisation. For example, insufficient accessibility and quality of pharmacy services might be reasons for liberalisation of the pharmacy sector, as can be seen in Norway. On the other hand, in this view, the liberalisation of, for example, the Spanish pharmacy market would not appear to be justified at this moment.

Furthermore, it has once more become clear that **health care is a special issue and needs regulations,** which is reflected by the fact that even **in the countries considered as very much deregulated, regulations do exist for pharmacies**, for example, with regard to the availability of pharmaceuticals or the tasks and duties of community pharmacies. Even if some changes are taking place a regulatory framework, be it statutory or not, is always necessary to guarantee a good quality of care. In this context, we would like to point to the fact that in the guaranteeing the good quality of pharmacy services and of professional pharmaceutical expertise lies an important role for regulatory bodies and professional associations in the pharmaceutical sector.

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ANNEX

ANNEX I

Institutions contacted directly during the project

Ireland

- Irish Pharmaceutical Union (IPU) - Interview
- Pharmaceutical Society of Ireland (PSI) - Interview
- Department of Health and Children (DoHC) - Interview
- National Center of Pharma-Economics (NCPE) - Interview
- Irish Patients Association (IPA) - Interview
- Health Services Executive (HSE), National shared services - Interview
- United Drug - Interview

The Netherlands

- Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP) / Royal Dutch Pharmaceutical Society - Interview
- Ministerie van Volksgezondheid Welzijn en Sport / Ministry of Health Welfare and Sports - Interview
- Nederlandse Patienten en Consumenten Federatie (NCPF) / Dutch Patients and Consumers Federation - Interview
- De Vier Vijzels - Interview
- Stichting Farmaceutische Kengetallen (SFK) / Dutch Foundation for Pharmaceutical Statistics

Norway

- Norges Apoteker Forening (NAF) / Norwegian Pharmacy Association - Interview
- Helse- og Omsorgsdepartementet / Ministry of Health and Care Services - Interview
- Statens Legemiddelverk / The Norwegian Medicines Agency (NoMA) - Interview
- Legemiddelindustriforeningen (LMI) / Association of Pharmaceutical Industry - Interview
- Norske Legeforening / Norwegian Medical Association - Interview
- Apokjeden AS (Apotek1) - Interview

Austria

- Österreichische Apothekerkammer / Austrian Chamber of Pharmacists - Interview
- Österreichische Bundesministerium für Gesundheit und Frauen / Austrian Federal Ministry of Health and Women

Spain

- Consejo General de Colegio de Farmacéuticos / Spanish General Council of Offical Colleges of Pharmacists

Finland

- Suomen Apteekkarilitto / Association of Finnish Pharmacies

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- Folkehelseinstituttet / Norwegian Institute of Public Health (WHO Collaborating Centre for Drug Statistics Methodology)
- Ordre National des Pharmaciens de France / National Council of French Pharmacists
- Panhellenic Pharmaceutical Association
- Pharmaceutical Group of the European Union (PGEU) - Secretariat

ANNEX II

Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG)
Austrian Health Institute

Community pharmacies in Europe

QUESTIONNAIRE

This questionnaire was answered by:

Name:

Address:

Telephone number:

Fax number:

E-mail:

Answering the questionnaire

Please fill in the requested figures or mark the correct answers with a cross (☒) and write answers on the line. If there is not enough space, we would ask you to answer on an extra sheet of paper.

If not stated differently, the questions refer

- to the current situation, and
- to community pharmacies only (hospital pharmacies are not included).

Distribution of pharmaceuticals

1. Do pharmacies have the monopoly of the retail of pharmaceuticals?

o Yes

o No, pharmaceuticals are also dispensed by:

o dispensing doctor

o other health professionals, namely: _____

_____

o other, (e.g. drugstores (not health professionals)): _____

_____

2. Could you please fill in (as far as possible) the following tables considering the number of registered community pharmacies and other dispensing outlets in your country (1st table), in urban areas (2nd table) and in rural areas (3rd table):

Country wide:								
	1990 [1]	**1995** [1]	**2000** [1]	**2001** [1]	**2002** [1]	**2003** [1]	**2004** [1]	**2005** [1]
Total number of community pharmacies								
If different types of pharmacies exist (e.g. private community pharmacies and subsidiary pharmacies) please specify types and numbers:								
……								
……								
……								
Total of other dispensing outlets								
If other dispensing outlets exist please specify types and numbers:								
…….								
…….								
…….								
Total of dispensing outlets								
Total of new pharmacies								
Total of closed pharmacies								

[1] Per 1 January

Urban areas * :								
	1990 [1]	**1995 [1]**	**2000 [1]**	**2001 [1]**	**2002 [1]**	**2003 [1]**	**2004 [1]**	**2005 [1]**
Total number of community pharmacies								
If different types of pharmacies exist (e.g. private community pharmacies and subsidiary pharmacies) please specify types and numbers:								
……								
……								
Total of other dispensing outlets								
If other dispensing outlets exist please specify types and numbers:								
……								
……								
Total of dispensing outlets								
Total of new pharmacies								
Total of closed pharmacies								

[1] Per 1 January

∗ Please provide the definition of **urban areas** as it was applied in the above table:

Urban areas contain more than _____ inhabitants per km^2 and / or

an average distance between pharmacies of less than _____ km.

Rural areas *:								
	1990 [1]	**1995 [1]**	**2000 [1]**	**2001 [1]**	**2002 [1]**	**2003 [1]**	**2004 [1]**	**2005 [1]**
Total number of community pharmacies								
If different types of pharmacies exist (e.g. private community pharmacies and subsidiary pharmacies) please specify types and numbers:								
……								
……								
Total of other dispensing outlets								
If other dispensing outlets exist please specify types and numbers:								
……								
……								
Total of dispensing outlets								
Total of new pharmacies								
Total of closed pharmacies								

[1] Per 1 January

∗ Please provide the definition of **rural areas** as it was applied in the above table:

Rural areas contain less than _____ inhabitants per km^2 and / or

an average distance between pharmacies of more than _____ km.

Establishment and ownership of pharmacies

3. Are there legal restrictions on the settlement of pharmacies?

o No, there is unrestricted freedom of settlement for pharmacies

o Yes, there are legal restrictions (e.g. a minimum distance to the next pharmacy or a minimum number of potential customers): _____

_____

4. What is for inhabitants of your country the average distance to the closest pharmacy?

The average distance to the closest pharmacy is _____kilometres.

Could you provide this information separately, for urban and rural areas of your country?

In urban areas the average distance to the closest pharmacy is _____ kilometres.

In rural areas the average distance to the closest pharmacy is _____kilometres.

5. Is it possible for persons who are not (full) pharmacists (see definition question 3) to receive a pharmacy license (i.e. to own a pharmacy)?

o No, only (full) pharmacists can receive licenses

o Yes, provided that a (full) pharmacists will be in charge of the pharmacy

o Yes, other criteria for the person that will be in charge of the pharmacy: _____

6. Are there certain groups (e.g. pharmaceutical wholesalers, prescribers) that can not receive pharmacy licenses?

o No

o Yes, groups that will not receive a pharmacy licence are: _____

_____

7. Is it allowed that pharmacies have more than one owner?

o No

o Yes

8. Is trade in pharmacy licenses allowed?

o No

o Yes

9. Is it allowed to own multiple pharmacy affiliates?

o No

o Yes

If yes: What are the main pharmacy chains in your country?

Name: _____Number of pharmacies:_____

Name: _____Number of pharmacies:_____

Name: _____Number of pharmacies:_____

Name: _____Number of pharmacies:_____

Name: _____Number of pharmacies:_____

What percentage of pharmacies is owned by pharmacy chains? _____

Pharmacy personnel

10. Could you please fill in the following table considering the number of pharmacists and other pharmacy personnel that are working in community pharmacies:

	1990[1]	**1995**[1]	**2000**[1]	**2001**[1]	**2002**[1]	**2003**[1]	**200**[1]	**2005**[1]
Number of pharmacists [2] (counted per head)								
Number of pharmacists [2] (full time equivalent (40hrs/w))								
Of which (please specify if possible, see definition below):								
Full pharmacists								
Prescriptionists								
Pharmacy technicians /assistants with the right to dispense pharmaceuticals								
Number of other pharmacy personnel [3]								
Of which (please specify if possible, see definition below):								
Pharmacy technicians /assistants without the right to dispense pharma-ceuticals								

[1] Per 1 January

[2] This includes active (full) pharmacists, prescriptionists and pharmacy technicians/assistants with the right to dispense medicines (under supervision of a pharmacist). (Full) Pharmacist: has received 5 year training, including at least 4 years full-time theoretical and practical training at university level and at least six months training on the job. He/she is allowed to dispense pharmaceuticals on its own and to supervise other pharmacy personal. Prescriptionist: has 3 year academic education (BA), may dispense pharmaceuticals on his/her own and may run a subsidiary/branch of a pharmacy but is not allowed to obtain a full pharmacy license, i.e. may not own a pharmacy. Not included are pharmacists working in hospital pharmacies or in pharmacy-like outlets (e.g. public health centers), pharmacists working in head quarters, research, pharmacy associations, etc., retired pharmacists and pharmacists in training.

[3] This includes active pharmacy technicians/assistants without the right to dispense medicines (e.g. preparator of pharmacy manufactured products), and other staff (support personnel including cleaning personnel, IT-experts, etc.). Not included is personnel working in hospital pharmacies or in pharmacy-like outlets (e.g. public health centers).

11. How long, on average, does a pharmacist work/stay at the same pharmacy?

_____

Training and education of pharmacy personnel

12. Could you please fill in the following table concerning the required education of pharmacists and other pharmacy personnel?

Profession	**Required qualification**	**Duration** (years)	**Practice training required** (yes/no)	**Continuous education required** (yes/no)
Full pharmacists	e.g., university			
Prescriptionists				
Pharmacy technicians /assistants with the right to dispense pharmaceuticals				
Pharmacy technicians /assistants without the right to dispense pharmaceuticals				

13. Do regulations exist concerning training and further education of pharmacists?

o No

o Yes, training / further education is mandatory for pharmacists

If yes, who defined these requirements?

o State (laws, decrees, ...) _____

o Pharmacists' federation (regulation/recommendation of the federation)_____

We would be grateful if you could submit laws or decrees concerned.

14. Is training or further education encouraged by pharmacist's federations?

o No

o Yes

15. By whom are training and/or further education provided?

o Professional associations: _____

o University: _____

o Other institutions: _____

16. On average how many pharmacists attend education and/or training per year?

_____

17. On average how many hours per year does a pharmacists spend on education/ training?

_____

18. Are special training programs available for pharmacists?

o No

o Yes (please specify)_____

19. Could you provide an estimate of the yearly costs for health care or hospitalisation due to (wrong) medication? *(Please provide an approximation if no exact figures are available)*

_____per year

Opening hours of pharmacies

20. Are the opening hours of pharmacies subject to regulations? *(multiple answers possible)*

o No

o Yes, subject to state's laws or regulations: _____

o Yes, subject to regulations from the pharmacists' federation: _____

We would be grateful if you could submit laws or decrees concerned

21. What are the regulations regarding the opening hours? (if no regulations exist please estimate average opening hours)

On weekdays (during the day): from _____ to _____ o'clock and

from _____ to _____ o'clock

Night duty: from _____ to _____ o'clock

Weekend duty: Saturday from _____ to _____ o'clock

Sunday from _____ to _____ o'clock

22. Does night duty differ from usual opening hours during the day? *(multiple answers possible)*

o No

o Yes, standby duty only (restricted access to the sales office, service is offered through a window): _____

o Yes, there are differences (such as limited range of products, number of staff): ____

_____

23. Does weekend duty differ from usual opening hours during the day? *(multiple answers possible)*

o No

o Yes, standby duty only (restricted access to the sales office, service is offered through a window): _____

o Yes, there are differences (such as limited range of products, number of staff): _____

_____

24. How many pharmacies in your country are open 24 hours every day? (If you do not know the exact number, please estimate the percentage)

_____ 24-hours-pharmacies *, or _____ percent (estimation)

* Definition of 24-hours-pharmacy: A pharmacy which is open to public 24 hours per day, 7 days per week. The pharmacy needs to have open access, not just provide standby duty.

25. How many pharmacies in your country are equipped with computers?

About _____ percent of the community pharmacies

Range and availability of pharmaceutical products

26. Could you please fill out the following table concerning the volume of pharmaceutical products:

Pharmaceuticals for human use* (not magistral or officina formula)	**1990** [1]	**1995** [1]	**2000** [1]	**2001** [1]	**2002** [1]	**2003** [1]	**2004** [1]	**2005** [1]
Registered pharmaceuticals								
Pharmaceuticals on the market								
Including:								
Prescription-only pharmaceuticals								
Reimbursable pharmaceuticals								
Generics								
Non-pharmaceutical products on the market								
∅ number of pharmaceuticals on stock /pharmacy [2]								

∅ = average

[1] Per 1 January

[2] In case data are not available in absolute terms, we would like to ask you to estimate the share of pharmaceuticals that an average pharmacy has on stock (percentage of all pharmaceuticals on the market)

* How did you count the pharmaceuticals?

o including different pharmaceutical forms (e.g. tablets, capsules)

o including different dosages

o including different pack sizes

27. Are there regulations on the availability of pharmaceuticals? *(multiple answers possible)*

o No

o Yes, a certain amount of drugs has to be on stock: _____

o Yes, in certain period of time a drug has to be available to the customer: _____

o Yes, further regulations: _____

_____

If yes, who defined these requirements?

o State (laws, decrees, ...)

o Pharmacists' federation (regulation/recommendation of the federation)

We would be grateful if you could submit laws or decrees concerned.

28. How often a day is a pharmacy delivered?

On average _____ deliveries per day

29. What is the mean delivery time of pharmaceuticals to customers? (This considers all registered pharmaceuticals, i.e. also pharmaceuticals not on stock)

Customers receive pharmaceuticals on average within _____

Generics and pharmacy manufactured goods

30. Is generic substitution allowed?

o No

o Yes: (please specify to what extent) _____

31. Is generic substation encouraged by the government? *(multiple answers possible)*

o No

o Yes, pharmacies may keep (up to) _____% of the difference between the actual price of the generic pharmaceutical and the maximum price of the pharmaceutical.

o Yes, by means of: _____

32. Does every pharmacy have a laboratory or a place to manufacture pharmaceuticals?

o No, number of pharmacies with ability to manufacture pharmaceuticals: _____

o No, percentage of pharmacies with ability to manufacture pharmaceuticals: _____%

o Yes

Pharmacies turnover

33. Could you please fill in the following table concerning the turnover (sales) of pharmacies:

	1990	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Prescriptions filled								
Total pharmacy turnover								
Of which:								
Turnover of pharmaceuticals								
Turnover of OTC								
Turnover of non-pharmaceuticals								

Liability

34. Are there regulations concerning the liability of pharmacists?

o No

o Yes, _____

We would be grateful if you could submit laws or decrees concerned.

Advertisement

35. Is advertising of pharmaceuticals permitted?

o No, advertising is prohibited for all types of pharmaceuticals

o Yes, advertising is permitted for the following types of pharmaceuticals:

_____

Reforms

36. Which substantial changes with regard to community pharmacies has your country seen in the last five years (e.g. generic substitution, regulations for ownership or establishment of pharmacies, contracts with the state or the social insurance). _____

_____

_____

_____

We would like to ask you to submit material with relevant information in general, regulations concerned and patient satisfaction studies.

Thank you very much for your cooperation!