Impact of pharmacy deregulation and regulation in European countries

Gesundheit Österreich
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Brief Summary

Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH (GÖG FP), a subsidiary of Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute was commissioned by the Association of Danish Pharmacies (Danmarks Apotekerforening) to survey and analyse community pharmacy systems in selected European countries.

Objective

The aim of the study was to understand the community pharmacy systems of countries with a deregulated community pharmacy sector (England, Ireland, the Netherlands, Norway, and Sweden) on the one hand and countries with a regulated community pharmacy sector (Austria, Denmark, Finland, and Spain) on the other hand, and to identify possible parallels between these two groups of countries.

Methodology

Fifteen indicators were developed to assess in each country the impact of the current community pharmacy system with regard to accessibility, quality and economics. Information and data were collected via desk-top research, a questionnaire-based survey among national pharmacy associations and interviews with stakeholders. Interrupted time line analyses were performed in order to evaluate the developments after policy changes, such as deregulation.

Results

The two groups of countries – those with a regulated and those with a deregulated community pharmacy sector – display different patterns, in particular with regard to the regulatory framework but also for some of the outcome indicators. While in the regulated countries statutory provisions for pharmacy establishment and ownership are in place, this is not the case in the deregulated countries.

Whereas England (with a wave of deregulation after 2005), Ireland (exceptionally statutory ownership rules from 1996 to 2001) and the Netherlands further deregulated their rather liberalised community pharmacy system, the community pharmacy systems in Norway and in Sweden changed within a short time from regulated to deregulated (in 2001 and in 2009 respectively). One of the goals which these countries intended to achieve by deregulating the pharmacy sector was to increase the accessibility of medicines. In fact, deregulation has led to the opening of new pharmacies and of OTC dispensaries, since OTC sale outside pharmacies is usually permitted. Nevertheless, deregulation yielded urban clustering of community pharmacies, and accessibility of pharmacies in rural areas was not observed to have improved.

The quality of the pharmacy services appears to be appropriate in all countries, including the deregulated ones. This is attributable to high professional standards among the pharmacists. The composition and numbers of pharmacy staff differ across the countries, since this is strongly connected to a country's organisation of the health care system. Some findings, however, indicated that there might be an increase in the workload of pharmacy staff after

deregulation. In addition, individual pharmacists tend to lose their professional independence after the liberalisation, since they can hardly compete with pharmacy chains or when they become employed by pharmacy chain owners. In the deregulated countries, pharmacy chains appear to be mainly owned by wholesalers, since there are either no limitations on who may own a pharmacy, or wholesalers are not exempted from pharmacy ownership. Pharmaceutical manufacturers and doctors, however, are usually explicitly not allowed to own pharmacies.

The pharmacy sector is currently under pressure; in particular the pharmacy remuneration has been and is still being challenged by regulators and media. The sale of OTC medicines and non-pharmaceuticals has continuously increased in pharmacy business – a trend which was observed to a greater extent in the liberalised countries.

It is often expected that through deregulation in the community pharmacy sector the prices of OTC medicines will go down. However, existing evidence does not show a reduction in the prices of OTC medicines after a deregulation.

Conclusions

Deregulation in the community pharmacy sector is often connected to certain expectations, in particular to improved accessibility and reduced medicines prices. In reality, these expectations could not be fully met. Liberalisation in the pharmacy sector can even have consequences, which might impede a good and equitable access to medicines, such as

- an uneven spread of community pharmacies within a country,
- the dominance of some market players, for example wholesalers and
- the economic pressure to increase the pharmacy turnover through the sale of OTC medicines and non-pharmaceuticals.

The rulings of the European Court of Justice concluded that limitations to the ownership and the establishment of community pharmacies might be justified for the sake of public health. The present study confirms the benefits of a statutory framework for the community sector to ensure equitable access to medicines.

Executive Summary

Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH (GÖG FP), a subsidiary of Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute was commissioned by the Association of Danish Pharmacies (Danmarks Apotekerforening) to survey and analyse the degree of (de)regulation of community pharmacy systems in a number of European countries.

Selected were five countries with a rather liberal community pharmacy sector (England, Ireland, the Netherlands, Norway, and Sweden) and four countries with regulated community pharmacy sectors (Austria, Denmark, Finland, and Spain).

The objective of the study was to perform a comprehensive cross-country analysis of the different community pharmacy systems, in particular with regard to fifteen indicators relating to one of the following three pillars

- accessibility,
- quality and
- economics.

Information and data were gathered via desk-top research, a questionnaire-based survey among the national pharmacy associations, and interviews with national stakeholders, in particular pharmacy associations, consumers' associations and public authorities.

The survey was undertaken in autumn 2011 and documented in a report which was finalized in December 2011. In March 2012 the report was published under the title "Impact of pharmacy deregulation and regulation in European countries".

Key findings on the countries surveyed

The group of deregulated countries comprises England, Ireland, the Netherlands, Norway, and Sweden. In these countries no regulations on the establishment of new pharmacies are in place and all natural and legal bodies (with limitations in some countries) are allowed to own one or more community pharmacies (multiple ownership). The deregulation in these countries has different historical backgrounds: England, Ireland and the Netherlands have been liberal for decades, with further initiatives for more competition in rather recent times, whereas the regulated community pharmacy systems of Norway and Sweden were liberalised in 2001 and 2009 respectively.

Key features of the deregulation in these countries were:

- England: the so-called "control of entry test" system, restricting market entry of community pharmacies wishing to provide state funded pharmaceutical services, including dispensing NHS (National Health Service) medicines, was completely revised in 2005 and exemptions from the "control of entry test" were introduced. A new contractual framework between the NHS and the community pharmacies was introduced at the same time; it took account of

the different kinds of services (essential, advanced, and local enhanced) pharmacies provide.

- Ireland: Ireland introduced establishment rules for the opening of new pharmacies in 1996, but revoked them in 2002. Also the new Pharmacy Act of 2007 does not include any establishment regulation. Internet sale of OTC medicines was permitted in 2006.

- The Netherlands: multiple ownership (pharmacy chains) was allowed in 1987. In 1992 the obligation for health insurance funds to have contracts with each pharmacy fell. While there had never been statutory establishment criteria in place in the Netherlands, the pharmacy association had applied some restrictions. This practice was forbidden by the Law on Competition in 1998.

- Norway: in 2001 the statutory establishment and ownership criteria for community pharmacies were abolished. Horizontal and vertical integration were allowed. In 2003 the sale of a restricted number of OTC medicines outside pharmacies was permitted.

- Sweden: The monopoly of the state company Apoteket AB, which had owned all Swedish community pharmacies and was the employer of all pharmacists, fell in 2009. Since then pharmacies may be owned by private persons or commercial entities as well as by Apoteket which has become one among several pharmacy owners. Commercial pharmacy chains were allowed. Part of this process called “reregulation” was also the liberalisation of the sale of OTC medicines which was allowed outside pharmacies.

All the regulated countries surveyed (Austria, Denmark, Finland and Spain) have statutory establishment rules, usually based on demographic and geographic criteria, allow only pharmacists to be the (key) owners of a community pharmacy and do not permit the forming of pharmacy chains.

Even within the two groups, the community pharmacy systems have developed individually, with country-specific peculiarities. Table 0.1 provides an overview of the key features of the community pharmacy systems of the nine countries surveyed, while Table 0.2 discusses the indicators selected in the sample of surveyed countries.

Table 0.1: Executive Summary – Characteristics of the community pharmacy systems in the nine countries surveyed, 2011

England	**Ireland**	**Netherlands**
• Prescription-only medicines are mainly dispensed by community pharmacies. Under certain circumstances, dispensing doctors are allowed to dispense POM. • Most community pharmacies are privately owned though in exceptional cases Primary Care Trusts (PCTs) run pharmacies. • Pharmacy chains and vertical partnerships, i.e. with pharmacy wholesalers and manufacturers, are allowed. • 39% of England's community pharmacies are independent contractors (owners with five pharmacies or fewer) and 61% multiple contractors (six pharmacies or more). • There are no legal controls over the location of pharmacies. • According to NHS regulations, if a pharmacy wishes to provide state funded NHS pharmaceutical services, it must apply to the relevant local health body for approval. Introduced in the mid-1980s, the so called "control of entry test" restricted market entry. • In 2003, the Office of Fair Trading recommended the total deregulation of the retail pharmacy market. • The government responded with a package of reforms, including a revised control of entry test and four complete exemptions to the test, coming into effect in April 2005. • The Health Act 2009 contains provisions to require PCTs to develop and to publish Pharmaceutical needs assessments (PNAs). • Since April 2005, most community pharmacies have provided services under a new contractual framework with three tiers of services – essential, advanced and local enhanced. • Good pharmacy practice regulations are in place. • NHS dispensing represents over 85% of turnover for a typical NHS funded pharmacy. • The remuneration of pharmacies is provided under a contractual framework for community pharmacies and is negotiated annually by the Department of Health and the Pharmaceutical Services Negotiating Committee.	• Ireland has always had a highly liberalised pharmacy sector, in particular with regard to establishment and ownership of pharmacies. • In the 1990s establishment rules for new pharmacies were introduced, but they were revoked in 2002. Currently there are no establishment rules for pharmacies. • Pharmacy chains and vertical integration are allowed. In the last years, more and more pharmacies were organized in chains (in particular in the cities). Nonetheless, Ireland still has a high number of individual pharmacists. • Retail pharmacy businesses were regulated in 2008, stipulating their need to register. Both pharmacies and retail pharmacy businesses have to comply with the "fitness to practise" regime. • Internet sale for OTC medicines was allowed in 2006. • There are a few (around 100) POM dispensing doctors left (particularly for rural areas). • Ireland has struggled for a long time with the training of pharmacists since there was just one college and not enough training places. Many Irish pharmacists were trained outside the country, mainly in the UK. Today three colleges offer a university education for pharmacists. • In 2007 the regulation that pharmacists trained outside Ireland are not allowed to own, manage or supervise a pharmacy in their first three years of practice in Ireland was revoked, thus implementing EU law. • There are some pharmacy-only OTC medicines, while medicines defined as General Sales Lists products may be dispensed outside pharmacies. • The pharmacy remuneration depends on the community drug scheme which is applicable for the patient / medicine dispensed. Pharmacy margins are currently under pressure. • In 2009 pharmacists had a dispute with the authorities. During the days of strike the National Health Service took over pharmaceutical provision.	• Key dispensaries of prescription-only medicines are community pharmacies. Every second hospital pharmacy sells medicines to out-patients. • The absence of a pharmacy within a community is often compensated by dispensing by family physicians (around 500 POM dispensing doctors). • Drugstores in the Netherlands have been allowed to sell OTC medicines for more than a century. • There have never been statutory geographic or demographic restrictions to the establishment of pharmacies. • The Royal Dutch Pharmaceutical Society applied its own establishment policy, but on 1 January 1998 the application of restrictions to the establishment of pharmacies was forbidden by the Law on Competition. • There are no state licenses required to own a pharmacy, but in order to run a pharmacy profitable contracts with health insurance funds are necessary. Since 1992 health insurance funds have no longer been obliged to have contracts with each pharmacy. • Multiple ownership had not been allowed until 1987. When the restriction on multiple ownership was revoked the first pharmacy chains were set up. • 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. • Currently 32% of the community pharmacies are organised as pharmacy chains. • The Royal Dutch Pharmacy Association has developed guidelines for pharmaceutical counselling in pharmacies. • The "preferential pricing policy" of the sickness funds (i.e. tendering for the least expensive active ingredients) also impacts pharmacy business.

Norway	Sweden	Austria
• Prescription-only medicines are mainly dispensed by community and hospital pharmacies. • The Norwegian Medicines Agency may allow pharmacies to run as a branch, using a bachelor of pharmacy (prescriptionist) as head, but under the supervision of a main pharmacy. • The Medicines Agency may allow pharmacies to establish pharmacy outlets in order to compensate for the absence of pharmacies in an area. A pharmacy outlet has the right to sell and deliver all OTC medicines. • Since 1 November 2003 so-called LUA ("medicines outside pharmacies") outlets, located for example in grocery stores, petrol stations, health stores, etc., are allowed to distribute a restricted number of OTC medicines. • On 1 March 2001 a new Pharmacy Act came into force. The act entailed a liberalisation with regard to establishment and ownership of pharmacies (no limits on the number or location of pharmacies and no competency requirements on the ownership of pharmacies). • The only limit for corporate pharmacies is that no pharmacy chain is allowed to own more than 40 percent of all pharmacies. • Since March 2001 the pharmaceutical market in Norway has become very much integrated, both horizontally because many pharmacies are now organised in chains, and vertically in that retailers and wholesalers now have the same owners. • 81 percent of the Norwegian pharmacies are in the ownership of one of the three large pharmacy chains, each vertically integrated with a pharmaceutical wholesaler. • Using WHO's guidelines for Good Pharmacy Practice (GPP) in community and hospital settings, voluntary trade standards for pharmacies (Standards for Pharmacy Practice) in Nordic countries have been developed. • According to an evaluation performed in 2003, the pharmacists' opportunity to provide patients with professional advice was perceived by many pharmacists to have been reduced, while the customers of the pharmacies appear to be satisfied with the advice they received. • The pharmacy profit consists of a percentage mark-up based on the pharmacy purchasing price and a fixed amount per package.	• The main actors in the Swedish pharmacy system are community pharmacies, which were all state-owned by the public company Apoteket AB until 2009. Until then, all medicines, including OTC products, were only allowed to be dispensed in these publicly owned community pharmacies. • In 2009 the pharmacy sector was liberalised. This process was called reregulation, and the monopoly of Apoteket fell. • The reregulation of the Swedish pharmacy system in 2009 was initiated by the Swedish government, aiming to increase accessibility to medicines and to reduce OTC medicines prices. • Today, about two thirds of all pharmacies are in the hands of private companies. The rest is still owned by Apoteket. • There are neither dispensing doctors nor branch pharmacies. • Until 2009, Internet sales were only carried out through Apoteket AB's website. OTC medicines have been available at this website since 2002 and POM since 2006. • The sale of OTC medicines outside pharmacies has been allowed in supermarkets and petrol stations since November 2009. • Pharmaceutical wholesale is organised as a single-channel distribution system. • The new legislation allows for both public and private establishment of pharmacies. • Full pharmacists with a master's degree as well prescriptionists with a bachelor's degree are allowed to manage a community pharmacy. Both may dispense POM. • In the first year after reregulation, around 200 new pharmacies were established, and more than twenty new additional pharmacy stakeholders came to the market. • Until July 2012 Apoteket AB will keep providing especially rural areas with about 900 representatives which are normally located in grocery stores. • Large pharmacy chains have been established after the reregulation. • There are neither regulations concerning nation-wide quality standards for pharmaceutical counselling nor guidelines. • Pharmacy remuneration is regulated by a statutory regressive margin scheme.	• Key POM dispensaries are community pharmacies and POM dispensing doctors. Five of the 46 hospital pharmacies act as community pharmacies. • While POM dispensing doctors (around 940) are fewer than pharmacies (nearly 1,300), there are still many POM dispensing doctors compared to other countries. • Each pharmacy is allowed to run at least one branch pharmacy (in total there are 23 branch pharmacies). • There is a very small list of OTC medicines which are allowed to be sold outside pharmacies, e.g. in drugstores. • Internet pharmacies are not allowed. • A drugstore chain benefits from a ruling of the European Court of Justice, stating that distance selling of OTC medicines from another EU country into Austria is allowed under certain conditions, and offers distance selling from a pharmacy located in the Czech Republic. • Establishment of community pharmacies in Austria is regulated. Establishment rules comprise geographic and demographic criteria. • Ownership is also regulated. Co-ownership is possible provided that the managing pharmacist (licensee) holds more than 50 percent. Vertical integration is thus possible but restricted. • During the last decade new pharmacies were opened in Austria, in particular in small communities where no pharmacy had been in place before. • 92.6% of the Austrian population is able to reach a pharmacy within 10 minutes. • On average 11 employees work in an Austrian community pharmacy, thereof three to four pharmacists. • Extemporaneous preparations play an important role in Austrian community pharmacies, both magistral preparations (i.e. produced individually for the costumer) and officinal preparations (i.e. ready-prepared medicines produced in advance always in the same composition). • If non-pharmaceuticals are provided in Austrian pharmacies, they have to comply with the legal provision that they must be "health related". • Guidelines for counselling are being developed. • Pharmacy remuneration is regulated by regressive margin schemes, one for customers with "preferential treatment" (e.g. sickness funds) and one for private customers.

Denmark	Finland	Spain
• Prescription-only medicines (POM) are dispensed by community pharmacies, including branch pharmacies and supplementary pharmacy units. • Branch pharmacies and supplementary units are attached to the main pharmacy and are operated at its expense. At least one pharmacist is required to be present during opening hours in pharmacies, branch pharmacies and supplementary units. • The Danish Medicines Agency has defined a range of OTC medicines which may be sold outside pharmacies. • Non pharmacy restricted OTC medicines may be sold in pharmacy outlets (attached to a pharmacy), OTC medicines outlets and delivery facilities. • In Denmark, only one internet portal, operated by the Association of Danish Pharmacies, sells POM. • Pharmacy establishment in Denmark is bound to a licensing system. • Pharmacy ownership in Denmark is restricted to pharmacists. • Multiple ownership is not allowed, therefore no pharmacy chains are established. • There is an equalization scheme among pharmacies to subsidise small scale pharmacies in rural areas. • Almost all medicines should be available immediately. If this is not possible, the medicines should be provided to the costumer within a reasonably short time, being defined as less than 24 hours. • Full pharmacists and pharmaconomists are allowed to dispense prescription-only medicines. • Non-pharmaceuticals sold in pharmacies are required to have a “natural belonging to pharmacy“. • Pharmacies have formulated a set of common standards for counselling at the counter. • Pharmacy mark-ups are regulated by law in the form of a linear mark-up based on a dispensary fee added to the pharmacy retail price of each pack.	• Dispensing of prescription-only medicines (POM) is limited to community pharmacies. • 98 percent of all community pharmacies are privately owned. Two community pharmacies (one with 16 branch pharmacies) are in the ownership of universities. • A private pharmacy is allowed to own up to three branch pharmacies and the Helsinki University Pharmacy is permitted to have up to 16 branch pharmacies. • If a branch pharmacy’s turnover exceeds 50% of the average pharmacy turnover, it becomes an independent pharmacy. • The number of community pharmacies has stayed rather stable, with a slight increase. • Establishment is regulated by the Finnish Medicines Agency (FIMEA) which takes a decision based on accessibility aspects and the opinion of the municipality concerned. • In rural areas, pharmacy service points, replacing the medicines chests since February 2011, may be established by a supervising pharmacy. The service points are only allowed to dispense a range of OTC medicines. • Nicotine replacement therapy (NRT) preparations are the only OTC medicines allowed to be sold outside pharmacies. • Neither multiple ownership nor vertical integration is allowed. • Pharmaceutical wholesale is organized as a single-channel system. • 98 percent of all prescriptions are filled immediately. Full pharmacists and prescriptionists (bachelors) are allowed to dispense prescription-only medicines. • There are voluntary and compulsory nation-wide standards for counselling in Finland. • Pharmacies are remunerated via a statutory mark-up, applicable for all medicines except NRT products. Pharmacies must pay a pharmacy fee based on their turnover, which is used to subsidize small pharmacies.	• Spain has a highly regulated pharmacy system. • In many areas (also in the community pharmacy sector), federal legislation is supplemented and adapted to regional peculiarities by the Autonomous Communities’ law. • Key and sole dispensaries of prescription-only medicines are community pharmacies. There are no POM dispensing doctors. • There are no branch pharmacies. • To ensure accessibility in rural areas, “farmacia botiquines”, acting under the supervision of a pharmacy, are established in exceptional cases. • Internet trade of OTC medicines has been allowed since 2006, but only via an authorised pharmacy. • Establishment criteria (geographic and demographic) are in place at the federal level and at the level of the Autonomous Communities. In 2000 the establishment rules of Autonomous Community Navarra were nearly fully liberalised. As a result, more pharmacies were established which impacted the average profit of the pharmacies and led to stock out. Eventually, some pharmacies closed. • Pharmacists must be the key owners of pharmacies. Co-ownership is allowed if 51 percent is in the ownership of a pharmacist. • Multiple ownership is forbidden, there are no pharmacy chains. • Extemporaneous preparations play a role. • Counselling is of key importance: One in three patients requesting an OTC medicine leaves the pharmacy without actually purchasing one. • Pharmacy remuneration is regulated by a regressive margin scheme. • In 2010 generic prices were decreased by 30%, but the prices of original products were not officially decreased, but discounted. All actors of the distribution chain, including pharmacists, contributed to the discount. • A pharmacy claw-back system is in place, this was also changed during the financial crisis.

EU = European Union, GPP = Good Pharmacy Practice, LUA = “medicines outside pharmacies”, NHS = National Health Service, POM = prescription-only medicine, OTC = Over-the-Counter, WHO = World Health Organization. The countries are listed alphabetically for the two groups (countries with a deregulated community pharmacy sector and then the regulated countries).

Source: The authors, based on the survey done in this study

Accessibility concerns for rural areas

The rationale of the establishment regulation for community pharmacies is to ensure an appropriate provision of community pharmacies, with equitable distribution across the regions, in particular between urban and rural areas: People in sparsely populated regions should be granted the same access to medicines as inhabitants in urban areas. Additionally, establishment rules aim to prevent the unlimited clustering of pharmacies at popular locations (e.g. town centres), which might harm the viability of the individual pharmacies and negatively impact the quality of pharmacy services due to economic pressure.

One of the goals which the countries intended to achieve through the deregulation of the pharmacy sector was to increase the accessibility of medicines. In Norway and Sweden deregulation has indeed resulted in the opening of a considerable number of new pharmacies. Additionally, OTC dispensaries were opened, since OTC sale outside pharmacies was permitted. However, the accessibility in rural areas has not improved because the new pharmacies were mainly established in towns.

For all five deregulated countries it was observed that the fall or non-existence of ownership rules has led to the establishment of pharmacy chains and vertical integration, with large international wholesale companies owning pharmacy chains which often dominate the market (particularly observed in Norway). This can influence the availability of medicines in the pharmacies in so far as medicines supplied by the wholesaler owning the pharmacy chain are predominantly available in the pharmacy and/or medicines less frequently asked for are not held in stock for profit reasons. Provisions – either statutory or internal rules – regarding medicines in stock and dispensing time, which are in place in some of the countries (Austria, Denmark, Finland, Norway, Spain), might contribute to preventing medicine shortages or long waiting times for the patients.

Pharmacists keep a high quality level

The quality of pharmacy services is and has been at a high level, even in deregulated countries. This is mainly attributable to the good qualification of pharmacists, a professional self-understanding as part of the health care system and quality standards established by the pharmacy owners.

However, concerns have been raised about a possible increase in workload in the deregulated countries which could impact the quality of pharmacy services (e.g. less time for counselling). In Norway, the overall number of community pharmacists increased in the last decade, but, since a lot of new pharmacies opened after the deregulation, the number of pharmacists per pharmacy decreased considerably.

The highest number of dispensing staff can be found in the Netherlands and Ireland (more than 11 dispensing staff per 10,000 inhabitants). These include pharmacists and qualified pharmacy technicians. Several Nordic countries share the characteristic that besides full pharmacists so-called prescriptionists, who are bachelors in pharmacy (or dispensing pharmacy technicians – “pharmaconomists” in Denmark) may also dispense (prescription-only) medicines. In Denmark and Finland three of four pharmacists are prescriptionists.

Pharmacy services are being expanded, and pharmaceutical care has started in all the countries surveyed. As a trend, more and more countries allow pharmacies to provide a wider range of services (e.g. flu vaccinations in Ireland), thus confirming the role of pharmacists as key actors in health care, including health promotion and prevention. The countries leading the extension of pharmacy services and enhancing the pharmaceutical care concept are traditionally England and the Netherlands.

The question if the quality of pharmacy services differs between individual pharmacies and chain pharmacies could not be answered satisfactorily in this study. While some interview partners reported about pharmacy chains being drivers for quality standards, this was challenged by others who attributed a sustainable quality assurance to independent pharmacists. The remuneration of specific pharmacy services could serve as a financial incentive of the health care system to promote pharmaceutical care.

Most of the countries surveyed have developed and/or implemented guidelines and standards for counselling. Only a few indicators regarding counselling (e.g. average counselling time) were available, but two country-specific studies illustrate the wide range of findings: A consumers' pool indicated a decrease in the patients' satisfaction with the information provided and the quality of counselling after the liberalisation in Sweden, while one out of three consumers coming to a Spanish pharmacy for the purchase of an OTC medicine leaves it without buying anything.

The role of pharmacy-made products (extemporaneous preparations) differs among the countries. In none of the countries is it of quantitative relevance in terms of sales, but it plays an important role in the pharmacists' self-understanding of their professional activities. Extemporaneous preparations are regularly produced in pharmacies in all the regulated countries except Denmark. In the deregulated countries an increasing trend to "outsource" the production of extemporaneous preparations could be observed.

In recent years, partly aggravated by the global financial crisis, the pressure on the pharmacy margins has grown, and, as one strategy for ensuring their profit, pharmacies in all countries tend to expand into the segments of OTC medicines and non-pharmaceuticals. In some countries (Austria, Denmark, Norway), there are restrictions requiring that the sale of non-pharmaceuticals should be connected to the health related character of a pharmacy or health care. In some deregulated countries, the share of sales with non-pharmaceuticals has gained considerable importance, accounting for one quarter of a pharmacy's turnover in Ireland and Norway.

Table 0.2: Executive Summary – Indicators of community pharmacy systems in the nine countries surveyed, 2011

Indicators	Deregulated countries	Regulated countries
Accessibility		
Provision with community pharmacies	The Netherlands, followed by Norway and Sweden, have a rather high number of inhabitants per pharmacy (8,400 and 7,500 respectively). England ranks in the middle.	The highest number of inhabitants (approx. 17,500) served by a pharmacy is in Denmark. At the other end, Spain has the lowest number of inhabitants per pharmacy (2,100). Austria and Finland rank in the middle.
Accessibility of prescription-only medicines (POM)	Further dispensaries for prescription-only medicines complement pharmacies, in particular in rural areas. These are POM dispensing doctors in England, Ireland, the Netherlands and Norway, and hospital pharmacies in Norway. Still, Sweden and Norway have the highest number of inhabitants served by a POM dispensary after Denmark.	In Austria, a relatively high number of POM dispensing doctors is active. As a result, the accessibility of POM dispensaries in total is higher in Austria and ranks third after Spain and Ireland. A POM dispensary in Denmark serves by far the highest number of inhabitants.
Accessibility of prescription-only medicines in rural areas	Branch pharmacies (Norway) and POM dispensing doctors (England, Ireland, Netherlands, Norway) guarantee accessibility of prescription-only medicines in rural areas. However, deregulation in Norway and Sweden which led to the establishment of new pharmacies did not improve the accessibility in rural areas.	Branch pharmacies (Austria, Denmark, Finland), so-called supplementary units (Denmark) and POM dispensing doctors (Austria) guarantee access to prescription-only medicines in rural areas. Additionally, in some regulated countries (e.g. Austria) pharmacies are preferably established at locations where no pharmacy exists.
Availability of medicines	Regulations regarding availability (e.g. deadlines for availability of medicines to customers, rules on medicines in stock) are rare in the deregulated countries. In Norway and Sweden a law requires availability of a medicine to the customer within 24 hours.	Regulations regarding availability of medicines are rather common. All four regulated countries have regulations regarding the medicines to be held in stock. In general, the majority of prescriptions can be filled immediately, at maximum within 24 hours.
Frequency of wholesale deliveries	Once or twice a day except for Norway (four times a week, fewer in rural areas).	Once a day in Denmark, twice a day in Finland due to only two short-line wholesalers (single channel system), three times a day in Austria and Spain.
Quality		
Availability of pharmacists	Ireland has the highest number of pharmacists per 10,000 inhabitants, but the share of pharmacists per pharmacy ranks in the middle of the countries surveyed. Ireland also has the second highest number of pharmacists per pharmacy (2.9) among the nine countries, while Sweden has by far the lowest number of full pharmacists per pharmacy (0.64). In Norway, the number of pharmacists per pharmacy has, due to the opening of new pharmacies, considerably decreased after the deregulation.	Finland and Spain have the second and third highest number of pharmacists per 10,000 inhabitants among the 9 surveyed countries. With regard to pharmacists in a pharmacy, Austria has the lead among the surveyed countries (4 pharmacists per pharmacy).

Indicators	Deregulated countries	Regulated countries
Availability of qualified staff	In Norway and Sweden, prescriptionists (bachelors in pharmacy) may dispense prescription-only medicines. In England, Ireland and the Netherlands, pharmacy technicians are also allowed to dispense POM. The highest number of dispensing staff per pharmacy (10 people: pharmacists and pharmacy technicians) is found in the Netherlands. In addition, there are qualified staff working in community pharmacies in all deregulated countries who are not allowed to dispense but support the dispensing staff.	In Finland, prescriptionists may also dispense (prescription-only) medicines, and in Denmark pharmacy technicians ("pharmaconomists") dispense prescription-only medicines. In Austria and Spain pharmacy assistants may not dispense medicines. Denmark has the highest number of total staff per pharmacy (more than 15 staff, thereof 10.5 dispensing staff). Austria ranks third (after the Netherlands) regarding staff per pharmacy, and Finland third (after the Netherlands) concerning dispensing staff per pharmacy. There are additional qualified staff working in community pharmacies in all regulated countries who are not allowed to dispense but support the dispensing staff.
Professional independence of pharmacists	Loss of professional independence: pharmacy chains, with pharmacies in ownership, entered and dominate the market. Overall, every second pharmacy is organized in a chain. The pharmacies are often vertically integrated, i.e. owned by a large wholesale company (e.g. 85% of all pharmacies are owned by three large pan-European wholesale companies in Norway).	No pharmacy chains are allowed, no multiple ownership (i.e. no other owners than pharmacists). The pharmacy sector is characterized by independent pharmacies.
Role of tailor-made products	Only a few pharmacies have a laboratory and can and do produce extemporaneous preparations. "Outsourcing" to production centres (England, Sweden) or cooperation among pharmacies (the Netherlands, Norway) is common.	Extemporaneous preparations play a role in Austria, Finland and Spain, as a service to the patients and confirming the competence of pharmacists. Their share in an average pharmacy turnover is low, however.
Focus on medicines	OTC medicines and in particular non-pharmaceuticals have an increasing share of a pharmacy's turnover (e.g. non-pharmaceuticals: about 25% in Norway and Ireland). This shift to non-pharmaceuticals was in particular observed after a deregulation.	Key focus on medicines, in particular prescription-only medicines. Still, non-pharmaceuticals increasingly contribute to sales of a pharmacy. Regulations require connecting the sale of non-pharmaceuticals to health care (Austria, Denmark).
Relevance of pharmaceutical counselling and further pharmaceutical services	Pharmaceutical counselling is a key activity of pharmacies. Concerns were raised about a possibly negative impact on counselling (time) due to increased workload. England and the Netherlands take, for traditional reasons, a lead in pharmaceutical care.	Pharmaceutical counselling is a key activity of pharmacies. A standard counselling situation is around four to five minutes (data from Austria and Denmark). All countries have started with an expansion of pharmacy services including pharmaceutical care.

Indicators	Deregulated countries	Regulated countries
Involvement in health promotion and prevention	Community pharmacies are major players in the health care systems, with an increasing role in health promotion and prevention which has a potential to be used even more. A focus on mere retail sales figures may compromise the role of pharmacies as partners in health care.	Community pharmacies are major players in the health care systems, with an increasing role in health promotion and prevention which has a potential to be used even more.
Economics		
Growth in pharmaceutical expenditure	High growth rates in Ireland, moderate growth in the United Kingdom and Sweden from 2000 to 2008. From 2008 on decreases in the pharmaceutical expenditure were observed in Ireland and Sweden. Norway had a negative growth in pharmaceutical expenditure due to cost-containment during the last years.	Spain has, after Ireland, the second highest growth in total pharmaceutical expenditure from 2000 to 2009. Since 2007 and 2008 respectively pharmaceutical expenditure decreased in most of the regulated countries (Austria, Finland; and Denmark).
Growth in public pharmaceutical expenditure	Same development as for total pharmaceutical expenditure.	Same development as for total pharmaceutical expenditure.
Average pharmacy margin	No data on margins for the deregulated countries available (only Sweden before the liberalisation – 21.3% in 2008).	Margins for prescription and/or reimbursement market: from 16.5% (Denmark) to 22.3% (Spain), margins for the total market from 21.8% (Denmark) to 23% (Finland).

Source: The authors, based on the survey done in this study

Throughout all the countries surveyed, the professional independence of pharmacists is considered as a high value. Individual pharmacists have lost their professional independence after deregulation when vertically integrated pharmacy chains were set up and, after a short time, dominated the market. The purchase of a pharmacy is economically challenging, often impossible for individual pharmacists when they have to bid against financially strong wholesalers in a tender. The loss of professional independence is particularly hard for experienced pharmacists having served many years of their professional life in an independent pharmacy.

Pharmacy margins under pressure, no indications of price reductions after deregulation

Cost-containment in the pharmaceutical sector, targeting all actors, has been on the agenda in all European countries. A few of the surveyed countries, in particular Denmark and Norway, succeeded in containing the pharmaceutical budgets, i.e. keeping the growth rates in pharmaceutical expenditure at a moderate level, during the last decade. At the other end, Ireland and also Spain have displayed high growth in total and public pharmaceutical expenditure since 2000. After 2008 the increases in pharmaceutical expenditure turned to negative in several countries (Austria, Denmark, Finland, Ireland, and Sweden; and later also in Spain) as they responded with cost-containment measures to the global financial crisis.

Differences regarding the level and growth of expenditure across the countries are not connected to the extent of regulation in the community pharmacy sector but result from economic wealth and overall pharmaceutical policies in the countries.

Data on average pharmacy margins on medicines are hard to be surveyed. We could only collect information from the regulated countries and from Sweden before the liberalisation. The pharmacy margins range from 16.5 percent for prescription-only medicines in Denmark to 23 percent for the total market in Finland.

OTC prices, which are often expected to decline after a deregulation, were not within the scope of this study. Few studies are available on the development of the OTC prices, and none of them could confirm a decrease in OTC prices after liberalisation.

Conclusions

Changes in the pharmacy sector have taken place in several countries, and further policy measures impacting the community pharmacy sector are under discussion. Pharmacy margins have been and continue to be a key target of the attention of policy makers.

In some countries the community pharmacy systems were radically changed after deregulation. The most recent example was the fall of the monopoly of state-owned pharmacy company Apoteket and the liberalisation of the sales of OTC medicines in Sweden.

Deregulation in the pharmacy sector is usually aimed to increase the accessibility of medicines and to reduce of the prices of (OTC) medicines.

However, these are often false expectations. Liberalisation in the pharmacy sector does not necessarily lead to more competition; and further regulations might be required to compensate. Competition tends to be compromised by the market dominance of new actors, in particular wholesale companies establishing large pharmacy chains. The professional independence of pharmacists could be at stake.

While more new pharmacies have been opened after a liberalisation of establishment and ownership rules, they tend to be established at attractive locations (urban clustering) and not in places (e.g. rural, sparsely populated areas) where no pharmacy had existed before.

Furthermore, there is no evidence that liberalisation has reduced medicine prices since they are influenced by other policies (e.g. statutory framework, strategies of third party payers, generic policies).

Being part of the overall health care system, the pharmacy sector is not a typical market and should therefore not be left to market forces alone.

If a deregulation of the pharmacy sector is intended, consequences should be considered, and possible negative implications to the detriment of the patients, in particular vulnerable people, and to public health care should be avoided.

Any policy measure – no matter if leading to more or less regulation – should be monitored and evaluated.

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ABPI	Association of British Pharmaceutical Industries
AEMPS	Agencia Espanñola de Medicamentos y Productos Sanitarios / Spanish Medicines Agency
AESGP	Association of the European Self-Medication Industry
APL	state owned production center of medicines (Sweden)
ASHP	American Society of Health System Pharmacists (USA)
BAPW	British Association of Pharmaceutical Wholesalers
BgPharma	Bond van Groothandelaren in het Pharmaceutische bedrijf / Association of Pharmaceutical Wholesalers (Netherlands)
BIA	Bioindustry Association (England)
BOGIN	Bond van de Generieke Geneesmiddelenindustrie Nederland / Association of Dutch Generic Manufacturers
BSc	Bachelor of Science
CBG	College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board (Netherlands)
CE	Continuous Education
CEE	Central and Eastern Europe
cf.	confer
CGCOF	General Council of Pharmacists (Spain)
COFARES	Cooperativa Farmacéutica de España
CPD	Continuing Professional Development
DDA	Dispensing Doctors‘ Association
DDD	Defined daily doses
DDKM	Danish Healthcare Quality Programme
DFU	Det Farmaceutiske Fakultet / Faculty of Pharmaceutical Sciences
DKMA	Danish Medicines Agency
DMP	Disease Management Program
DoH	Department of Health (England)
DoHC	Department of Health and Children (Ireland)
DP	Drug Payment (Ireland)
DTP	Direct-to-Pharmacy
e.g.	Exempli gratia (= for example)
ECJ	European Court of Justice
EEA	European Economic Area
EFP	Especialidades Farmaceuticas Publicitarias (Spain)
EJC	European Court of Justice
EMA	European Medicines Agency
ESP LPS	Essential Small Pharmacy Local Pharmaceutical Services scheme
ESPS	Essential Small Pharmacies Schemes
EU	European Union
FHI	Folkehelseinstituttet (Norway)

FIMEA	Lääkealas turvallisuus – ja kehittamiskeskus, Säkerkets- oc utvecklingscenter for läkemedelsomradet / Finnish Medicines Agency
FTE	Full time equivalent(s)
GDP	Gross Domestic Product
GMS	General Medical Services (Ireland)
GÖG	Gesundheit Österreich GmbH / Austrian Health Institute
GÖG FP	Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH
GP	General practitioner
GPhC	General Pharmaceutical Council (England)
GPP	Good Pharmacy Practice
GSK	Glaxo Smith Kline
GSL	General Sales List (England)
HE	Health expenditure
HOM	Hospital only medicine(s)
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)
IEP	Irish pound
IMB	Irish Medicines Board (Ireland)
inh.	Inhabitants
IPHA	Irish Pharmaceutical Healthcare Association (Ireland)
IPU	Irish Pharmacy Union (Ireland)
IPU	Irish Pharmaceutical Union (Ireland)
ISB	Irish Statute Book
KELA	Kanseläkelaitos / Social Insurance Institution (Finland)
km	kilometre
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie / Royal Dutch Pharmacy Association
LMI	Legemiddelindustriforeningen / Association of Pharmaceutical Manufacturers (Norway)
LTI	Long Term Illness (Ireland)
LUA	Legemidler Utenom Apotek / medicines outside pharmacies (Norway)
mill.	millions
MSc.	Master of Science
MUR	medicines use reviews
n.a.	not available
NAM	National Agency for Medicines (Finland)
NCU	National Currency Units
NHS	National Health Service (England, Ireland)
NIGeL	Norsk Industriforening for Generiske Legemidler / Norwegian Association of Generics-orientated Pharmaceutical Manufacturers

Nivel	Nederlands Instituut voor onderzoek van de Gezondheidszorg / Dutch institute for research in health care
NOK	Norwegian crowns
NoMA	Norwegian Medicines Agency
NRT	Nicotine replacement therapy
NVQ	National Vocational Qualification (England)
NZa	Nederlandse Zorgautoriteit / Dutch Healthcare Authority
OAB	Apotekens Omstrukturering AB (Sweden)
ÖAK	Österreichische Apothekerkammer (Austria)
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen (business area of GÖG) – Austrian Health Institute
OECD	Organisation of Economic Co-operation and Development
OFT	Office of Fair Trading (England)
OPD	Out-patient department
OPG	Onderlinge Pharmaceutische Groothandel / Reciprocal Pharmaceutical Wholesaler (Netherlands)
OTC	Over-the-counter
PCRS	Primary Care Reimbursement Service (Ireland)
PCT	Primary Care Trust (England)
PGEU	Pharmaceutical Group of the European Union
PHIS	Pharmaceutical Health Information System
PNAs	Pharmaceutical Needs Assessments
POM	Prescription-only medicines
PPP	Purchasing Power Parities
PPP	Pharmacy Purchasing Price
PPRS	Pharmaceutical Pricing Reimbursement Scheme
PRP	Pharmacy Retail Price
PSI	Pharmaceutical Society of Ireland (Ireland)
PSNC	Pharmaceutical Services Negotiating Committee
PWC	Price Waterhouse Coopers
quo.	quoted
reg.	Regulation existing
ROHTO	Centre for Pharmacotherapy Development
RPSGB	Royal Pharmaceutical Society of Great Britain
SD	Self-dispensing
SDU	Syddansk Universitets / University of Southern Denmark
SFK	Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics (Netherlands)
SFT	Seguimiento Farmacoterapeútico / Pharmaceutical Follow-up (Spain)
SM	Self-medication
STM	Sosiaali- ja Terveysministriö (Finland)
Tab.	Tablet
TLV	Dental and Pharmaceutical Benefits Agency (Sweden)

UK	United Kingdom
VAT	Value Added Tax
VNA	Verenigde Nederlandse Apotheken / United Dutch Pharmacies
vs.	versus
WGP	Wet Geneesmiddelenprijzen / Law on Medicines Prices (Netherlands)
WHO	World Health Organization
WHO CC	WHO Collaborating Centre (in this case: the WHO CC for Pharmaceutical Pricing and Reimbursement Policies in Vienna)
WMG	Wet Marktordening Gezondheidszorg / Law on Marketing in Health Care (Netherlands)
ZGA	Zorggroep Almere / Health Care group Almere (Netherlands)

1 Introduction

Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH (GÖG FP), a subsidiary of Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute, was commissioned by the Association of Danish Pharmacies (Danmarks Apotekerforening) to carry out a survey and analysis of community pharmacy systems in a selection of European countries. The project started in July 2011, and GÖG FP submitted the final report to the commissioning party in December 2011. In March 2012 this report was published under the title “Impact of pharmacy deregulation and regulation in European countries”. In addition, a summary report, containing the brief and the executive summary and the conclusions were published at the same time.

1.1 Background

The pharmacy sector has been undergoing in some cases considerable changes in several European countries, targeting, among others, establishment rules (e.g. demographic and/or geographic criteria for opening new pharmacies), the ownership of pharmacies (e.g. vertical integration), the role of further actors distributing prescription-only medicines and/or the sale of OTC medicines. Deregulation took place in some of the European countries.

Some years ago the European Commission launched infringement proceedings against several Member States. Major decisions in this context were the rulings on Germany and Italy which concerned the right to own and operate a pharmacy which was granted exclusively to pharmacists. The German case involved several pharmacists and their professional associations challenging a decision to allow a Dutch public limited company to operate a branch pharmacy in the German town of Saarbrücken (ECJ 2009a). The Italian case was an action brought by the European Commission alleging that the Italian law contravened EU law (ECJ 2009b). A similar case concerned the Spanish region Asturia (ECJ 2010a, ECJ 2010b).

On 19 May 2009 the ECJ ruled that while restrictions on ownership and operation of pharmacies constitute a restriction on freedom of establishment and the free movement of capital, these restrictions can be justified. Each EU Member State has discretion to determine its own level of protection of public health, and thus EU Member States' national legislation may restrict pharmacy ownership and operation to persons having the status of a pharmacist.

For years the EC proceedings had been pending against several countries targeted, and on 23 November 2011 the European Commission announced the dropping of all charges against Member States regarding the pharmacy sector (PGEU 2011).

Overall, the changes in the pharmacy sector were attributable to national decisions. This was also the case in Sweden: The European Commission had addressed the issue of the monopoly of Apoteket, Sweden’s sole owner of all pharmacies of the countries, but finally the ECJ basically confirmed the exclusive right of Apoteket to sell medicines. However, it was a

new government which launched a process called “reregulation” which concerned both ownership structures as well as the liberalisation of the sale of OTC medicines.

In some countries drivers for starting and continuing the liberalisation of the pharmacy sector were competition authorities whose representatives argued that competition would bring medicines prices down and improve pharmacy services.

The current global financial crisis has aggravated the pressure on all health sectors, including the pharmacy system. Across Europe, a decrease in the pharmacy margins (or change in the pharmacy remuneration) is one of the measures undertaken by the countries struggling with the financial crisis (Vogler et al. 2011). Further measures are to be expected, targeting not only the pharmacy remuneration, but also the organisation of the pharmacy system.

In Denmark, the Danish government has set up a ministerial working group with the aim to evaluate the Danish community pharmacy system. The task comprises a comparison of the Danish community pharmacy system with those in a number of other European countries.

To obtain updated information on community pharmacy systems in other European countries, the Association of Danish Pharmacies (Danmarks Apotekerforening) asked Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH (GÖG FP), a subsidiary of Gesundheit Österreich GmbH (GÖG) / Austrian Health Institute, to carry out a survey and analysis of community pharmacy systems in a selection of European countries.

In 2006, the Austrian Health Institute (then called Österreichisches Bundesinstitut für Gesundheitswesen, ÖBIG) published the report „Community Pharmacy in Europe: lessons from deregulation – case studies”. The study, which had been commissioned by the Pharmaceutical Group of the European Union (PGEU), could not provide any evidence that the goals of competition and cost-containment, which were considered as the two key aims of deregulation, have been achieved through deregulation of community pharmacies. On the contrary, unfavourable side-effects could be observed, such as extreme market power by non-pharmacy 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 (Vogler et al. 2006).

1.2 Objective

The aim of this study is to survey and analyse the community pharmacy systems in nine European countries, both countries with a deregulated pharmacy system and ones with a more regulated system. The pharmacy systems in the countries surveyed will be comparatively analysed with regard to

- accessibility
- quality, and
- economics.

in order to assess a possible impact of deregulation and regulation.

The analysis will be carried out on a country macro level from the public health and patient perspective.

1.3 Outline

The outline of this report is as follows:

- Introduction (chapter 1) and methodology (chapter 2)

  After this introductory chapter, the study design chosen for addressing the research question of this report and methodological approaches are presented.

- Country reports – deregulated countries (chapters 3 – 7)

  The community pharmacy systems of the deregulated countries selected will be described according to a homogeneous outline taking account of the indicators to be analysed. Five countries with a deregulated pharmacy system are analysed: England, Ireland, the Netherlands, Norway, and Sweden.

- Country reports – regulated countries (chapter 8 – 11)

  The description of the community pharmacy in four countries with a regulated pharmacy system (Austria, Denmark, Finland, and Spain) follows the same outline as the one of the deregulated countries.

- Comparative analysis (chapter 12)

  In a comparative analysis, several indicators developed for accessing the impact of the community pharmacy system with regard to accessibility, quality and economics are benchmarked and discussed for the nine countries.

- Lessons learned (chapter 13) and conclusions (chapter 14)

  In the concluding chapters, lessons learned based on the indicators analysed will be discussed, summaries provided and conclusions drawn.

2 Methodology

2.1 Study design

For surveying, analysing and comparing the community pharmacy systems in the selected European countries, indicators were defined and a set of countries for the baskets of deregulated and regulated countries was chosen.

It should be noted that most of the authors of this study also worked on the report "Community Pharmacy in Europe – Lessons learned from deregulation – case studies" (Vogler et al. 2006) where a similar methodological approach was applied. However in the present report the basket of countries is broader, and the previous indicators have been critically revised.

2.1.1 Indicators

A total of 15 indicators were identified for analysing the community pharmacy systems in the selected countries. The indicators are both of quantitative and qualitative character and they are built around the three pillars accessibility, quality and economics.

Table 2.1 provides an overview of the indicators selected.

Table 2.1: Methodology – Indicators relating to the three pillars of accessibility, quality, and economics selected and applied in this study

Accessibility	Quality	Economics
Provision with community pharmacies Accessibility of prescription-only medicines Accessibility of prescription-only medicines in rural areas Availability of medicines Frequency of wholesale deliveries	Availability of pharmacists Availability of qualified staff in community pharmacies Professional independence of pharmacists Role of tailor-made products Focus on medicines Relevance of pharmaceutical counselling and other pharmaceutical services Involvement in health promotion and prevention	Growth in pharmaceutical expenditure Growth in public pharmaceutical expenditure Average pharmacy margin

Source: The authors

2.1.2 Country baskets

Two country baskets were defined: one with countries whose community pharmacy sector has undergone a deregulation, and a second group of countries with a regulated pharmacy sector.

Table 2.2 lists the countries of the two groups.

Table 2.2: Methodology – Baskets of deregulated and regulated countries

Countries with a deregulated community pharmacy system	Countries with a regulated community pharmacy system
England	Austria
Ireland	Denmark
The Netherlands	Finland
Norway	Spain
Sweden	

Note: Following the devolution (Bevan 2010) in the United Kingdom's health care system, there are now four different systems, and it was decided to only include the English health care and pharmacy system.

Source: The authors

The group of deregulated countries is a heterogeneous group: deregulation took place to a different extent and at different points in time.

2.2 Literature review

A literature review was performed, especially at the beginning of the project and continued throughout the whole project. We did a search in the electronic databases of PubMed and GoogleScholar. Search terms included "pharmacy", "pharmacy sector", "liberalisation", "deregulation" alone and in combination with each other. Additionally, the bibliography of included studies was checked for other relevant studies. Further, we considered a broad range of grey literature and materials which we were familiar with and which was suggested to us by the commissioning party and the interview partners.

While the search strategy favoured studies published in English, we included in the course of time an increasing amount of literature in the countries' languages. In case of missing translations of the reports, we contacted either the authors or other cooperation partners in the countries to provide us with a summary of the main results in English.

We focused on reports and materials produced during the last decade.

For hard data on the underlying health care systems which were needed for the comparisons unless collected in the primary survey (cf. section 2.3), we referred to international databases and resource centres in order to guarantee comparability. These were primarily the OECD,

EUROSTAT and PHIS databases as well as the market data provided by the self-medication association AESGP.

2.3 Survey

Information and data needed on the community pharmacy sector in the countries surveyed was, as agreed in the work plan with the commissioning party, collected via a primary survey in the countries.

The survey tool was a questionnaire which we had pre-filled out. The respondents were asked to fill in the missing data and check the information provided by us.

The respondents were, with one exception, representatives from the national pharmacy associations who had been contacted beforehand by the commissioning party, the Association of Danish Pharmacies, to ensure a good cooperation basis. The Association of Danish Pharmacies also supported the project team by advising on possible respondents. In the Netherlands, a well-known pharmacist and pharmacy expert, who is also represented in several committees, was chosen as contact person.

In Austria – the country where the project team is hosted – we followed a slightly different approach. Instead of a pre-filled out questionnaire, a first draft country report was shared with the Austrian Chamber of Pharmacists, and during a personal meeting the provision of missing data and a check of information were requested.

Data were collected as of end of September 2011. Nonetheless, important developments at a later stage (e.g. a ruling of the European Court of Justice in November 2011) were integrated in the report.

The questionnaires were sent to the relevant national pharmacy associations in the second half of September and at the beginning of October 2011. The respondents were asked to reply within a time period of about two weeks which, as a rule, was not feasible for them. All nine contact persons answered the questionnaire, the latest questionnaire was returned on 11 November 2011. The inclusion of the information and data of the returned questionnaires into the country reports was accompanied, for all countries surveyed, with regular contacts to the respondents for clarifying open questions, and the project team members were happy that the contact persons with the national pharmacy associations were committed to cooperate and to be available for answers. In some cases, additional interviews were carried out.

The project team undertook a total of 16 interviews with stakeholders of the countries. The interviews were mainly performed as telephone interviews and partially as personal interviews when we could benefit from meeting possible interview partners on some other occasions (e.g. the PPRI Conference in Vienna, Austria at the end of September 2011, the ICIUM Conference in Antalya, Turkey in November 2011). The interviews were held on the basis of an interview guide. One key target was representatives of patients' and/or consumers' associations. Priority was given to interviews in deregulated countries. For

Denmark (country of the commissioning party) and Austria (country hosting the project team's institution) no interviews with other stakeholders than pharmacists were held.

Table 2.3 provides an overview about the interview partners. The interviews were performed between September and December 2011 and were reported in internal minutes. The interviews had a duration of 20 to 80 minutes.

Table 2.3: Methodology – Overview of interviews and contacts

Country	**Pharmacies** (associations unless otherwise indicated)	Consumers	Competent authorities	Others
England	Questionnaire survey, review of draft country report, contacts for clarifications 1 interview (with another person than the respondent of the questionnaire)	-[1]	2 interview with regulatory authorities[2]	-
Ireland	Questionnaire survey, review of draft country report, several contacts for clarifications	1 interview	1 interview with P+R authority 1 interview with competition authority	-
Netherlands	Questionnaire survey, one interview, review of draft country report, several contacts for clarifications[3] 1 interview with pharmacy association	-	1 interview with P+R authority	-
Norway	Questionnaire survey, one interview, review of draft country report, several contacts for clarifications	1 interview	1 interview with P+R authority	1 interview with research institute
Sweden	Questionnaire survey, review of draft country report, several contacts for clarifications	1 interview	1 interview with regulatory authority	-
Austria	Personal interview, requests for data, review of draft country report, contacts for clarifications	-	-	-
Denmark	Questionnaire survey, review of draft country report, contacts for clarifications	-	-	-
Finland	Questionnaire survey, review of draft country report, several contacts for clarifications	-	1 interview with regulatory authority	1 interview[4]

Country	Pharmacies (associations unless otherwise indicated)	Consumers	Competent authorities	Others
Spain	Questionnaire survey, review of draft country report, several contacts for clarifications	-	1 interview with P+R authority	1 interview with industry associations 1 interview with researcher (policy expert)

P+R = pricing and reimbursement

[1] Requests to have an interview with the patients association were not successful

[2] The project team refrained from an interview with a representative of the competition authority but considered their publications.

[3] Pharmacist, pharmacy expert, ex-board member of pharmacy association

[4] Interview partner from an institution, but gave the interview in his/her competence as a researcher

Source: data gathering by GÖG FP

2.4 Coordination and review

The study was performed in close cooperation with the commissioning party, the Association of Danish Pharmacies. The commissioning party was informed about the survey with the national pharmacy associations and supported the project team in building bridges to the respondents.

The draft versions of the country reports were shared with both the commissioning party and the respondents of the questionnaires. They were asked to check the completeness and the correctness of the information. All nine respondents provided feed-back by answering our questions for clarification. Additionally, some of them reviewed the draft reports and even worked on providing some updated information.

Furthermore, we received feed-back on the draft country reports as well as on the draft tables and figures of the comparative analysis and the conclusions from the commissioning party.

3 England

3.1 Framework

In England, prescription-only medicines are normally dispensed from a registered pharmacy by, or under the supervision of, a pharmacist. Under certain circumstances, in areas where patients have difficulty accessing a community pharmacy, primary care doctors (dispensing doctors) can dispense prescription-only medicines (Lluch/Kanavos 2010). Dispensing doctors do not provide a full pharmaceutical service and cannot supply over-the-counter medicines. Internet and mail order pharmacies are also allowed. OTC medicines on the "General Sales List" (GSL) (cf. section 3.3.2.1) can be sold unsupervised by for example supermarkets and petrol stations.

England has a National Health Service (NHS) funded centrally mainly through general taxation. The NHS provides universal access to healthcare at no cost for the patient, with a few exceptions, among which prescription charges for out-patients. There are currently 152 Primary Care Trusts (PCTs) in England, which are responsible for commissioning or providing primary medical care services to their populations and have a major role around commissioning secondary care and providing community care services (Palnoch et al. 2007). PCTs control 80 percent of the NHS budget. Community pharmacy owners (contractors) require inclusion on a list held by their PCT in order to fill NHS prescriptions. Inclusion on the PCT's list is described as holding a pharmacy contract with the NHS (PSNC 2011b).

The 1968 Medicines Act states that retail premises for medicines must be registered and owned by a pharmacist, a partnership of pharmacists or a "body corporate" (for example a limited company*).* Apart from any relevant planning or building conservation laws, there are no legal controls over the location of pharmacies in respect of, for example, setting a minimum distance between pharmacies. However, according to NHS regulations, if a pharmacy wishes to provide state funded NHS pharmaceutical services, it must apply to the relevant local health body for approval. Introduced in the mid-1980s, the so called "control of entry test" restricted market entry. According to this test, no new contractor could be entered onto a NHS list, unless it is "necessary or expedient" to secure the adequate provision of pharmaceutical services locally. In 2003, The Office of Fair Trading (OFT) carried out a market study of the retail pharmacy market (OFT 2003). They recommended total deregulation to improve competition and improve access to and the quality of pharmaceutical services. The government responded with a package of reforms, including a revised control of entry test and four complete exemptions to the test. These four exemptions are:

- Pharmacies open for at least 100 hours per week,
- Pharmacies in designated large, out of town, shopping centres,
- Pharmacies in one-stop primary care centres and
- Internet-based and wholly mail-order pharmacies.

These reforms came into effect on 1 April 2005. In 2006, a review was undertaken on the impact of these reforms on the pharmacy market (DoH 2006). The OFT also published a review of the reforms in March 2010 (OFT 2010). The report showed that by July 2009 the

market entry had increased by 8.8 percent (an estimated 855 net new pharmacies) without a negative impact on existing pharmacies or increased market exit. An average pharmacy's dispensing volume continued to rise, all be it more slowly than before due to new entries. However, the competitive effects of the new entries were not yet fully played out, as it takes new pharmacies several years to reach "normal" trading levels. In addition, the OFT report stated that over 60 percent of the new entrants were pharmacies prepared to open for at least 100 hours per week. A further 25 percent of new entrants were successful through the revised control of entry test.

In 2008, the then government published a Pharmacy White Paper setting out their program for a 21st century pharmaceutical service (DoH 2008). A consultation on reforms that were proposed in the White Paper took place in 2008. As part of their response to this consultation, the Government amended the primary legislation in the Health Act 2009.

The Health Act 2009 contains provisions to require Primary Care Trusts to develop and to publish Pharmaceutical needs assessments (PNAs). Regulations to give effect to these provisions came into force in spring 2010. According to the draft National Health Service (Pharmaceutical Services) regulations 2012, the PCTs will then use these PNAs as the basis for determining entry of new pharmacies to the NHS pharmaceutical services market. If the new draft regulations are implemented, the current control of entry system will be replaced with one based on the needs or improvements identified in a PCT's PNAs. Three of the four exemptions will be removed, and only the "distance-selling" exemption will be retained with tightened criteria (DoH 2011).

It is allowed for anyone, including pharmacists, non-pharmacists and companies, to own a pharmacy. In each pharmacy there must be a pharmacist in personal control at all times when the pharmacy is open. In addition each company must appoint a superintendent pharmacist who is responsible for ensuring all legal and ethical requirements of pharmacy practice.

Most community pharmacies are privately owned although in exceptional cases Primary Care Trusts (PCTs) run pharmacies. Pharmacy chains are allowed. Vertical partnerships/mergers, i.e. with pharmacy wholesalers and manufacturers are allowed subject to the Competition Act.

The General Pharmaceutical Council (GPhC) took over as the regulator for pharmacy professionals in England from the Royal Pharmaceutical Society of Great Britain (RPSGB) in September 2010.

The pharmaceutical industry comprises of two main sectors:

- The research based sector, which is largely represented by the Association of British Pharmaceutical Industries. The ABPI represents most pharmaceutical companies active in the UK, and it represents the industry in discussions and formal consultations with government on policy matters pertinent to the industry. The ABPI also represents the industry in negotiations with the government on the Pharmaceutical Price Regulation Scheme. The Biotechnology sector is represented by the Bioindustry Association (BIA).

- The Generics Manufacturers are represented by the British Generics Manufacturers Association, which represents the larger manufacturers.

The distribution channel normally comprises of manufacturers (research based or generic) selling to wholesalers who sell on the pharmacies. Some research based manufacturers have their own distribution arrangements (see below). Wholesaling is split in to two sectors – full-line wholesalers, which supply a full range of medicines, and short-line wholesalers, which tend to specialise in supplying a smaller range of high volume generic medicines. In addition, some pharmacy changes are part of vertically integrated companies comprising wholesale and retail pharmacy.

Over 1,600 wholesale authorisations have been issued within the UK. Of the 11 full-line wholesalers, three with a combined wholesale market share of almost 90 percent have near national coverage (Celesio, Alliance Boots, Phoenix). Eight full-line wholesalers operate regionally. Nearly all wholesalers are a member of the British Association of Pharmaceutical Wholesalers (BAPW).

Most medicines (93 percent) are distributed by national wholesalers, while regional wholesalers are a minority. However, approximately 11 percent of medicines are delivered by short-line wholesalers. The wholesale distribution model has undergone significant changes in the past five years with the evolution of agency and reduced wholesaler arrangements. As a result, full-line wholesaling is declining and short-line wholesaling is on the ascendancy (Kanavos et al. 2011). Agency distribution relates to Direct-to-Pharmacy (DTP) arrangements. In the UK, there has been a significant uptake of DTP arrangements over the past three years. GSK was first, Pfizer second (now including Wyeth). With just Astra Zeneca and Eli Lilly these cover over 30 percent of the market. Additionally, there are also optional offers by some companies to sell direct or via mainline wholesalers (Kanavos et al. 2011).

The new forms of distribution are considered as an opportunity for the industry to gain insight into the pharmacy sector (personal communication from a pharmacy representative).

3.2 Accessibility

3.2.1 Accessibility of medicines dispensaries

3.2.1.1 Provision of POM dispensaries

As of 31 March 2011, there were 10,951 retail pharmacies operating with NHS contracts in England.

The most obvious and easily quantified effect of the 2005 the reforms has been a net increase in the number of retail pharmacies with NHS contracts in England relative to the previous situation. Since 2005, 1,215 pharmacies have entered the market, an increase of 12 percent. Hospital pharmacies are not included in Table 3.1 since they do not provide pharmacy service to out-patients (James/Kullman 2009).

Table 3.1: England – Number of pharmacies (in contract with NHS) and other POM dispensaries[1], as of 31 March 1990 – 2011

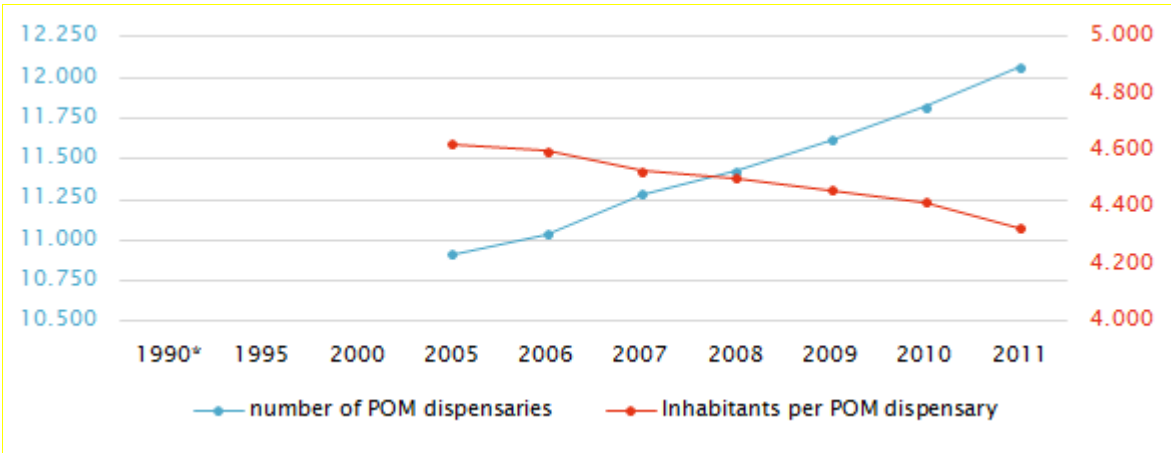
POM dispensaries[1]	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies (all privately owned)	n.a.	n.a.	9,767	9,736	9,872	10,133	10,291	10,475	10,691	10,951.
POM dispensing doctors	n.a	n.a	n.a	5,279	5,353	5,311	5,553	5,731	5,778	5,830
POM dispensing practices	n.a	n.a	n.a	1,179	1,166	1,149	1,135	1,139	1,129	1,118
Internet pharmacies dispensing POM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total of POM disppenaries[2]	n.a.	n.a.	n.a.	10,915	11,038	11,282	11,426	11,614	11,820	12,069

n.a. = not available, POM = Prescription-only medicine

[1] Retailers which are allowed to dispense prescription-only medicines (POM).
[2] Here not the POM dispensing doctors but the number of POM dispensing practices was included.

Source: DDA 2011, DoH 2006, NHS 2011

Figure 3.1: England – Number of POM dispensaries and inhabitants per POM dispensary, 1990 – 2011



Note: The numbers of inhabitants are as of 30 June for each year. For 2011 population numbers were not yet available, therefore number of inhabitants as of 30 June 2010 was taken.

Source: DDA 2011, DoH 2006, NHS 2011

3.2.1.2 Provision of POM dispensaries in rural areas

Incentive schemes to establish in rural areas are not open to new pharmacies any more. In the past some pharmacies were subsidized under the Essential Small Pharmacies Schemes (ESPS) which helped pharmacies in rural or low population areas. The Essential Small Pharmacy Scheme ended on 31 March 2006, and was replaced by the Essential Small Pharmacy Local Pharmaceutical Services scheme (ESP LPS) from 1 April 2006. The ESP LPS which replaced the ESPS arrangements was available only for pharmacies that applied by 31 October 2005. ESP LPS terms are set out in binding contracts, signed by individual

contractors and PCTs normally for five years. In 2010, the Minister issued directions granting an extension to those pharmacies that continued to meet the conditions of ESP LPS until March 2013. Essential Small Pharmacy LPS are permitted to dispense only up to 26,400 prescription items a year. If this threshold is exceeded, the PCT is required to give notice that the pharmacy will be removed from the ESP LPS arrangements (PSNC 2011a).

The liberalisation of the pharmacy market with regard to geographical criteria has probably been responsible for more openings of pharmacies in urban areas. Despite this clustering, however, the number of pharmacies has not risen considerably.

According to “Pharmacy in England” published by the Department of Health in 2008 (DoH 2008), as at 31 March 2007 96 percent of the population in the 10 percent most deprived areas could reach a pharmacy within 10 minutes by walking or public transport, compared with 84 percent at 31 March 2006. Almost 100 percent are now within 20 minutes of a pharmacy. The position has improved substantially for those in the 10 percent most deprived areas, suggesting that pharmacies opened in or near deprived areas that previously had poorer access.

Between 2003 and 2006, the percentage of people not within 10 minutes' travel to a pharmacy by public transport or walking fell from 16.2 percent to 15.7 percent. Of the people living in the 10 percent most deprived areas in England 77 percent can get to a pharmacy by public transport or walking within 10 minutes, compared to 84 percent nationally (DoH 2006).

The NHS Information Centre collects information from PCTs on openings and closures according to distance from the nearest existing pharmacy. These data permit an analysis of the effect of the 2005 reforms on the spatial distribution of pharmacies and in particular of the extent and effects of clustering of new entry around existing pharmacies. Before the reforms, the majority of closures (60.6 percent) occurred within 500 metres of an existing pharmacy, while most openings (53.9 percent) occurred over 1 kilometre away, although both trends were weakening over time. The trend in openings was reversed following the 2005 reforms, when the majority of new pharmacies opened within 1 kilometre of an existing establishment. Of 791 new pharmacies recorded as opening since the reforms, only 21.9 percent did so further than 1 kilometre away from an existing pharmacy. These are likely to have included a disproportionate number of pharmacies opening under the out-of-town shopping centre exemption, as well as supermarket and edge-of-town health and beauty pharmacies that are less closely tied to high streets and secondary locations close to surgeries. Overall, this evidence suggests that an effect of the reforms has been to facilitate entry in areas already served by pharmacies, and that new pharmacies are about competition rather than improving access (OFT 2010).

POM dispensing doctors provide services to patients chiefly in rural areas, meeting the need for dispensing in places where a pharmacy may otherwise be unviable.

3.2.2 Availability of medicines

There are no specific service requirements for community pharmacies in England concerning the amount and range of medicines that must be in stock or concerning the maximum

timeframe within which medicines must be delivered to the patient. But there is a legal provision stating that a pharmacy must dispense a prescription in reasonable time. However, this reasonable promptness may vary depending on the kind of medicine, for common medicines it may be within one on the same day or within two days, while for other medicines which are difficult to supply two days might not be reasonable (personal communication).

England, moving from a parallel importer to a parallel exporter, has experienced at several occasions shortages of medicines in pharmacies. The new distribution models (e.g. Direct-to-Pharmacy, cf. section 3.1) are also considered as a cause for the shortages (personal communication).

Table 3.2: England – Pharmacy service requirements, 2011

Service requirements	Regulation	Practise
Medicines in stock	Not regulated.	No information available.
Requirements concerning space	Not regulated.	No information available.
Dispensing within a certain time period	Legal obligation to dispense within a reasonable time.	Depending on the kind of medicine.
Frequency of delivery	Not regulated.	Pharmacies are on average delivered 2 times per day.

Source: NPA 2011

3.3 Quality of pharmacy services

3.3.1 Pharmacy staff

3.3.1.1 Availability of pharmacists and other qualified staff

In order for pharmacists and pharmacy technicians to practise in Great Britain they must be registered with the General Pharmaceutical Council (GPhC). The GPhC is responsible for the regulation of two professions: pharmacists and pharmacy technicians. Although the education and training for both groups of professionals is different, there are common features. Both groups have to pass academic/professional courses to be eligible to register and both groups have to do continuing professional development (CPD) when they are registered. Pharmacists are registered with the General Pharmaceutical Council. Following the Privy Council's approval of the Health Care and Associated Professions Order 2009, statutory registration of pharmacy technicians started on 1 July 2009 and has been mandatory since 1 July 2011. As well as defining the education and training for pharmacists and pharmacy technicians, the GPhC also sets standards for pharmacy support staff.

Registered pharmacy technicians are allowed to dispense medicines, but not without the involvement of a pharmacist.

Table 3.3: England – Qualification requirements for pharmaceutical personnel, 2011

Profession	Required qualification	Duration	Compulsory practice training	Compulsory continuous education	Legal basis
Full pharmacists	Masters degree in pharmacy from one of the accredited universities	4 years	Yes, one year practical training in a community or hospital pharmacy	Yes, continuing professional development (CPD) is compulsory	Regulations of the General Pharmaceutical Council
Pharmacy technicians / assistants with the right to dispense pharmaceuticals	Post secondary education NVQ level 3[1]	-	-	Yes, continuing professional development (CPD) is compulsory	Regulations of the General Pharmaceutical Council
Medicines Counter Assistant (MCA)	NVQ level 2[1]	-	-	No	Regulations of the General Pharmaceutical Council
Dispenser/Dis-pensing Assistant	NVQ level 2[1]	-	-	No	Regulations of the General Pharmaceutical Council

[1] NVQ = National Vocational Qualification

Source: NPA 2011

It takes five years to qualify as a pharmacist. During a four-year master's degree, trainee pharmacists become experts in medicines and their use. To register as a pharmacist, they must complete one year of hands-on experience. There are currently approximately 24,000 pharmacists in Great Britain. It is however not known how many of these are working in community pharmacies.

3.3.1.2 Professional independence of pharmacists

Deregulation measures and heightened competition from supermarkets and multiples have led to increases in market concentration and forced many independents into closure (Schmidt/Pioch 2005).

At the end of July 2009 England had 10,578 community pharmacies, thereof 4,449 (42 percent) independent contractors or contractors owning less than ten pharmacies and 5,359 (51 percent) multiple contractors (100 pharmacies or more).

Table 3.4: England – Pharmacy chains, as of July 2009

Name of pharmacy chain	% of market share	Pharmacies in ownership
Boots UK Limited	18.3	1,939
Lloyds Pharmacy Ltd.	12.9	1,368
L Rowland & Co (Retail) Ltd.	3.8	402
National Co-operative Chemists Ltd.	3.0	314
Tesco Stores Ltd	2.4	255
Sainsbury's Supermarkets Ltd.	2.1	220
Other Co-operative	2.0	207
Superdrug Stores Plc	1.8	194
Asda Stores Ltd.	1.5	162
Co-op healthcare Ltd.	1.4	152
Day lews Chemists Ltd.	1.4	146
Multiple (100+) total	**50.7**	**5,359**
Wm Morrison Supermarkets Plc.	0.8	80
Gordemead Ltd.	0.6	62
H.I. Weldrick Ltd.	0.5	55
Paydens Ltd.	0.5	51
W.R. Evans (Chemist) Ltd.	0.5	49
PCTA Healthcare Ltd.	0,5	48
Other chains with 10 – 99 pharmacies	4.0	425
Multiple (10-99) total	**7.3**	**770**
Multiple (< 10) or sole owner total	**42.1**	**4,449**

Source: OFT 2010

In 2002 the pharmacy multiple (more than 10 pharmacies) accounted for 39 percent of all outlets (over the UK as a whole). The largest share of any one company is now that of Boots (18.3 percent), following the merger with Alliance Unichem (owner of Moss Pharmacies) to form Alliance Boots in 2006. Boots and Superdrug offer a much wider variety of health and beauty products than most other pharmacies and together account for about 20 percent of NHS contracts. The other main business model – in-store supermarket pharmacies – account for almost seven percent of the total (OFT 2010).

Competition in the OTC sector from other retailers, e.g. supermarket, is strong. According to an interview partner from the regulatory field, the "traditional pharmacies have resisted", and they account for a good quality of counselling (cf. section 3.3.2.4), but they are continuously losing market shares (personal communication).

3.3.2 Product range

3.3.2.1 Medicines

The system categorizes medicines as follows:

- Prescription medicines are dispensed by a pharmacist to a prescription from a doctor or other health professional and charged to the customer at the national prescription charge (or provided free of charge if the customer is exempt).
- Over-the-counter (OTC) medicines are medicines that can be sold to consumers without a prescription and for which retailers have been free to set their own price since 2001. They are of two kinds:
  - pharmacy (P) medicines which must be sold under pharmacist supervision
  - "General Sales List" (GSL) medicines, which can be bought off the shelf and can be supplied by non-pharmacy retailers.

So called "specials" can be manufactured by pharmacies but are nowadays increasingly manufactured by companies which hold a "specials" license issued by the Medicines and Healthcare products Regulatory Agency (MHRA). The number of pharmacies in England, which have their own facilities to manufacture medicines, is very small (NPA 2011).

3.3.2.2 Non-pharmaceuticals

With regard to non-pharmaceuticals, there are no specific regulations (e.g. limits to sell only specific products) for their sale in pharmacies. Non-pharmaceuticals which are commonly sold in pharmacies in England are baby products and toiletries.

Boots and Superdrug are two pharmacy chains which offer a relatively wide variety of health and beauty products compared to other pharmacies.

3.3.3 Pharmacy services

3.3.3.1 Services provided by pharmacies

Increasingly, pharmacies are being funded by the NHS to provide clinical services to customers. Since April 2005, most community pharmacies have provided services under a new contractual framework with three tiers of services – essential, advanced and local enhanced (NPA 2011).

The essential services that have to be offered by each community pharmacy include

- dispensing and repeat dispensing,
- services such as health promotion and healthy lifestyle advice,
- support for self care and
- disposal of medicines.

Amongst the voluntary advanced services is

- the nationally agreed Medicines Use Review service. A pharmacist reviews a person's use of their medicines, offers advice on appropriate use to promote adherence and may make recommendations for changes to the person's GP. A total of 1.7 million Medicines Use Reviews were conducted by community pharmacy contractors in England in 2009-2010.

A pharmacy can also provide local enhanced services. The most common local enhanced services are

- stop smoking schemes,
- flu vaccination,
- supervised administration (of methadone for drug misusers),
- patient group directions (for example to supply emergency hormonal contraception or nicotine replacement therapy),
- minor ailment schemes: Some pharmacies run a minor ailment service, which means that they can supply medicines for certain specific conditions (e.g. a cough or a cold) on the NHS. It is up to local Primary Care Trusts (PCTs) to decide whether pharmacies in their area provide these services (for further references in RPSGB 2008).

Some of the interview partners judged these modifications in the contractual arrangements as the major change in the pharmacy sector of the last year. The changes were considered as a win-win situation for both the government and the pharmacies, and to have contributed to more transparency (personal communication from a pharmacy sector's representative).

Since 2003, a training for pharmacists to become supplementary prescribers has been in place, and in 2006 "pharmacist prescribing" was introduced in England, as part of a Department of Health Initiative to increase patient access and choice. Between 2008 and 2010, 2 to 3 percent of pharmacists were qualified prescribers (Chemist and druggist 2011, DoH 2005). In an interview the perception was shared that patients might often not be aware of the possibility of pharmacy prescribing; but if they are, they usually appreciate it due to limited accessibility to general practitioners (personal communication).

3.3.3.2 Pharmaceutical counselling

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 brought about important changes to the Medicines Act 1968 concerning pharmacists in charge of registered pharmacies – the responsible pharmacist. The changes:

- make clear what the pharmacist in charge of a registered pharmacy must do to ensure patient and public safety relating to the sale and supply of all medicines from the pharmacy,
- provide a legal framework that underpins quality systems in the pharmacy to ensure safe and effective working.
- support and enable pharmacists as professionals responsible and accountable for the safe and effective sale and supply of medicines to the public.

All pharmacy staff are required to respect the confidentiality of patient information and to follow the NHS Code of Practice on Confidentiality, the Common Law on confidentiality and the Data Protection Act.

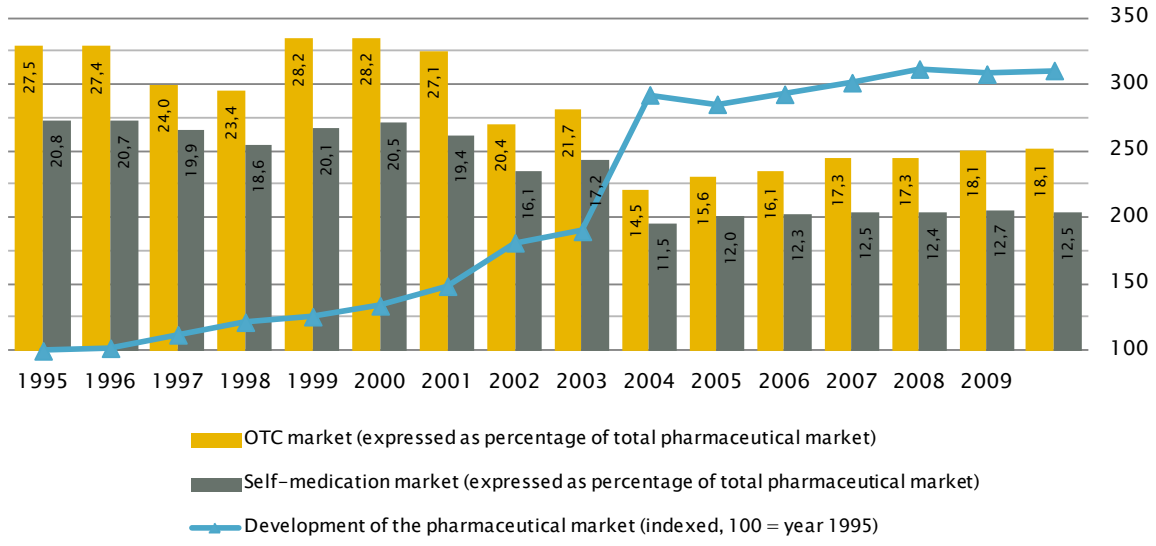
In order to keep quality standards of pharmaceutical counselling high, there are good pharmacy practice regulations in England, which are being assured by professional audit or mystery shopping.

3.4 Economics

3.4.1 Market data

The total pharmaceutical market in the UK has increased over the past 15 years. The sudden large increase between 2003 and 2004 in Figure 3.2 might not display the actual development of the total pharmaceutical market. Nevertheless, we have found in the data source no indications for differences in price levels at which data were documented. Persons contacted in the United Kingdom in the course of the project were not familiar with a sudden large increase in the UK's pharmaceutical market in 2003.

Figure 3.2: United Kingdom – Development of pharmaceutical market, 1995 – 2010



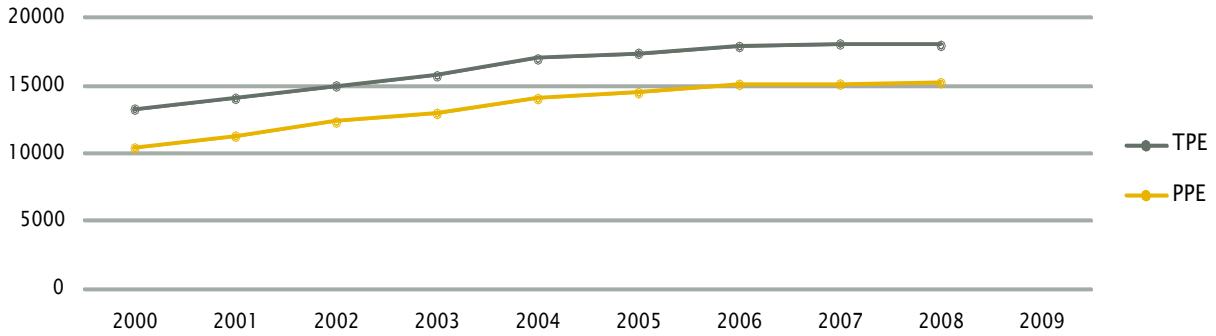
OTC = Over-the-counter

Source: AESGP 1995-2011

3.4.2 Pharmaceutical expenditure

Total pharmaceutical expenditure in the UK is estimated at € 13,304 million in 2000 and at € 18,010 million in 2008, an increase of 35 percent. However, this increase corresponds to an increase of 46 percent in the public sector (cf. Figure 3.3).

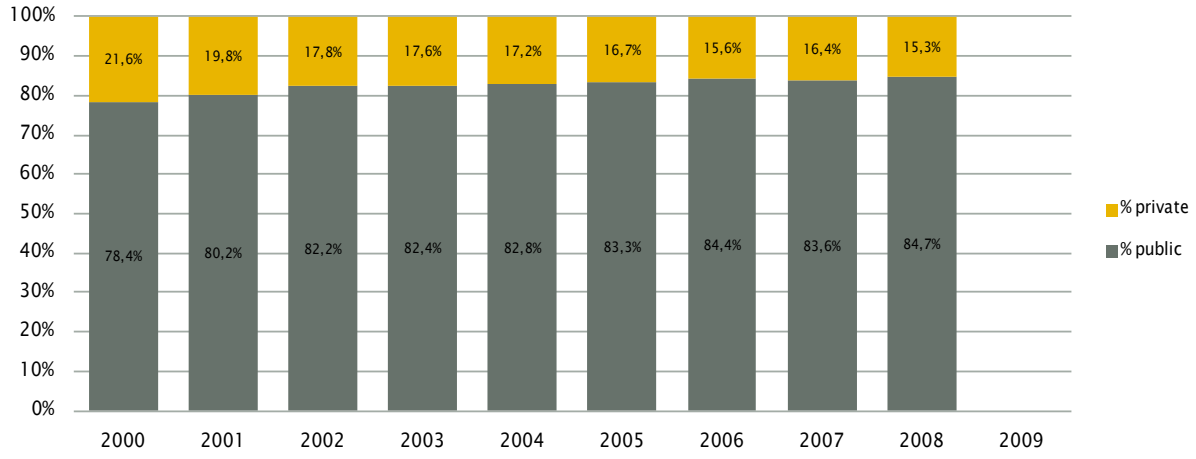
Figure 3.3: United Kingdom – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

The public share of the total pharmaceutical expenditure increased from 78.4 percent in 2000 to 84.7 percent in 2008. The share of private pharmaceutical expenditure therefore has decreased from 21.6 percent in 2000 to 15.3 percent in 2008.

Figure 3.4: United Kingdom – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

3.4.3 Pharmacy remuneration and turnover

The pharmacy margin is – formally – unregulated, and a flat dispensing fee of €1.52 is one of the margins added to pharmacy remuneration. Other fees may also be collected via additional services, such as low level diagnostics and basic counselling services (Kanavos et al. 2011). Pharmacy remuneration is determined, in fact, under a contractual framework for community pharmacies and is negotiated annually by the Department of Health (DH) and the Pharmaceutical Services Negotiating Committee (PSNC) - the organisation that represents the interests of community pharmacies (PSNC 2011b).

The total funding available for distribution is the budget adjusted for any variance from the previous year. Funding available for distribution is allocated across two main sources of funding being (PSNC 2011b):

1. PCT recharges from PCTs' general funding, and
2. PCT pharmaceutical budget which pays for the allowed buying profit

Fees, allowances and generic drug prices are set out in the monthly Drug Tariff and are paid by NHS Prescription Services and then recharged to PCTs as appropriate.

Every year fees, allowances and generic medicines reimbursement prices are adjusted in October to ensure the total funding is distributed as accurately as possible by the year end in March. Margins are assessed for adequacy by PSNC and DH. (PSNC 2011b).

NHS funding is largely prescription volume based so profitability depends on securing prescription volume. The other major determinant is the composition of items dispensed: generic or branded.

For generic medicines, the Pharmaceutical Pricing Reimbursement Scheme (PPRS) which controls profits does not apply. To manage and control prices of generic medicines, the Manufacturer (M scheme) and the Wholesaler (W scheme) schemes were introduced in England in 2005. The main aim of these schemes was to set reasonable reimbursement limits - Drug Tariffs - for generic medicines by increasing the transparency in the cost of goods, pricing of generics and discounts given to community pharmacists (Caisse Nationale d'Assurance Maladie 2011). The scheme was drawn up by the Department of Health and the British Generics Manufacturer Association (BGMA). Margins on generic medicines are significantly higher than on branded medicines. Contractors bundle up their prescriptions at the end of the month and submit them to NHS Prescription Services by the 5th of the following month. NHS Prescription Services then make an advance payment at the start of the next month. This is calculated as 80 percent of the contractor's expected payment based on submitted script numbers and their average item value (average value of each prescription item dispensed) from the previous month. The final payment is made a month later (PSNC 2011b).

926.7 million prescription items were dispensed in 2010; an increase of 4.6 percent (40.7 million items) on 2009 and 67.9 percent on 2000. There were, on average 17.8 prescription items dispensed per head of population compared with 17.1 in 2009 and 11.2 in 2000 (NHS 2011).

The number of prescriptions filled per community pharmacy amounted to 56,506 in 2000, compared to 86,680 in 2010. The number of prescriptions filled per pharmacist in 2010 was approximately 18,912 (NHS 2011).

NHS dispensing represents over 90 percent of turnover for a typical independent pharmacy (PSNC 2011b). According to another source, the income of a average NHS funded pharmacy consisted of 85 percent from NHS prescriptions, 7.5 percent from OTC sales and 7.5 percent of non-pharmaceuticals (personal communication from a regulatory authority).

4 Ireland

4.1 Framework

The main actors of the Irish pharmacy system are community pharmacies. Prescription-only medicines (POM) and some specific OTC medicines may only be dispensed by community pharmacies. According to the Irish Pharmacy Union (IPU, IPU 2011b), which is the representative body for community pharmacists, Ireland currently has 1590 community pharmacies (cf. Table 4.1).

In addition, POM dispensing doctors support the pharmaceutical provision, mostly in very rural areas (cf. section 4.2.1.2) and hospitals dispensing POM to out-patients. The number of POM dispensing doctors in Ireland though is negligible and is constantly decreasing. In 2009, 117 POM dispensing doctors existed in Ireland in 2009 (HSE-PCRS 2009). The majority of dispensing doctors are situated in the very rural parts of western Ireland, especially on the islands (IPU 2011b, IPU/Logan 2011).

Drugstores and several other retail outlets (e.g. corner shops, petrol stations, supermarkets) are allowed to sell a limited number of OTC medicines, so-called General Sales List (GSL) products. The Irish Medicines Board (IMB) provides a list of medicines that may be sold outside pharmacies (IMB 2009).

Internet pharmacies were neither allowed for POM nor for OTC medicines in Ireland before 2006. A key change of the regulatory revision was the exemption of OTC medicines from the prohibition on the sale by mail order in 2005. Since then, internet sale of OTC medicines has been permitted (PGEU 2010e).

A quantification of an overall number of OTC suppliers is difficult because of the high variety and number of outlets.

In Ireland 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. Physicians who practice in the same area cannot establish pharmacies. During the last decade, the ownership structures have changed considerably (cf. section 4.3.1.2).

Multiple ownership is allowed, the number of chains has been increasing (cf. section 4.3.1.2) as companies like Celesio and Alliance Boots continue to expand their portfolio. Most recently, the supermarket chain, Tesco, has opened two pharmacies in Ireland (personal communication, Sheehan 2011).

Ireland has always been relatively liberalised concerning the pharmacy system, but in 1996 regulations on the establishment of pharmacies were for the first time introduced (Vogler et al. 2006, PWC/IPU 2011). Community pharmacies had to fulfill the criterion of “definite public need” to be established. “Definite public need” was defined by a mixture of demographic,

geographic and viability criteria. Rationales introduced on the minimum distance of pharmacies of five kilometers in rural areas and of 250 meters in urban areas were established to avoid clustering of pharmacies in towns and to assure a wider spread of outlets. The 1996 pharmacy regulations created a de facto restriction on the number of new pharmacies. Legal proceedings were initiated by two pharmacy chains (Mc Sweeney Group and Dame Street Pharmacy) because of applications denied (Gorecki 2010).

The abolishment of these establishment criteria has been recommended in an OECD report (OECD 2001) in November 2001, but also by the national competition authority (CA 2001). As a consequence, Ireland set up a High Level Pharmacy Group to examine the Irish pharmacy sector. In January 2002, the Irish Department of Health and Children (DOHC) decided to revoke the regulations of 1996 (Vogler et al. 2006). Since then no establishment rules for pharmacies in Ireland are valid. No establishment rules have been included in the current Pharmacy Act of 2007.

The reform of the Pharmacy Act 2007 (ISB 2007) brought the following changes:

- The restriction on pharmacists educated in other European Union (EU) or European Economic Area (EEA) countries from owning, managing or supervising a pharmacy in Ireland that is less than three years old was removed. This is in particular relevant since many Irish citizens underwent training as a pharmacist outside Ireland, mostly in the UK, due to limited university places in Ireland for a long time.

- A “fitness to practise” regime was introduced for pharmacists to ensure high standards of pharmaceutical provision, and the Pharmaceutical Society of Ireland (PSI) now has the statutory basis to conduct enquiries.

- In 2008, a regulation for pharmacy retail businesses (ISB 2008) was passed, and they are – like pharmacists – also subject to a fitness to practise provision.

Latest discussions in the Irish pharmacy system have concerned prescription fees for patients who up until now have not paid for their medication, needle exchange and flu vaccinations.

Significant media attention was given to the dispute involving community pharmacies in August 2009 (PharmaTimes 2009), during which most pharmacies closed for 10 days in response to the announcement of the government to significantly reduce pharmacy payments. During the days of the strike, the national health service took over the pharmaceutical provision for patients, and public opinion and media expressed support for the government.

The pharmaceutical industry and wholesale companies in Ireland are highly represented. Ireland’s pharmaceutical sector hosts 13 of the world’s top 15 pharmaceutical companies. 120 pharmaceutical companies have a presence in Ireland, and 24,500 people are employed in pharmaceutical industry (IPHA 2010). In the year 2005 Ireland’s pharmaceutical industry became the world’s biggest net ex-porter of medicines (Vogler et al. 2006).

In the 1990s, the Irish government attracted a number of international research based companies to establish in Ireland. The Irish Pharmaceutical Healthcare Association (IPHA) represents the international research based pharmaceutical industry in Ireland. Members include both manufacturers of prescription-onlyand non-prescription or consumer health care medicines (IPHA 2011).

The Association of Pharmaceutical Manufacturers of Ireland (APMI) counts in membership Irish based companies with a focus largely on generic medicines. Industry's involvement in pricing and reimbursement is through the framework agreements between industry (the IPHA Agreement and the APMI Agreement) and the Health Service Executive (HSE).

Community pharmacies are able to be directly supplied by the industry, though normally the predominant sources of supply are wholesalers.

While there are 157 wholesale licences (many of them to manufacturers) authorised (IMB 2011) there are four full-line pharmaceutical wholesalers acting in Ireland (GIRP 2011). Thereof, three of them accounted for a market share of more than 90 percent (Macarthur 2007), are members of the wholesale association (Pharmaceutical Distributors Federation, PDF) and are thus the three principal full wholesalers in Ireland.

- United Drug is the biggest wholesale company in Ireland. The company has met difficulties in the Irish market, but still has high sales figures due to international operations (Mulligan 2011).
- Celesio has three businesses, Movianto (pre-wholesale), Cahill May Robert's Ltd wholesale Company and Unicare Pharmacies Ltd (which are in the process of being rebranded to Doc Morris). Celesio therefore provides for a whole internal distribution chain. Three branches of Cahill May Robert´s in Dublin, Cork and Sligo provide services for about 1,200 retail customers and 197 hospitals. Cahill May Robert´s is the market leader in hospital wholesale and distribution with 2,500 deliveries per day (CMRG 2011).
- Uniphar is a wholesale cooperation owned by pharmacists also owning pharmacies (Table 4.6). The UniPhar Group has wholesale depots located in Dublin, Cork, Limerick and Sligo.

Vertical integration is of relevance in Ireland. This concerns both (wholesale) companies owned by pharmacists which are common and wholesalers involved in the ownership of pharmacies (see also section 4.3.1.2).

4.2 Accessibility

4.2.1 Accessibility of medicines dispensaries

4.2.1.1 Provision of POM dispensaries

As of January 2011, 1,590 community pharmacies were established in Ireland, their number having increased from 1,178 in 1995 (cf. Table 4.1).

The number of POM dispensing doctors has been decreasing. While in 1995 215 POM dispensing doctors (cf. sections 4.1 and 4.2.1.2) were active, their number had declined to 117 in 2009. Some hospital pharmacies may supply medicines to out-patients as long as they are registered with the Pharmaceutical Society of Ireland as Retail Pharmacy Businesses. This is done in rather rare cases, e.g. for specific patient groups, e.g. HIV positive patients, treatment of tuberculosis (Vogler et al. 2010).

Table 4.1: Ireland – Number of pharmacies and other POM dispensaries, as of 1 January, 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2007	2009	2010	2011
Community pharmacies (all privately owned)	n.a.	1,178	1,244	1,468	1,487	n.a.	n.a.	1,555	n.a.	1,590
POM dispensing doctors	n.a.	215	179	135	n.a.	n.a.	n.a.	117	n.a.	n.a.
Internet pharmacies dispensing POM	0	0	0	0	0.	0	0	0	0	0
Total of POM dispensaries	**n.a.**	**1,393**	**1,423**	**1,603**	**n.a.**	**n.a.**	**n.a.**	**1,672**	**n.a.**	**n.a.**

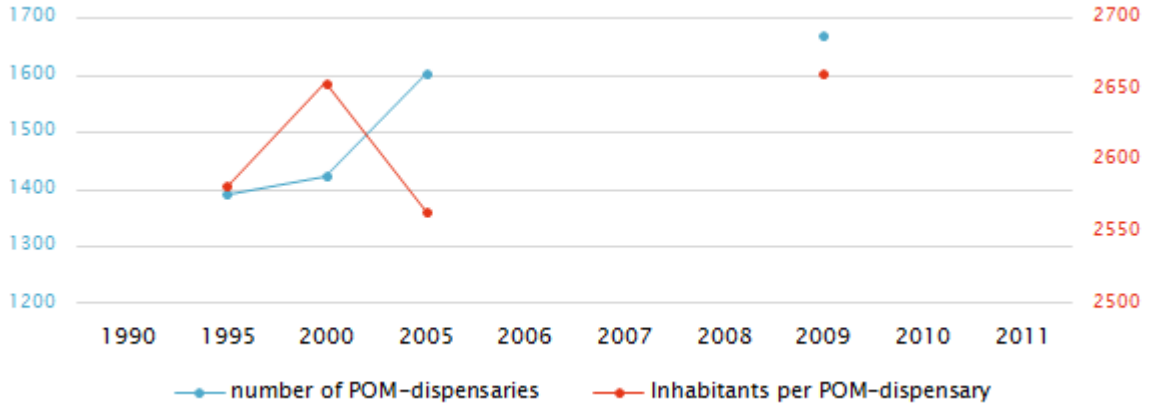
POM = prescription-only medicine, n.a. = not allowed

[1] Retailers which are allowed to dispense prescription-only medicines

Source: Elliot et al 2007, IPU - Internal Stats Sept 2011, PWC/IPU 2009, HSE-PCRS 2009

The number of community pharmacies and the number of POM dispensaries in Ireland has increased since 1995 independently from the regulatory framework regarding establishment rules. In the years when establishment criteria were in place, the number of pharmacies grew as well, since pharmacies were still granted permission to open as long as they meet the criteria. In 2009 the number of inhabitants supplied per POM dispensary was 2,650 (cf. Figure 4.1).

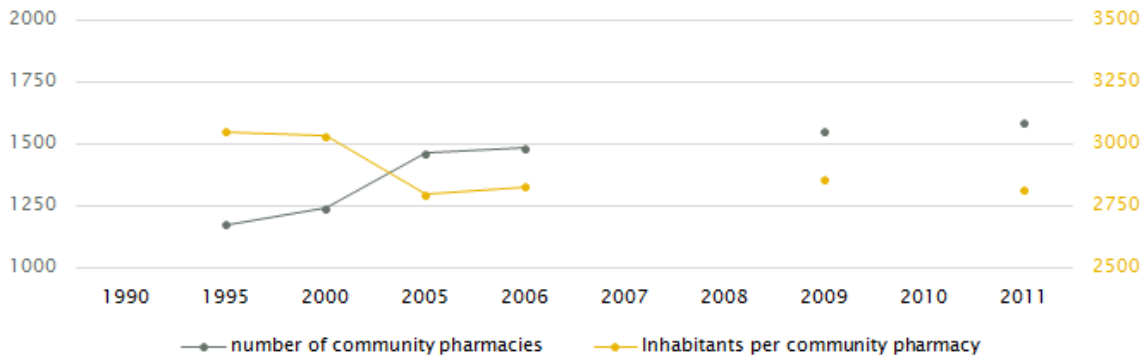
Figure 4.1: Ireland – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM dispensary, 1990 – 2011



Source: Elliot et al. 2007, IPU - Internal Statistic Sept 2011, PWC/IPU 2011 HSE-PCRS 2009

In 2009 about 2,850 inhabitants were served by each community pharmacy on average (cf. Figure 4.2, PWC/IPU 2011).

Figure 4.2: Ireland – Number of community pharmacies and number of inhabitants per community pharmacy, 1990 – 2011



Source: Elliot et al. 2007, IPU - Internal Stats Sept 2011, PWC/IPU 2011, HSE PCRS - Report 2009

4.2.1.2 Provision of POM dispensaries in rural areas

There are no incentives for pharmacies to establish in rural areas.

Doctors are only allowed to dispense medicines if there is no community pharmacy within five kilometres. If a community pharmacy subsequently is opened in an area where a doctor dispenses medicines, the doctor is obliged to cease dispensing within one year. According to IPU, it is assumed, that, because of the low number of self-dispensing doctors, the majority of Irish inhabitants has a community pharmacy within five kilometres (IPU 2011b).

Table 4.2 shows the distribution of Irish community pharmacies according to the size of the location in 2009. The share of pharmacies organised in chains is higher, the bigger the location gets. Chains are more common in large towns and cities with over 20,000 inhabitants. Patients in rural areas tend to be supplied by single shops.

Table 4.2: Ireland – Location of pharmacy outlets in Ireland by size of location, 2009

No. of pharmacies	Pharmacies organised in chains	Singles shop	Total
Villages (<1,500 inhabitants)	105	174	279
Small towns (1,500 – 5,000 inhabitants)	125	171	296
Mid-sized towns (5,000 – 20,000 inhabitants)	154	176	330
Large towns (20,000 – 30,000 inhabitants)	49	45	94
Cities (> 30,000 inhabitants)	318	238	556
Total	751	804	1,555

Source: PWC/IPU 2011

4.2.2 Availability of medicines

There are no specific service requirements for community pharmacies in Ireland concerning certain amounts of medicines needed to be in stock or deliveries to customers within a certain period of time. However the pharmacist´s Code of Conduct requires the provision of appropriate service to patients (PSI 2010).

Typically, the average number of medicines in stock in a pharmacy is 7,000 items. In 2006 7,309 pharmaceuticals were authorised including different dosages and pharmaceutical forms (Elliott/Byrne 2007). Medicines can be provided to the customer on average within 12, but at maximum 24 hours. Pharmacies on average receive deliveries twice a day (IPU 2011b).

4.3 Quality of pharmacy services

4.3.1 Pharmacy staff

4.3.1.1 Availability of pharmacists and other qualified staff

Pharmacy workforce in Ireland consists of full pharmacists, qualified assistants with the right to dispense, pharmacy technicians without the right to dispense and other pharmacy staff. While pharmacists and qualified assistants are registered with the Pharmaceutical Society of Ireland, there is no register for pharmacy technicians.

In 2009 12,255 pharmacy staff calculated with full time equivalents (FTE) worked in community pharmacies in Ireland, of which 2,735 FTE were full pharmacists (cf. Table 4.3).

Table 4.3: Ireland – Staff working in community pharmacies, as of 1 January, 2007 – 2010

Pharmacy staff	2007	2008	2009	2010
Number of pharmacy staff counted per head				
Number of pharmacists[1]	4,504	4,465	4,451	4,567
Qualified assistants[2]	535	535	537	515
Pharmacy technicians[3]	n.a.	n.a.	n.a.	n.a.
Number of pharmacy staff, full time equivalents				
Number of pharmacists [1]	n.a.	2,709	2,735	n.a.
Other staff[4]	n.a.	10,191	9,520	n.a.
Total full time equivalents	**n.a.**	**12,899**	**12,255**	**n.a.**

[1] Active (full) pharmacists
[2] Active pharmacy assistants with the right to dispense medicines under certain conditions
[3] No right to dispense medicines, no data available since there is no register for pharmacy technicians
[4] All other staff, including pharmacy assistants and pharmacy technicians

Source: PSI 2010, PWC/IPU 2011

The prerequisite for being a full pharmacist is a four year university degree; additionally a 12 monthtraining is required (cf. Table 4.4). Following completion on the university degree and the practice training, students are awarded a Masters in Pharmacy. The practical training has to be completed under the supervision of a tutor pharmacist. At least six months of this training must be spent in a hospital or community pharmacy. Pharmacy courses are provided by the Trinity College in Dublin, the University College Cork and the Royal College of Surgeons of Ireland in Dublin (PWC 2011, Vogler et al. 2006). 180 students register every year for the university courses for pharmacists. The Pharmaceutical Society of Ireland is in the process of introducing a five year integrated Master in Pharmacy course which will incorporate the practice training (information by IPU).

Although continuous education is not yet compulsory, 75 percent of pharmacists attend continuous education activities (PGEU 2010e).The Pharmaceutical Society is in the process of introducing mandatory Continuous Professional Development (CPD) by 2014 and has established an Institute to assist in this (information by IPU).

Pharmacists have to register with the Pharmaceutical Society of Ireland (PSI) which is the statutory body for pharmacists. Due to the introduction of “fitness to practise” rules the PSI has now the mandate to sanction poor professional performance or professional misconduct of pharmacists (ISB 2007).

The staff group of “qualified assistants” or “assistants to pharmaceutical chemists” is allowed to dispense medicines in the temporary absence of a pharmacist. The training for this group, which lasted three years, is no longer offered. In 2010 515 “qualified assistants” were left in Ireland (cf. Table 4.4).

Pharmacy technicians without the right to dispense medicines need a certificate, for which a training of two years and a practice training of 100 days is required (cf. Table 4.4). Around 400 students register for this qualification each year (PGEU 2010a) updated information by IPU).

Table 4.4: Ireland – Qualification requirements for pharmaceutical personnel, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	University (pharmaceutical school)	4	Yes, 12 months	Voluntary, but compulsory for tutors of trainees – training of 30 hours a year	CPD will become mandatory by 2014 under the Pharmacy Act 2007
Qualified assistants (with the right to dispense medicines under certain conditions)	Qualified Assistants – no longer trained	3	Yes as apprentices	No	This cohort is no longer trained, therefore numbers will reduce over time
Pharmacy technicians (without the right to dispense medicines)	Certificate	2	Yes – 100 days	No	No official register

CPD = Continuous professional development

Source: IPU 2011b

Concerning the liability of pharmacists, the pharmacy is, under the terms of the Community Pharmacy Contractor Agreement, obliged to have a Professional Indemnity Insurance which covers all staff who work in the pharmacy (Vogler et al. 2006).

4.3.1.2 Professional independence of pharmacists

As multiple ownership has always been allowed, especially since the mid-1990s pharmacy chains have become a reality in the Irish pharmacy sector (Vogler et al. 2006). The single shop/chain ratio has changed in favour of chains in the last years.

In 2002, 92 percent of all pharmacies were owned by pharmacists and 8 percent by non pharmacists. By 2008 the percentage of pharmacies owned by pharmacists decreased to 87 percent (PGEU 2010f). In 2009 88 percent of Irish community pharmacies were owned by pharmacists (PWC/IPU 2011). According to the 2011 IPU Annual Report (IPU 2011b) 85 percent of all community pharmacies were pharmacist owned and 15 percent were non-pharmacist owned in April 2011.

Ownership of one or more pharmacies (multiple ownership) is allowed. To assure quality each pharmacy has to be supervised by a full time supervising pharmacist. The proportion of pharmacy chains, i.e. grouping of more than two outlets, and single shops has remarkably changed from 2002 (35 percent of all pharmacies are organized in chains and 65 percent are single shops) to 2008 (45 percent chains and 55 percent single shops). Chains are defined as being grouped in two or more pharmacies (PGEU 2010f). In 2009 52 percent were single shops (PWC/IPU 2011). Also the share of chains has been increasing, especially in pharmacies that are not owned by pharmacists (cf.Table 4.5) (IPU 2011b).

Table 4.5: Ireland – Number of pharmacist and non-pharmacist owned community pharmacies, 2011

Community pharmacies	Total	Percentage
Pharmacist owned	*1,344*	*85% of all pharmacies*
- Thereof: single shops	753	56% of pharmacy owned pharmacies
- Thereof: chains	591	44% of pharmacy owned pharmacies
Non-pharmacist owned	*235*	*15% of all pharmacies*
- Thereof: single shops	69	29% of non-pharmacy owned pharmacies
- Thereof: chains	166	71% of non-pharmacy owned pharmacies
Total number	**1,579**	**100%**

Data as of 27 April 2011

Source: IPU 2011a

As displayed in Table 4.6, the biggest of these chains with a 4.53 percent of market share in September 2011 is Unicare owned by the wholesale group Celesio, followed by IPOS with a market share of 3.96 percent owned by Uniphar, which is a wholesale cooperation owned by pharmacists. In October 2011, the Mc Sweeney group, which was said to be in financial difficulty due the different factors, including the recession, was placed under examinership (Irish Examiner 2011).

Table 4.6: Ireland – Pharmacy chains, as of September 2011

Pharmacy chain	Owner	Market share	Number of pharmacies in	
			ownership	Membership (franchise)[1]
Unicare/Celesio	Celesio (wholesaler)	4.53%	72	0
IPOS	Uniphar (wholesaler, cooperation owned by pharmacists)	3.96%	63	0
Boots The Chemists	Alliance Boots	3.46%	55	0
Hickey	Paddy Hickey (Irish pharmacist)	1.64%	26	0
Mc Cabe	Roy Mc Cabe (Irish pharmacist)	1.26%	20	0
Mc Cauleys	Sam Mc Cauley (Irish pharmacist)	1.57%	25	0
Bradleys	Brian Pagni (Irish pharmacist)	1.00%	16	0
Mc Sweeney[2]	G Hof (individual, group's founder and main shareholder)	0.88%	14	0

[1] Membership here is not ment as membership in the IPU but as a franchise system, where individual owners of pharmacies may take part in a chain.

[2] In October 2011, the McSweeney Group was placed under examinership and 4 of its pharmacies were closed.

Source: IPU - Internal Statistics, September 2011, updated information by IPU

4.3.2 Product range

4.3.2.1 Medicines

In Ireland, dispensing of prescription-only medicines is restricted to pharmacies, medicines designated pharmacy-only (P) can only be sold in pharmacies and medicines designated for General Sales List (GSL) can be sold in pharmacies and in other retail outlets.

- POM: Prescription-only medicines are only allowed to be dispensed in pharmacies, and there is no self-service. POM must be dispensed under the supervision of a pharmacist.

- OTC medicines: Over-the-counter medicines are categorized into pharmacy only (P) and General Sales List (GSL). P can only be supplied in pharmacies under supervision of a pharmacist. Self-service of P medicines is not allowed. General Sales List products may be sold both in pharmacies and outside pharmacies and are available for self-service. OTC medicines accounted for 11.4 percent of the total pharmacy turnover and 15.3 percent of pharmacy turnover on medicines in 2009 (cf. Table 4.7).

In February 2011, emergency hormonal contraception was made available without prescription but sales are restricted to pharmacies following a consultation with the pharmacist (personal communication of a government official and IPU).

In October 2011, new legislation was passed to allow pharmacists to supply and administer the seasonal influenza vaccine to patients. The Health Service Executive pays pharmacists to supply and administer the vaccine to patients over 65 years with medical card eligibility; all other vaccinations are treated as private transactions (personal communication of a government official and IPU).

Pharmacists are permitted to produce extemporaneous preparations on foot of a prescription, i.e. the general practitioner writes a prescription for a particular cream, ointment or mixture and the pharmacist produces it for the patient; this does not happen very frequently as most prescriptions are for pre-prepared preparations.

4.3.2.2 Non-pharmaceuticals

Toiletries, dental products, baby products, first aid products, foot care, photo supplies, e.g. films or batteries, perfumes, hairdryers, electric shavers, etc. are examples of non-pharmaceuticals which are frequently provided by Irish pharmacies (IPU 2011b). The turnover of non-pharmaceuticals accounted for 25.3 percent of the total turnover of pharmacies in 2009 (cf. Table 4.7). There are no special regulations concerning pharmacies selling non-pharmaceutical products apart from the prohibition of selling cigarettes (including electronic cigarettes) and alcohol in pharmacies.

4.3.3 Pharmacy services

4.3.3.1 Services provided by pharmacies

Further pharmacy services, in addition to the dispensing of medicines and counselling, are provided by pharmacies, such as disposal of waste medicines, measurement of blood pressure, cholesterol, glucose or weight, pregnancy tests, smoking cessation and supply of medicines for nursing homes. Medicines use review is not common in Ireland yet although a pilot project was recently completed.

Currently, the Irish health service is developing clinical care pathways for chronic diseases that may result in a role for community pharmacists in chronic disease management. For example, clinical care programmes are being developed for chronic diseases such as diabetes, stroke, heart failure, asthma, etc. The aim is to try and ensure that the patient receives as much care as possible at primary care level rather than in the more costly care part of the health service.

Further, the introduction of a sale of a drug replacement therapy different to Methadone in pharmacies is under consideration although the costs for this therapy are estimated to be rather high (personal communication of government official).

One of the latest innovations in pharmacy services provided by Irish pharmacies is the availability of flu vaccinations in pharmacies. About 550 community pharmacies in Ireland have already started to provide a pharmacy vaccination service for seasonal influenza (IPU 2011b, IPU/Logan 2011). According to representatives from the NHS, the introduction of a vaccination service by pharmacies is considered to positively impact the accessibility of

medicines since vaccinations are made available in pharmacies less bureaucratically for the patients.

In November 2011, a Needle Exchange Service was rolled out in 50 pharmacies. The scheme will be kept under review and it is planned that it will eventually roll out to all pharmacies (personal communication of IPU).

4.3.3.2 Pharmaceutical counselling

According to the Regulation of Retail Pharmacy Businesses Regulations 2008 Article 9 (PSI) each prescription must be reviewed by a registered pharmacist prior to dispensing and supply of the medicine. This review should include screening for any potential therapy problems which may be due to therapeutic duplication, interactions with other medicines (including serious interactions with OTC medicines, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse. Additionally it must be ensured that each patient has sufficient information and advice for the proper use and storage of the prescribed medicine.

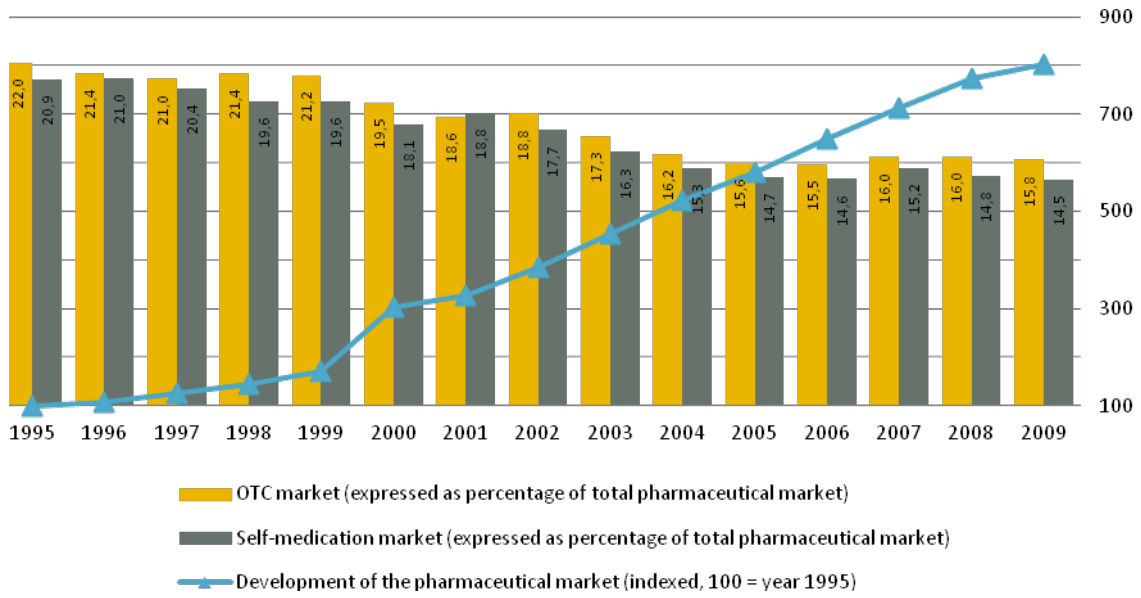
For OTC medicines it is to be assured that the patient is aware of the appropriate use of the medicine (ISB 2008: Art. 10).

4.4 Economics

4.4.1 Market data

Figure 4.3 shows the development of the total pharmaceutical market from 1995 to 2009. The Irish pharmaceutical market grew from IEP 4,688 million / € 291 million in 1995 to € 2,333 million in 2009. In absolute terms, also the OTC market and the self-medication market rose while their shares slightly decreased (cf. Figure 4.3).

Figure 4.3: Ireland – Development of pharmaceutical market, 1995 – 2009



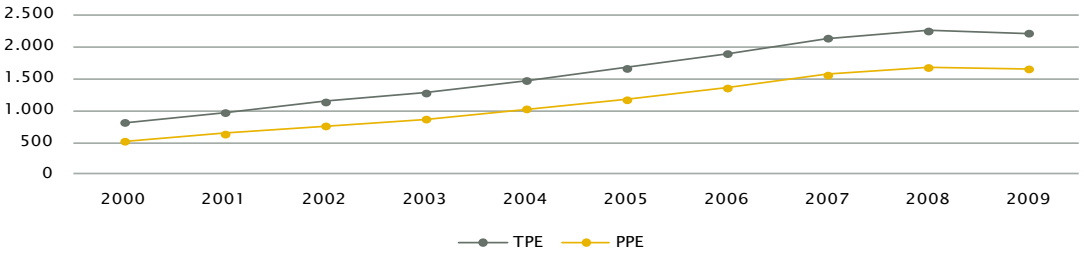
Note: Break from 1999 to 2000 due to change in price type (from pharmacy trade price to consumer price)

Source: AESGP 1995-2011

4.4.2 Pharmaceutical expenditure

Total pharmaceutical and public pharmaceutical expenditure in Ireland grew from 2000 to 2009 (cf. Figure 4.4). Total pharmaceutical expenditure increased from € PPP 820 million in 2000 to € PPP 2,224 million in 2009, and the respective figures for public pharmaceutical expenditure were € PPP 524 million in 2000 and € PPP 1,661.6 million in 2009.

Figure 4.4: Ireland – Total and public pharmaceutical expenditure in million Euro PPP, 1995 – 2011

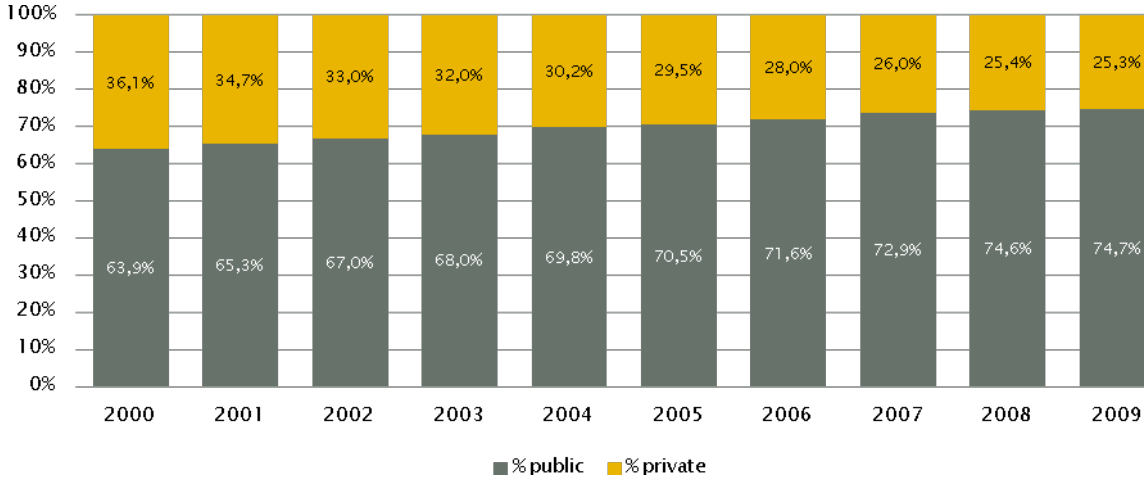


TPE = total pharmaceutical expenditure, PPE = public pharmaceutical expenditure

Source: OECD 2011, PHIS 2011

The share of public pharmaceutical expenditure increased during this period of time, from 63.9 percent in 2000 to 74.7 percent in 2009 (cf. Figure 4.5).

Figure 4.5: Ireland – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

4.4.3 Pharmacy remuneration and turnover

As stated in section 4.2.3, the remuneration of pharmacies depends on the community drug scheme under which a medicine is dispensed: There are the General Medical Service (GMS) scheme which provides free access to medicines for low income people and their dependants; the Drug Payment (DP) scheme for those who do not fall under the GMS and have to pay a monthly co-payment of € 120.-, and the Long Term Illness (LTI) scheme for patients suffering a number of specific chronic conditions (for a description of these and further Drug Payment Schemes see Elliott/Byrne 2007, HSE 2011, There are different fees for different tasks, e.g. also a fee for extemporaneous dispensing, or professional judgment without dispensing.

For all State schemes, pharmacists are paid through a regressive fee structure:

- € 5 for the first 1,667 items dispensed in a month,
- € 4.50 for the next 833 items dispensed in a month, and
- € 3.50 for all other items dispensed in a month.

For the DP and LTI schemes, pharmacists are also paid a 20 percent mark-up on the reimbursable price of medicines; there is no mark-up on the GMS scheme.

Pharmacies supplying dispensing doctors are reimbursed on the basis of the basic trade price with an add-on of 20 percent. Oral medicines and some ostomy and urinary appliances are VAT zero-rated. All other medicines for external use or application are taxed with 21 percent VAT (PPI 2011).

Several stakeholders, including the competition authority and the consumer association, welcome increased competition, e.g. the entry of the supermarket chain Tesco, into the market and consider it as a supportive factor to decrease prices of prescription-only medicines (personal communication, Sheehan 2011).

The Department of Health intends to promote generics uptake by introducing generic substitution in the coming months (IPU 2011b). INN prescribing is, on a voluntary basis, allowed in Ireland but is very low (PHIS 2011).

In 2009 67 million items of prescription medicines were dispensed on over 17 million prescriptions filled (HSE-PCRS 2009).

In 2009 the average community pharmacy turnover was €1,953,000 (PWC/IPU 2011). The pharmacy turnover of POM medicines stayed relatively stable from 2000 to 2009 at a rate of 61.0 percent to 63.3 percent. While the share of OTC turnover has decreased from 20.0 percent to 11.4 percent, the share of non-pharmaceuticals has increased from 19.0 percent to 25.3 percent between 2000 and 2009 (cf. Table 4.7).

Table 4.7: Ireland – Pharmacy turnover by product category, 2000 – 2009

Medicines dispensed and pharmacy turnover (in €)	**2000**		**2008**		**2009**	
Prescriptions filled (in items)	-		*48,211,863*		50,721,919	
Total pharmacy turnover	927,000	*100.0%*	1,983,000	*100.0%*	1,953,000	*100.0%*
Of which:						
Turnover of POM (total)	565,470	*61.0%*	1,218,000	*61.4%*	1,236,000	*63.3%*
Turnover of OTC medicines (total)	185,400	*20.0%*	241,000	*12.2%*	223,000	*11.4%*
Turnover on non-pharmaceuticals (total)	176,130	*19.0%*	525,000	*26.4%*	493,000	*25.3%*

Source: Vogler et al. 2006, PWC/IPU 2011, HSE-PCRS 2009

5 The Netherlands

5.1 Framework

In the Netherlands prescription-only medicines are mostly dispensed in pharmacies. On 1 January 2011 there were 1,980 pharmacies (SFK 2011). Furthermore, there is dispensing of medicines by dispensing doctors (526) and since April 2000 out-patient clinics in hospitals may also dispense pharmaceuticals to non-patients. Drugstores in the Netherlands have been allowed to sell OTC medicines for a long time already (since approximately 1850). Nowadays more than 80 percent of OTC medicines are sold through approximately 4,000 drugstores or drugstore departments within supermarkets. A restricted range of OTC medicines can be sold for example by supermarkets or gas stations, through self-service. Internet pharmacies are also allowed to dispense prescription-only medicines in the Netherlands (SFK 2011).

There have never been statutory geographic or demographic restrictions to the establishment of pharmacies in the Netherlands. However, the Royal Dutch Pharmaceutical Society (KNMP) has been applying its own establishment policy which could be accompanied by 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 has been to ensure a minimum number of customers 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 advice 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 had already often been disregarded by pharmacists who were not a member of the KNMP (Vogler et al. 2006).

Since 1992 health insurance funds have no longer been obliged to contract each pharmacy. They are merely obliged to make sure that health care is well organised for the insured. 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) (Vogler et al. 2006).

There are no state licenses required to own a pharmacy, but in order to run a pharmacy profitable contracts with health insurance funds are necessary. The inspectorate and the Law on Medicines require for each pharmacy a responsible pharmacist who is accountable for all actions in his/her practice (Vogler et al. 2006).

Multiple ownership had not been allowed until 1987. When the restriction on multiple ownership fell, the first pharmacy chains were set up, however only a few at that time. Until 1999 the owner of a pharmacy had to be a pharmacist, but there were a few exemptions made for foundations or sickness funds 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). Since 2009 this development slowed down and even stopped, mainly due to the changed economic situation (SFK 2011).

The bulk of POM and OTC medicines are distributed by wholesalers. There are five full line wholesalers (which are also members of the wholesale association BgPharma) which have a combined market share of more than 90 percent. Three of the full line wholesalers are owned by foreign wholesalers. Some of them are also parallel traders. On average wholesalers have one or two distribution centers in the Netherlands (Storms/Schreurs 2010).

The interests of the innovative pharmaceutical industry are represented by Nefarma, which currently has 35 members (Nefarma 2011). Neprofarm represents manufacturers of OTC medicines and has 26 members (Neprofarm 2011). Generics manufacturers are represented by Bogin, which has five members (Bogin 2011).

Since 2005, healthcare insurance companies in the Netherlands are allowed to operate under a preferencial pricing policy for generics. The preferencial pricing policy – part of a series of reforms following the privatization of health insurance in 2006 – was devised with the intent to control costs by creating a system of managed competition (tendering) amongst insurance providers. Under the preferencial pricing policy, a number of major healthcare insurers only reimburse the lowest-priced medicine of a large group of pharmaceuticals for which the patents have expired. A different pharmaceutical can be designated as preferred every six to twelve months. Healthcare insurers negotiate directly with pharmaceutical companies on the price of generic medicines that have the same composition or active substance (Kanavos et al. 2011, Zuidberg 2010).

5.2 Accessibility

5.2.1 Accessibility of medicines dispensaries

5.2.1.1 Provision of POM dispensaries

In the Netherlands prescription-only medicines (POM) are mainly dispensed in pharmacies. Furthermore, there is dispensing of prescription-only medicines by:

- POM 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.

- Internet pharmacies: they are allowed to dispense OTC medicines and also prescription-only medicines in the Netherlands. Currently there are four internet pharmacies active in the Netherlands.

OTC medicines are allowed to be sold in drugstores. A restricted range of OTC medicines may also be dispensed through other outlets, such as supermarkets or gas stations.

The dispensing of OTC medicines in a drugstore requires that the manager or a staff member has a special personal drugstore license. For the sale of medicines in the "general sale" category (cf. section 5.3.2.1) supervision of a licensed person is not deemed necessary.

Table 5.1: The Netherlands – Number of pharmacies and other dispensaries, as of 1 January 1990 – 2011

Dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Number of POM dispensaries (i.e. retailers which are allowed to dispense prescription-only medicines)										
Community pharmacies		1,513	1,588	1,732	1,784	1,825	1,893	1,948	1,976	1,980
POM dispensing doctors	784	707	670	569	567	559	553	539	526	n.a.
Hospital pharmacies dispensing POM to out-patients	-	-	-	10 [1]	15 [1]	n.a.	30	35	49	54
Internet pharmacies dispensing POM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	<10
Total of POM dispensaries[2]	**n.a.**	**2,220**	**2,258**	**2,311**	**2,366**	**2,399[3]**	**2,476**	**2,522**	**2,551**	**n.a.**
Number of OTC dispensaries										
Drugstores	n.a.	n.a.	3,900	n.a.	n.a.	n.a.	3,500	n.a.	n.a.	4,000 [1]
Supermarkets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	3,000 [1]
Other dispensaries	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1,000 [1]
Total of OTC dispensaries	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**8,000 [1]**

n.a. = not available, POM = prescription-only medicine, OTC = Over the counter

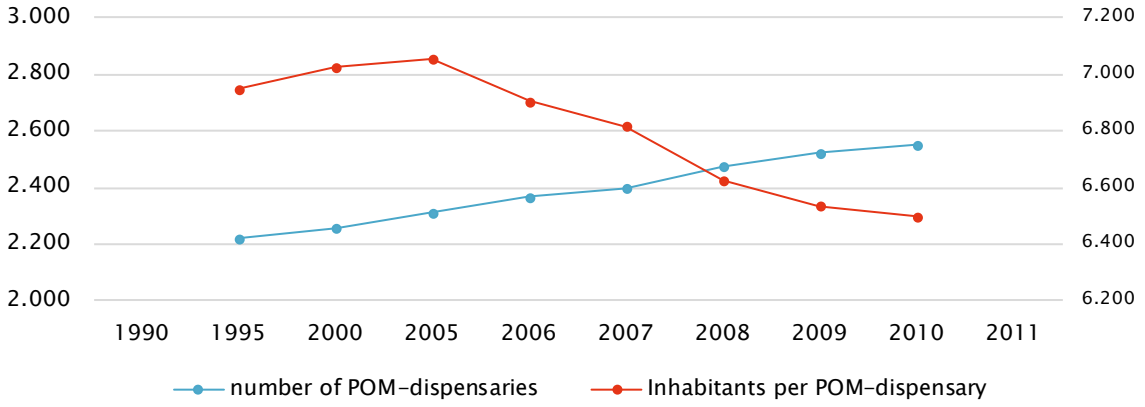
[1] No official number available, approximation
[2] Does not include the number of internet pharmacies dispensing POM, as this number is not available.
[3] Exact number of hospital pharmacies dispensing POM to out-patients is not available. 15 (number from previous year) were counted.

Source: SFK 2005-2011, Vogler et al. 2006, Nivel 2010

Table 5.1 and Figure 5.1 display the development in the number of dispensaries for prescription-only medicines (POM) and the number of inhabitants per POM dispensary. On 1

January 2011 there were 1,980 community pharmacies, which are all privately owned. In total there were more than 2,550 POM dispensaries, each providing on average 6,500 inhabitants with pharmaceuticals. Whereas the last ten years have shown an increase in the number of pharmacies, the number of dispensing doctors went down (cf. Table 5.1). 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 5.1).

Figure 5.1: The Netherlands – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM dispensary, 1990 – 2011



POM = Prescription-only medicine

Source: SFK 2005-2011, Vogler et al. 2006, Nivel 2010

5.2.1.2 Provision of POM dispensaries in rural areas

Of the 418 Dutch municipalities 44 did not have a pharmacy in 2011, compared to 55 in 2008. These municipalities are mainly situated in the Northern part and in the South-Western part (Zeeland) of the Netherlands, which are the less densely populated areas. The absence of a pharmacy is often compensated through dispensing by family physicians. If the distance to the nearest pharmacy is at least 4.5 kilometres, the Ministry of Health, Welfare and Sport can grant to a family physician a licence to dispense POM, in order to compensate for the absence of a pharmacy (RIVM 2011).

There are no specific regulations for pharmacies in rural areas. Neither are there (financial) incentives for pharmacies to establish in rural areas.

5.2.2 Availability of medicines

Since 1996 there have been no regulations on the minimum amount and types of pharmaceuticals that a pharmacy must have in stock. According to the Dutch Pharmacy Standard (Nederlandse Apotheek Norm) from the KNMP amount and types of medicines kept by a pharmacy must correspond to its usual customer needs. Pharmacies are allowed to specialise e.g. for specific disease classes. Examples of such initiatives are a pharmacy within an out-patient clinic for rheumatic patients and a pharmacy for diabetes patients.

Since 1 July 2005 a number of healthcare insurers have been making use of the so-called preferencial pricing policy. According to this policy, healthcare insurers have a statutory entitlement to designate specific pharmaceutical labels, within a group of medicines with the same active ingredient and mode of administration, which are eligible for reimbursement (cf. Section 5.1). According to an interview partner of the Dutch pharmacy association, the preferencial pricing policies of the healthcare insurers partly determine the stock of the pharmacies.

No official requirements for pharmacies regarding the exact timeframe within which a medicine must be delivered to the patient are in place. As a rule, medicines should always be delivered within 24 hours, some antibiotic or urgently needed medicines even faster. In practice, the pharmacist is able to dispense most medicines within 5 to 10 minutes. The Dutch Pharmacy Standard defines guidelines for selecting and making arrangements with wholesalers. Pharmacies should have an arrangement with the wholesaler, not only for regular deliveries but also for extra deliveries, e.g. in case of an emergency (KNMP 2006).

In 2009, 1,723 medicines were authorized of which 1,608 were actually on the market (counted on active substance level) (Storms/Schreurs 2010). In most of the cases, medicines can be provided to the patient directly. Pharmacies are on average delivered once a day. If necessary, additional (urgent) deliveries are possible.

Table 5.2: The Netherlands – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	Should meet regular needs	No information available.
Requirements concerning space	Guidelines e.g. with regard to accessibility of the premises, room for consulting, storage space, providing privacy to the patient are laid down in the Dutch Pharmacy Standard	No information available.
Dispensing within a certain time period	No official regulations laid down in a law, but as a rule, medicines should always be delivered within 24 hours, some antibiotic or urgently needed medicines even faster.	Most medicines are dispensed to the patient within 5 to 10 minutes.
Frequency of delivery	No specific regulations.	Pharmacies are on average delivered once a day.

Source: KNMP 2006, KNMP 2011, personal communication with a pharmacist

5.3 Quality of pharmacy services

5.3.1 Pharmacy staff

5.3.1.1 Availability of pharmacists and other qualified 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. In every community pharmacy a responsible pharmacist should always be present. The responsible pharmacist is allowed to leave the pharmacy for meetings with physicians or for house visits. Prescription-only and OTC medicines may also be dispensed by pharmacy assistants who have always been allowed to perform many of the tasks of the pharmacist, such as the manufacturing of medicines, the filling of prescriptions and counselling. The required secondary education for pharmacy assistants takes four years (Vogler et al. 2006).

All practicing pharmacists are obliged to gather a minimum of 200 training points (one point for each hour of continuous training attended) per five years. Pharmacy assistants 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. Pharmacy technicians can also earn credits through attending courses, with the aim to keep them up-to-date and to provide opportunities for upgrading (with regard to salary or position within the pharmacy) (personal communication).

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 5.3: The Netherlands – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	University	6 years	During university: 6 months Post-graduate: 2 years	Yes	Law on Professions in individual Healthcare (Wet op Beroepen in de individuele Gezondheidszorg)
Pharmacy technicians /assistants with the right to dispense pharmaceuticals	3 years full time only dispensing under direct supervision of pharmacist	3 years	During 3 years: 9 months	Yes	Law on Professions in individual Healthcare (Wet op Beroepen in de individuele Gezondheidszorg)

Source: Vogler et al. 2006, personal communication with a pharmacist

As Table 5.3 shows, the total number of practicing community pharmacists has increased by 30 percent since 1995. Whereas the number of pharmacies has also increased by 30 percent since then, the number of pharmacists per pharmacy has been reasonably constant (approximately 1.5) since 1995. The number of assistants per pharmacy has increased from 7.0 in 1995 to 8.2 in 2011. However, more than half of the pharmacy assistants work part time. This is partly related to the fact that, among other things, the job of a pharmacy assistant tends to be a female occupation (99 percent of pharmacy assistants are women) (SFK 2011).

Table 5.4: The Netherlands – Staff working in community pharmacies, as of 1 January 1990 – 2011

Pharmacy staff counted per head	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Pharmacists	1,970	2,188	2,472	2,734	2,789	2,825	2,871	2,912	2,877	2,858
Pharmacy assistants with the right to dispense pharmaceuticals	8,310	10,630	12,189	14,641	15,096	15,427	16,027	16,312	16,548	16,203
Total of staff allowed to dispense medicines	10,280	12,818	14,661	17,375	17,885	18,252	18,898	18,939	19,425	19,061
Other staff	857	1,983	2,549	5,057	5,162	5,457	5,809	6,436	6,657	6,928
Total of pharmacy staff	**11,137**	**14,801**	**14,738**	**22,432**	**23,047**	**23,709**	**24,707**	**25,357**	**26,082**	**25,989**

Source: Vogler et al. 2006, Pharmacist 2011

In 2009 the average processing rate was 18,700 prescriptions per full-time pharmacy assistant. The increasing processing rate is partly due to the fact that pharmacists have been forced to reduce their personnel costs because of the inadequate dispensing fees. However, since 1 July 2008, medicines dispensed in weekly dose packs are accounted for every week, rather than every two, three or four weeks as they were before. This means that since July 2008 the total number of prescriptions dispensed by pharmacists has been considerably higher than in previous years. This makes it difficult to have a reliable comparison with previous periods (SFK 2011).

5.3.1.2 Professional independence of pharmacists

In the Netherlands multiple ownership of pharmacies was not allowed until 1987. The first few pharmacy chains developed in the early 1990s. Until 1999 the owner of a pharmacy had to be a pharmacist. Only in exempt occasions foundations or sickness funds were allowed to own pharmacies. Since 1999 it is 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, Alliance). Two pharmacy chains (Prickartz and Thio Pharma) are owned by pharmacists. Currently 32 percent of the community pharmacies are owned by pharmacy

chains, compared to 35 percent in 2010. Over the past years, the percentage of pharmacies in ownership of pharmacy chains has been rather stable (SFK 2011).

Table 5.5: The Netherlands – Pharmacy chains, 2010

Name of pharmacy chain	Name of owner and category	% of market share	Number of pharmacies in ownership	Number of pharmacies in membership (franchise)
Mediq	OPG (wholesaler)	10.6	210	0
Lloyds / Escura	Brocacef (wholesaler)	5.8	115	39
Kring apotheek	Alliance (wholesaler)	3.7	73	252
Verenigde Nederlandse Apotheken (VNA)	VNA (foundation)	4.0	80	0
Medsen Apotheek	Apotheken in Overdracht (organisation for pharmacy entrepreneurs)	3.5	70	0
Prickartz	Verenigde Apotheken Limburg (organisation of pharmacists)	1.3	26	0
Thio Pharma	Thio Pharma (organisation of pharmacists)	1.3	25	0
Zorggroep Almere (ZGA)	ZGA (coordinating organisation for primary health care in Almere)	1,1	21	0
Service Apotheek	A cooperation of independent pharmacies	n.a.	0	300
Total			**620**	**591**

Source: SFK 2011, personal communication with SFK

According an interview partner from the Pharmacy Association, 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. In this case, pharmacies are not owned by a chain, but they are a member of a chain and apply the same concept (e.g. corporate design) as the chain-owned pharmacies.

Professional independence of Dutch pharmacists is not just influenced by ownership, but, according to this interview partner, also the healthcare insurers' preferencial pricing policies (cf. section 5.2.2) have made the profession of pharmacists less "free".

5.3.2 Product range

5.3.2.1 Medicines

The Medicines Evaluation Board (CBG) has the authority to classify medicines into a prescription-only medicine (POM) or into an over-the-counter (OTC) medicine.

On 1 July 2007 the new medicines law (Geneesmiddelenwet) came into force. The new law divides medicines into four categories:

- “prescription-only” medicines: Prescription medicines that may only be dispensed in pharmacies
- “pharmacy-only” medicines: OTC medicines that may only be dispensed in pharmacies
- “pharmacy and drugstore only” medicines: OTC medicines that may only be dispensed in pharmacies and in drugstores
- “general sale” medicines: OTC medicines that may be dispensed in pharmacies and drugstores and in other outlets, such as supermarkets or gas stations

Not every pharmacy is equipped to manufacture medicines, as this is not required by law. The contract with the health insurance however states that the pharmacy must take care that manufactured medicines can be delivered. For cost reasons (fees do not outweigh investments in manufacturing facilities and material) many pharmacies have joined co-operations with centralized manufacturing facilities. In the past years, several central pharmacies that manufacture pharmaceuticals for other pharmacies have been established. The share of pharmacy-manufactured pharmaceuticals has been reasonably stable since 2000. In 2007 the number of pharmacy manufactured pharmaceuticals was 6.5 million, which amounts to approximately 3,600 pharmacy manufactured medicines per pharmacy. Of the total of 145 million prescriptions filled in 2007, 4.5 percent was pharmacy manufactured, in 2009 this was only 2.1 percent (SFK 2008, SFK 2010).

5.3.2.2 Non-pharmaceuticals

With regard to non-pharmaceutical products, are there no specific regulations (e. g. limits to sell only specific products) for their sale in pharmacies. Non-pharmaceuticals that are commonly sold in pharmacies include bandages, cosmetics, and medical devices.

5.3.3 Pharmacy services

5.3.3.1 Services provided by pharmacies

Apart from the dispensing of medicines, all pharmacies in the Netherlands provide repeat dispensing and the disposal of waste medicines.

Patients in the Netherlands tend to be very loyal and usually always visit the same pharmacy. This offers an opportunity of creating a relationship between patient and pharmacy and building a high quality database, e. g. for medication reviews. Currently, approximately 50 percent of Dutch pharmacies offer to their clients medication use reviews. Other additional services provided by pharmacists include diabetes management programs (approximately 80 percent), asthma management programs (approximately 100 percent), glucose measurement (approximately 90 percent), blood pressure measurement (approximately 50 percent) and cholesterol measurement (approximately 20 percent) (personal communication of a pharmacist).

Night services are organised locally, within groups of pharmacies (personal communication).

Many pharmacies have their own website, through which they offer all kinds of services, including for example medicines use reviews, repeat prescribing and forms for requesting a personal consult with the pharmacist (personal communication).

5.3.3.2 Pharmaceutical counselling

The Royal Dutch Pharmacy Association (KNMP) has developed guidelines for pharmaceutical counselling in pharmacies. From 2012, these guidelines will form part of the basis for remuneration of pharmacies by health insurance companies.

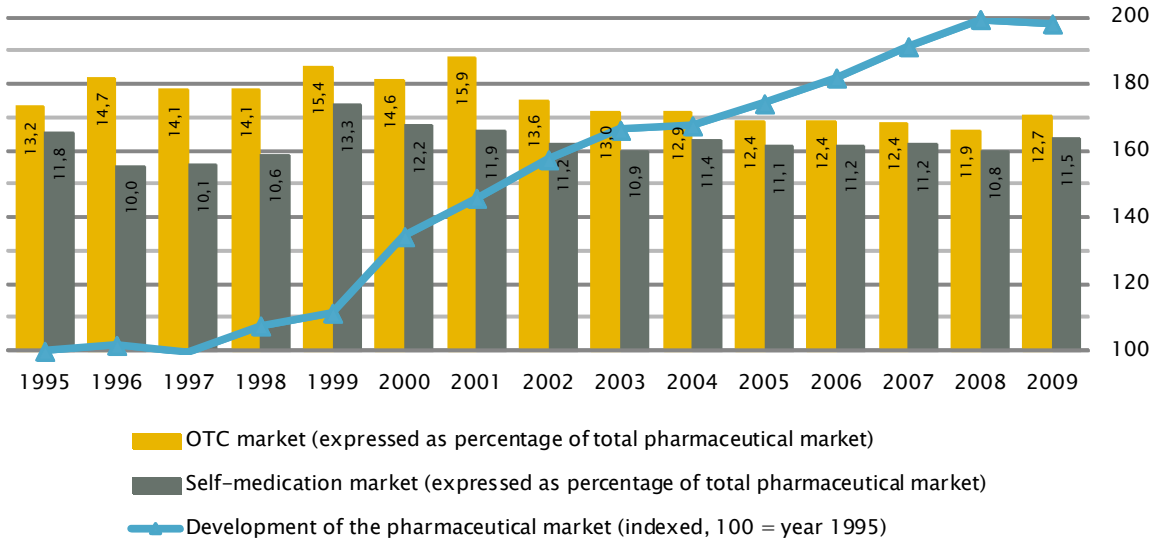
Normally, pharmaceutical counselling takes five minutes per patient for the first issue of a prescription. Repeat issues generally take less than five minutes, unless extra information is needed by the patient(personal communication).

5.4 Economics

5.4.1 Market data

As can be seen from Figure 5.2, the total pharmaceutical expenditure has doubled since 1995. The shares of OTC and self-medication as a percentage of the total pharmaceutical market have been rather stable over the past years.

Figure 5.2: The Netherlands – Development of pharmaceutical market, 2002 – 2009



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

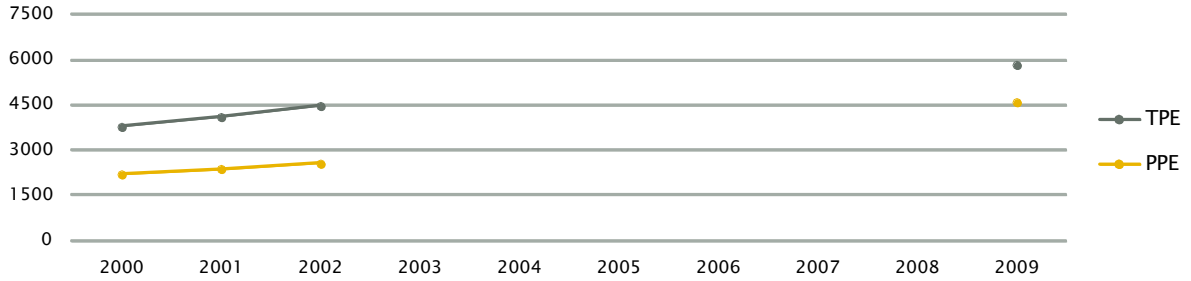
Data indicated at consumer price level

Source: AESGP 1995-2011

5.4.2 Pharmaceutical expenditure

In the Netherlands, the total and public pharmaceutical expenditure increased substantially from 2000 to 2009. Total pharmaceutical expenditure increased from € PPP 3,784.2 million in 2000 to € PPP 5,845.9 million in 2009. Public pharmaceutical expenditure increased from € PPP 2,204.8 million to € PPP 4,605.7 million in 2009.

Figure 5.3: The Netherlands – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009

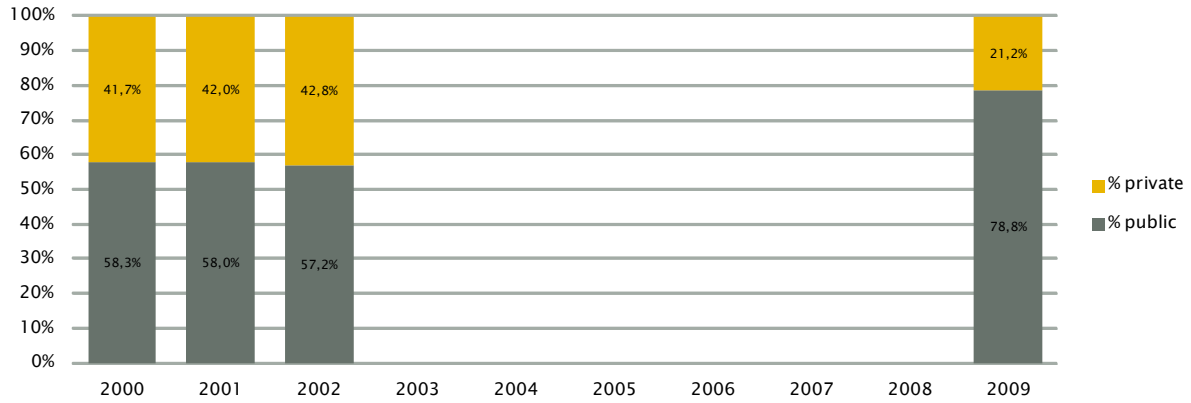


TPE = total pharmaceutical expenditure, PPE= public pharmaceutical expenditure
Data on pharmaceutical expenditure in the years 2003 to 2008 in the Netherlands are not available

Source: OECD 2011, PHIS 2011

The public share of the total pharmaceutical expenditure has increased from 58.3 percent in 2000 to 78.8 percent in 2009.

Figure 5.4: The Netherlands – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000 – 2009



Data on pharmaceutical expenditure in the years 2003 to 2008 in the Netherlands are not available.

Source: OECD 2011, PHIS 2011

5.4.3 Pharmacy remuneration and turnover

The law on medicine prices (Wet geneesmiddelenprijzen (WGP)) sets the maximum price (WGP-limit) for a specific branded medicine. The law on marketing in health care (Wet

marktordening gezondheidszorg (WMG)) sets the price the pharmacist will get for dispensing a (prescription) medicine. Basically the pharmacist will get a price for the medicine and a fixed dispensing fee. The dispensing fee is a fixed price (€ 5.99), independent of the amount of the medicine (however, in general medicines are dispensed for a 90-day period). An extra fee is added if the medicine is dispensed for the first time (+ € 5.99) and for dispensing during evening, night and Sunday (+ € 11.97). The price for the medicine is based on the official pharmacy purchase price (PPP). The PPP is reduced by a 8.53 percent claw-back (maximum reduction € 6.80) (Z-Index 2010).

OTC medicines are neither included in the WGP (so no restrictions on pricing for the manufacturer), nor in the WMG (so the pharmacy is free to set a retail price, but no dispensing fee is added). Thus, there is free pricing for OTC medicines at all price types (Z-Index 2010).

The average community pharmacy created a turnover of € 2,489,000 from the sale of medicines included in the basic benefit package in 2010. This was € 48,000 more than in 2009.

Between 2008 and 2009 the average turnover of a pharmacy decreased by € 29,000. The fall was partly due to the lowering of the prices of generic medicines, a process that was strongly influenced by health insurers' preferencial pricing policies (SFK 2011).

In the Netherlands, healthcare insurers have a statutory entitlement to designate specific pharmaceutical labels, within a group of pharmaceuticals with the same active ingredient and mode of administration that are eligible for reimbursement. This policy seeks to stimulate price competition between manufacturers. A number of healthcare insurers have been making use of this entitlement since 1 July 2005 (Kanavos et al. 2009, Habl et al. 2008, Zuidberg 2010) (also section 5.1.).

Another cause for the decreased pharmacy turnover in 2009 has been the restricted reimbursement of sleep-inducing medication and sedatives. Since 1 January 2009 these types of medicines are reimbursed only in case of a very restricted number of indications.

The Dutch Health Care Authority (NZa) increased the maximum fees for the provision of pharmaceutical care, which meant that earnings in the form of pharmacy fees for the dispensing of prescription medicines increased by € 76,000 to € 623,000 in 2010. The income of a pharmacy practice consists of this fee income plus purchasing advantages (minus the claw back) (SFK 2011).

At the beginning of December 2009 NZa set maximum fees for pharmaceutical care that applied from 1 January 2010. These fees are based on the principle that the average maximum fee should work out at € 7.91. The maximum fees are based on the reimbursement of the practice costs of a standard pharmacy as defined by NZa. But in fact, despite the increase in the fees from 1 January 2010, the maximum dispensing fees do not cover the costs. In practice, most pharmacies did not earn the average fee of € 7.91 in 2010 (SFK 2011).

6 Norway

6.1 Framework

In Norway, prescription-only medicines (POM) are mainly dispensed through community and hospital pharmacies. In January 2011 there were 649 community pharmacies and 33 hospital pharmacies that are also open for out-patients and 81 branch pharmacies (Apotekforeningen 2011a). The Norwegian Medicines Agency (NoMA) may allow pharmacies to run as a branch if there is no one with a master in pharmacy (pharmacists) available for hire. In that case, the Norwegian Medicines Agency may allow the pharmacy to run using a bachelor of pharmacy (prescriptionist) as head, but under the supervision of a non-branch pharmacy. The use of branches is primarily intended for areas with a severe shortage of masters in pharmacy. A pharmacy owner cannot decide by themselves that his/her pharmacy is to be run as a branch. The decision is entirely the Norwegian Medicines Agency (Apotekforeningen 2011a). Currently, there are approximately 7,300 inhabitants per pharmacy.

In rare occasions, the Ministry of Health and Care services may grant a doctor the right to dispense medicines. Doctors in the rural areas operating far from the pharmacy are allowed to dispense POM when normal availability is restricted due to weather or geographical complications. The number of doctors with such a licence is estimated to be around ten (Apotekforeningen 2011b).

The NoMa may allow pharmacies to establish pharmacy outlets in order to compensate the absence of pharmacies in an area. A pharmacy outlet has the right to sell and deliver all OTC medicines. Most of the pharmacy outlets are located in grocery shops. Currently there are approximately 1,100 pharmacy outlets in Norway, about half of the pharmacies have an outlet (Apotekforeningen 2011a).

Since 1 November 2003 so-called LUA ("medicines outside pharmacies") outlets, located for example in grocery stores, gasoline stations, health stores, etc., are allowed to distribute a restricted number of OTC medicines. The list of medicines that can be sold in these LUA outlets is defined by the Norwegian Medicines Agency and covers approximately 50 OTC medicines. LUA outlets are not connected to a pharmacy and do not employ pharmacists. As of 1 January 2011 there were approximately 7,000 of these LUA outlets in Norway.

There are a few internet pharmacies in Norway which are allowed only to sell OTC medicines.

Before 2001, the Norwegian pharmacy sector was subject to strict regulations. The Norwegian Board of Health used to decide on the establishment (number and location) of new pharmacies by means of a five year "pharmacy plan", and Norway had a relatively low number of pharmacies per inhabitants compared to other European countries.

On 1 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 to induce a shift in bargaining power from the manufacturers towards the wholesalers/pharmacies.

Another aim which the government wanted to achieve via the liberalisation was the decrease of the prices of OTC medicines (personal communication from some interview partners). The act entailed a liberalisation process with regard to establishment and ownership of pharmacies in that it sets no limits on the number or locations of pharmacies and puts no competency requirements on the ownership of pharmacies. Pharmaceutical manufacturers and prescribers are not allowed to own a pharmacy. All pharmacies must be run by a pharmacist. According to the Norwegian law on competition, the only boundary for corporate pharmacies is that no pharmacy chain is allowed to own more than 40 percent of all pharmacies. Pharmacy businesses require a license to own a pharmacy ("Apotekkonsesjon") and a license to run the pharmacy ("Driftskonsesjon") (Anell 2005, Apotekforeningen 2011b, Econ Analyse AS 2004, Vogler et al. 2006).

The liberalisation in the pharmacy sector was part of a larger political trend towards deregulation, e.g. following liberalisation in energy supply and telecommunications (Vogler et al. 2006).

Since March 2001 the pharmacy market in Norway has become very much integrated, both horizontally and vertically: horizontally because many pharmacies are now organised in chains, and vertically in that retailers and wholesalers now have the same owners. Vertically integrated pharmacy chains have bought most of the existing pharmacies in Norway and established a lot of new ones. The landscape of the community pharmacy sector changed indeed very quickly after the deregulation (Anell 2005, Vogler et al. 2006).

As of 1 January 2011 there were three vertically integrated pharmacy chains operating in Norway, owning a total of 554 pharmacies: Boots Apotek (146), Apotek 1 (236) and Vitusapotek (172) (Apotekforeningen 2011a). These are owned by full-line wholesalers which belong to the leading pharmaceutical distribution companies in Europe. These wholesalers are also strongly into the business of parallel exports, which go especially to Germany (personal communication). In addition there is a chain of 55 semi-independent pharmacies (Ditt Apotek) and some totally independent pharmacies.

Before the drafting of the new pharmacy law, an official committee investigated the pros and cons of different competitive policies. Of the committee, the minority, consisting of the representatives of three different ministeries as well as the professor heading the comittee, saw no reason for banning vertical integration. The Ministry of Health and Care services chose to follow the minority on this issue. The rationale for the Ministry of Health to allow vertical integration was that it would create more powerful purchasers that are able to better negotiate discounts with manufacturers. In fact, one of the interview partners considered the manufacturers of the losers of the deregulation. Currently, the manufacturers are trying to gain control on the wholesale segment, and they call for a single-channel wholesale system such as in Finland (cf. chapter 10) and Sweden (cf. chapter 7, personal communication).

The Norwegian Pharmacy Association (Apotekforeningen) represents the Norwegian pharmacies and has an important role in developing information systems, ethical standards, etc.

All the major pharmaceutical companies are represented in Norway, but only a few of them have established their own manufacturing units in the country. Ten companies have production facilities in Norway. The biggest ones are GE, Nycomed Pharma and Fresenius Kabi. Direct distribution from the manufacturer to the end-user is in general not allowed.

The main industry organisations are the Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustriforeningen/LMI) for research-orientated companies and the Norwegian Association of Generics-orientated Pharmaceutical Manufacturers (Norsk Industriforening for Generiske Legemidler – NIGeL).

6.2 Accessibility

6.2.1 Accessibility of medicines dispensaries

6.2.1.1 Provision of POM dispensaries

On 1 January 2011 there were 649 community pharmacies in Norway. Compared to the year 2001, the year in which the new pharmacy act came into force, the number of community pharmacies has increased by 63 percent (252 pharmacies). The largest number of new openings was seen in 2001, when 65 new pharmacies were established. Before the liberalisation in the pharmacy sector took place, the number of pharmacies increased on average by seven per year (Apotekforeningen 2011a, Vogler et al. 2006).

Including POM dispensing doctors and hospital pharmacies that are allowed to dispense POM to out-patients makes a total of 692 POM dispensaries and 7,110 inhabitants per POM dispensary on 1 January 2011. In January 2000 the number of inhabitants per POM dispensary in Norway amounted to 11,457.

Table 6.1: Norway – Number of pharmacies and other dispensaries, as of 1 January, 1990 – 2011

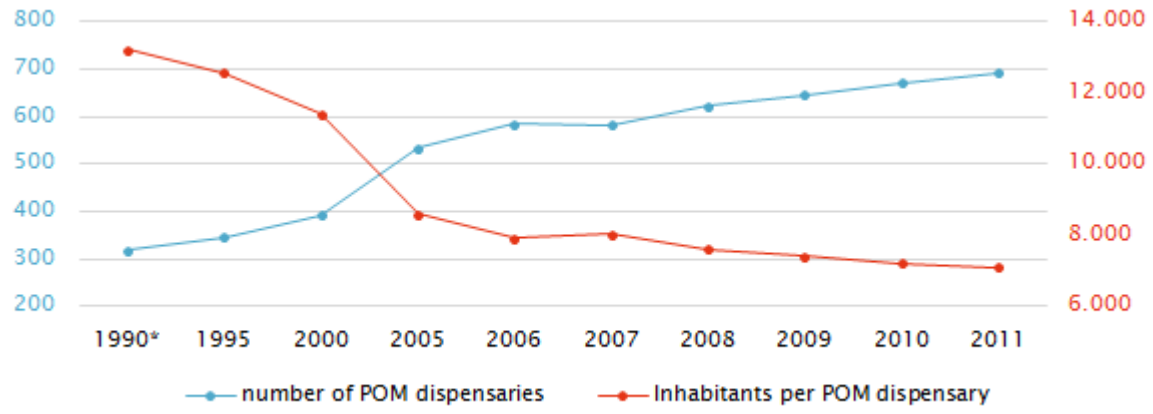
Dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Number of POM dispensaries (i.e. retailers which are allowed to dispense prescription-only medicines)										
Community pharmacies, all privately owned	301	319	365	505	523	542	580	603	629	649
Including: Branch pharmacies	n.a.	69	105	138	n.a.	n.a.	102	97	88	81
POM dispensing doctors	n.a.	n.a.	n.a.	n.a.	32	10	10	10	10	10
Hospital pharmacies dispensing POM to out-patients	19	27	27	30	31	31	33	33	33	33
Internet pharmacies dispensing POM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total of POM dispensaries	**320**	**346**	**392**	**535**	**586**	**583**	**623**	**646**	**672**	**692**
Number of further retailers (OTC dispensaries, only allowed to dispense OTC medicines)										
Pharmacy outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1,106
LUA outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	7,000[1]
Total of OTC dispensaries	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	**8,106[1]**

LUA = "medicines outside pharmacy", n.a. = not available, POM = prescription-only medicine

[1] This is an approximation

Source: Apotekforeningen 2011a, Vogler et al. 2006

Figure 6.1: Norway – Number of prescription-only medicines (POM) dispensaries and number of inhabitants per POM dispensary, 1990 – 2011



PO

M = prescription-only medicine

Source: Apotekforeningen 2011a, Vogler et al. 2006

An analysis made for the Association of Danish Pharmacies by GEOMATIC shows that the Norwegians have, on average, 6.8 km to the nearest pharmacy. 21 percent of the population in Norway has less than one kilometre to the nearest pharmacy and more than 50 percent of the population has less than three kilometres to the nearest pharmacy (Danmarks Apotekerforening 2011a).

6.2.1.2 Provision of POM dispensaries in rural areas

While establishment of pharmacies in rural areas has not been particularly stimulated by the government, no pharmacy has closed in the rural, scarcely populated areas, 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 in 2001, this agreement has been applied three times; three pharmacies have been saved (Apotekforeningen 2011a). On July 2011 this agreement expired and by the time this report was written, it was still unclear whether or not it will be renewed (personal communication).

Since 2001 the number of pharmacies in each of the 19 Norwegian provinces, also so the less densely populated ones, has increased. The main part however of the new pharmacy establishments since 2001 have taken place in more densely populated urban areas, in which the number of citizens per pharmacy were higher than average. As of 31 December 2010 250 of the total number of 430 municipalities had a pharmacy and 91 percent of the Norwegian inhabitants lived in a municipality with a pharmacy (Apotekforeningen 2011a). According to the consumers' association, while the accessibility in rural areas has always been a problem, no improvement since the deregulation was perceived (personal communication).

In order to secure the availability of necessary medicines in rural areas, branch pharmacies (Filialapotek) were established, from which medicines (POM and OTC medicines) are dispensed and supplied to patients under the supervision of the pharmacy. In addition, a small number of doctors operating in rural areas are allowed to dispense POM medicines when normal availability is restricted due to weather or geographical complications. Finally, since 1 November 2003 so called LUA ("medicines outside pharmacies") outlets, located for example in grocery stores, gasoline stations, health stores, etc., are allowed to distribute a restricted number of OTC medicines (Vogler et al. 2006).

6.2.2 Availability of medicines

In Norway, there are no statutory provisions regarding the minimum range of medicines which pharmacies must always have in stock. Pharmacies are obliged to have in stock all medicines which are regularly asked for (this may differ per pharmacy) and to be able to deliver all medicines within 24 hours. Regulations concerning service requirements and information about the real practice are summarised in Table 6.2.

As of January 2010, there are no minimum opening hours for pharmacies. Two 24 hours pharmacies are located in Oslo (personal communication). In case of an emergency, most

people visit the emergency ward of a hospital and receive medication there (Vogler et al. 2006). Accessibility was considered to have improved which is attributed not only to an increase in the number of pharmacies, but also longer opening hours (personal communication from two interview partners).

Table 6.2: Norway – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	The amount of medicines, the equipment and supplies for administering medicines, and the dressings kept by a pharmacy must correspond to its usual customer needs.	No information available.
Dispensing within a certain time period	All medicines (including those not in stock) have to be supplied within 24 hours.	Medicines in stock are dispensed directly, others within 24 hours.
Frequency of delivery	No specific regulations.	On average, pharmacies receive deliveries from wholesalers four times per week, in rural areas these may be fewer.

Source: Apotekforeningen 2011b

6.3 Quality of pharmacy services

6.3.1 Pharmacy staff

6.3.1.1 Availability of pharmacists and other qualified staff

The professional staff of pharmacies consists of a pharmacy manager, employed pharmacists, prescriptionists, pharmacy technicians and sometimes nurses. Pharmacy managers are pharmacists who have a license to run a pharmacy, and they are formally responsible in case of errors or negligence conducted in the pharmacy. Prescriptionists are entitled to run a branch pharmacy or a pharmacy outlet, and are thus allowed to dispense prescriptions.

The required university education of pharmacists takes five years (master in pharmacy), whereas that of prescriptionists takes three years (bachelor in pharmacy). According to the Health Personnel Act, the employer has the obligation to provide for and organise necessary updating of the pharmacy staff's competence. A minimum number of training hours or training schemes are not defined (Apotekforeningen 2011b).

Table 6.3: Norway – Staff working in community pharmacies, as of 1 January 1995 – 2010

Pharmacy staff	1995	2000	2005	2006	2007	2008	2009	2010
Number of pharmacy staff, full time equivalents								
Pharmacists	730	859	949	1,001	n.a.	1,058	1,185	1,286
Prescriptionists	771	882	1,056	1,095	n.a.	974	1,010	1,018
Total of staff allowed to dispense medicines	**1,501**	**1,741**	**2,005**	**2,096**	**n.a.**	**2,032**	**2,195**	**2,304**
Pharmacy technicians without the right to dispense medicines	3,383	4,071	3,976	3,803	n.a.	3,125	3,109	3,092
Other staff	n.a.	217	168	249	n.a.	169	160	162
Total of pharmacy staff	**4,884**	**6,029**	**6,149**	**6,148**	**n.a.**	**5,326**	**5,464**	**5,558**
Number of pharmacy staff counted per head								
Pharmacists	n.a.	727	857	913	1,028	1,141	1,239	1,303
Prescriptionists	n.a.	742	884	929	949	1,004	1,010	1,042
Total of staff allowed to dispense medicines	**n.a.**	**1,469**	**1,741**	**1,842**	**1,977**	**2,145**	**2,249**	**2,345**
Pharmacy technicians without the right to dispense medicines	n.a.	3,186	3,068	3,033	3,102	3,111	3,078	3,034
Other staff	n.a.	173	168	144	154	174	154	53
Total of pharmacy staff	**n.a.**	**4,828**	**4,977**	**5,019**	**5,233**	**5,430**	**5,481**	**5,432**

n.a. = not available

Source: Apotekforeningen 2005-2010, Vogler et al. 2006

Since 2000, the nation-wide number of pharmacists has increased by almost 79 percent when counted per head or by 50 percent when counted as full time equivalents. In spite of the large increase in pharmacies, the number of pharmacists (counted per head) per pharmacy has increased from 1.99 on 1 January 2000 to 2,07 on 1 January 2010. This increase in pharmacists, which was against the expectations, is considered to be attributable of the opening of a pharmacy school in Norway in the 1990s and pharmacists coming from neighbouring countries (mainly Sweden) (personal communication). When counted as full time equivalents, the number of pharmacists per pharmacy decreased in the same period from 2,35 to 2,04. The number of staff, counted per head, per pharmacy decreased from 12.2 (16.5 FTE) in 2000 to 8.1 (8.8 FTE) in 2010. This reduction has at least been partly compensated by an increased efficiency; purchasing routes are more coordinated and some tasks (e.g. administration) have been taken over by the central chain offices (Vogler et al. 2006).

Table 6.4: Norway – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	Master of pharmacy	5 years	Yes	No	Pharmacy Act
Prescriptionists	Bachelor of pharmacy	3 years	Yes	No	Pharmacy Act.
Pharmacy technicians / assis-tants without the right to dispense medicines	Secondary school	3 years	Yes	No	Pharmacy Act

Source: Apotekforeningen 2011b

6.3.1.2 Professional independence of pharmacists

On 1 January 2011, 81 percent of the Norwegian pharmacies was in ownership of one of the three large international pharmacy chains, each vertically integrated with a pharmaceutical wholesaler (Apotekforeningen 2011a). Even an interview partner who was in favour of the deregulation process reported that the independence of the pharmacies was strongly affected by the pharmacy chains. Table 6.5 shows the distribution of the number of pharmacies that are fully or partly owned by the pharmacy chains.

There are 33 publicly owned hospital pharmacies in Norway, which dispense POM to out-patients. The hospital pharmacies are part of the specialist health care service. These are organised as independent health authorities, owned by the regional health authorities. Two of these hospital pharmacies are owned by charitable trusts, which have agreements with the health authority.

All the hospital pharmacies and several of the pharmacies which are not wholly owned by a pharmacy chain are members of Ditt Apotek. Ditt Apotek is an agreement based chain (purchasing and range co-operation) which NMD Grossisthandel AS, a wholesale company, offers to pharmacists who own and run their own pharmacies. On 1 January 2011 there were 24 freestanding and independent pharmacies in Norway (Apotekforeningen 2011a).

The Norwegian Competition Authority has published investigations in the effects on the liberalisation (Dalen 2003, Konkurransetilsynet 2009) and has criticized the oligopolistic structure of the market. One recommendation was a regulation of essential infrastructure to ensure similar competitive conditions (Konkurransetilsynet 2009).

Table 6.5: Norway – Pharmacy chains, as of 1 January 2011

Name of pharmacy chain	Name of owner and category	% of market share 2010	Number of pharmacies in ownership	Number of pharmacies in membership (franchise)
Alliance Apotek / Boots Apotek	Alliance healthcare (wholesaler)	19[1]	146	0
Vitusapotek	NMD Grossisthandel AS (wholesaler)	22[1]	172	1
Apotek 1	Apokjeden Distribusjon AS (wholesaler)	38[1]	236	15
Ditt Apotek	Pharmacists	4[1]	0	55
Total:		**83[1]**	**554**	**71**

[1] This is an approximation

Source: Apotekforeningen 2011a

6.3.2 Product range

6.3.2.1 Medicines

Pharmaceuticals are either classified as prescription-only or Over-the Counter (OTC) medicines. Some prescription medicines ("blue prescriptions") are at least partly paid by the Norwegian national insurance scheme, other prescription medicines ("white prescriptions") are fully paid for by the patient.

OTC medicines are all non-reimbursable and thus fully paid by the patient. Since 1 November 2003 a restricted list of approximately 50 OTC medicines has been defined by the Norwegian Medicines Agency. The so-called LUA ("medicines outside pharmacies") medicines on this list may be sold in outlets, which are located for example in grocery stores, gasoline stations and health stores and which are neither supervised by a pharmacist nor a prescriptionist.

OTC medicines made up about one third of all medicines packaged sold through community pharmacies in 2010 (Apotekforeningen 2011b).

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 facilities. The share of pharmacy manufactured medicines in the pharmacies' turnover is rather small. This was the reason for the government to abolish the set of rules which required production facilities in every pharmacy.

6.3.2.2 Non-pharmaceuticals

In the past years, many pharmacies have been equipped to accommodate self-service zones for health-related merchandise. Non-pharmaceutical products sold through pharmacies are, besides medical devices (e.g. band aids and dressings), skin care products.

Pharmacies may sell any non-pharmaceutical products as long as there is no mismatch in selection of goods in the pharmacy and the public‘s expectation of what to find in pharmacies. The share of turnover made through the sale of non-pharmaceuticals was 23.9 percent in 2010. There is no specific maximum to the share of non-pharmaceuticals in the pharmacies’ turnover, and money was said “to lie with non-pharmaceuticals” (personal communication).

6.3.3 Pharmacy services

6.3.3.1 Services provided by pharmacies

Besides medicines dispensing, all pharmacies in Norway offer their customer repeat dispensing and a disposal of waste medicines (cf. Table 6.6).

In 2006 an investigation of pharmaceutical care and services provided in other countries was carried out and services and needs which would be useful to provide in Norwegian pharmacies were identified. This resulted in the report “Health Services in Pharmacies”, which was published in January 2007 (Helsedirektoratet 2007). Based on the report the Ministry of Health and Care Services asked the Norwegian Directorate of Health to establish working groups for each of the services suggested in order investigate their impact on public health, the resource allocation and the patient perspective.

In April 2009, the Directorate of Health published a report called “Health-Aid in Pharmacies”. The report advised that Medicines Use Reviews and Smoking Cessation programs should be established in Norwegian pharmacies. A project managed by the Directorate of Health, investigating the cost efficiency of Medicines Use Reviews in pharmacies, is currently under development (personal communication).

Already, pharmacies are increasingly offering additional services, such as blood pressure measurement or specific disease (e.g. asthma, diabetes) management programs.

Nonetheless, pharmacy services were seen to be only at the beginning, and their expansion and thus strengthening the role of pharmacists might entail conflicts among health professionals, since doctors may oppose to this shift of responsibility (personal communication from an interview partner from a regulatory authority).

Table 6.6: Norway – Services provided by community pharmacies, 2011

Pharmacies providing this service	Type of service
All	Dispensing prescriptions, disposal of waste medicines
Most	Supervised administration of methadone and buprenorphine, multidose packaging
Some	Medicines Use Review, blood pressure measurement, glucose measurement, weight measurement, smoking Cessation

Source: Apotekforeningen 2011b

Pharmacists were seen as an essential component of the health care system. This perception was confirmed by the report which evaluated a specific programme during the pandemic 2009/2010 (Pöyry Econ 2011).

Generic substitution is allowed, as well as INN prescribing (PHIS 2011). Generic promotion plays an important role in Norway and is also supported by the pricing system in place (cf. section 6.4.3).

6.3.3.2 Pharmaceutical counselling

Using WHO's guidelines for Good Pharmacy Practice (GPP) in community and hospital settings, voluntary trade standards for pharmacies (Standards for Pharmacy Practice) in Nordic countries have been developed, defining four areas as the pharmacies' core activities (Apotekforeningen 2003):

- Prescriptions and requisitions
- Self care
- Rational prescribing and medicine use
- Health promotion and ill-health prevention

The Nordic Guidelines for Good Pharmacy Practice are based on the principle that the needs and expectations of the customer/patient shall be the focus of the pharmacy's work. The standards in the guideline form a basis for the own monitoring of the quality of pharmacy services. The minimum requirements for pharmacy operations are laid down in the Pharmacy Act and in other legal regulations (Apotekforeningen 2003).

In 2003 the Norwegian company "Econ Analyse AS" evaluated the Norwegian Pharmacy Act on behalf of the Norwegian government. According to this report some pharmacists feared that the quality of pharmacy services had deteriorated due to an increase in workload. The pharmacists' opportunity to provide patients with professional advice was perceived by many pharmacists to have reduced. Over half of the interviewed pharmacists believed that the advice given on prescription-only medicines was 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 stated that the extent of incorrect dispensing did not appear to have increased (Econ Analyse AS 2004).

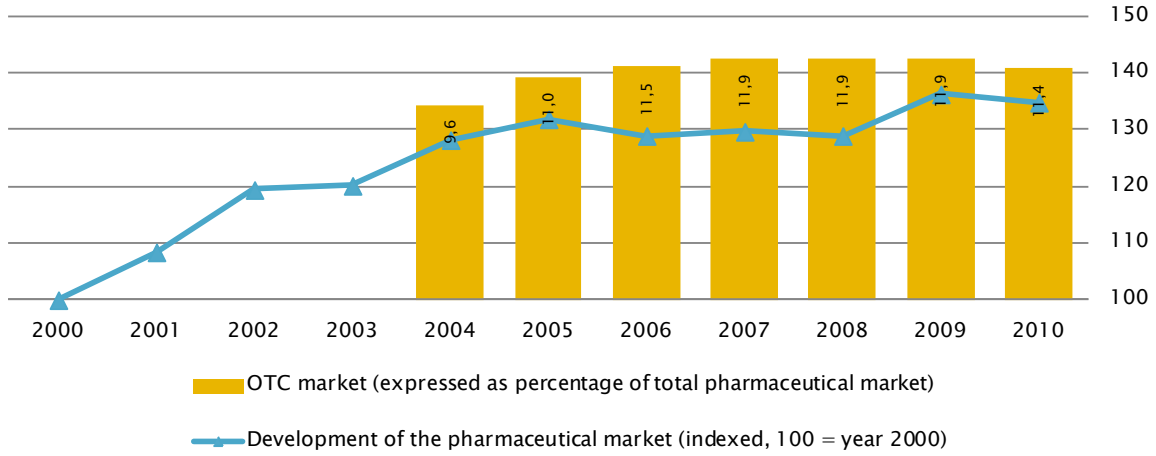
In 2008/2009, the Norwegian Medicines Agency scrutinized the Pharmacy Act. This resulted in a report, which was sent to the Ministry of Health and Care Services, suggesting slight changes in the law and other regulations. In essence, the changes were mostly minor adjustments, based on the fact that they were pleased with the existing Pharmacy Act (personal communication). Overall, the interview partner believed that the quality of pharmacy services have improved during the years, and this was also attributed to pharmacy chains implemented quality program (personal communication).

6.4 Economics

6.4.1 Market data

Figure 6.2 displays the development of the Norwegian pharmaceutical market between 2000 and 2010. The total pharmaceutical market in Norway increased steadily between 2000 and 2005 and was relatively stable between 2005 and 2010. The market share of OTC medicines was 9.6 percent in 2004 and 11.4 percent in 2010.

Figure 6.2: Norway – Development of pharmaceutical market, 2000 – 2010



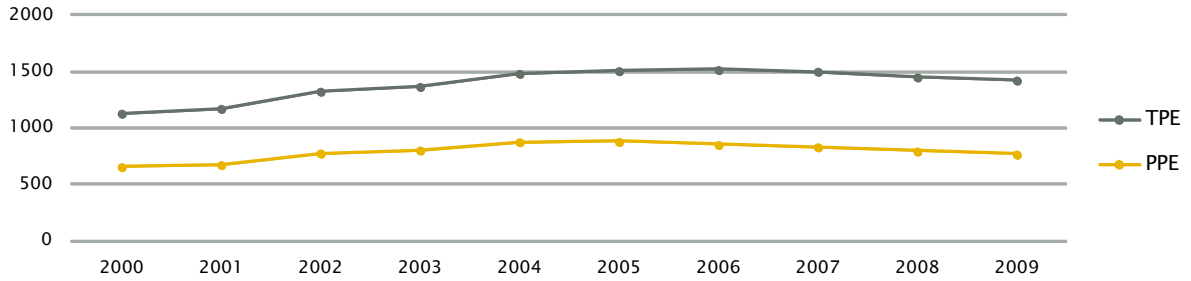
OTC = Over-the-counter

Source: Legemiddelindustrien 2000-2011

6.4.2 Pharmaceutical expenditure

The total pharmaceutical expenditure in Norway increased from NOK 6,896 million (€ 1,130.9 million) in 2000 to NOK 9,363 million (€ 1,483.7 million) in 2004. After 2004 it has decreased to NOK 9,015 million (€ 1,423.9 million) in 2009 (cf. Figure 6.3).

Figure 6.3: Norway – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009



PPE = public pharmaceutical expenditure, TPE = total pharmaceutical expenditure

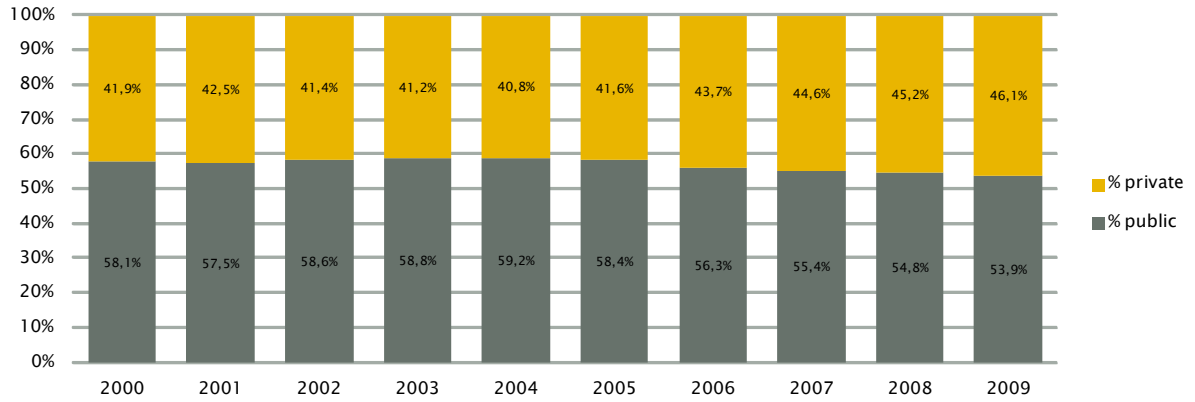
Source: OECD 2011, PHIS 2011

According to a study from Håkonsen, the direct price control involving international reference pricing of prescription drugs, and the subsequent price revisions, that occurred from the year 2000 onwards, resulted in predictable and substantial price reductions (Håkonsen et al. 2009). In addition, a price model called the stepped price model (*Trinnprismodellen*) came into effect in January 2005. Under this scheme, a maximum reimbursement price is set for affected pharmaceuticals (both branded and generics). The maximum price level is automatically reduced in stages (steps) following patent expiry. The size of the cuts depends on annual sales prior to the establishment of generics competition and time since competition was established. Within the step-price system there are no regulations of pharmacy mark ups. Pharmacists therefore have a financial incentive to carry out generics substitution and dispense the cheaper product. (Festøy et al. 2011, Apotekforeningen 2011a)

In general doctors are obliged to prescribe the cheapest equivalent product unless there are serious medical reasons for prescribing a more expensive alternative. The reimbursement system regulates prescription practices to a certain degree since the prescribing party in general will prescribe a reimbursed medicine instead of a non-reimbursed therapeutically equivalent pharmaceutical. The “preferred medicine” scheme, which was introduced in March 2004, also influences prescribing. For some therapeutic equivalent medicines a first-choice scheme (~ a preferred product) is established. The prescribing party has to (by law) prescribe the first-choice product unless there are medical reasons for not doing so. This is an alternative to therapeutic reference pricing and was introduced to ensure the use of the most cost-effective medical treatment (Festøy et al. 2011).

The Norwegian health care system’s most important feature is the predominance of tax-funded public provision together with limited out-of-pocket payments. In comparison with the year 2000, the public share of the total pharmaceutical expenditure has decreased from 58.1 percent in 2000 to 53.9 percent in 2009 (cf. Figure 6.4).

Figure 6.4: Norway – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

6.4.3 Pharmacy remuneration and turnover

The NoMA controls the maximum prices of prescription medicines in the pharmacies (pharmacy retail price, PRP) by 1. setting a maximum pharmacy purchasing price (PPP) prices and 2. defining the maximum pharmacy mark-ups.

The pharmacy profit consists of a percentage mark-up based on the wholesale price (pharmacy purchasing price) and a fixed amount per package. In 2009 the gross mark-up for prescription-only medicines was changed. Based on the pharmacy purchasing price the pharmacy mark-up for prescription-only medicines is currently defined as follows (Apotekforeningen 2011a).

- 7 percent for the first NOK 200.- / € 25.51
- 4 percent for the amount above NOK 200.- / € 25.51
- a fixed sum of NOK 22.00 / € 2.81 per package

There is a pharmaceutical tax of 0.55 percent of the pharmacy purchasing price. It applies to all medicines, including OTC medicines, and is paid by the pharmacies and other outlets allowed selling OTC medicines. Some of the tax is redistributed to the pharmacies as subsidies. Additionally a tax of 2 percent on sales in retailers such as grocery stores, gasoline stations etc, which is collected from the wholesalers (Festøy et al. 2011).

In the year 2010 the average community pharmacy margin for medicines in Norway amounted to 19.4 percent of the pharmacy retail price net referring to the total pharmacy market, and it was 17.7 percent of the pharmacy retail price net for reimbursement market (Apotekforeningen 2011b).

There is no control on the pricing of non-prescription (OTC) medicines in Norway, neither at the level of pharmacy purchasing price nor is there a statutory mark-up.

One aim of the deregulation was the decrease OTC prices (cf. section 6.1), but the interview partners expressed quite different perceptions the development of the OTC prices and little evidence was available on this issue. In fact, there were studies displaying Norwegian prices as being rather low in the European context (Brekke et al. 2008) but this concerned the regulated prescription-only segment, including generics. A study (Norwegian Medicines Agency 2010) was performed on the development of prices of medicines sold in and outside pharmacies from the 2003 and 2010. It found that prices across the outlets vary, with gas stations and kiosks having the highest prices and grocery stores being cheapest. Compared to pharmacies, the prices of the less expensive generic alternative in pharmacies were about at the same level as of the most well known products in the grocery stores. The study concluded that the pharmacies do rather not compete on prices, displaying an average difference between the lowest and highest prices in all pharmacies of 9.9 percent.

Nonetheless, the study showed that the prices in pharmacy increased more than the prices in the other outlets in the period surveyed. While no comparative study on the development of the prices non-pharmaceuticals, which account for an important share of a pharmacy's turnover (around 24 percent, cf. Table 6.7) among pharmacies and other outlets, is available, it should be noted that according to the consumers' association Norwegian consumers have a willingness to pay higher prices in pharmacies because of expected better counselling in the pharmacies (personal communication).

Another study looking at the costs of pharmacies, based on the annual costs of pharmacies from 1998 to 2003, concluded that, while the availability to pharmacy services has increased, the costs of the individual pharmacies have not decreased as a consequence of the liberalisation (Rudholm 2008).

Table 6.7 shows the development of pharmacy turnover between 2006 and 2010. Pharmaceuticals, including OTC medicines, account for the largest part of pharmacy´s turnover, but dropped between 2007 and 2010 from 79.9 percent to 75.7 percent. OTC medicines accounted for between 9.5 percent (2007) and 8.7 percent (2010) of the pharmaceutical sales in community pharmacies. The rather high relevance of sales of non-pharmaceuticals was already mentioned.

A total of 73,811,555 medicine packages (prescription-only medicines and OTC medicines) were sold in 2010 (Apotekforeningen 2011b). For the years before liberalisation the numbers of medicine packages dispensed per year are not available, making a comparison impossible.

In the year 2010 the number of medicine packages sold through community pharmacies or hospital pharmacies (662 in total) amounted to 111,498. The number of medicine packages sold per pharmacist or prescriptionist (2,304 in total) was 32,036.

Table 6.7: Norway – Number of medicines dispensed and pharmacy turnover, 2005 – 2010

Turnover	2005	2006	2007	2008	2009	2010
Medicine packages sold (in millions)	70.8	71.7	72.8	74.3	74.9	73.8
Total pharmacy turnover in million NOK	n.a.	16,021	16,559	17,485	18,283	18,791
Of which:						
Turnover of medicines	n.a.	n.a.	13,238	13,697	14,051	14,221
Turnover of OTC	n.a.	n.a.	1,571	1,636	1,676	1,638
Turnover on non-pharmaceuticals	n.a.	n.a.	3,321	3,788	4,232	4,570

Source: Apotekforeningen 2011b

7 Sweden

7.1 Framework

The main actors in the Swedish pharmacy system are community pharmacies, which were all state-owned by the public company Apoteket AB until 2009 (Blöndal 2009, Vogler et al. 2003). Until then, all medicines, including POM (prescription-only medicines) and OTC (over-the-counter) medicines, were only allowed to be dispensed in these publicly owned community pharmacies. Today, after the so-called reregulation of the system, in which the monopoly of Apoteket fell, about two thirds of all pharmacies are in the hands of private companies (cf. Table 7.2, section 7.2.1.1). The rest of the pharmacies are still owned by Apoteket AB.

To provide for a high accessibility to medicines in rural areas, Apoteket AB, which is still a big market player, holds about 890 so-called Apoteksombuds acting as Apoteket representatives. Normally these representatives are integrated into grocery stores especially in rural areas (cf. section 7.2.1.2). They operate places with small OTC medicines stocks. Additionally written prescriptions are accepted for an order and pick up service but more than 95 percent of all prescriptions in Sweden nowadays are already filled as e-prescriptions (Apoteket 2011). This distribution channel of representatives will only be retained by Apoteket AB until 1 July 2012 (Apoteket 2009).

In Sweden, there are no dispensing doctors or hospitals dispensing to out-patients in place (cf. Table 7.2) (PGEU 2010g, Stenberg 2009). Regarding the accessibility of pharmacies it has to be mentioned that, though Swedish hospital pharmacies do not serve out-patients in general, a number of community pharmacies (both private and state owned Apoteket) are also located at hospital premises (personal communication).

There are no branch pharmacies in Sweden (Apoteket 2011).

Until 2009, Internet sales were only carried out through Apoteket AB's website. OTC medicines have been available at this website since 2002 and POM since 2006. The patients had access to their electronic prescriptions by using an electronic ID. Medicines could be delivered to the patient's home, to a post office, to a pharmacy representative or to a local pharmacy. Counselling was performed via telephone or at a pharmacy. The Apoteket's call centre initiated the contact to the consumers once a year and each time after ordering a medicine. Since 2009 sale of OTC medicines via internet pharmacies other than Apoteket AB is allowed (PGEU 2010c).

The sale of OTC medicines outside pharmacies is allowed in supermarkets and petrol stations since November 2009 based on a bill (Swedish Government 2008) presented on 11 June 2009 (cf. Table 7.1). The first step in this direction was already made one year before, when the sale of nicotine replacement products had been allowed for retailers other than Apoteket AB. The sale of OTC medicines is subject to certain restrictions. The customers have to contact a store employee to access the medicines. Recently there were about 7,000 OTC dispensaries in Sweden (Apoteket 2009).

Table 7.1: Sweden – Timeline of the reregulation, 1970 – 2013

Date	Measures
1971-2009	All community pharmacies in Sweden are in state ownership
May 2005	Ruling by the European Court of Justice concerning the Swedish pharmacy monopoly
Autumn 2006	Election of a new government
March 2008	A draft bill on restructuring the ownership and activities of Apoteket AB (Swedish Government 2008) was presented to the Riksdag on 13 March 2008. It had proposals for restructuring the ownership and activities of Apoteket AB but while it did not include the proposals of the pharmacy market inquiry, it contained preparations for them.
June 2008	Opening of the market for the sale of NRT (nicotine replacement therapy) products outside pharmacies
February 2009	The government introduced the bill to relieve the pharmacy monopoly
April 2009	The Swedish Parliament (Riksdag) voted in favour of the implementation of the act (Swedish Government) to relieve the pharmacy monopoly – also private companies will be allowed to own pharmacies The government presented a proposal for a raised pharmacy retail margin
June 2009	Discussion of draft bill about sale outside pharmacies for a broad spectrum of OTC medicines
July 2009	The reregulation (abolishment of the monopoly) got into force and prices for originator medicines were reduced to the lowest generic price (but a maximum of 65 percent of the original price). State owned community pharmacies were sold in clusters. The rest (150 community pharmacies) was sold individually.
November 2009	Implementation of an act (Swedish Government) for the allowance of OTC medicines sale outside pharmacies Increased pharmacy margin implemented
2013	The regulation that pharmacies have to be kept open for three years after purchase will expire. A change in profitability for pharmacies due to the reregulation starts.

Source: Author's compilation based on different sources, including Apoteket 2009, Apoteket 2011, Göransson/Wallén 2010, OAB 2009, Swedish Government 2009a and 2009b, Thyberg 2010

The reregulation of the Swedish pharmacy system in 2009 was initiated by the Swedish government, which took office after the election in autumn 2006 (Redman et al. 2007). A precedent ruling of the European Court of Justice in May 2005 is considered to have contributed to this decision of the new Swedish government (Bengtsson 2006), but it was an internal Swedish decision. The European Court of Justice had decided that the Swedish community pharmacy system organized as a state monopoly is liable to place at a disadvantage medicines from other Member States as compared to trade in Swedish medicines. Further, the ruling stated that although a total abolition of State monopolies of a commercial character is not required, it is required that the monopoly is adjusted in such a way as to ensure that no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States (ECJ 2005). According to Apoteket AB the state owned pharmacy system had been criticized both by the Swedish

citizens and the Swedish pharmacists already before 2009 (Apoteket 2011). Compared to other European countries the Swedish pharmacy monopoly has been characterized by a high number of costumers per pharmacy due to a few number of pharmacies and limited opening hours (OAB 2009).

The Swedish government argued that putting an end to the Apoteket monopoly would improve the availability of medicines for customers in the form of more pharmacies and longer opening hours. Further it was expected to contribute to the creation of a downward pressure on prices as more providers enter the market (Regeringskansliet 2011).

The reregulation process consisted in selling about two thirds of the pharmacies owned by Apoteket AB to different types of owners to generate a more competitive environment (Filipe 2011).

The sale of community pharmacies is handled by Apotekens Omstrukturering AB (OAB), which had also been in charge of the restructuring process of Apoteket AB. The pharmacies had to be sold in clusters comprising between ten and 199 pharmacies. The purchasers were four big chains (cf. section 7.3.1.2) (PGEU 2010f). Around 150 of the pharmacies were selected to be sold to entrepreneurs and small business owners in a separate process (Apoteket 2011).

As a result, Apoteket is no longer the exclusive pharmaceutical dispensary, but remains a key competitor in the market. As part of the liberalisation, the government proposed unrestricted pricing of OTC medicines and that portions of the OTC range should be released for sale in other retail outlets. These new OTC rules went into effect on 1 November 2009 (Swedish Government).

Since 2009 the Dental and Pharmaceutical Benefits Agency (TLV) has been charged with the task of monitoring and supervising the pharmacy market. The agency evaluates if pharmacies have been following the applying regulations such as those related to the substitution of medicines at pharmacies (TLV 2011). Generic substitution in Sweden is obligatory, whereas INN prescribing (by active ingredient name instead of the brand name) is not allowed (PHIS 2011).

All in all, the reregulation is expected to lead to more community pharmacies, better service and more generous opening hours for the costumers. Another expected result is price pressure resulting in lower prices on pharmaceuticals. But the authors heard about the fears of pharmacists of a loss of pharmaceutical responsibility because of the increasing number of chains (Apoteket 2011).

The Government's Pharmacy Market Reform Bill (Regeringskansliet 2011) and the Medical Products Agency's directives introduced the new requirements of pharmacy establishment and ownership in Sweden.

Establishment rules under the new legislation allow for both public and private establishment of pharmacies. Manufacturers of medicines and prescribers are not allowed to establish pharmacies. Also companies, where a manufacturer of medicines has a deciding influence,

are excluded from establishing a community pharmacy in Sweden (OAB 2009). For each new pharmacy a permit from the Medical Products Agency is required. The Medical Products Agency maintains the supervision over all community pharmacies in Sweden. The opening of the pharmacy market for non-governmental players was launched on 1 July 2009. All licensed community pharmacies have to secure the availability of all POM and provide pharmaceutical expertise (cf. Table 7.1) (Apoteket 2009).

In Sweden, full pharmacists with a master's degree, but also prescriptionists with a bachelor's degree (cf. section 7.3.1.1) fulfil the requirements and are allowed to manage a community pharmacy. Every pharmacy has to be staffed with qualified personnel. During the opening hours, a pharmacist must be present at every pharmacy. Moreover, a pharmaceutical responsible person, who is allowed to be in charge of a maximum of three pharmacies, is required in Sweden (OAB 2009).

The Swedish wholesale market consists of two companies, Kronans Droghandel (Oriola KD) and Tamro (Phoenix group), which are allowed to deliver to pharmacies, primary care centres and hospitals, but not directly to patients.

Pharmaceutical wholesale is organized as a single-channel distribution system, which is characteristic for Sweden and Finland. In a single-channel system the market power of wholesalers is higher than in other European countries with a distribution system with more channels (Vogler/Habl 2003). The pharmaceutical companies have distribution agreements for their products with one of the two wholesalers, which therefore rather act as wholesale logistics providers. Neither Kronans Droghandel nor Tamro are full-line wholesalers, therefore pharmacies have to order the products from both wholesalers. The wholesale consists of warehousing and distribution only. The two Swedish wholesalers as a consequence are not exposed to business risk relating to the products (OAB 2009).

Wholesale margins are not statutory, but negotiated directly between the two wholesalers and the pharmaceutical companies (Redman et al. 2007). The margins of the two wholesalers are relatively low compared to other countries (OAB 2009), whereas ex-factory prices used to be comparably high in Sweden (Vogler/Habl 2003).

Currently, there is an evaluation by the Dental and Pharmaceutical Benefits Agency (TLV) ongoing, which looks into the goal fulfillment (has the regulation contributed to higher accessibility?), an international comparison of pharmacy margins and a survey of the pharmacy market in Sweden (e.g. companies owing pharmacies). According to TLV data will be available and then be published in spring 2012 (personal communication from TLV).

In general, there is an understanding for a need of the monitoring and the evaluation of the impact of the reregulation. Also the Swedish Agency for Public Management has been commissioned for an assessment; the final report is due in mid-2013 (Statskontoret 2011).

7.2 Accessibility

7.2.1 Accessibility of medicines dispensaries

7.2.1.1 Provision of POM dispensaries

Before the reregulation in 2009 the accessibility to medicines, including OTC medicines, was criticized for requiring, at least for some parts of Sweden, a long travel to the nearest pharmacy. The state owned pharmacies were in addition under pressure for operating on short opening hours (Apoteket 2011).

In Sweden, there are currently 1,250 community pharmacies, and 1,320 pharmacies are approved by the Medical Product Agency and opened. That means that 70 pharmacy licenses have already been approved, but the holders of the license are still in the process of opening the pharmacy (Apoteket 2011).

Table 7.2: Sweden – Number of POM dispensaries, as of 1 January 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies	749[1]	804	820	885	850	n.a.	883	n.a.	892	1,250
Of which:										
Private pharmacies[2]	0	0	0	0	0	0	0	n.a.	n.a.	760
Public pharmacies[3]	n.a.	804	820	885	850	(all)	883	n.a.	n.a.	485
POM dispensing doctors	0	0	0	0	0	0	0	0	0	0
Hospital pharmacies dispensing POM to out-patients[4]	n.a.	(90)	(86)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Internet pharmacies dispensing POM	0	0	0	0	1[5]	1[5]	1[5]	1[5]	1[5]	1[5]
Other POM dispensaries	0	0	0	0	0	0	0	0	0	0
Total of POM dispensaries	n.a.	804	820	885	851	n.a.	884	n.a.	893	1,251

[1] as of 31 December

[2] owned by private entities / private persons

[3] owned by units of the state, as it was the case for Apoteket

[4] only in exceptional cases, thereof not included in the number of total of POM dispensaries

[5] internet pharmacy run by Apoteket, since 2006 also allowed to dispense POM

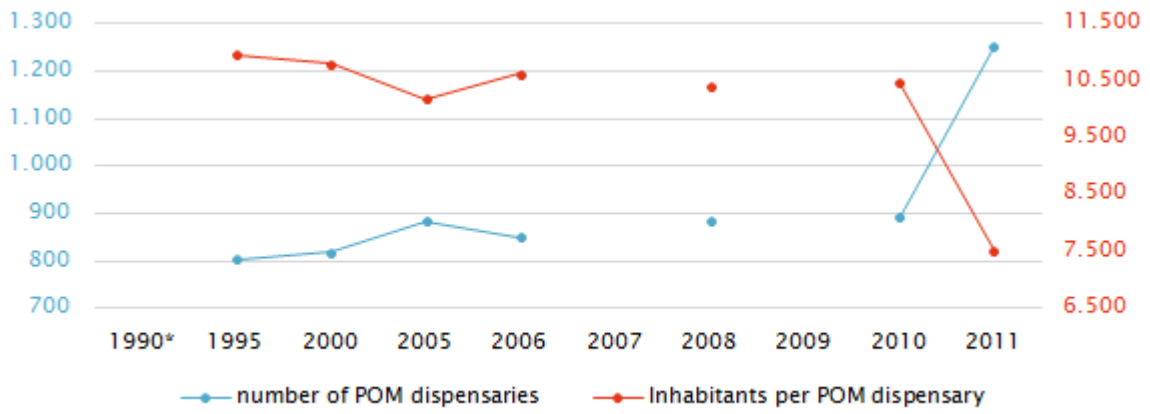
Source: Redman et al. 2007, Apoteket AB 2010

Of the 1,250 community pharmacies as of 1 January 2011 485 pharmacies are still owned by the state (cf. section 7.1) and 760 pharmacies are already privately owned (cf. Table 7.2).

Because of an increase in POM dispensaries, the number of inhabitants per POM dispensary has been decreasing (cf. Figure 7.1). The number of inhabitants per community pharmacy

also decreased from 1990 to 2011 (cf. Figure 7.2). Especially from 2010 to 2011 the number of community pharmacies increased and led to a decrease in the number of inhabitants per community pharmacy.

Figure 7.1: Sweden – Number of POM dispensaries and inhabitants per POM dispensary, 1990 – 2011



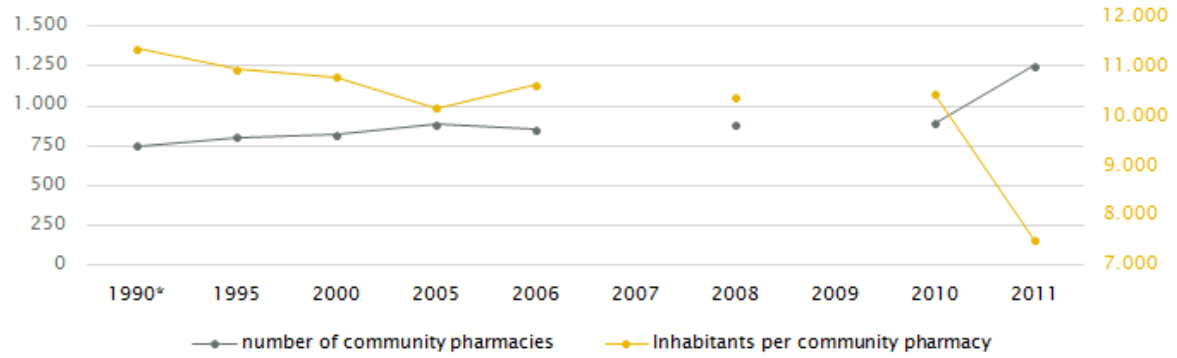
* 1990: per 31 December

Source: Redman et al. 2007, Apoteket AB 2010

Increasing accessibility was a goal of the Swedish government when implementing the reregulation in 2009 (cf. section 7.1). While before the reregulation (2008) the number of inhabitants per community pharmacies was at about 10,400, it has now decreased to about 7,500 inhabitants per community pharmacy.

From the reregulation in July 2009 till December 2010, around 200 new pharmacies were established, and more than twenty new additional pharmacy stakeholders. Some districts in Sweden that did not previously got a pharmacy now have one, for example Insjön and Älmsta. No pharmacy that existed before reregulation has at this point in time been closed. According to the Competition Authority providing these data while accessing the impact of the reregulation, this resulted in improved accessibility for many consumers (Konkurrensverket 2010).

Figure 7.2: Sweden – Number of community pharmacies and inhabitants per community pharmacy, 1990 – 2011



* 1990: per 31 December

Source: Redman et al. 2007, Apoteket AB 2010

7.2.1.2 Provision of POM dispensaries in rural areas

Until July 2012 Apoteket AB will keep providing especially rural areas with about 900 representatives (cf. section 7.1), which are normally located in grocery stores. These representatives sell a small range of OTC medicines but also provide for a pick up and order system of written prescriptions. Apoteket AB as the now largest pharmacy chain in Sweden also supplies hospitals, out-patient and nursing facilities and the pharmacy representatives. The internet pharmacy apoteket.se also intended to improve the access to medicines in Sweden (Apoteket 2009). Apoteket AB offered e-commerce and a 24 hour service (cf. section 7.2.2) before the reregulation, but since then the service has been only provided during business hours. In March 2011, Familjeapoteket.se got the permission to operate as an internet pharmacy. This is the only (pharmacists) service during ordinary business hours (Familjeapoteket 2011).

While there are currently no specific establishment regulations for pharmacies in rural areas, there are safeguard washout regulations that those community pharmacies sold from the state to private companies have to be kept running at least three years after purchase. This rule applies for both, pharmacies bought in clusters and the 150 pharmacies individually sold. The consolidation of pharmacies will start from January 2013 as a consequence (Apoteket 2011). This rule is especially important for rural pharmacies. An extension of the three years agreement is possible, but depends on individual negotiations of municipalities and pharmacies, mostly pharmacy chains (OAB 2009).

More than 7,000 selling points for OTC have registered to the authorities. Those OTC medicines dispensaries do not need any approval by the authorities. The number of dispensaries definitely has increased since the reregulation in 2009, yet there is no evidence if they were established also in rural areas (Apoteket 2011, Danmarks Apotekerforening 2011a).

Currently, the average distance to the nearest pharmacy in Sweden in total is 3.9 kilometres. 29 percent of the inhabitants in Sweden have a distance less than one kilometre to the nearest pharmacy. More than 50 percent of the inhabitants in Sweden have a distance less than three kilometres to the nearest pharmacy. As of mid-2011, the distance to pharmacy in Sweden was reported to have been reduced by an average of 150 meters since the reregulation started.

While the accessibility to medicines is generally claimed to have improved due to the reregulation (Konkurrensverket 2010), there are quite some differences in the number of pharmacy per inhabitant amont the regions (Sveriges Apoteksförening 2011).

7.2.2 Availability of medicines

The only rule to be fulfilled by community pharmacies is that the medicine has to be available to the customer within 24 hours. Pharmacies in rural areas are exempted from this rule. It should be made possible that all prescription-only medicines are available within 24 hours on normal working days (OAB 2009). Before 2009 the 24 hours was an internal rule in Apoteket AB, but not in law (Apoteket 2011).

There is no regulation regarding the frequency of wholesale deliveries to pharmacies. Normally, pharmacies are delivered once a day. If night deliveries are made, the wholesaler may access the pharmacy through a locked space using a key or code, the deliveries usually are unpacked in the morning (OAB 2009).

There are requirements for good pharmacy practice in Sweden, this is being assessed by professional audit or mystery shopping. Sweden also has a reporting and learning system.

7.3 Quality of pharmacy services

7.3.1 Pharmacy staff

7.3.1.1 Availability of pharmacists and other qualified staff

Before the reregulation in 2009 all pharmacists were employees of the state-owned pharmacy company Apoteket AB. The actual number of pharmacists working in community pharmacies is not available (cf. Table 7.3).

The pharmacy workforce in Sweden consisted of 3,077 registered pharmacists in 2008. 564 of them were working in community pharmacies (PGEU 2010h).

Before the reregulation, in 2008, about 37 percent of the community pharmacies had between one and six employees and another 37 percent had between seven and 20 employees. Only a small number of community pharmacies had more than 20 employees. On average, every community pharmacy had 9.4 employees, of which 5.5 pharmaceutical specialists (pharmacists and prescriptionists), in 2008. In Sweden, it is common that pharmacy staff is “borrowed” or shared with other pharmacies. The borrowed personnel are

divided in three categories. There are personnel regularly borrowed because of not enough hours for a new employee, personnel needed to cover employees on holiday or sick leave and specialist personnel borrowed for occasional reasons (OAB 2009).

Table 7.3: Sweden – Staff working in community pharmacies, as of 1 January 2000 – 2011

Pharmacy staff (counted per head)	2000	2005	2006	2007	2008	2009	2010	2011
Number of pharmacists [1]	n.a.	n.a.	564	n.a.	564	n.a.	n.a.	n.a.
Number of other staff	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total staff counted per head	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

[1] This includes full pharmacists (masters in pharmacy) and prescriptionists (bachelors in pharmacy). Not included are pharmacists working in hospital pharmacies or in other health centers, pharmacists working in pharmaceutical companies, in research, in pharmacy professional associations, etc., retired pharmacists and pharmacists in training.

Source: PGEU 2010e, PGEU 2010h, Apoteket 2011

There are three categories of qualified staff at Swedish pharmacies. Full pharmacists, prescriptionists and pharmacy technicians (Björkman et al. 2008).

In Sweden full pharmacists as well as prescriptionists are allowed to manage a community pharmacy (cf. section 7.1). To become a full pharmacist the requirement of a five years university education including a six month practice training has to be fulfilled. The university education is completed with a master's degree in pharmacy. Prescriptionists need a bachelor's degree in pharmacy, which requires a three year university education also including six month of practice.

In Sweden two pharmacy faculties offer a university education in pharmacy. Each year, about 300 students register for this study, 200 students annually graduate (PGEU 2010e).

Pharmacy technicians, who do not have the right to dispense medicines, have to attend and complete high-school, their education is a post-secondary program with a duration of 1.5 years (cf. Table 7.4). Pharmacy technicians are also responsible for advice giving in the self-service section.

Table 7.4: Sweden – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	University education - master	5	Yes, 6 month included in university education	Not required, but all employees have to do different self education programs agreed upon with the pharmacy manager.	Not available
Prescriptionists	University education - bachelor	3	Yes, 6 month included in university education	Not available	Not available
Pharmacy technicians / assistants	Post-upper secondary program (high-school level)	1.5	Not available	Not available	Not available

Source: Apoteket 2011

Continuous education is not required, yet all pharmacy employees have to attend self education programs upon agreement with the responsible pharmacy manager (PGEU 2010e).

According to a recent study of the Consumers' Association (Konsument verket 2011) the consumers had the perceiption that the competence of the staff has deteriorated after the reregulation. One reason might be that the more educated staff now work in back-office and meet the patients at fewer occasions (personal communication, this observation was not part of the study). Another study aiming to explore if Apoteket AB would be able to retain customers after the reregulation showed a high retention rate, which was, among others, attributed to a great confidence towards Apoteket AB's pharmacists (Khan/Khan 2010).

7.3.1.2 Professional independence of pharmacists

All Swedish pharmacies were fully owned by the state and organised within the state-owned pharmacy chain Apoteket AB until 2009. Apoteket had the exclusive right to sell medicines to Swedish customers/patients and was responsible for all community pharmacies in Sweden (cf. section 7.1). After the reregulation many publicly owned pharmacies were sold to private companies. In the first selling round where pharmacies were sold in clusters (cf. section 7.1):

- ApoPharm AB (Apotek Hjärtat) acquired in this first step 208 community pharmacies with a turnover of SEK 7.3 billion/€ 687.40 million and about 1,500 employees.
- Kronans Droghandel Retail AB, which is owned by Oriola-KD and KF, acquired171 pharmacies with a turnover of SEK 4.6 billion/€ 433.20 million and 930 employees.
- Medstop Holding AB, owned by Segulah purchased 62 pharmacies with a turnover of SEK 3.1 billion/€ 291.90 million and 660 employees.

- And, Vårdapoteket i Norden AB, which is owned by Investor and Priveq Investment, acquired 24 pharmacies with a turnover of SEK 1.4 billion/€ 131.83 million and 230 employees (Apoteket 2009).

Meanwhile, further sellings were undertaken and today's landscape of pharmacy chains is characterized by a number of big pharmacy chains, as displayed in Table 7.5.

Table 7.5: Sweden – Pharmacy chains, as of 1 September 2011

Name of pharmacy chain	Name of owner and category	Number of pharmacies in ownership	Number of pharmacies in membership (franchise)
Apoteket	Swedish state	335	0
ApoPharm AB (Apotek Hjärtat)	Altor - private equity company	280	0
Kronans Droghandel Retail AB	Oriola-KD, Finnish wholesaler and KF Förbundet, Swedish cooperative	200	0
Apoteksgruppen	Franchise model between Swedish state and private owners	150	0
Doc Morris	Celesio	80	0
Medstop Holding AB	Segulah, private equity company	65	0
Cura Apoteket	ICA AB, international retail group	40	0
Vårdapoteket i Norden AB	Investor and Priveq Investment, private equity company	25	0
Foxfarmaci	Private equity company	2	0

Private equity company = Investment company investing in the private equity of operating companies. These companies are also referred to as financial sponsors raising a pool of capital or private equity funds for the supply of equity to a company. Private equity companies normally receive a periodic management fee and a share in profits earned from the private equity funds managed.

Source: Apoteket 2011

A qualitative study exploring the willingness of pharmacists after the reregulation to purchase a pharmacy showed only one out of the six interview partners had the intention to buy a pharmacy. The reasons for not wanting to buy a pharmacy were, apart from feeling as too old, was that most respondents felt great uncertainty for the future, they could not predict how the market would develop, the information about the help available from the government was considered scarce and that they wanted to focus on their profession, that is, pharmacy (Bergvist et al. 2009).

7.3.2 Product range

7.3.2.1 Medicines

Medicines in Sweden are categorized in POM and OTC medicines. POM may be sold in community pharmacies and via the internet pharmacies of Apoteket and Familjeapoteket. Self-service of POM is not allowed. OTC medicines are subdivided in two categories,

pharmacy-only and general sale medicine (AESGP 2011). However, the list of pharmacy-only OTC medicines comprises only a few medicines (Apoteket 2011). All Apoteket representatives deliver POM in a way that patients can pick up the prescription-only medicines the day after leaving their prescription at the representatives.

As part of the reregulation the Swedish government implemented a free pricing of OTC medicines and the sale of the majority OTC medicines in other retail outlets than pharmacies (cf. section 7.1). These new OTC rules went into effect on 1 November 2009 (cf. Table 7.1). Outside pharmacies OTC medicines may not be sold to persons under the age of 18 years, but they may in pharmacies (Apoteket 2011). General sale OTC medicines now are available in goods stores and supermarkets (Apoteket 2009).

There are no specific regulations for the sale of OTC medicines in community pharmacies. The free pricing of OTC medicines, which results in a higher margin of OTC products compared to POM, is an incentive for pharmacists to sell more OTC products in Sweden (Apoteket 2011). Self-service of OTC products is allowed. In the self-service section of a pharmacy customers are given advice on how to treat minor ailments or, when judged necessary, are recommended to see a healthcare professional. Mainly pharmacy technicians work in this section, but a prescriptionist or a pharmacist must be available.

One study displayed a positive attitude of consumers towards the sale of OTC medicines outside pharmacies (Leal et al. 2011). This was also confirmed by an interview partner from consumer's association, who, however, took this perception in the perspective that, while patients appreciate a liberalised sale of OTC medicines, this appears not to be as important to them as other dimensions such as competence of staff and information (personal communication).

It is not common that community pharmacies produce medicines. No community pharmacy has a laboratory or place to manufacture medicines. The production of medicines is centralized at the state owned production centre (APL, www.apl.se). Yet, competition starts to grow, one private production centre is trying to establish on the market (Apoteket 2011).

7.3.2.2 Non-pharmaceuticals

Non-pharmaceuticals commonly sold in Swedish community pharmacies are health products and cosmetics. There are no specific regulations (e.g. limits to sell only specific products) for the sale of non-pharmaceuticals in pharmacies (Apoteket 2011). Profit is made by non-pharmaceuticals and OTC medicines to compensate pressure on prescription medicines prices.

7.3.3 Pharmacy services

7.3.3.1 Services provided by pharmacies

In 2011, all community pharmacies in Sweden provide the services of dispensing, repeat dispensing, disposal of waste medicines, provision of emergency contraception. One community pharmacy currently provides night service.

In 2008, 300 community pharmacies offered medicines use reviews, 150 pharmacies offered blood pressurement, 100 pharmacies offered smoking cessation and 70 pharmacies provided weight measurement. Three community pharmacies provided vaccinations in 2008 (PGEU 2010g).

2004 was the “Year of health” in Sweden, the focus of this health promotion campaign was the improvement of health by changing lifestyle. During this year, new health products and information were presented in all pharmacies. Some selected pharmacies provided a health points programme with the establishment of an information area in the pharmacy. The staff of these pharmacies was provided with previous preparations on three topics, smoking, stress and diet and exercise (Björkman et al. 2008).

7.3.3.2 Pharmaceutical counselling

There are neither regulations concerning nation-wide quality standards for pharmaceutical counsellingnor guidelines in Sweden. Counselling is remunerated as part of the margin (Apoteket 2011).

Counselling in the self-service section of a pharmacy providing some OTC medicines is mostly done by pharmacy technicians, yet a pharmacist or prescriptionist must be available. Prescribed medicines are only dispensed by pharmacists and prescriptionists, who are also responsible for the counselling of the costumer filling prescriptions. Since 2011 identified problems with a medicine can be documented in all pharmacy computers and since 2011 some pharmacies offer a special profile customer program for comprehensive advice giving. In August 2007 about 5,900 profiles were already registered (Björkman et al. 2008).

In the last decades there has been taking place a shift towards an increased focus on the provision of information and advice-giving at community pharmacies in Sweden. In 2002 a counselling service was developed and implemented in Sweden. The initial consultation of a pharmacist should have a duration of about 30 minutes in a separate or semi-separate area of the pharmacy. The follow-up conversations were set shorter. This service is provided by pharmacists specially trained in pharmaceutical care (Montgomery 2009). As of today, there is no information on average counselling time available (Apoteket 2011).

In 2006, when Apoteket AB was still the owner of all community pharmacies, a total of 90 million consumer visits were registered and 64 million prescriptions were dispensed, for update information see above. Additionally, the Apoteket call centre handled about 6 million calls in 2006 (Björkman et al. 2008).

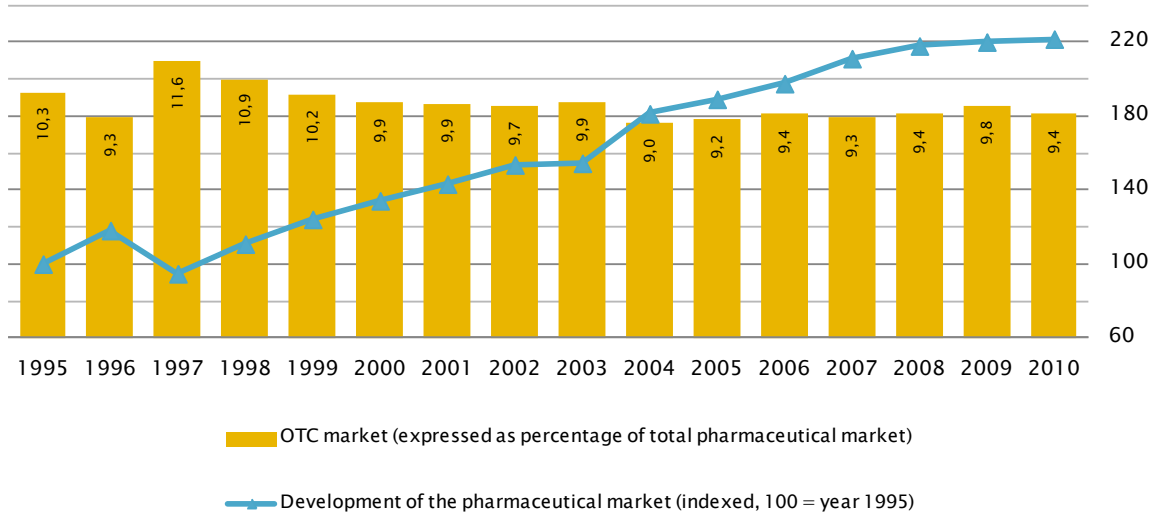
According to consumers perception, the information provided in the pharmacies, including appears to be deteriorated after the reregulation (Konsument verket 2011).

7.4 Economics

7.4.1 Market data

Since 1995 the Swedish pharmaceutical market has more than doubled (cf. Figure 7.3). The share of OTC medicines in percent of the total pharmaceutical market respectively has stayed stable at about 9.5 percent over the past years. A possible impact of the sale of OTC medicines outside pharmacies since 2009 may not yet be fully reflected in the data as presented in Figure 7.3. Sale of OTC medicines is expected to increase in the next years.

Figure 7.3: Sweden – Development of pharmaceutical market, 1995 – 2011

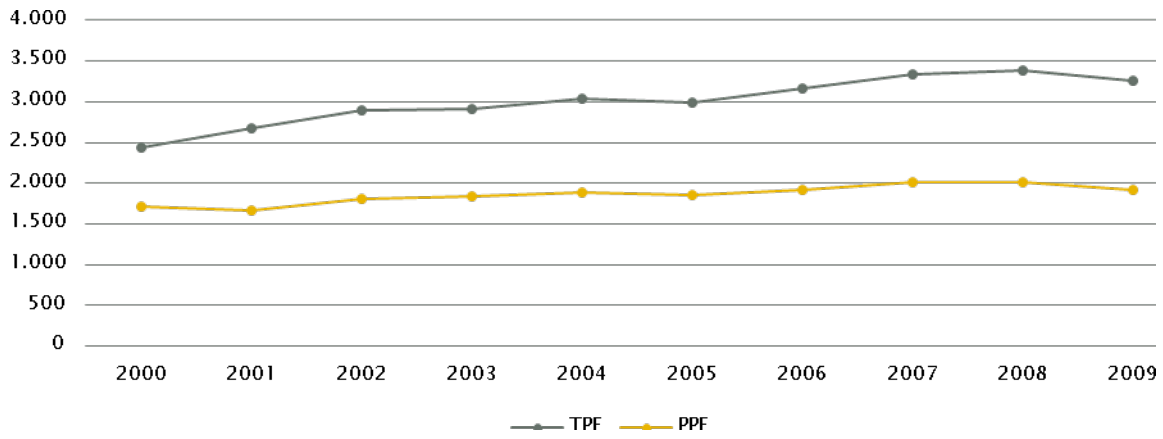


Source: AESGP 1995-2011

7.4.2 Pharmaceutical expenditure

Pharmaceutical expenditure, including public pharmaceutical expenditure, has moderately increased during the last decade. There was a decrease in 2008, the year before the reregulation. This is attributed to a range of cost-containment measures undertaken (Wettermark et al. 2008).

Figure 7.4: Sweden – Total and public pharmaceutical expenditure in million Euro PPP, 2000 – 2009

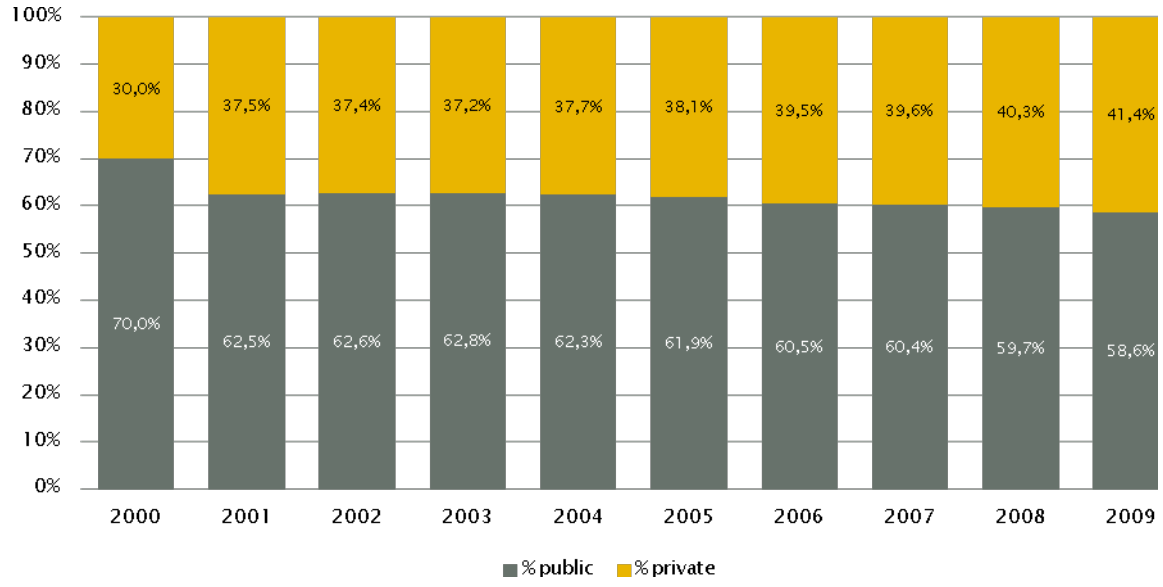


TPE = total pharmaceutical expenditure, PPE = public pharmaceutical expenditure

Source: OECD 2011, PHIS 2011

Overall, the share of public pharmaceutical expenditure as percentage of total pharmaceutical expenditure decreased from 70 percent in 1990 58.6 percent in 2009, with a particular decrease in the 1990s. In the first years of the new millennium Sweden succeeded in containing pharmaceutical expenditure without a shift from public payers to the private households. Sweden attributed this to a sustainable generics policy and the promotion of a more rational use of medicines (Vogler et al. 2008).

Figure 7.5: Sweden – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure, 2000 – 2009



Source: OECD 2011, PHIS 2011

7.4.3 Pharmacy remuneration and turnover

In 2010, the first year after the liberalisation of OTC medicines sale, the turnover of OTC medicines in pharmacies amounted to about SEK 3,297 million / € 345.7 million, corresponding to 9 percent as a share of pharmacy medices turnover (SEK 36,293 million / € 3,805 million) in 2010. The sale of OTC medicines outside pharmacies amounted to SEK 614 million /€ 64.38 million, corresponding to 15 percent of the total sales of OTC, with the remaining 85% of the total OTC sales (SEK 3,297 million / € 345.7 million) made in the pharmacies. A major part of the OTC sales outside pharmacies i.e. SEK 522 million / € 54.7 million, was made in places like department stores and supermarkets. Gas stations contributed with 11 percent to the sale outside pharmacies (LIF 2011).

Turnover figures are not available for Swedish community pharmacies. The number of dispensed medicines increased from 55.5 million prescriptions filled in 2000 to 67.3 million prescriptions filled in 2010 (cf. Table 7.6). The number of OTC medicines supplied is not available.

Table 7.6: Sweden – Number of medicines dispense, as of 1 January 1990 – 2010

Medicines dispensed (in mio units)	1990	1995	2000	2005	2006	2007	2008	2009	2010
Prescriptions filled	n.a.	n.a.	55.5	61.3	62.6	64.1	65.5	66.3	67.3

Source: LIF 2011

Prices of medicines and their reimbursement in Sweden are regulated. The pharmacy margins are regressive, using four categories ranging from less than € 8.08 to greater than € 646.40 at the Pharmacy Purchasing Price (PPP) level. The average pharmacy margin was 21.3 percent including non-reimbursable medicines in 2008 (Kanavos et al. 2011). In 2011, the average pharmacy margin for medicines in Sweden amounted to 16.2 percent of the pharmacy retail price net for the reimbursement market (Apoteket 2011).

The low mark-ups in the distribution chain and no VAT for prescription medicines secure very low public prices of medicines in contrast to the ex-factory prices, which are among the highest in Europe (Moise/Docteur 2007). The VAT for OTC medicines is currently at 25 percent (PHIS 2011, PPI 2011).

Generic substitution is mandatory (cf. section 7.1) (PHIS 2011). The pharmacist has to dispense the least expensive medicine on the Swedish market, which triggers competition in generics. Especially brand medicines had to reduce their prices after the policy measures in 2009 (cf. Table 7.1).

The pharmacy reimbursement system is currently under review, and major changes in the current and next year are expected especially concerning ceiling prices when generic competition is growing (AESGP 2011). According to TLV the pharmacy margins will be changed in 2013; the current evaluation of the reregulation (cf. section 7.1) is intended to prepare the decision on the change of the margin scheme (personal communication).

Since November 2009 a fee-for-service is applied in Sweden. The state pays a fee for each prescription sold.

The price of the reregulation was estimated to be about SEK 460 million/about € 45 million annually.

8 Austria

8.1 Framework

The main actors in Austria which are allowed to dispense prescription-only and OTC (over-the-counter) medicines are community pharmacies and POM dispensing doctors. While the latter's number is lower than the one of pharmacies, there are still many POM dispensing doctors compared to other countries. In 2011 1,276 community pharmacies are in place (cf. Table 8.1). A community pharmacy is allowed to have at maximum one branch pharmacy. Branch pharmacies work under the supervision of a (main) community pharmacy. In 2011 23 pharmacies have a branch pharmacy (cf. Table 8.1).

POM dispensing doctors are allowed to dispense both prescription-only and over-the-counter medicines in municipalities without a pharmacy. They may only provide medicines to their own patients. POM dispensing doctors represent nearly half of all POM dispensaries, in 2011 940 POM dispensing doctors provide medicines to their patients in Austria (cf. Table 8.1).

Additionally very few hospital pharmacies are allowed to dispense medicines to out-patients. In 2011 five of the 46 hospital pharmacies act like a community pharmacy dispensing to out-patients (Zimmermann/Vogler 2009). The number of hospitals dispensing to out-patients has been constant at five for decades (cf. Table 8.1).

Drugstores are allowed to sell a very restricted range of non-pharmacy OTC medicines, e.g. herbal teas, remedies and cosmetics listed in the so-called "Abgrenzungsverordnung", an enactment defining which are medicines and which not. The role of drugstores in the retail of medicines used to be negligible, as the government used to be restrictive in granting licenses for the sale of medicines outside pharmacies. During the past few years there has been an increase in the number of OTC selling drugstores (Vogler et al. 2006). Pressure from drugstore chains for further liberalisation has been an issue for more than a decade.

Internet pharmacies and e-trade are not allowed – neither POM nor OTC medicines – in Austria. According to the ruling in case C-322/01 (DocMorris) by the European Court of Justice (ECJ), distance selling of OTC medicines from another EU country into Austria is allowed under certain conditions. The product supplied must be exactly the same as the product authorized and sold in Austria, including its authorization number. Additionally the distance seller has to be a pharmacy. The advertising of distance selling of OTC medicines generally is not allowed in Austria (PGEU 2010c). However, the drugstore "DM" offers OTC medicines via a website. DM makes use of the ECJ ruling and cooperates with a Swiss mail-order pharmacy called "Zur Rose". The registered pharmacy office of "Zur Rose" is located in Czech Republic (Zur Rose 2011) where distance selling and internet pharmacies are allowed (AESGP 2011).

The main regulations concerning the Austrian pharmacy system are the

- Pharmacy Act, which regulates the establishment of pharmacies.
- Regulation on Operation of Pharmacies (BMG 2005).
- Medicines Law, which regulates the production and marketing of medicines in Austria.

Establishment and ownership of community pharmacies in Austria is regulated and limited. Specific requirements have to be met by community pharmacies for being granted a license (Vogler/Fröschl 2007, ÖAK 2011b).

Personal requirements for establishing a pharmacy are laid down in the Pharmacy Act. Austrian citizenship or citizenship of an EEA Member State or Switzerland and professional qualification (university degree and one year practical training – cf. section 1.3.1) is a prerequisite. Establishment is also bound to a management permit, which means that the establishing pharmacist must have at least five years of working experience in a pharmacy. Furthermore the person willing to establish a community pharmacy has to be of reliability, full legal capacity, good state of health and has to be able to command German necessary for managing a pharmacy

Further prerequisites are also regulated in the Pharmacy Act. A physician must have his/her permanent practice within the community. The distance to the next pharmacy has to be at least 500 meters, and 5,500 persons have to be supplied by each existing pharmacy. If a POM dispensing doctor provides medicines, at least two general practitioners with sickness fund contracts have to have their permanent practice in the community.

The equipment of a pharmacy is regulated in the Austrian Regulation on the Operation of pharmacies of 2005 (BMG 2005). Each pharmacy must provide for a minimum size of 120 m^2, thereof a sales office and material stock room with 60m^2, a laboratory with 15 m^2 and the "standby" room with 10m^2. Additionally a bathroom and lavatory have to be furnished. In practice, the size of a pharmacy normally is about 200 m^2 in total (ÖAK 2011b, Vogler et al. 2006, RIS 2005).

An increasing number of pharmacies in Austria were opened in the last years. During the last ten years 166 new community pharmacies were established. In places with pharmacies already established (except the capitals of the regions) 57 and in the capitals 49 new pharmacies were established from 2000 to 2010. In small villages without a pharmacy 60 pharmacies were established (ÖAK 2011b).

Each community pharmacy may have at maximum one branch pharmacy, provided that the distance to the nearest pharmacy is more than four kilometers. In Austria there was a total of 23 branches in 2011 (ÖAK 2011b).

Ownership rules for community pharmacies in Austria are as follows: There is no absolute ban on outside ownership (partial ownership of non-pharmacists is not prohibited) and no prohibition of multiple ownership (one branch pharmacy per each pharmacy is allowed). Legal entities and natural persons may hold ownership of a pharmacy, while a pharmacist has to hold more than 50 percent of the ownership. The management of pharmacies is

strictly limited to full pharmacists (cf. section 8.3.1). Managing pharmacists have to fulfil the mentioned criteria and may only run one pharmacy (i.e. hold one pharmacy license) and one branch pharmacy, which is under supervision of its main pharmacy (Vogler/Fröschl 2007, PGEU 2010f).

In May 2009 the European Court of Justice decided in an infringement procedure against Germany and Italy that the regulations on pharmacies' ownership are in accordance with the EU's legislation. In 2005 an infringement procedure concerning the same issue has also been initiated against Austria. ECJ judgments on Germany and Italy are considered to be a model for other countries, including Austria (GÖG/BMG 2009). The procedure was pending for some years, but on 23 November 2011 the EU Commission decided to close all pending infringement proceedings against the community pharmacy sector, including Austria (ÖAK 2011a, PGEU 2011).

Co-ownership is allowed in so far as community pharmacies may be owned by partnerships. However, the managing pharmacist (licensee) must own more than half of the shares in that partnership and has the exclusive power of management and representation of the partnership. Already nearly half of all Austrian community pharmacies operate within this legal status (ÖAK 2011b). All other pharmacies are managed as individual enterprises (sole proprietorship), meaning that the pharmacy is totally owned by the holder of pharmacy license. Stock corporations are forbidden. Vertical integration (i.e. wholesalers owning pharmacies) is thus possible, but restricted.

Austrian pharmacies predominantly are delivered by wholesalers. Direct deliveries by the industry are not prohibited, but not common practice. POM dispensing doctors can only purchase pharmaceuticals from community pharmacies in the European Economic Area (EEA). About 35 wholesale companies are operating in Austria, of which 8 are full-liners. The three leading wholesalers are Herba Chemosan Apotheker-AG, Phoenix Arzneiwarengroß-handlung GmbH und Kwizda GmbH. These three companies have an altogether market share of round 75 percent (Vogler/Fröschl 2007).

There are about 220 pharmaceutical manufacturers in Austria, most of them being small or middle-sized companies.

8.2 Accessibility

8.2.1 Accessibility of medicines dispensaries

8.2.1.1 Provision of POM dispensaries

In 2011 there are 1,276 community pharmacies. 23 of them have a branch pharmacy, which operates under supervision of its main pharmacy. The number of community pharmacies increased from 950 community pharmacies in 1990 to 1,276 in 2011 (cf. Figure 8.1)The number of branch pharmacies has also nearly doubled in this period of time (cf. Table 8.1).

As displayed in Table 8.1 the number of dispensing doctors is comparably high. They play an important role in the access to medicines, in particular in rural areas (cf. sections 8.1 and 8.3.1). For historic reasons there are a few hospital pharmacies (five) which may dispense medicines to out-patients.

Table 8.1: Austria – Number of pharmacies and other POM dispensaries[1], as of 1 January 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies[1]	950	1,004	1,086	1,172	1,184	1,200	1,217	1,233	1,252	1,276
Branch pharmacies	12	14	20	19	19	17	18	18	23	23
POM dispensing doctors	947	983	987	992	992	978	962	955	950	940
Hospital pharmacies dispensing POM to out-patients[2]	5	5	5	5	5	5	5	5	5	5
Internet pharmacies dispensing POM	0	0	0	0	0	0	0	0	0	0
Other POM dispensaries	0	0	0	0	0	0	0	0	0	0
Total of POM dispensaries	**1,914**	**2,006**	**2,098**	**2,103**	**2,200**	**2,200**	**2,184**	**2,251**	**2,230**	**2,244**

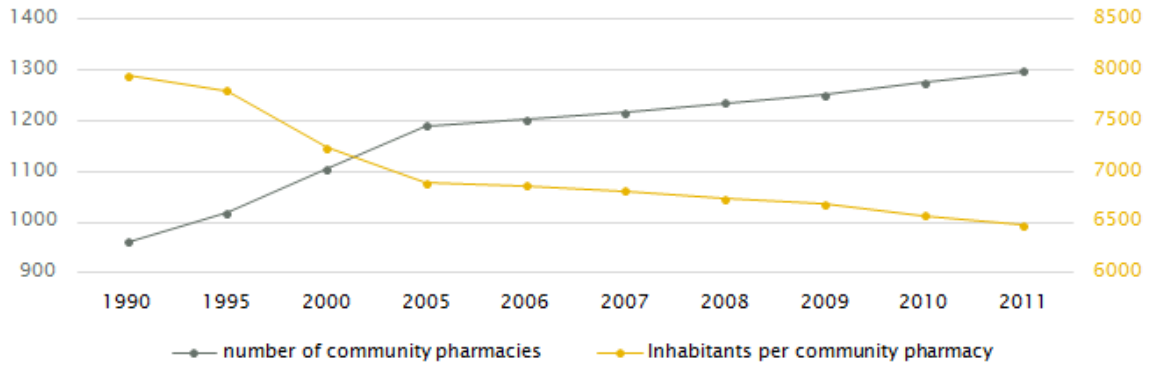
[1] Indicated excluding branch pharmacies

[2] Only five of the 46 Austrian hospital pharmacies may acta s a community pharmacy

Source: ÖAK 2011b, Vogler et al. 2006, Vogler/Fröschl 2007, Leopold et al. 2008

Because of an increasing number in community pharmacies, the number of inhabitants per community pharmacy has been decreasing (cf. Figure 8.1): The number of inhabitants per community pharmacy decreased from around 8,000 in 1990 to around 6,500 in 2011.

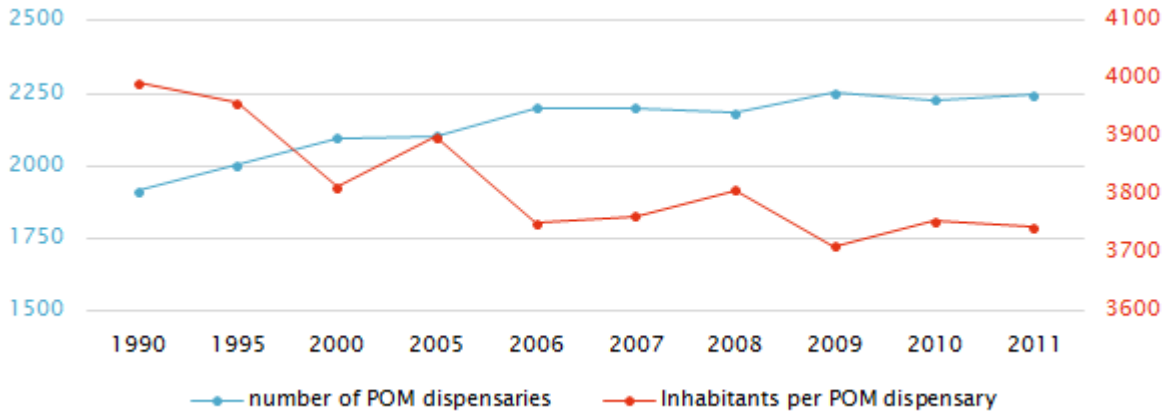
Figure 8.1: Austria – Number of community pharmacies and inhabitants per community pharmacy, 1990 – 2011



Source: ÖAK 2011b, Vogler et al. 2006, ÖAK 2011c

Austria has a comparatively high number of doctors who are allowed to dispense to their patients. If they are considered, this changes the ratio considerably: A POM dispensary serves around 3,750 inhabitants in 2011; this is an improvement compared to the year 2000 (around 3,800 inhabitants per pharmacy) which is attributable to the opening of new pharmacies (cf. Figure 8.2).

Figure 8.2: Austria – Number of POM dispensaries and inhabitants per POM dispensary, 1990 – 2011



POM dispensaries include: community pharmacies incl. branch pharmacy, hospital pharmacies acting as a community pharmacy and POM dispensing doctors

Source: ÖAK 2011b, ÖAK 2011c, Vogler et al. 2006

8.2.1.2 Provision of POM dispensaries in rural areas

More than 50 percent of all pharmacies can be considered as rural pharmacies: in 2010 664 out of 1,276 pharmacies were located in rural areas. If the revenue of rural pharmacies is below the average, the pharmacy is entitled to different forms of benefits provided by the Chamber of Pharmacists, e.g. financial support for night duties. There are no incentives for establishment of pharmacies in rural areas (PGEU 2010e).

According to an analysis concerning the distribution of community pharmacies in 2010, 399 community pharmacies were situated in communities of up to 6,000 inhabitants, 262 in communities of more than 6,000 and few than 20,000 inhabitants, and 615 in communities of more than 20,000 inhabitants. 312 of the pharmacies are situated in the capital of Austria, Vienna (ÖAK 2011b).

92.6 percent of the Austrian population is able to reach a pharmacy within ten minutes. In some small villages branch pharmacies have been established to improve the access to medicines in rural areas. If needed and demanded, many pharmacies provide for home delivery of pharmaceuticals (ÖAK 2011b). Over the past ten years the largest increase in the number of pharmacies (60 new pharmacies) was observed in smaller communities that had not had a pharmacy before (cf. section 8.1).

8.2.2 Availability of medicines

Table 8.2 shows the service requirements laid down in several regulations and their implementation in practice.

Table 8.2: Austria – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	According to the Austrian regulation on the operation of pharmacies of 2005, a minimum amount of pharmaceuticals has to be in stock, to secure the correct provision of pharmaceuticals to the population. Also reimbursable medicines have to be kept in stock, this is paid for by social insurance.	Around 80 to 90 percent of all on the market available medicines are in stock in Austrian community pharmacies. If not in stock, medicines normally can be quickly demanded and ordered. The assortment in stock on average is about 6,000 pharmaceuticals, which corresponds to 16,000 packages (ÖAK 2011).
Requirements concerning space	According to the Austrian regulation on the operation of pharmacies of 2005 the space requirements of pharmacies. Each pharmacy must provide for a minimum size of 120 m^2.	In practice, the size of a pharmacy normally is about 200 m^2.
Dispensing within a certain time period	No specific regulations.	According to a survey 96% of all costumers get the prescribed medicine at their first visit of the pharmacy (Vogler et al. 2006).
Frequency of delivery	No specific regulations.	Pharmacies in Austria are, in general, delivered three times per day by pharmaceutical wholesale. In case of emergencies, immediate delivery, even for one package, is possible (e.g. by taxi).

Source: ÖAK 2011c, Vogler et al. 2006

8.3 Quality of pharmacy services

8.3.1 Pharmacy staff

8.3.1.1 Availability of pharmacists and other qualified staff

In 2010 14,600 persons worked in community pharmacies in Austria (cf. Table 8.3). The number of staff has consistently been rising in the past years.

In 2008 the staff of a mean-pharmacy consisted of one self-employed pharmacist, three employed pharmacists with an average working time of 26 hours per week, four to five pharmaceutical-commercial assistants or qualified pharmacy assistants, apprentices and two to three other employees (e.g. cleaning staff). On average 11 persons worked in an Austrian community pharmacy in 2008 (PGEU 2010e).

Table 8.3: Austria – Staff working in community pharmacies, as of 1 January 2000 – 2011

Pharmacy staff (counted per head)	2000	2005	2006	2007	2008	2009	2010	2011
Number of pharmacists	**4,211**	**4,746**	**4,815**	**4,929**	**4,991**	**5,046**	**5,160**	**5,275**
Of which:								
Aspirants (for 1 year after masters degree)	201	256	230	224	195	190	195	201
Number of other staff	**6,590**	**8,315**	**8,339**	**8,638**	**8,775**	**9,011**	**9,440**	**9,730**
Of which:								
Aspirants (for 1 year after masters degree)	201	256	230	224	195	190	195	201
Trainees (apprentice)	727	1,019	953	982	1,011	1,122	1,183	1,254
Total staff counted per head	**10,801**	**13,061**	**13,154**	**13,567**	**13,766**	**14,057**	**14,600**	**15,005**

Source: ÖAK 2011b, ÖAK 2011c, Vogler et al. 2006

In Austrian pharmacies only full pharmacists are allowed to dispense medicines. The self-employed pharmacists are the owners of pharmacies offering workplaces to other full pharmacists (employed). The ratio of self-employed and employed pharmacists in Austria, which has stayed relatively stable between 2007 and 2011, is depicted in Table 8.4.

Table 8.4: Austria – Self-employed and employed full pharmacists, 2007 – 2011

Community pharmacists	Self-employed	%	Employed	%
2007	1,288	26,1	3,641	73,9
2008	1,321	26.5	3,670	73,5
2009	1,333	26,4	3,713	73,6
2010	1,351	26,2	3,809	73,8
2011	1,376	26.1	3,899	73.9

Source: ÖAK 2011b

More than one third of the total pharmacy staff is pharmacists. In 2011 5,275 pharmacists worked in Austrian community pharmacies (cf. Table 8.3).

The required qualification to be a full pharmacist in Austria is a university study and additionally one year of practice training ether in community or hospital pharmacies (cf. Table 8.5). Three universities (Vienna, Graz and Innsbruck) offer the training. The number of accredited students per year has increased in the past few years.

The studies have a minimum duration of four and a half years. The average duration of studies though is longer (14.3 semesters in 2008/2009 in Vienna, 12.1 semesters in Graz and 12.2 semesters in Innsbruck) because of the complex matters and also for organisational reasons.

Of the other pharmacy staff (9,730 persons in 2011), 4,707 held a degree in pharma-commercial assistance. 1,254 people still were in apprentice for pharma-commercial assistance and 207 people were in their practice year after pharmacy studies at university (cf. Table 8.5). In 2008 0.15 pharmacy interns and 4.39 pharmacy assistants worked on average in an Austrian community pharmacy (PGEU 2010c).

The training of pharma-commercial assistants consists of an apprenticeship with a duration of three years. During three years of education the applicants are trainees. 80 percent of the training is provided in the pharmacy. At the end of the three years of training, a final exam has to be passed and is honoured with the “PKA-badge”, visible for the costumer. Additional education of pharma-commercial assistants is provided by the Austrian pharmacists association. The main responsibilities of pharma-commercial assistants are administration of the range of provided products, assistance at producing pharmacy-produced medicines. Pharma-commercial assistants do not have the right to dispense medicines.

Table 8.5: Austria – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	University, master degree	4,5 years (9 semesters)	Yes, duration of 1 year after master degree	No	Pharmacy law (Apotheken-gesetz) and Enactment of Pharmaceutical Staff (Pharmazeutische Fachkräfte-verordnung)
Pharma-commercial assistants	Apprentice	3	No	No	Entactment of training for pharma-commerical assistants (PKA-Ausbildungsver-ordnung)

Source: ÖAK 2011c

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 195 training courses for pharmacists, which are attended by more than 14,400 pharmacists. On average

a pharmacist spends 30 hours per year on education and training, which is equivalent to two courses per year (Vogler et al. 2006).

8.3.1.2 Professional independence of pharmacists

Multiple ownership of pharmacies in the form of chains is not allowed in Austria. A pharmacist may open one branch pharmacy at maximum, which practices under the supervision of a main pharmacy. Co-ownership is only allowed to the extent that a pharmacist holds the majority (cf. section 8.1).

8.3.2 Product range

8.3.2.1 Medicines

Prescription-only medicines are only allowed to be dispensed in pharmacies and by dispensing doctors. There is no self-service of POM. Prescription-only medicines have to be dispensed by a pharmacist.

OTC (over-the-counter) medicines in Austria are divided into two groups. The larger group, pharmacy-only OTC medicines may only be sold in pharmacies. In addition, there is a limited list of pharmacy OTC medicines, for example vitamin preparations and antiacids may also be sold outside pharmacies (e.g. in drugstores). According to the Austrian Medicines Act self-service of OTC medicines is not allowed, thus Austria is one of the few countries where this is the case (AESGP 2011).

Pharmacy-produced medicines play an important role in Austria, both magistral preparations, which are produced individually for the costumer in the pharmacies, and officinal preparations which are ready-prepared medicines produced in advance always in the same composition and placed on the market under the same trade name. Every pharmacy has its own laboratory to manufacture medicines. The preparation of pharmacy-produced medicines is an additional and common service provided by community pharmacies in Austria (ÖAK 2011b). Especially doses or different forms (capsules, suppositories instead of tablets etc.) for elderly or children can be provided within this service. Most magistral preparations are made for skin diseases (ointments). Already 44 percent of these prescriptions are magistral preparations. Austria is one of three countries (Germany, Switzerland, Austria) where eye drops and ointments are produced in pharmacies (ÖAK 2011b).

8.3.2.2 Non-pharmaceuticals

Austrian pharmacies also provide non-pharmaceutical products such as homeopathic products under certain restrictions. Alternative remedies, dressing, tests, nutrition for diets or children or cosmetics are dispensed in Austrian community pharmacies. The principle of “health relation” has to be met so that the “impression of a pharmacy” is not disturbed (ÖAK 2010).

8.3.3 Pharmacy services

8.3.3.1 Services provided by pharmacies

Besides filling prescriptions, dispensing a range of medicines and consulting patients, which is standard for community pharmacies, several pharmacies provide further services. Most pharmacies provide disposal of waste medicines, measurement of blood pressure, cholesterol, glucose and weight, and smoking cessation. Health checks including measurement of blood sugar, blood pressure, cholesterol, abdominal girth, weight, breath of smokers etc. are being provided, they were made better known to the public with the campaign “10-minutes for your health” in 2006. 123,000 Austrians participated in this campaign (ÖAK 2011b).

Side effects and interactions have been checked in the framework of the “medicines safety belt” project and e-medication pilot projects by Austrian community pharmacies. The practical implementation of the medicines safety belt was that the pharmacist asked the patient for permission to include the data of what medication he/she is taking into the database. While the “medicines safety belt” project was piloted in one province in 2008 (ÖAK 2009, Morak et al. 2010), it was then followed up by the e-medication project in model regions in three provinces in a test phase in 2011 (ELGA 2011, ÖAK 2011b). At the time of writing the future of e-medication is still unclear.

Substitution programs provided by Austrian community pharmacies have been successfully involved in addictive drugs substitution programs. The number of patients in substitution programs has risen from 4,464 to 13,460 patients between 2000 and 2009 (GÖG/ÖBIG 2010).

The Pharmacy Act, the Medicines Act, the Regulation on Operation of Pharmacies and other laws and regulations guarantee a good pharmacy practice with the provision of quality standards. Regional administrative authorities are responsible to control pharmacies regularly for compliance to medicines and pharmacy legislation. A representative of the Chamber is involved in these audits. Mystery shopping is done by individual pharmacies (around 300 pharmacies per year). Additionally the Chamber’s regional offices in Vienna, Styria and Salzburg carry out some initiatives (PGEU 2010h).

8.3.3.2 Pharmaceutical counselling

One of the core competences of pharmacists is the provision of professional advice when dispensing medicines. Besides counselling on the correct application and possible side-effects, pharmacists also offer advice on nutrition, vaccinations and precautionary measures in travelling. 64.6 percent of all counselling conversations in Austria have a duration of four to ten minutes. 32.2 percent have a duration of one to three minutes, and 3.1 percent have a duration over ten minutes (ÖAK 2011b).

As concerning chronic diseases, pharmacists play an important role in consulting patients in Austria (ÖAK 2011b).

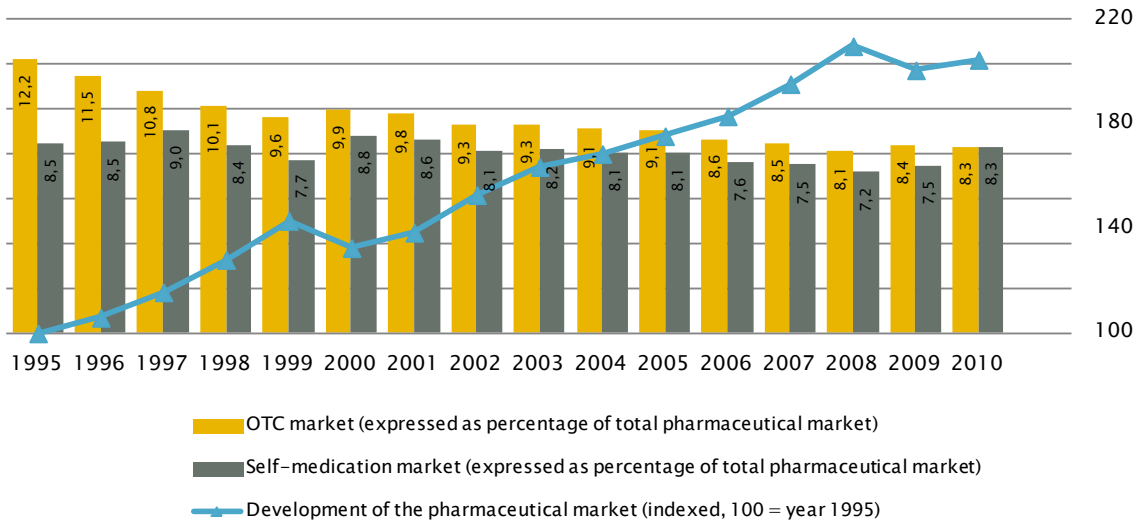
According to the Austrian Chamber of Pharmacists there no guidelines for counselling yet, but the integration of community pharmacies into disease management programmes (DMP) is being in a pilot phase.

8.4 Economics

8.4.1 Market data

While the total pharmaceutical market has more than doubled from 1995 to 2011, the share of OTC medicines has decreased as can be observed from Figure 8.3. The market share of self-medication products has been rather constant.

Figure 8.3: Austria – Development of pharmaceutical market, 1995 – 2011



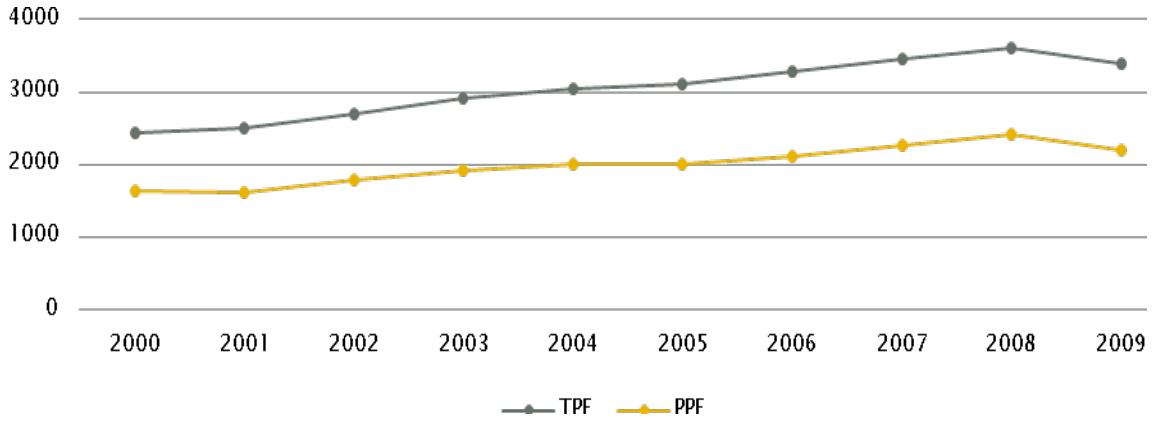
Data indicated as consumer price level

Source: AESGP 1995-2011

8.4.2 Pharmaceutical expenditure

Total pharmaceutical expenditure as a percentage of the total health expenditure amounted to 12.5 percent in 2009 (OECD 2011) which corresponded to about € PPP 3,500 million (cf. Figure 8.4). Both total and public pharmaceutical expenditure increased from 2000 to 2009 (cf. Figure 8.4).

Figure 8.4: Austria – Total and public pharmaceutical expenditure in million Euro PPP, 1995 – 2009



PPE = public pharmaceutical expenditure, TPE = total pharmaceutical expenditure

Source: PHIS 2011, OECD 2011

Austria has a comparably high share of public pharmaceutical expenditure of about two thirds. Public pharmaceutical expenditure as share of the total pharmaceutical has slightly decreased from 66.7 percent in 1990 to 65.2 percent in 2009 (Figure 8.5).

Figure 8.5: Austria – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure, 1990 – 2009

Source: PHIS 2011, OECD 2011

8.4.3 Pharmacy remuneration and turnover

In Austria all medicines are regulated via regressive mark-up schemes for both wholesalers and pharmacies.

Wholesalers are remunerated via a statutory regressive mark-up scheme applicable to all medicines. There are two different mark-up schemes, one for medicines listed in the so-called yellow or green boxes of the “reimbursement code”, i.e. two specific reimbursement categories of the positive list, and one scheme for all other medicines (ÖAK 2011b).

According to the Austrian Pharmaceutical Tax Enactment (BMGF 2003) pharmacies are remunerated via a statutory mark-up scheme applicable to all medicines. Like wholesale mark-ups, pharmacy mark-ups are regressively staggered. There are two different schemes, both adding on the pharmacy purchase price, which are applied depending on the customers (ÖAK 2010, Leopold et al. 2008): one for so-called privileged costumers (i.e. purchasers receiving preferential treatment, e.g. social health insurance institutions) (cf. Table 8.6) and one for private costumers (cf. Table 8.7).

Table 8.6: Austria – Pharmacy mark-up scheme for purchasers receiving preferential treatment, 2011

Pharmacy purchase price (PPP) in €	Pharmacy mark-up as % on PPP	Pharmacy retail price (PRP) in €
0.00-10.00	37.0%	-
10.01-10.15	-	€ 13.70
10.16-20.00	35.0%	-
20.01-20.45	-	€ 27.00
20.46-30.00	32.0%	-
30.01-30.94	-	€ 39.60
30.95-60.00	28.0%	-
60.01-62.44	-	€ 76.80
62.45-100.00	23.0%	-
100.01-104.24	-	€ 123.00
104.25-120.00	18.0%	-
120.01-124.21	-	€ 141.60
124.22-150.00	14.0%	-
150.01-155.45	-	€ 171.00
155.46-200.00	10.0%	-
200.01-207.55	-	€ 220.00
207.56-350.00	6.0%	-
350.01-357.07	-	€ 371.00
More than 357,08	3.9%	-

PPP = pharmacy purchase price, PRP = pharmacy retail price

Source: Austrian Pharmaceutical Tax Enactment, 30 December 2003

Table 8.7: Austria – Pharmacy mark-up scheme for private customers, 2011

Pharmacy purchase price (PPP) in €	Pharmacy mark-up as % on PPP	Pharmacy retail price (PRP) in €
0.00-7.29	55.0%	-
7.30-7.58	-	€ 11.30
7.59-15.70	49.0%	-
15.71-16.25	-	€ 23.40
16.26-26.25	44.0%	-
26.26-27.19	-	€ 37.80
27.20-63.09	39.0%	-
63.10-65.44	-	€ 87.70
65.45-90.74	34.0%	-
90.75-94.26	-	€ 121.60
94.27-108.99	29.0%	-
108.99-113.38	-	€ 140.60
113.39-130.80	24.0%	-
130.81-135.73	-	€ 162.20
135.74-203.43	19.5%	-
203.44-211.39	-	€ 243.10
211.40-363.30	15.0%	-
363.31-371.37	-	€ 417.80
371.37	12.5%	-

PPP = pharmacy purchase price, PRP = pharmacy retail price

Source: Austrian Pharmaceutical Tax Enactment, 30 December 2003

Pharmacies with a social health insurance turnover above the median pharmacy's turnover, have to contribute to the public health system by granting a special discount to social insurance of 2.5 percent. Medicines with a purchase price of € 200,- are exempted from this contribution (ÖAK 2011b).

The average pharmacy margin for reimbursable medicines amounted to 18.18 percent in 2010. It has been decreasing over the years (22.27 percent in 2001) which is attributable to the market entry of more high-price medicines (thus with a lower mark-up due to the regressive scheme) (ÖAK 2011b).

The VAT on medicines is 10 percent, social insurance gets the VAT reimbursed. An add-on of 15 percent on the prices of medicines calculated according to the Austrian Tax Enactment (§ 6) is added by pharmacists and POM dispensing doctors for private customers (ÖAK 2010 and 2011b, Leopold et al. 2008).

Table 8.8 shows the development of pharmacy turnover between 1990 and 2010. Medicines account for the largest part of pharmacy's turnover. Non-pharmaceuticals only contribute a relatively small part to the pharmacy turnover.

Table 8.8: Austria – Prescriptions and pharmacy turnover, 1990 – 2010

Prescriptions and turnover	1990	1995	2000	2005	2006	2007	2008	2009	2010
Prescriptions filled (in million items)	35.8	41.1	44.4	n.a.	n.a.	n.a	n.a.	n.a.	n.a
Medicines prescribed (in million Items)	n.a.	n.a.	101.4	103.6	107.7	112.5	117.6	117.1	118.0
Total pharmacy turnover in million €	**893**	**1,330**	**1,892**	**n.a.**	**2,621**	**2,801**	**2,990**	**3,113**	**3,170**
Of which (in %)									
Turnover of medicines	91.0	91.7	91.5	n.a.	n.a.	n.a	n.a.	n.a.	n.a
Turnover of OTC medicines	23.5	22.4	20.0	n.a.	n.a.	n.a	n.a.	n.a.	n.a
Turnover on non-pharmaceuticals	9.0	8.3	8.5	n.a.	n.a.	n.a	n.a.	n.a.	n.a

Source: ÖAK 2011b, Vogler et al. 2006

9 Denmark

9.1 Framework

In Denmark, prescription-only medicines (POM) are dispensed by community pharmacies, including branch pharmacies and supplementary pharmacy units (Thomsen et al. 2008). Branch pharmacies and supplementary units are attached to the main pharmacy and are operated at its expense. At least one pharmacist is required to be present during opening hours in pharmacies, branch pharmacies and supplementary units (Danmarks Apotekerforening 2011a, Danmarks Apotekerforening 2011c).

In principle, the Danish Medicines Agency (DKMA) can, under specific conditions laid down in the Pharmacy Act, give allowance to a doctor to dispense medicines and other goods bought at a defined pharmacy to his/her patients. However, the last permission granted by the authorities expired in 2002, and no new doctor has been authorised after 2001. Therefore, there were no POM dispensing doctors operating in Denmark in the last few years (Danmarks Apotekerforening 2011c).

Hospital pharmacies are generally not allowed to dispense medicines to out-patients (Er 2009, Vogler et al. 2010). However if a medicine is categorised as hospital-only medicine (HOM) or patients getting treatment via out-patient departments (OPD) in hospitals, patients can be provided with medicines from the hospital pharmacy. Patients can also freely be provided with medicines for a couple of days from the hospital pharmacy when they are discharged from hospital (Danmarks Apotekerforening 2011c).

Apoteket.dk, which is an internet portal operated by the Association of Danish Pharmacies on behalf of all community pharmacies, is Denmark's only internet pharmacy allowed to dispense the full range of medicines, including POM. Apoteket.dk has been operating since 2004 (Danmarks Apotekerforening 2007/2008) and is visited by nearly 70,000 Danes every week (Danmarks Apotekerforening 2011c). In addition, several Danish internet pharmacies offer non-pharmacy restricted OTC medicines (DKMA 2011b). Legislation does not allow for web-only pharmacies, i.e. distribution of POM and OTC medicines via the internet alone, but the internet pharmacies need to be brick-and-mortar pharmacies (Thomsen et al. 2008).

OTC medicines, which are not pharmacy-restricted (see also section 9.3.2.1), can also be sold outside a pharmacy. OTC medicines dispensaries have to provide a minimum range of OTC medicines defined by the Danish Medicines Agency, including painkillers, topical nasal decongestants, motion sickness medicines, cough suppressants, lozenges for sore throat and nicotine chewing gums. Shops which only sell nicotine replacement therapy (NRT) products are exempt from this minimum range rule (DKMA 2011b). Overall, the growth of OTC medicines measured in DDD sold outside pharmacies has been rather strong over the years, with a total increase of 56 percent from 2001 to 2010 (Danmarks Apotekerforening 2011a) fading out in the last few years (DKMA 2010).

Pharmacy outlets, OTC medicines outlets and delivery facilities are outlets and stores where patients may collect prescription-only medicine dispensed at a pharmacy (for further

explanation see below), but the places do not dispense pharmacy-restricted medicines directly. OTC medicines can be bought in pharmacy outlets and OTC medicines outlets, but not in delivery facilities (Danmarks Apotekerforening 2011a). The number of these outlets and stores is about 950 in total, and exceeds the number of community pharmacies (cf. Table 1.1).

The three types of OTC medicines dispensaries are the following:

- A pharmacy outlet is attached to a pharmacy, operated at the pharmacy's expense and staffed by qualified personnel, but a pharmacist is not required, as the pharmacy outlet may only dispense OTC medicines including pharmacy-restricted OTC medicines (Danmarks Apotekerforening 2011a). Pharmacy outlets can sell – but not dispense – prescription-only medicines in a closed bag ordered from and dispensed by the mother pharmacy. In total there are about 130 pharmacy outlets in Denmark.

- OTC medicines outlets are mostly integrated in shops, e.g. supermarkets and dispense only several OTC medicines allowed for sale outside pharmacies by the DKMA. These outlets are also allowed to offer a delivery service of POM, which are delivered from a community pharmacy to the outlet (DKMA 2011b). There are about 600 OTC medicines outlets.

- Delivery facilities do not stock medicine. They receive addressed dispatches from one or several pharmacies and pass them on to the individual customer. Before mid-2011 delivery facilities were only served by pharmacies in the neighbourhood – but after mid-2011 it has been allowed to establish medicines delivery facilities outside the pharmacy neighbourhood. About 15 out of a total of 200 delivery facilities have been opened by a pharmacy not in the neighbourhood (Danmarks Apotekerforening 2011c).

Pharmacy establishment in Denmark is bound to a licensing system. The number and location of pharmacies as well of its branch pharmacies (and supplementary units) are determined by the DKMA and the Ministry of Health. Vacant licenses are advertised by the DKMA which then evaluates the applications and informs the Ministry of Health of the suitable applicants for the vacant pharmacy license. The Minister then decides based on the DKMA's recommendation who will receive the pharmacy license (Danmarks Apotekerforening 2010, Danmarks Apotekerforening 2011a, DKMA 2011b). Under specific circumstances pharmacies can qualify for subsidies granted by the Minister for Health which are financed via a fund by pharmacies in Denmark (cf. section 1.4.3, Danmarks Apotekerforening 2011c).

Pharmacy ownership in Denmark is restricted to pharmacists. Any qualified pharmacist (master in pharmacy) from an EU/EEA Member State can own a pharmacy (PGEU 2010f). Pharmacists nowadays tend to participate in one or more purchasing associations, which provide for a more economic organisation of buying, selling and marketing of medicines. Some of these purchasing associations are operating as companies, others act as associations (cf. Section 1.3.1.2, Danmarks Apotekerforening 2011c).

Denmark's wholesale system is based on multi-channel distribution, which primarily consists of two full-line wholesale companies: Nomeco Ltd. and Tjellesen Max Jenne. Ltd. In July 2009 K.V. Tjellesen Ltd. and Max Jenne Ltd. were taken over by Celesio and were consolidated to Tjellesen Max Jenne (Tjellesen Max Jenne A/S 2011). Nomeco Ltd. is still Denmark's largest wholesaler, which is since 1998 fully owned by the Finnish company Tamro (Macarthur 2007). The DKMA also had authorised about 250 companies for wholesale activities in the pharmacy sector (Thomsen et al. 2008).

9.2 Accessibility

9.2.1 Accessibility of medicines dispensaries

9.2.1.1 Provision of POM dispensaries

Currently, there are 316 community pharmacies, of which 69 branch pharmacies and 18 supplementary units which provide the Danish population with prescription-only medicines. The number of community pharmacies has slightly changed in the period from 1990 to 2011, with slight increases first and decreases later in time (cf. Table 9.1).

There are neither POM dispensing doctors nor hospital pharmacies dispensing POM to out-patients in place (cf. section 9.1).

Apoteket.dk, which has been established in 2004, is the only internet pharmacy in Denmark authorised to dispense POM. Apoteket.dk is a portal serving all community pharmacies.

Table 9.1: Denmark – Number of community pharmacies and other POM dispensaries[1], as of 1 January 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies	307	338	331	323	322	322	322	320	318	316
Of which:										
Branch pharmacies	36	41	43	47	53	55	57	59	64	69
Supplementary units	0	0	0	4	10	13	18	18	19	18
POM dispensing doctors	0	0	0	0	0	0	0	0	0	0
Hospital pharmacies dispensing POM to out-patients	0	0	0	0	0	0	0	0	0	0
Internet pharmacies dispensing POM[2]	0	0	0	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Total of POM dispensaries	**307**	**338**	**331**	**323**	**322**	**323**	**323**	**320**	**318**	**316**

POM = prescription-only medicine

[1] Retailers which are allowed to dispense prescription-only medicines

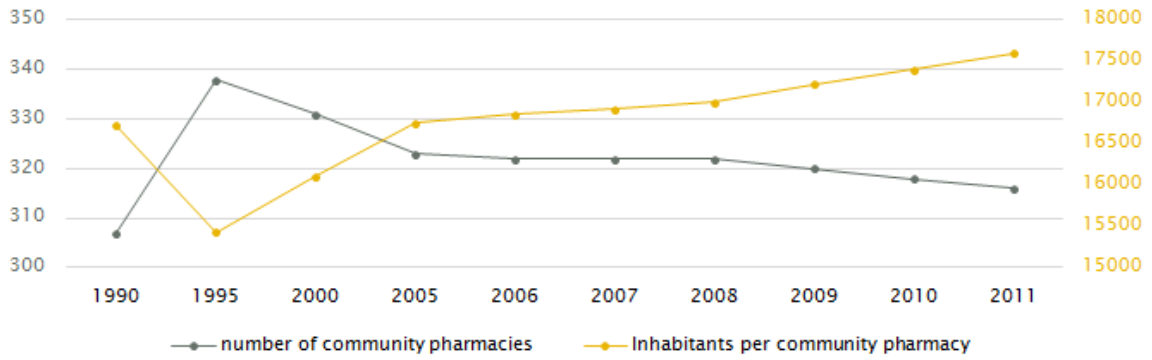
[2] The internet portal is serving community pharmacies, thus it is not included in the total number of POM dispensaries.

Source: Danmarks Apotekerforening 2010, DKMA 2011b

Denmark has a comparably high number of inhabitants per pharmacy, which is nearly twice as high as in other Nordic countries. As the number of pharmacies is comparatively low and has only slightly increased while the Danish population grew, the number of inhabitants per pharmacy increased from 15,430 in 1995 to 17,600 in 2011 (cf. Figure 9.1).

Nonetheless, distance to pharmacy still is relatively short (cf. section 9.2.1.2), and 50 percent of the Danish population have a distance less than two kilometres to the nearest pharmacy (for further details see below section 9.2.1.2). 91 percent of the Danes are satisfied or very satisfied with the distance to the nearest pharmacy. Additionally, on average Danish pharmacies are bigger than in other countries and thus capable of serving more inhabitants (Danmarks Apotekerforening 2011c).

Figure 9.1: Denmark – Number of community pharmacies and inhabitants per community pharmacy, 1990 – 2010



Source: Danmarks Apotekerforening 2010, DKMA 2011b

9.2.1.2 Provision of POM dispensaries in rural areas

Like for the other pharmacies, establishment of POM dispensaries in rural areas is also decided by the DKMA (Danish Medicines Agency). To set incentives for pharmacies to apply for licenses in rural areas, the authorities implemented an equalization scheme among the pharmacies (PGEU 2010j). Pharmacies with large turnover are obliged to pay a sales tax, which is used to subsidise small scale pharmacies in rural areas (cf. section 9.4.3). About 44 rural pharmacies were considered as not likely to be economically sustainable without the rural equalisation scheme. The subsidisation of these pharmacies, mostly situated in rural parts of North-Jutland, South-Jutland and South Zealand is therefore considered necessary to provide for an overall good and equal availability of medicine in Denmark (Danmarks Apotekerforening 2011c).

On average every Dane has 3.8 kilometres to the nearest pharmacy, but nearly 50 percent even less than 2 kilometres. Many small villages have their own pharmacy outlet, an OTC outlet or a delivery facility. Included these units, the average distance to the nearest dispensary is about 1.6 kilometres. 75 percent of the population is able to collect their medicine in a delivery facility less than two kilometres from their home (Danmarks Apotekerforening 2010).

In the most rural area of Denmark, North-Jutland, the average distance to the nearest pharmacy is 5.3 kilometres, while it is 2.0 kilometres in the capital city of Copenhagen and surroundings (Danmarks Apotekerforening 2011c).

9.2.2 Availability of medicines

Table 1.2 shows the service requirements in Danish community pharmacies. All pharmacies have to fulfil the obligation to provide all pharmacy restricted medicines, including POM and OTC medicines and all non-pharmacy restricted OTC medicines on prescription, resulting in a minimum stock of medicines or the ability to deliver medicines within 24 hours (Herborg et al. 2007).

Dispensing within a certain period of time is not subject to specific regulations, but agreed upon by authorities and pharmacies (cf. Table 9.2).

Table 9.2: Denmark – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	According the Consolidation Act (Consolidation Act 2008) pharmacies have to provide all types of medicines and also have to have a suitable and adequate stock in relation to the demand. Pharmacies are as well obliged to procure a medicine that is not in stock (Danmarks Apotekerforening 2011a)	The regulations concerning medicines in stock are fulfilled by each pharmacy (see below on the practice regarding dispensing within a certain time period).
Requirements concerning space	No specific regulations.	Not available
Dispensing within a certain time period	No specific regulations. However, there is a general understanding between the authorities and pharmacies that almost all medicines should be available immediately. If this is not possible, the medicines should be provided to the costumer within a reasonable short time, being defined as less than 24 hours.	98 to 99 percent of all dispensed medicines are available immediately. The rest, one to two percent, is provided within 24 hours.
Frequency of delivery	No specific regulations.	Pharmacies in Denmark are delivered once a day. In special circumstances the delivery can be “express”, i.e. “immediately” where pharmacies in certain (few) urgent cases have the possibility of getting express delivery immediately from the wholesaler, if the patient cannot wait till delivery the next day

Source: Danmarks Apotekerforening 2011a, Danmarks Apotekerforening 2011c

Authorities in Denmark regulate pharmacy’s on-call duties. Firstly, there are 11 pharmacies that stay open all nights and in the weekends. Apart from these pharmacies are divided into three different categories with specific requirements. Category one pharmacies have on-call duty and have to keep open until 22.00 hours on working days and on Saturdays until 14.00 hours and from 18.00 to 22.00 hours. Category two pharmacies are obliged to on-call duty and to keep open outside the normal hours at least one hour on working days, at least two hours on Saturdays and at least three hours on Sundays or holidays. Category three pharmacies are not obliged to have longer opening hours, but still to be on on-call service (PGEU 2010d).

Most community pharmacies in Denmark offer, though not legally obliged, home delivery services within the normal opening hours. If this service is offered, pharmacies have to charge a fee to cover the expenses. Community pharmacies, which operate in addition to the normal opening hours, are obliged to offer home delivery service without charging the costumer a fee. Home delivery outside normal opening hours is only provided if a doctor considers it as necessary (PGEU 2010b). Most pharmacies also offer on-line shopping.

9.3 Quality of pharmacy services

9.3.1 Pharmacy staff

9.3.1.1 Availability of pharmacists and other qualified staff

In Denmark full pharmacists and a specific professional group, the so-called pharmaconomists, are allowed to dispense prescription-only medicines. The number of pharmacists working in community pharmacies has been decreasing since 1990: In 2011 757 pharmacists work in community pharmacies, which corresponds to 546 full time equivalents (FTE) (cf. Table 9.3).

Since 1990 the number of FTE pharmaconomists working in community pharmacies has been stable, amounting to around 2,550 in 2011 (cf. Table 9.3).

Staff without the right to dispense consists of pharmaconomist students (578 FTE in 2011), and other pharmacy personnel (850 FTE in 2011, cf. Table 9.3).

Table 9.3: Denmark – Staff working in community pharmacies, as of 1 January 1990 – 2011

Number of pharmacy staff	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Number of pharmacists counted per head	912	799	743	726	742	758	763	749	734	757
Number of pharmacy staff in FTE	**3,327**	**3,094**	**3,040**	**3,109**	**3,104**	**3,192**	**3,170**	**3,117**	**3,137**	**3,103**
Of which:										
Full pharmacists[1]	717	639	600	564	565	568	580	550	546	546
Pharmaconomists[2]	2,610	2,455	2,440	2,545	2,539	2,624	2,590	2,567	2,591	2,557
Pharmaconomist students	n.a.	211	290	464	456	497	513	528	533	578
Number of other pharmacy personnel	1,115	868	860	1,041	1022	1,103	802	829	870	850
Total number of pharmacy staff (FTE)	**4,442**	**4,173**	**4,190**	**4,614**	**4,582**	**4,792**	**4,731**	**4,766**	**4,774**	**4,760**

FTEs = Full time equivalents

[1] Data indicated exc. pharmacy owners. Number of pharmacy owner can be derived from Table 9.1; it is the number of community pharmacies excl. branch pharmacies and supplementary units. For 2011, for instance the number of full pharmacists would be increased by 229 pharmacy owners, making up a total of 775 pharmacists.

[2] Pharmaconomists = Pharmacy technicians / assistants with the right to dispense POM

Source: Danmarks Apotekerforening 2010, DKMA 2011b

Training of pharmacists is provided by two institutions, the Faculty of Pharmaceutical Sciences (DFU) at the University of Copenhagen and University of Southern Denmark in Odense (SDU)(Ministeriet for Børn og Undervisning 2011). A three plus two year's education with a master's degree is required. Included in the training is a six-month internship in a pharmacy and an optional course on quality-assured medicine use (cf. Table 1.4). Continuous education for full pharmacists is not obligatory, but often fulfilled. The pharmacies document their staff's qualifications. Most continuous education programs are offered in co-operation with Pharmakon (Danish College of Pharmacy Practice), a conference and training centre for pharmacists owned by the Association of Danish Pharmacies. At the DFU also a one year additional training in Drug Management is offered for full pharmacists (Herborg et al. 2007, Pharmakon 2011).

230 undergraduate students are accepted every year by the DFU. About 65 percent of all pharmacy graduates have over many years found their employment in private companies, e.g. the pharmaceutical industry, 20 percent are employed in the public sector including hospital pharmacies and 15 percent of all graduates on average start working in community pharmacies (DFU 2011).

The education of pharmaconomists is provided by Pharmakon in a three year program, which is regulated by the Ministry of Education (cf. Table 9.4, Herborg et al. 2007, Pharmakon 2011). In September 2007 a new education regulation for pharmaconomists was implemented with the goal of an improved preparation of the students for their responsibilities in community pharmacies. Pharmaconomists, who have the right to dispense prescription-

only medicines, have to be able to counsel costumers about medicines, carry out health care and to control the quality of the pharmacy services (Danmarks Apotekerforening 2007/2008).

Table 9.4: Denmark – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	MSc degree in pharmacy at the Faculty of Pharmaceutical Sciences (University of Copenhagen), University of Southern Denmark or any pharmacy school in the EU/EEA	3 + 2 years	Six-month pharmacy internship and optional course on quality-assured medicine use	Neither CE nor CPD is compulsory, but practically all pharmacists attend CPD activities. The pharmacies have to keep documentation of staff qualifications for inspection and quality audits.	Consolidation Act 814 of 29/06/2010 and Consolidation Act 754 of 17 June 2010
Pharmaco-nomists, technicians with the right to dispense POM	Practically oriented training with periods of theory at Pharmakon. Eight theoretical courses (7 of 3 weeks and 1 of two weeks) and a practical training period partly at Pharmakon and partly in a pharmacy	3 years	Including a practical training period between the theoretical courses at a pharmacy	No, but in 2007 a certificate programme was established – postgraduate education in clinical pharmacy and public health is offered	Education regulation for pharmaconomists of 1 September 2007. Consolidation Act 769 of 27/06/2007. Consolidation Act 657 of 28/7/1995.

CE = Continuous Education, CPD = Continuing Professional Development

Source: Danmarks Apotekerforening 2011c

9.3.1.2 Professional independence of pharmacists

Every pharmacy must be owned by a pharmacist, resulting in a high economic responsibility of the pharmacy owner for the financing of the pharmacy and its operations (Danmarks Apotekerforening 2011a).

Multiple ownership in Denmark is not allowed, therefore no pharmacy chains are established in Denmark. However, individual pharmacists are allowed to own up to four pharmacies, including supplementary units, and pharmacists more and more participate in purchasing associations (cf. section 9.1). Table 9.5 shows the number of pharmacies collaborating in several purchasing associations.

Table 9.5: Denmark – Number of pharmacies in membership (franchise) of purchasing associations, 2011

Purchasing associations	Number of pharmacies in membership (franchise)
A-apoteket	127
Aptekeren A.m.b.a.	55
Apotekernes A.m.b.a.	Co-operative owned by all Danish pharmacists, which produces, buys, sells and markets a wide range of quality products, especially personal care, skin care, baby care and supplements.
ditApotek A.m.b.a.	58
Pharma+	20

Source: Danmarks Apotekerforening 2011c

9.3.2 Product range

9.3.2.1 Medicines

The dispensing of POM is exclusively provided by community pharmacies including branch pharmacies or supplementary units. Self-service of medicines is neither allowed for POM nor for OTC medicines, prescription-only medicines and pharmacy restricted OTC medicines must be dispensed by a pharmacist or a pharmaconomist.

OTC medicines are divided into four groups (AESGP 2011):

- Dispensing group HA whose sale is restricted to pharmacies (pharmacies, branch pharmacies, supplementary pharmacy units and pharmacy outlets)
- Dispensing group HF whose sale is not restricted to pharmacies (to be sold for example in pharmacies, branch pharmacies, supplementary pharmacy units, and pharmacy outlets, OTC outlets and supermarkets,)
- Dispensing group HX whose sale is not restricted to pharmacies with a maximum of one pack per person per day may be dispensed
- Dispensing group HX18 whose sale is not restricted to pharmacies, but of which maximum one pack per person over 18 year per day may be dispensed
- Dispensing group HV which are veterinary products (Danmarks Apotekerforening 2007/2008, DKMA 2011a). Sale is not restricted to pharmacies.

The full range of OTC medicines is sold in pharmacies (dispensing groups HA, HF and HX and HX18). 500 out of 700 packs OTC medicines have additionally been authorised by the DKMA (Danish Medicines Agency) for sale outside pharmacies (dispensing groups HF and HX, HX18, cf. section 9.1). Self-service of OTC medicines is not allowed in Denmark, neither

in pharmacies nor in OTC medicines outlets etc. Regardless the range of OTC medicines provided every outlet selling OTC medicines has to fulfil the following rules:

- Dispensing of medicines to persons under the age of 15 is prohibited (for HX18 it is over the age of 18)
- Medicines purchased cannot be exchanged
- Medicines with an expired date, opened packaging or of questionable quality have to be removed from the sales area (DKMA 2011a).

There are no specific incentives for the sale of OTC medicines in community pharmacies in Denmark for the sector, as the total annual gross margin including OTC sales for all pharmacies together is limited to a predefined amount (Danmarks Apotekerforening 2011c), see details section 9.4.1.).

Pharmacy produced medicines are not common in Denmark, as only two pharmacies produce magistral preparations. 0.5 percent of the turnover of all pharmacies may be accounted for magistral preparations.

9.3.2.2 Non-pharmaceuticals

Non-pharmaceutical products commonly sold in Danish community pharmacies are food supplements, medical equipment and special skin-care products. It is important that non-pharmaceuticals sold in pharmacies have a natural belonging to pharmacy (Consolidation Act number 855 of 4/8/2008 with later changes). Self-service for non-pharmaceuticals is allowed in community pharmacies and in other OTC medicines dispensaries.

9.3.3 Pharmacy services

9.3.3.1 Services provided by pharmacies

Danish community pharmacies provide several services for their costumers (cf. Table 9.6).

Table 9.6: Denmark – Services provided by community pharmacies, 2011

Pharmacies providing this service (number of pharmacies)	Type of service (number of pharmacies)
All (316)	Dispensing prescriptions Repeat dispensing Disposal of waste Provision of emergency contraception Dose-dispensing[1]
Most	Inhalation Technique Assessment (273) Smoking cessation (174) Blood pressure management (140)
Some	Medicines use review (102) Blood sugar measurement and counselling (48) Cholesterol measurement (47) On-call night duty (39)
A Few	Weight measurement (27) Full night services (11)

[1] All pharmacies sell dosis medicines, ten pharmacies offer dose dispensing.

Source: Danmarks Apotekerforening 2011c, PGEU 2010g

Smoking cessation is provided by many Danish pharmacies; this being as a consequence of the prohibition to smoke in public places since August 2007. Smoking cessation has existed since the end of 1990-tisies. The service “A short talk about smoking and how to quit”, which has been subsidized by the Ministry of Health, was free of charge until 2010. A number of local municipalities still pay pharmacies for smoking cessation courses today (Danmarks Apotekerforening 2006/2007).

All Danish pharmacies offer dose dispensing to avoid wrong dosage. The packaging is carried out by ten pharmacies delivering to the rest of the pharmacies. This service started in 2001. According to the Danish Medicines Agency 46,500 Danes benefited from this service by the end of 2010. The dose packaged pharmaceuticals make up 3.3 percent of the total pharmaceutical consumption in relation to DDD (Danmarks Apotekerforening 2006/2007).

Medicinkombination.dk is a service which is provided by the Danish Medicines Agency and which has been created in cooperation with the Association of Danish Pharmacies. Clear information about interactions for medicines bought on internet is provided. This service is part of the e-services also established on the website of apoteket.dk (Danmarks Apotekerforening 2006/2007).

In 2004, the Personal Electronic Medication Profile (PEM) was launched on the national health website www.sundhed.dk as a facility for all Danish residents, Sundhed.dk is a service provided by the Ministry of Health, the Danish Regions and the Local Government Denmark (KL, being the interest group and member authority of Danish municipalities). The Association of Danish Pharmacies was a driving force in the development of the site. The profile gives individual medicine users, general practitioners (GPs), pharmacists and, from

2009, primary care nurses, an overview of medicines bought by patients. In 2007 the Danish Medicines Agency launched a central prescription server. Since then most prescriptions are electronically sent from doctors to pharmacies (Danmarks Apotekerforening 2006/2007).

From 2007 the pharmacies also provide a SMS-service to help people remember to take their medicines. The SMS service is free, and people only pay ordinary SMS charge for the SMS service for confirmation and unsubscribing.

9.3.3.2 Pharmaceutical counselling

Pharmacies work in accordance with Good Pharmacy Practice. A good pharmacy quality service system is to be implemented in all community pharmacies in Denmark. Quality of pharmacy services is checked via professional audits, mystery shopping and consumer satisfaction surveys. The development of a reporting and learning system is in progress (PGEU 2010i). Standards for the quality of pharmacies are also being laid down in the widespread Danish Quality Model for the Health System (DDKM) where accreditation is externally audited (Danmarks Apotekerforening 2011c).

While there are no compulsory nation-wide quality standards for pharmaceutical counselling in Denmark, in order to ensure a uniform level of quality in the entire pharmacy sector, pharmacies have formulated a set of common standards for counselling at the counter in 2007.

Detailed studies of waiting times started to be carried out regularly from 2008 on. An average waiting time of five minutes or less at community pharmacies had been reported since then. A study of the Association of Danish Pharmacies as of October 2011 (Danmarks Apotekerforening 2011b) showed the result of an average waiting time of 3.7 minutes for about 414,000 Danes. Only 3.5 percent of the costumers waited more than 10 minutes. In order to reduce waiting times, it is more and more common, that Danish pharmacists use pharmacy robots (automated storage and retrieval systems; Danmarks Apotekerforening 2011c).

The counselling time is on average around 4 minutes in a standard dispensing situation.

Counselling in Denmark is remunerated as a part of the pharmacy margin (Danmarks Apotekerforening 2011c).

9.4 Economics

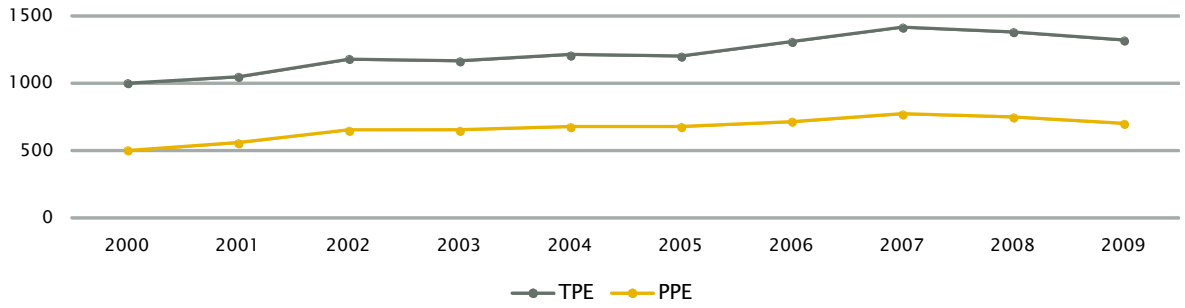
9.4.1 Market data

The pharmacy turnover with medicines increased of 130 and 80 percent in the periods from 1990 to 2010 and 2000 to 2010 respectively. The share of OTC medicines in percent of the total turnover from medicine decreased from 18.8 percent in 1990 and 9.9 percent in 2000 to 7.5 percent in 2011 (cf. Figure 9.2).

9.4.2 Pharmaceutical expenditure

In Denmark, total pharmaceutical and public pharmaceutical expenditure increased from 2000 to 2009. While in 2000 total pharmaceutical expenditure was € PPP 1,005 million, it amounted to € PPP 1,325 million in 2009. Public pharmaceutical expenditure increased from € PPP 510 million in 2000 to € PPP 707 million in 2009 (cf. Figure 9.2).

Figure 9.2: Denmark – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009

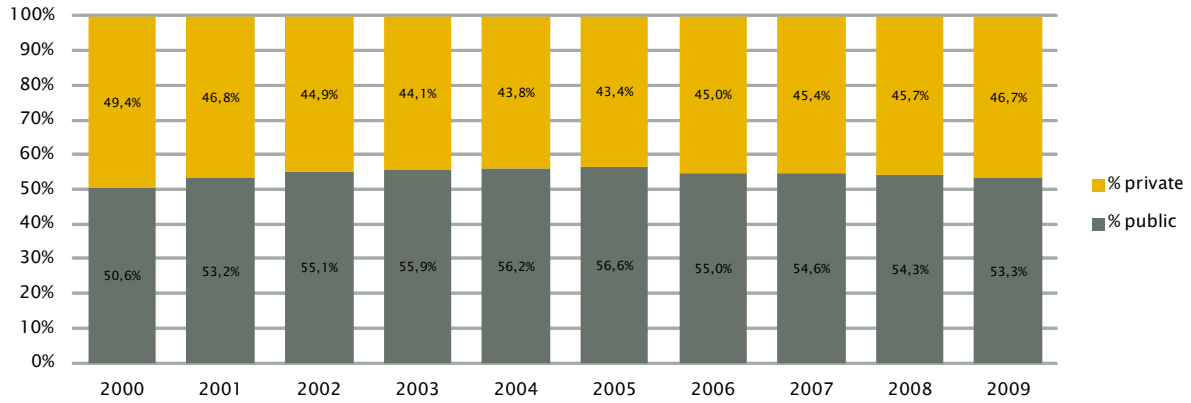


TPE = total pharmaceutical expenditure, PPE = public pharmaceutical expenditure

Source: OECD 2011, PHIS 2011

Public pharmaceutical expenditure as share of total pharmaceutical expenditure has slightly changed, however by an increase from 50.6 percent in 2000 to 53.3 percent in 2009 (cf. Figure 9.2). In Denmark medicines are therefore funded in nearly equal parts by private and public actors.

Figure 9.3: Denmark – Share of public and private pharmaceutical expenditure in percent of total pharmaceutical expenditure (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

9.4.3 Pharmacy remuneration and turnover

Medicines prices are set at the wholesale level. The wholesale margin is not statutory regulated but negotiated between the wholesaler and the pharmaceutical company. It is therefore not publicly known (Thomsen et al. 2008, PPI 2011, Vogler et al. 2011a).

Once every two weeks, the pharmaceutical industry is allowed to change the price which implies a new reference price (Habl et al. 2008, PPI 2011).

Pharmacy mark-ups are regulated by law (Executive Order, No 1000 of 19/10/2011on the Calculation of Consumer Prices of Medicinal Products), they apply to all pharmacy only medicines (including non-reimbursable medicines and non-liberalised OTC products). Prices on liberalised OTC medicines are set freely.

Pharmacy remuneration is in the form of a linear mark-up based on a dispensary fee added to the pharmacy retail price (PRP) of each pack (see below) and it is reimbursable if the medicine is reimbursable. In Denmark, several other fees for services are applied, e.g. prescription fee and phone prescription fee. Delivery is also possible, and the patient have to paid a delivery fee out of pocket (Thomsen et al. 2008).

The pharmacy mark-up is calculated added on a dispensing fee of DKK 10,- / € 1.35 (incl. VAT; DKK 8,- excl. VAT). The variable factor of the mark-up is regularly changed in Denmark. The last change took place on 31 October 2011. The current conversion formula from the pharmacy purchase price excl. VAT (PPP) to the pharmacy retail price (incl. VAT) is as follows:

Pharmacy retail price = DKK 10.00 + 1.25 × (PPP × 0.086 + PPP + 9.86) (DKMA 2011c)

In 2010 the average pharmacy margin for POM amounted to 16.5 percent of the pharmacy retail price (excl. VAT). For all medicines including POM and OTC medicines, the average pharmacy margin in 2010 was 21.8 percent of the pharmacy retail price.

The net remuneration of medicines is the same for every package of medicine, regardless of the price and package size. The whole pharmacy sector does not profit of this incentive because authorities determine the total annual gross margin sum for all pharmacies. However, if the number of POM packages goes up, the total gross margin sum is adjusted slightly to partly compensate for the measured activity. There are no incentives neither for individual pharmacists nor for the pharmacy sector as a whole to sell more expensive medicines because of the fixed net remuneration per package sold (Danmarks Apotekerforening 2011c).

Pharmacy turnover thus for the pharmacy sector as a whole is determined by the authorities. Every second year, the Association of Danish Pharmacies and the Ministry of Health negotiate the gross margin sum, which corresponds to the contribution margin of the entire sector for all products and services. In 2010 the agreed margin sum constituted around DKK 2.6 billion / € 349 million. The gross margin must be able to cover the costs of operating the pharmacies and the proprietor pharmacists' own salaries. There are considerable differences

in the turnover of the individual pharmacies. In 2010 the smallest pharmacy had a turnover of DKK 12.3 million / € 1.65 million, whereas the largest had a turnover of DKK 190 million / € 25.5 million (Danmarks Apotekerforening 2011a, Danmarks Apotekerforening 2011c).

Pharmacies with a relatively large turnover are obligated to pay a sales tax which is aimed at subsidising small scale pharmacies in rural areas. 3.6 percent of the turnover exceeding the average turnover of pharmacies in Denmark has to be contributed by the high turnover pharmacies for this internal redistribution. Small-scale pharmacies in urban areas do not get subsidised (Danmarks Apotekerforening 2010).

Total pharmacy turnover more than doubled from 1990 to 2010. The biggest share is contributed by medicines, which accounted for DKK 9,663 million / € 1,298 million in 2010 (cf. Table 9.7).

OTC medicines and non-pharmaceuticals only contribute a small part of the pharmacy turnover. OTC medicines contributed 7.5 percent and non-pharmaceuticals nearly 12 percent to the total pharmacy turnover in 2010 (cf. Table 9.7).

Table 9.7: Denmark – Pharmacy turnover, 1990 – 2011

Pharmacy turnover in million DKK / in million € and in percent	**1990**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Total pharmacy turnover In million DKK	**5,200**	**6,900**	**8,800**	**11,400**	**11,900**	**12,200**	**12,100**	**12,200**	**12,400**	**n.a.**
Of which:										
Turnover of medicines (total) In million DKK	3,950	5,479	7,167	9,275	9,694	9,700	9,500	9,430	9,663	n.a.
Turnover of medicines (%)	77.0	79.4	80.5	80.9	80.9	80.0	79.0	77.5	77.7	n.a.
Turnover of OTC medicines In million DKK	975	833	815	833	850	880	870	930	930	n.a.
Turnover of OTC medicines (%)	18.8	12.1	8.9	7.3	7.1	7.0	7.0	8.0	7.5	n.a.
Turnover on non-pharmaceuticals In million DKK	166	530	839	1,068	1,178	1,290	1,363	1,445	1,475	n.a.
Turnover on non-pharmaceuticals (%)	3.2	7.7	9.5	9.4	9.8	10.6	11.5	11.7	11.9	n.a.
Turnover from sales to other pharmacies In million DKK	66	35	22	205	264	300	340	350	375	n.a.
Turnover from sales to other pharmacies In (%)	1.3	0.5	0.3	1.8	2.2	2.0	2.8	2.9	3.0	n.a.

Source: Danmarks Apotekerforening 2010, DKMA 2011b

10 Finland

10.1 Framework

In Finland dispensing of prescription-only medicines (POM) is limited to community pharmacies. In 2010 812 community pharmacies were operating (cf. Table 10.1). 794 (97.8 percent) of all community pharmacies are privately owned. 18 community pharmacies are in the ownership of universities: the university pharmacies of Helsinki with 16 branch pharmacies and the university pharmacy of Eastern Finland in Kuopio (Martikainen 2007, Vogler 2006).

In 2011 there are 24 hospital pharmacies which are not allowed to dispense POM to out-patients. Only patients, who are discharged or temporarily transferred to out-patient care, may obtain medicines from the hospital pharmacy to ensure the continuation of their medication. This service of hospitals is free of charge and only applicable for a limited period of time (one or two days; Nähri 2009). Additionally medicines for specified dangerous infectious diseases (TBI, HIV etc.) are dispensed to out-patients (Apteekkariliitto 2011).

POM dispensing doctors do not exist. To provide for a high accessibility to medicines also in rural areas, pharmacy service points (they were called medicines chests before 1 February 2011) may be run by supervising pharmacies. These service points are not allowed to dispense POM, but a range of OTC medicines. Since 1 February 2011 dispensing OTC and prescription-only medicines via internet has been possible for pharmacies. Currently there are 18 pharmacies which provide OTC medicines via internet in Finland (cf. Table 10.1). Dispensing of POM via internet is possible only with electronic prescriptions. The possibility is provided for in the law but it is not possible in practice yet.

The dispensing of medicines (POM and OTC medicines), with the exception of nicotine replacement therapy preparations (NRT), by other dispensaries, e.g. drugstores, is not allowed.

NRT preparations, which are OTC, are allowed for sale outside pharmacies. They may be dispensed in tobacco-selling retail stores, grocery stores and kiosks as well as in bars and restaurants on the basis of the authorisation granted by the municipality where the sales outlet is located (FIMEA 1987: §54 and §57).

The main regulation concerning the Finnish pharmacy system is the Medicines Act (FIMEA 1987) which regulates the establishment and ownership of community pharmacies in Finland. Additionally the Medicines Decree plays an important role (FIMEA 2011). Establishment is regulated by the Finnish Medicines Agency FIMEA which takes a decision considering accessibility aspects and the opinion of the concerned municipality.

The Finnish Medicines Agency (FIMEA) took up in operations in 2009, replacing two former bodies, the National Agency for Medicines (NAM) and the Centre for Pharmacotherapy Development (ROHTO) (FIMEA 2009). The new government, elected in 2010, started a discussion especially on savings of public pharmaceutical expenditure and decided a

programme about 113 cost savings in the reimbursement system. A working group preparing the implementation of savings was installed. The pharmaceutical policies will be dominated by the Pharmaceutical Policy Program 2020 which addresses multi-professional cooperation, quality and medicines safety.

The Medicines Agency (FIMEA) grants licenses for pharmacies. Vacant licenses may only be applied for by pharmacists from Finland, the EU or EEA. An applying pharmacist has to hold a master's degree of pharmacy science. Licenses are temporary, personally and expire for pharmacists at the age of 68 or if a new license is granted to a pharmacist. Licenses may not be rent or sold.

Neither multiple ownership nor vertical integration is allowed. A private pharmacy is allowed to own up to three branch pharmacies and the Helsinki university pharmacy is permitted to have up to 16 branch pharmacies, all subject to authorization by FIMEA (FIMEA 1987). Case C-84/11 of the European Commission concerning a preliminary decision of a Finnish court, deals with the differences between establishment of private and university branch pharmacies. Especially, when determining the place of establishment of branch pharmacies, rules are more stringent for branch pharmacies by privately owned pharmacies (ECJ 2011). The case has not been closed yet.

If a branch pharmacy's turnover exceeds 50 percent of the average pharmacy turnover, it becomes an independent pharmacy. Some private pharmacies, however, have cooperative structures, which appear to have some kind of a chain character though legally being independent actors. Branch pharmacies may have different opening hours, a narrower selection of medicines and only have to be supervised by a pharmacist with a bachelor's degree. A pharmacist with a master's degree yet has to be the owner of the branch pharmacy. Branch pharmacies mostly are located in areas where the establishment of independent pharmacies is considered as not possible economically due to a small population (personal communication).

A licensed pharmacist may establish a pharmacy service point (previously called medicines chest), if authorized by FIMEA, in sparsely populated areas or a village centre, which does not provide an operating basis for a branch pharmacy. In exceptional cases, such pharmacy service points may also be established in the catchment area of the pharmacy or the area of an adjoining municipality to safeguard the accessibility of medicines. The Finnish Medicines Agency may convert a pharmacy service point into a branch pharmacy if the turnover of the service point is equivalent to at least half of the average turnover of all the country's private branch pharmacies and the operating basis for a branch pharmacy is in place in other respects. The licensed pharmacies of the University of Helsinki and the University of Eastern Finland may not establish pharmacy service points. Only a limited selection of OTC medicines may be sold from a licensed pharmacy service point under the supervision of a pharmacy (FIMEA 1987: §52a).

Licensed pharmacies including the pharmacies of the University of Helsinki and the University of Eastern Finland may provide pharmacy services also via an online pharmacy service. The administrator of an online pharmacy service must maintain a website on the

Internet. A notification must be submitted to the Finnish Medicines Agency before providing such online pharmacy service (FIMEA 1987: §52b).

The distribution of medicines in Finland is regulated, and wholesale is based on a single-channel system, which means that a wholesaler has the exclusive right for the distribution of a manufacturer's total medicines supply. The Finnish Medicines Agency (FIMEA) oversees the operation of the pharmaceutical distribution, including wholesale. Wholesalers need a permission to operate. There are three distributing wholesalers, Oriola Oy,Tamro Finland and Magnum Medical, operating in Finland. They all operate nation-wide (Mossialos/Srivastava 2008). Since the price is set at the wholesale level, manufacturers and the three pharmaceutical wholesalers negotiate on the ex-factory price. The wholesale margin therefore is freely negotiated with the granting of discounts being allowed, the results of the negotiations are not public. There are no pre-wholesaling stocks, which is cost-effective for the pharmaceutical companies (Peura et al. 2007).

10.2 Accessibility

10.2.1 Accessibility of medicines dispensaries

10.2.1.1 Provision of POM dispensaries

In 2010 there were 812 community pharmacies in Finland. The number of community pharmacies has slightly increased since 1990 (cf. Figure 10.1). The number of pharmacies, owned by universities has been stable at 18 since 2005 (cf. Table 10.1, section 10.1). All other pharmacies are privately owned single outlets. The number of community pharmacies includes branch pharmacies. Their number also has stayed relatively stable over the past ten years (cf. Table 10.1).

24 hospital pharmacies may supply free of charge medicines required for uninterrupted treatment of patients discharged from hospital or health centre wards or temporarily transferred to out-patient care (cf. section 10.1) (FIMEA 1987). Medicines that are prescribed according to the legislation concerning dangerous communicable diseases (HIV, tuberculosis etc.), for narcotic drug addictions or weaning or replacement therapy would be examples for this exemption.

Table 10.1: Finland – Number of pharmacies and other POM dispensaries[1], as of 1 January 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies	**749**	**788**	**793**	**807**	**804**	**806**	**809**	**811**	**812**	**n.a.**
Thereof Branch pharmacies	162	205	200	201	198	198	198	196	194	n.a.
Of which:										
Private pharmacies (owned by private entities / private persons)	732	771	776	789	786	788	791	793	794	n.a.
Public pharmacies (owned by units of the state, i.e. cities)	17	17	17	18	18	18	18	18	18	18
POM dispensing doctors	0	0	0	0	0	0	0	0	0	0
Hospital pharmacies dispensing POM to out-patients[2]	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Internet pharmacies dispensing POM	0	0	0	0	0	0	0	0	0	0
Other POM dispensaries	0	0	0	0	0	0	0	0	0	0
Total of POM disppenaries	**749**	**788**	**793**	**807**	**804**	**806**	**809**	**811**	**812**	**n.a.**

n.app. = not applicable, POM = prescription-only medicine

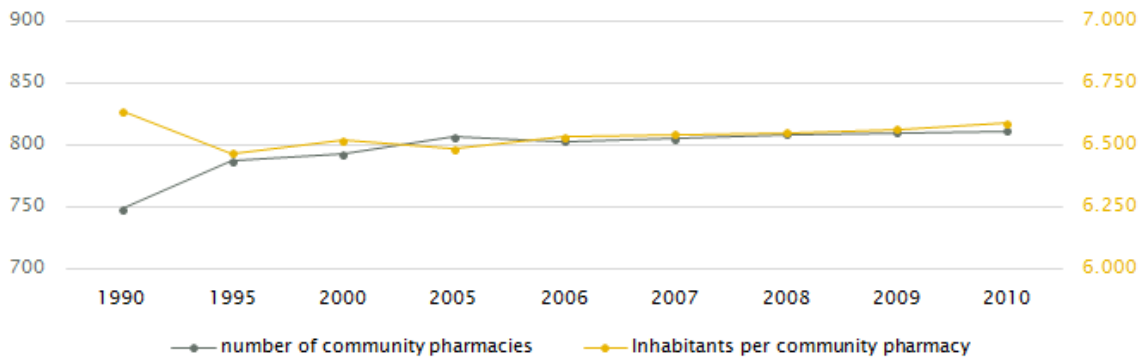
[1] Retailers which are allowed to dispense prescription-only medicines

[2] Hospital pharmacies may only dispense to out-patients in exceptional situations

Source: Apteekkariliitto 2011

Due to a relatively stable number of community pharmacies since 1990, the number of inhabitants per community pharmacy has not changed significantly over time. It amounts to approximately 6,500 inhabitants per community pharmacy (including university pharmacies and all branch pharmacies) (cf. Figure 10.1).

Figure 10.1: Finland – Number of community pharmacies and inhabitants per community pharmacy, 1990 – 2010



Source: Apteekkariliitto 2011 based on FIMEA data

10.2.1.2 Provision of POM dispensaries in rural areas

There are no incentives for pharmacies to establish in rural areas. But in order to provide a high accessibility to medicines in Finland, pharmacy service points may be established by community pharmacies in rural areas. Doctors are not allowed to dispense medicines.

Normally pharmacy service points are located in post offices or grocery stores. Only OTC medicines may be dispensed, which must be performed under the supervision of the main pharmacy. To provide the patient with further information also phone calls to a pharmacist in the main pharmacy can be made. Pharmacy service points replace the former medicines chests which may still operate as long as their licence is valid. Their number has steadily declined because of an increase of branch pharmacies and declining population in rural areas (Macarthur 2007). The major reason for the decline was that the licences were not granted by the Finnish Medicines Agency (FIMEA). Medicines service points are granted a wider range of possibilities to supply patients than the disappearing medicines chests. Customers may bring their prescriptions to the service point, where a pharmacist or prescriptionist may be available some days per week. The prescription-only medicine is then provided from the main pharmacy and delivered to the costumer at the pharmacy service point. Prescriptions may also be collected from the service point by pharmacy and medicines may then be also to the customer by mail or by other transportation. Medicines service points therefore are not allowed to have a POM stocking, they may only provide some OTC medicines from stock (personal communication).

The provision with medicines in rural areas therefore is mostly provided by pharmacies, branch pharmacies and pharmacy service points set up by Finnish community pharmacies. The university pharmacies are not allowed to establish such pharmacy service points. Yet, it is to be taken into account that only branch pharmacies but not pharmacy service points are allowed to sell POM (cf. section 10.1).

99 percent of all Finns live in a community with pharmacy services, provided either by a full pharmacy or a branch pharmacy.

30 percent of the Finnish population lives within one kilometre to the nearest pharmacy. 86 percent of the population have a distance of five kilometres to the nearest pharmacy. Only six percent of the population have a distance of ten kilometres or more. The average distance to a pharmacy is 3.87 kilometres in Finland (Yliopistonapteekki 2011).

10.2.2 Availability of medicines

Table 10.2 shows the service requirements laid down in several regulations and their implementation in practice.

Table 10.2: Finland – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	According to § 55 Medicines Act the amount of medicines, the equipment and supplies for administering medicines, and the dressings kept by a pharmacy must correspond to its usual customer needs.	98.4% of all prescriptions can be dispensed immediately when the customer comes to pharmacy. Thus the requirement is fulfilled.
Requirements concerning space	No specific regulations.	No information available.
Dispensing within a certain time period	No specific regulations.	In Finland the “dispensing security” is annually measured. 98.4% of all prescription-only medicines can be dispensed immediately and 98.5% can be dispensed at the same day in 2011 (Association of Finnish Pharmacies).
Frequency of delivery	No specific regulations.	Pharmacies are on average delivered two times per day. There are three delivering wholesalers in Finland (cf. section 10.1), which distribute pharmaceuticals within 24 hours from the order (except on holidays and week-ends, which is considered as a problem).

Source: Apteekkariliitto 2011

The availability of medicines can also be measured by the number of medicines authorized in a country. In Finland the number of authorized human medicines increased from 3,994 in 2000 to 7,018 in 2009. (The introduction of generic substitution in 2003 and of the reference price system in 2009 both have remarkably contributed to an increase in the total number of generic products in the market and therefore also impacted the increase in authorized human medicines (personal communication).

10.3 Quality of pharmacy services

10.3.1 Pharmacy staff

10.3.1.1 Availability of pharmacists and other qualified staff

In 2009 5,258 pharmacists, of which 1,407 full pharmacists and 3,840 prescriptionists, worked in community pharmacies in Finland (cf. Table 10.3). Prescriptionists need a bachelor's degree and may supervise branch pharmacies but not full community pharmacies (cf. section 10.1), their number has increased from 3,184 in 1995 to 3,862 in 2009. Prescriptionists are allowed to provide mostly the same services as pharmacists, i.e. they may dispense prescription medicines without direct supervision of a pharmacist. Nevertheless, the pharmacist is responsible for defining working procedures (Peura et al. 2007).

Table 10.3: Finland – Staff working in community pharmacies, as of 1 January 1990 – 2011

Pharmacy staff (counted per head)	**1990[1]**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010[2]**	**2011**
Number of pharmacists[3]	4,114	4,275	4,560	5,109	5,131	5,246	5,227	5,258	5,240	5,247
Of which:										
Full pharmacists	1,070	1,091	1,227	1,405	1,382	1,407	1,391	1,396	1,396	1,407
Prescriptio-nists	3,044	3,184	3,333	3,704	3,749	3,839	3,836	3,862	3,844.	3,840
Number of other staff [3]	2,171	2,328	2,623	3,249	3,105	3,060	3,520	3,067	3,071	3,032.
Of which:										
Pharmacy technicians /assistants [5]	593	534	536	n.a.	499	469	451	445	419	n.a.
Total staff	6,285	8,397	7,183	8,358	8,236	8,306	8,747	8,325	8,311	8,279

[1] excluding university pharmacies

[2] per 31 December 2011

[3] This includes active (full) pharmacists and prescriptionists. Not included is staff working in hospital pharmacies or in pharmacy-like outlets (e.g. public health centres).

[4] Other staff include all technical staff, which is not separated by tasks. Technical staff in Finland is responsible for all kinds of supportive tasks, such as logistics, billing, basic IT etc. In small pharmacies technicians are "multi-responsible" for several tasks. Cleaning often is outsourced.

[5] This includes technicians, who have limited rights to dispense OTC medicines. They may not provide information. Training has been abolished.

Source: KELA 1990-2009, Apteekkariliitto 2011

The number of community pharmacists including full pharmacists and prescriptionists has increased from 4,275 in 1995 to 5,247 in 2011.

The education of full pharmacists and prescriptionists is regulated in the Finnish Act on health-care professionals (cf. Table 10.4).

Full pharmacists need a master's degree in pharmacy science, the education has a duration of five to six years, including a practice training. Prescriptionists, which may dispense medicines without the supervision of a full pharmacist and may supervise branch pharmacies, need a bachelor's degree (three years) in pharmacy science also including a practise training. The training of pharmacy technicians with the right to dispense OTC medicines has been abolished.

Continuous education is mandatory for both prescriptionists and full pharmacists. The Association of Finnish Pharmacies encourages continuous education, which is provided by universities, professional organisations and other institutions. Also the Association of Finnish Pharmacies itself provides professional training of quality systems, automatic dose dispensing and together with the Pharmaceutical Learning Centre the programs with a focus on care of asthma, diabetes and coronary heart disease patients. About 70 percent of all pharmacists attend continuing education per year (Vogler et al. 2006).

Table 10.4: Finland – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	M.Sc.Pharm. (upper university	5 - 6 years	Yes	Yes	Act on health-care professionals 55/1994 5§
Prescriptionists	B.Sc.Pharm. (lower university	3 years	Yes	Yes	Act on health-care professionals 55/1994 5§
Pharmacy technicians /assistants with the right to dispense OTC medicines	Training was abolished.				
Pharmacy technicians/ assistants without the right to dispense medicines	Secondary school (= high school level)	3 years	Yes	No	Not available.

Source: Apteekkariliitto 2011

10.3.1.2 Professional independence of pharmacists

Multiple ownership of pharmacies is not allowed, yet a pharmacist may only own up to three branch pharmacies and the university pharmacy of Helsinki may own 16 branch pharmacies (cf. section 10.1). Vertical integration is not permitted.

According to an international pool Finns consider proprietary pharmacists, together with pilots and fire officers, as the most trustworthy professionals. 94 percent of the respondents in Finland trust in proprietary pharmacists (Apteekkariliitto 2011).

10.3.2 Product range

10.3.2.1 Medicines

Pharmacies in Finland dispense both POM and OTC medicines:

- Prescription-only medicines may only be dispensed by pharmacists. Subgroups in this category exist for medicines affecting the central nervous system and narcotics which have to be especially supervised by the Finnish Medicines Agency (FIMEA). The Agency is responsible for the classification of medicines in POM, its subgroups according to the Narcotics Act and OTC medicines (Peura et al. 2007).
- Most Over-the-counter (OTC) medicines except for NRT preparation may only be dispensed by pharmacies (pharmacy-only OTC medicines). A safe use of OTC medicines in Finland is ensured by advice and guidance of the pharmacy staff in the pharmacies (personal communication from an authority representative).

There are no direct incentives for the sale of OTC medicines in community pharmacies. Yet the regressive margin scheme provides for an indirect incentive for less expensive medicines, often OTC medicines in community pharmacies (cf. Table 10.6, section 10.4.3, Peura et al. 2007).

Nicotine replacement therapy (NRT) preparations are the only medicines which may be sold outside pharmacies (cf. chapter 1.1). NRT products must not be sold to individuals under 18 years. The sales assistants are not allowed to give any supervising at the purchasing situation. Sale from vending machines is prohibited. Municipalities may charge applicants for retail marketing authorisations for nicotine products. Municipalities may also charge holders of retail marketing authorisations an annual supervision fee for monitoring measures. The Finnish Medicines Agency may order separate instructions for use to be attached to NRT products sold by retail outlets. Where necessary, the Finnish Medicines Agency issues regulations on the content of such instructions (FIMEA 1987: §54 and §57).

Self-service of prescription-only medicines is not allowed. Self-care medicines may be placed in a customer area, but pharmaceutical advice and guidance is obligatory for self-care medicines. Self-service of NRT products in other retail outlets is allowed (AESGP 2011).

Most pharmacies in Finland have a laboratory or a place to manufacture pharmaceuticals. Pharmacists though prepare less than 1 percent of the medicines sold in these laboratories (Vogler et al. 2006).

10.3.2.2 Non-pharmaceuticals

Non-pharmaceuticals only play a small role compared to medicines in community pharmacies in Finland. They account for a comparatively low percentage of the pharmacy

turnover. In 2010 the non-pharmaceuticals accounted for 7.3 percent of the pharmacy turnover (cf. Table 10.7). Vitamins, bandages, tests etc. are commonly sold in pharmacies (personal communication).

In the last years non-prescription medicines in Finnish pharmacies have been moved to the customer area (self-care section) in front of the pharmacy counter. However, this is not self-care as there must be pharmacist available as stipulated in the Fimea's regulation.

10.3.3 Pharmacy services

10.3.3.1 Services provided by pharmacies

All community pharmacies in Finland provided the services of dispensing prescriptions, repeat dispensing and emergency contraception in 2010. Most pharmacies also offer disposal of waste medicines. Some community pharmacies provide manual dose dispensing, automatic dose dispensing, blood pressure measurement and asthma management. Smoking cessation, glucose measurement, cholesterol measurement and medicines reviews are provided by a few community pharmacies in Finland. Only one community pharmacy has night service (cf. Table 10.5).

Table 10.5: Finland – Services provided by community pharmacies, 2010

Pharmacies providing this service (number of pharmacies)	Type of service (number of pharmacies)
All (811)	Dispensing Prescriptions Repeat Dispensing Provision of Emergency Contraception
Most	Disposal of waste medicines (686)
Some	Manual dose dispensing (302) Other – Automatic Dose dispensing (269) Blood pressure measurement (184) Asthma management (92) Medicines Use Review (66)
A Few	Smoking Cessation (39) Glucose measurement (13) Cholesterol measurement (7) Vaccination (6) Night services (1)

Source: Apteekkariliitto 2011

10.3.3.2 Pharmaceutical counselling

There are voluntary and compulsory nation-wide standards for pharmaceutical counselling in Finland. Paragraph 57 of the Finnish Medicines Act regulates the counselling in community pharmacies. Every effort must be made, through the advice and guidance of all pharmacists to ensure that the users of the medicines are aware of the correct and safe use of the

medicine. In addition, the patients have to be informed about the prices of medicines and about other factors affecting their choice of medicines (Apteekkariliitto 2011, FIMEA 1987).

Finland has quality standards on good pharmacy practice and sticks also to ISO 9001:2000/ISO 9001:2008, EFQM. The assessment of quality of practice is being secured by professional audit and mystery shopping (PGEU 2010h).

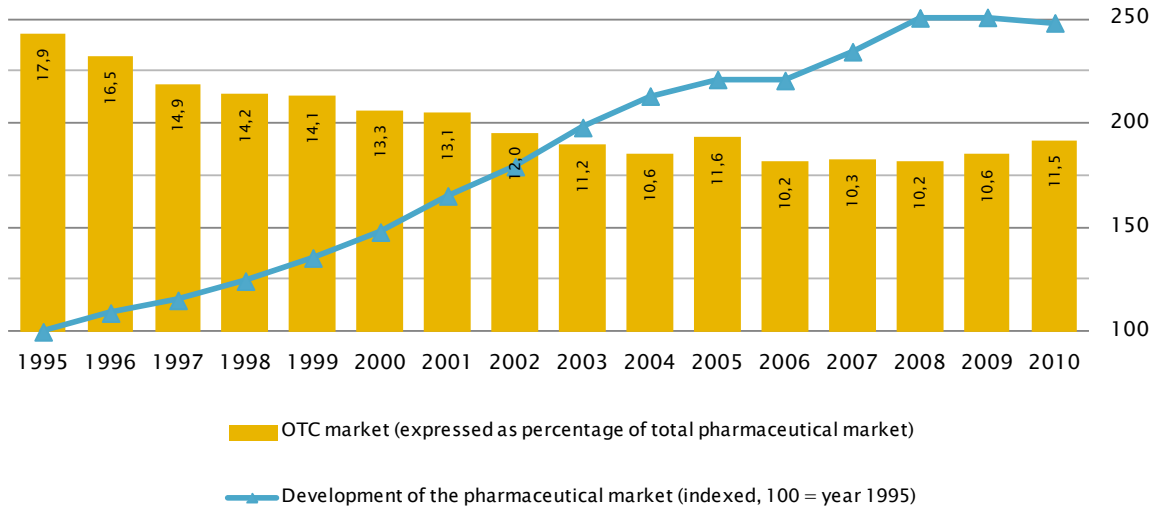
Counselling in Finnish community pharmacies is remunerated as a part of the margin.

10.4 Economics

10.4.1 Market data

The total pharmaceutical market has more than doubled from 1995 to 2010. The share of OTC medicines has recently slightly increased, yet on the long run decreased from 17.9 percent in 1995 to 11.5 percent in 2010 (cf. Figure 10.2).

Figure 10.2: Finland – Development of the pharmaceutical market, 1995 – 2010



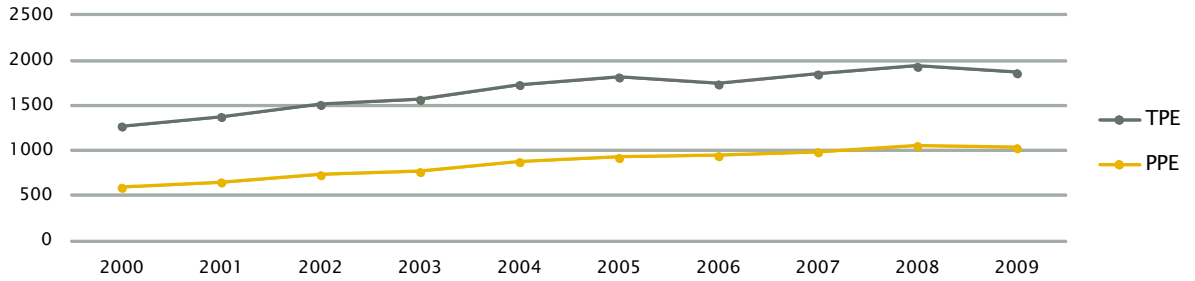
Data indicated at pharmacy purchasing price level

Source: AESGP 1995-2011

10.4.2 Pharmaceutical expenditure

In Finland total and public pharmaceutical expenditure increased from 2000 to 2009. Total pharmaceutical expenditure rose from € PPP 1,271.8 million in 2000 to € PPP 1,860.7 million in 2009. Public pharmaceutical expenditure increased from € PPP 592.4 million to € PPP 1,030.8 million 2009 (cf. Figure 10.3).

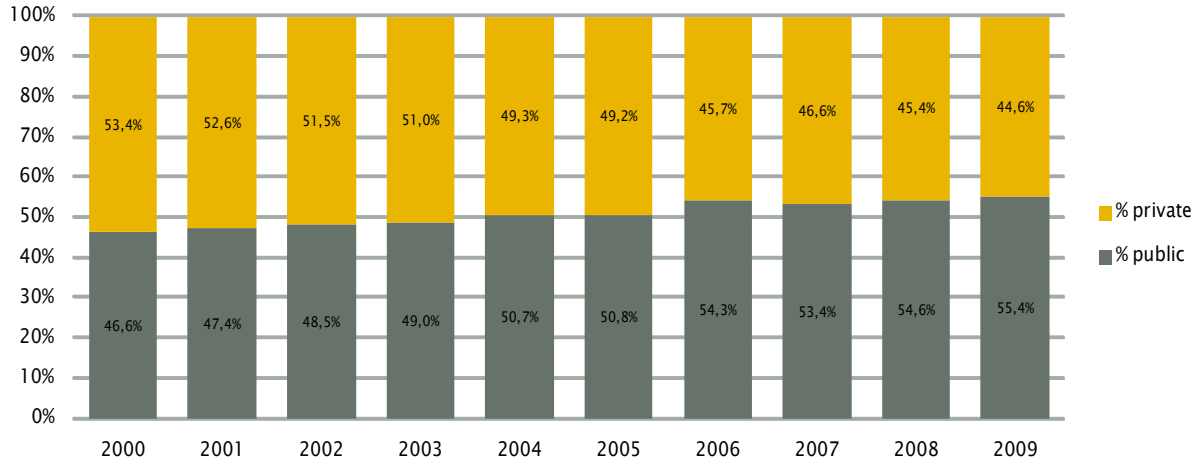
Figure 10.3: Finland – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

The public share of the total pharmaceutical expenditure has increased from 46.6 percent in 2000 to 55.4 percent in 2009. The share of private pharmaceutical expenditure therefore has decreased from 53.3 percent in 2000 to 44.6 percent in 2009 (cf. Figure 10.4).

Figure 10.4: Finland – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000–2009



Source: OECD 2011, PHIS 2011

10.4.3 Pharmacy remuneration and turnover

Pharmacies in Finland are remunerated via a statutory mark-up scheme, which applies for all medicines except NRT products and is regulated by the Government Decree on pharmacy margin 2002/1087. Additionally pharmacies in Finland are paid a fee of € 0.43 (incl. VAT 9 percent; corresponding to € 0.39 excl. VAT) for any prescription dispensed.

Pharmacies in Finland have to pay a special tax, called pharmacy fee, which is calculated from its turnover. The average pharmacy fee is about 7 percent of the turnover. This pharmacy fee subsidizes small pharmacies because the small pharmacies pay a lower fee than the larger ones, thus getting better margin. The smallest pharmacies do not pay the fee at all.

Table 10.6: Finland – Pharmacy mark-up scheme, 2011

Pharmacy purchase price (PPP) in €	Pharmacy mark-up coefficient in % of PPP
0 – 9.25 €	1.5 x PPP + 0.50 €
9.26 – 46.25 €	1.4 x PPP + 1.43 €
46.26 – 100.91 €	1.3 x PPP + 6.05 €
100.92 – 420.47 €	1.2 x PPP + 16.15 €
420.48 € and more	1.125 x PPP + 47.68 €

Source: Government Decree on pharmacy margin (1087/2002), updated information from (PPI 2011)

In 2010, the average margin for medicines in Finland amounted to 23 percent of the pharmacy retail price net referring to the total pharmacy market.

In theory, there are incentives for pharmacists, in the way how pharmacy remuneration is organized to sell more medicines, but not to sell more expensive medicine. However, pharmacies cannot influence the content of prescriptions, and promoting unnecessary medicine use is prohibited by law, also with self-care medicines.

Currently, a proposal of a new structure of the remuneration system is under consideration (personal communication).

The value-added tax (VAT) on all medicines (prescription-only and OTC products) was increased from eight to nine percent in July 2010. The tax increase was part of a legislative package agreed by the government the year before. The tax hike lifted annual medicine costs by about €2 0 million, of which patients had to pay about € 8.5 million and the Social Insurance about € 11.5 million (Apteekkariliitto 2011).

Table 10.7 shows the development of pharmacy turnover between 1990 and 2011. Medicines account for the largest part of pharmacy's turnover ranging between 92.71 percent and 95.2 percent. OTC medicines accounted for between 12.2 percent and 15.8 percent of the pharmaceutical sales in community pharmacies. Non-pharmaceuticals contribute a slightly rising share to the pharmacy turnover.

Table 10.7: Finland – Number of medicines dispensed and pharmacy turnover, as of 1 January 1990 – 2010

Prescriptions and turnover	1990	1995	2000	2005	2006	2007	2008	2009	2010
Prescriptions filled (in million items)	30.4	30.784	37.934	42.161	42.468	45.747	48.252	48.725	n.a.
Total pharmacy turnover in million €	n.a	1,048.7	1,440.7	2,092.4	2,068.8	2,161.8	2,320.4	2,323.2	2,302.5
Of which:									
Turnover of medicines	n.a.	n.a	95.0%	95.2%	94.8%	94.7%	94.5%	93.7%	92.71%
Turnover of OTC medicines	n.a.	n.a	15.8%	14.5%	12.2%	12.9%	12.7%	13.11%	13.3%
Turnover on non-pharmaceuticals	n.a	n.a	5.0%	4.8%	5.2%	5.3%	5.5%	6.3%	7.3%

Source: Apteekkariliitto 2011, KELA 1990-2009, Peura et al. 2007

The number on medicines dispensed (including OTC medicines) in total is not available. In 2009 48.7 million prescriptions were filled (KELA 1990-2009). In 2010 the Helsinki university pharmacy and its 16 branches processed about 4.6 million prescriptions (Yliopistonapteekki 2011).

11 Spain

11.1 Framework

Dispensing of prescription-only and of over-the-counter medicines is provided by community pharmacies in Spain. Community pharmacies therefore are the main actors of the pharmacy system in Spain, all pharmacies are privately owned. Community pharmacies may dispense prescription-only (POM and OTC (over-the-counter) medicines. In 2011 there are around 21,000 community pharmacies in Spain (cf. Table 11.1). Establishment and ownership of pharmacies are regulated. Ownership is basically limited to pharmacists (some forms of co-ownership is allowed, see below). Every pharmacist may own only one pharmacy. Therefore pharmacy chains do not exist in Spain. Branch pharmacies do neither exist, but there are so called “farmacia-botiquin”, which operate under supervision of a community pharmacy. Dispensing of medicines must be done by the pharmacy holder to which the “botiquin” is connected, and only in exceptional cases by the pharmacy technician. While they are basically defined by a federal law (Decree 1277/2003) as “health facilities authorised for possession, conservation and delivery of medicines and health products, by reason of existence of special difficulties of accessibility to a pharmacy”, specific regulations have additionally been developed at regional level.

There are no POM dispensing doctors in place, because of the high number of community pharmacies also in very rural areas. According to Medicines Law 29/2006, there is a professional incompatibility between prescribing and dispensing, and prescribers (doctors) are not allowed to dispense medicines. Moreover, according the Pharmacy Association, the establishment rules implemented in Spain guarantee the needed number of community pharmacies, even in rural areas (CGCOF 2011). Hospital pharmacies may dispense a selection of specific medicines (including some hospital-only medicines), as defined on a list by the Ministry of Health, Social Affairs and Equality, to out-patients (Martínez Vallejo et al. 2010).

The sale of POM via internet is prohibited by Medicines Law 29/2006. OTC medicines may be dispensed via internet pharmacies, provided that they are dispensed by an authorized pharmacy with the intervention of a pharmacist (PGEU 2010c). Nevertheless there is no specific regulation developed for this OTC online dispensing.

OTC medicines are manly sold by community pharmacies. Only “para-pharmaceuticals” like cosmetic products, phytotherapy, nutraceuticals etc. can be sold through other channels outside pharmacies such as supermarkets, specialist shops and para-pharmacies, with no license requirements (CGCOF 2011).

The main regulations concerning the Spanish pharmacy system are the

- The General Law 14/196 on Health, which defines pharmacies being subject to health planning and requirements for ownership.

- Act 16/1997 concerning the basic regulation of services in pharmacies, it regulates the establishment of pharmacies.
- Medicines Law 29/2006 regulating all the activities concerning pharmacy and around the medicine (provision, dispensing, independence, transparency, medicines legally recognized, definitions, quality/safety/effectiveness/identity requirements, authorization process, prescription/dispensing conditions, etc.).
- Law 2/2007 defining professional associations.

To establish a licensed pharmacy in Spain, regional authorities apply a set of demographic and geographic establishment criteria. The main aim is to ensure the accessibility and quality of pharmacy services and a sufficient supply of medicines to the population according to the health needs of each Autonomous Community of Spain. The Autonomous Communities take into account demographic and geographic criteria in their pharmacy planning. Each Autonomous Community has enacted legislation adapting these two general criteria to their own specific requirements. Yet, in most Autonomous Communities the minimum distances between pharmacies have been set at 250 metres and at 2,800 inhabitants per pharmacy (CGCOF 2009).

However, the Autonomous Community of Navarra liberalised their establishment rules significantly. In 2000, the Navarra Law on Pharmaceutical Care established the rule of opening of a new community pharmacy for every 700 inhabitants which was a liberalisation compared to the previous situation (Ilmo 2001). Additionally, the minimum distance between community pharmacies has been reduced to 150 metres. As a consequence the number of community pharmacies in Navarra has rapidly increased, especially in more populated areas (Borrell/Fernandez-Villadangos 2010). The number of pharmacies increased from 308 in 2000 to 531 in 2004. This has lead to pharmacies working on a very tight margin of stock, in some cases this has already caused under-supply (Vogler et al. 2006). In 2008 there were 583 community pharmacies, of which 190 in the capital city and 393 in the provinces, in Navarra. From 2004 to 2008 subsequently the number of pharmacies has not as fast increased as before, and eventually some pharmacies even had to close (personal communication by pharmaceutical system researcher and expert). In 2008, by the Law 20/2008, the Pharmacy Law was modified and the maximum number of community pharmacies per municipality was set to be per 700 inhabitants.

The practice of limiting the number of pharmacies had been dealt with in the European Court of Justice in June 2010. Young pharmacists from Asturia were denied a permit by the regional government to open a pharmacy (they did not succeed in the selection procedure, information CGCOF). The European Court of Justice (cases accumulated C-570/07 y C-571/07) ruled that the demographic and geographic limits set by Asturian legislation for the opening of new pharmacies constitute a restriction on the freedom of establishment (ECJ 2010a, ECJ 2010b). However, such measures can be, according to the Court, justified, provided that the following conditions are met: The measures have to be of general interest, they have to apply in a non-discriminatory manner, they have to be appropriate for attaining the objective and they must not go beyond what is necessary for attaining the objective (AESGP 2011).

Ownership of community pharmacies in Spain is limited to pharmacists. Every pharmacist has to register in the official college of pharmacists of the province in which they are practicing, which are the professional bodies that, among others, ensure the compliance with deontology rules and in charge of disciplinary sanctions. These regional colleges are represented at national level by the General Council of Pharmacists of Spain (CGCOF). The General Council is the representation, coordination and cooperation body of the pharmacy profession, which represents over 64,203 members (Martínez Vallejo et al. 2010).

Co-ownership is allowed, providing that the partnership of pharmacists (or a pharmacist) owns at least a 51 percent of a pharmacy (Law 2/2007, of 15 March, modified by Law 25/2009).

According to different interview partners (competent authority, associations, research) no change (liberalisation) with regard to ownership and establishment rules is expected. Overall, the current system is judged as a very valuable and sustainable one, also with regard to ensuring accessibility in rural areas.

Medicines are mainly provided by wholesalers. Direct sale from industry to pharmacy only accounts for about three percent. Together with other Mediterranean European countries, Spain is among the ones with a high number of wholesale companies in Europe (Costa-Font/Puing-Junoy 2004, Närhi 2009). There are about 106 wholesalers on the market, with the main groups Cofares, Alliance Healthcare and Hefame, together representing approximately 40 percent of the total market (AESGP 2011). Regional wholesalers (55 companies) account for the largest part of the market share (58 percent) in Spain (Kanavos et al. 2011). Most of these regional wholesalers are owned by pharmacist-owned co-operatives, which, in total, control 75 percent of the market.

Wholesalers are represented by their association Fedifarm. In 2003 the requirement for wholesalers to provide information to manufacturers on the destination of medicines purchased was introduced. For medicines in Spain, manufacturers have to sell at the price approved by the Spanish National Health Service, but they can apply a different price if the medicines are sold in other countries than Spain (Costa-Font/Puing-Junoy 2004). This “dual pricing” (specified in Article 101 of the Medicines Law) was allowed to prevent parallel exports. However, meanwhile, parallel exporting is no longer an issue since the key destination market, United Kingdom, has become a parallel exporter, while Spain has moved from a parallel exporting to a parallel importing country (Garau/Mestre-Ferrandiz 2006, Macarthur et al. 2006) literature, personal communication by pharmaceutical system researcher and expert).

COFARES (Cooperativa Farmacéutica de España) is the largest pharmaceutical cooperative and wholesaler in Spain. There are other regional cooperatives in Asturias (COFAS), León, Cantabria, Galicia, Madrid, Aragón (SAFA, which was taken over Alliance UniChem in 1998), etc. (CGCOF 2011).

There are around 250 pharmaceutical companies with production activity in Spain, most of them being small- to medium-sized enterprises (Farmaindustria 2011). Price control is with

the federal government (the manufacturer negotiates an agreement with the pharmaceutical companies (Martinez et al. 2010).

11.2 Accessibility

11.2.1 Accessibility of medicines dispensaries

11.2.1.1 Provision of POM dispensaries

In 2011 there are 21,364 community pharmacies. The number of "farmacia-botiquin", i.e. pharmacy outlets under the supervision of a pharmacy, is not available. Hospital pharmacies dispense medicines for all in-patients, but only for specific medicines (not available at community pharmacies) and for patients previously attended in the hospital, hospital pharmacies can dispense to out-patients. The number of community pharmacies has increased (cf. Figure 11.1) from 17,651 community pharmacies in 1990 to 21,364 in 2011 (cf. Table 11.1). Not included in the Table 11.1 are the "farmacia-botiquines", i.e. pharmacy outlets under the supervision of a pharmacy, which provide pharmaceutical provision in villages in with a very low number of inhabitants. They are very exceptional and rare.

Table 11.1: Spain – Number of community pharmacies and other POM dispensaries[1], as of 1 January 1990 – 2011

POM dispensaries	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Community pharmacies	17,651	18,593	19,439	20,461	20,579	20,741	20,941	21,057	21,164	21,364
POM dispensing doctors	0	0	0	0	0	0	0	0	0	0
Hospital pharmacies dispensing POM to out-patients	All hospital pharmacies may dispense certain medicines to out-patients, here they are not counted as frequent POM dispensaries.									
Internet pharmacies dispensing POM	0	0	0	0	0	0	0	0	0	0
Other POM disppenaries	0	0	0	0	0	0	0	0	0	0
Total of POM dispensaries[2]	**17,651**	**18,593**	**19,439**	**20,461**	**20,579**	**20,741**	**20,941**	**21,057**	**21,164**	**21,364**

POM = prescription-only medicine

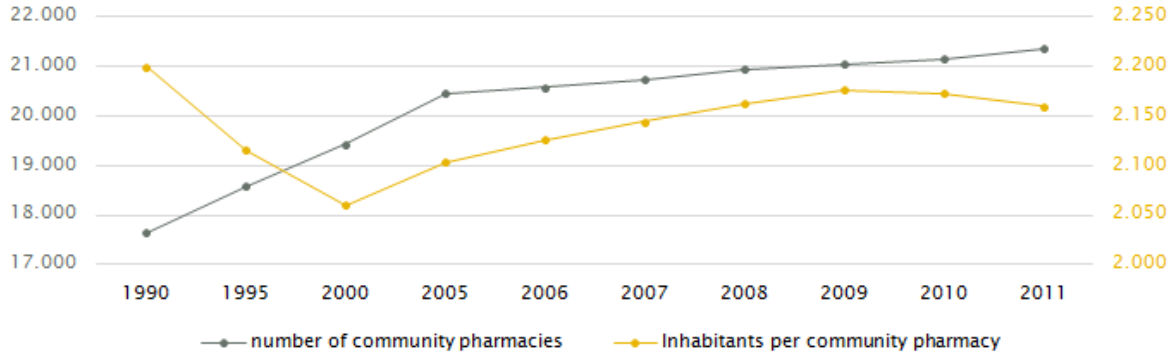
[1] Retailers which are allowed to dispense prescription-only medicines

[2] Number of total POM dispensaries without farmacia-botiquins and hospital pharmacies

Source: CGCOF 2009, PHIS 2010b

The total number of community pharmacies in Spain corresponds to the number of POM dispensaries. Because of an increasing number in community pharmacies, the density of community pharmacies has been increasing (cf. Figure 11.1).

Figure 11.1: Spain – Number of community pharmacies and inhabitants per community pharmacy, 1990 – 2010



Source: CGCOF 2009, Martinez et al. 2010

11.2.1.2 Provision of POM dispensaries in rural areas

Pharmacy planning in Spain takes into account population density, geographic characteristics and population distribution of each Autonomous Community and therefore concentrates on equal availability of medicines between urban and rural areas.

Rural areas are defined by Law 45/2007 for the sustainable development of rural areas, as the "geographical space formed by the aggregation of smaller local municipalities or entities defined by the competent authorities which have a population less than 30,000 inhabitants and a density less than 100 inhabitants per km^2".

98.9 percent of the Spanish population resides in municipal districts with at least one community pharmacy (CGCOF 2010). This results in 87 percent of the population having a pharmacy within 250 m of their home, and 97.3 percent of the population having a pharmacy at a distance of 5 km or less, using to reach it between 2.5 and 6 minutes.

The number of inhabitants per pharmacy in 2010 was 2,201 in total, 1,952 in province capitals and 2,344 in the rest of municipalities. 21.3 percent of all community pharmacies are established in villages of fewer than 5,000 inhabitants (Antares 2011).

Pharmaceutical services of “botiquines” are exceptional and rare because in Spain, as mentioned above, there are 21.3 percent of community pharmacies established in villages with less that 5,000 inhabitants; 2,078 are established in villages with less than 1,000 inhabitants and 1,076 of them in areas with less than 500 inhabitants. With this distribution, the establishment of “botiquines” is reserved to sparsely populated areas or areas with certain accessibility difficulties. “Botiquines” are only able to operate under supervision of and complementary to a community pharmacy (CGCOF 2009). The number of these pharmacy outlets dispensing POM and OTC medicines is not available (CGCOF 2011).

There are no economic incentives regulated at a national level for pharmacies to be established in rural areas, but according to different regional legislations, pharmacists

working in rural pharmacies get additional points (in professional practice) in public competition for the assignment of new pharmacies.

11.2.2 Availability of medicines

Table 11.2 shows the service requirements laid down in several regulations and their implementation in practice.

Table 11.2: Spain – Pharmacy service requirements, 2011

Service requirements	Regulation	Practice
Medicines in stock	A minimum legal stock is legally required for pharmacies (Ordonance 5 of May 1965). Non-compliance of the regulation is subject to serious sanctions. The sanctions regime has been updated by Law 29/2006. The Autonomous Communities may elaborate their own list of legal minimum stock adapted to their particularities.	Mostly the regulations are fulfilled, also because of the sanctions.
Requirements concerning space	There are specific regulations laid down by the Autonomous Communities: for example, Aragón establishes a minimum 80 m^2, Cantabria 70 m^2 and The Basque Country 75 m^2.	No information available.
Dispensing within a certain time period	No specific regulations.	Medicines are normally made available to the costumer on average within 3 to 4 hours.
Frequency of delivery	No specific regulations.	Pharmacies are on average delivered 3 times per day (Kanavos et al. 2011). A wide network of pharmaceutical distributors (most of them pharmacist cooperatives) allows for a fast and frequent delivery also for pharmacies in rural areas.

Source: CGCOF 2011, Kanavos et al. 2011

11.3 Quality of pharmacy services

11.3.1 Pharmacy staff

11.3.1.1 Availability of pharmacists and other qualified staff

In 2011 43,682 registered pharmacists work in community pharmacies in Spain (cf. Table 11.3). 55 percent are holders of pharmacy licenses, who bear all professional responsibilities

for the services provided in the pharmacy. The characteristics of license holders are laid down in regional laws 37.3 percent are adjoints, their number may be fixed by the Autonomous Communities. Pharmacy adjoints are pharmacists working in collaboration with the holder, regent or substitute in a community pharmacy where s/he is not the holder or owner. 6.6 percent are so-called substitutes, who are also full qualified pharmacists working under exceptional circumstances (disease, temporary disability, public service, etc.) instead of the pharmacist holder of the authorization or regent on a temporary basis. A regent is a pharmacist that is not the owner of the pharmacy but is authorized and appointed as such in cases of death or permanent disability, as well as by legal incapacity or by legal statement of absence (of the pharmacist owner) and on a temporary basis. The number of pharmacy technicians working as auxiliary staff was 0.8 percent in 2010 (CGCOF 2009, CGCOF 2011).

The number of community pharmacists has more than doubled from 19,824 in 1990 to 43,682 in 2011.

Table 11.3: Spain – Staff working in community pharmacies, as of 1 January 1990 – 2011

Pharmacy staff (counted per head)	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Number of pharmacists [1]	19,824	23,112	28,863	37,075	38,311	40,680	41,128	42,371	43,603	43,682
Number of other staff	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total staff counted per head	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

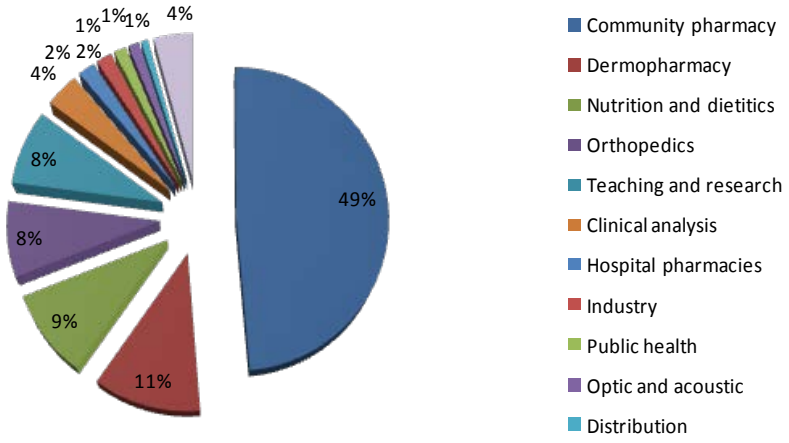
n.a. = not available

[1] This includes pharmacists. Pharmacists working in hospital pharmacies or in other health centres, pharmacists working in pharmaceutical companies, in research, in pharmacy professional associations, etc., retired pharmacists and pharmacists in training, are not included

Source: CGCOF 2011

To become a pharmacist a University Degree in Pharmacy is required. The university education has duration of five years, including six month practice training. The requirements for pharmacists are laid down in the Royal Decree 1837/2008 and Order CIN/2137/2008. At the moment 20 faculties provide a degree in Pharmacy. There are currently 19,000 registered students, resulting in 2,500 to 2,700 degrees awarded every year (data corresponding to 2008/2009, CGCOF 2009).

Figure 11.2: Spain – Working fields of pharmacists, 2009



Source: CGCOF 2009

Continuous education is voluntary (cf. Table 11.5). About 300 places for continuous education for pharmacists are offered by universities. Additionally some private institutions and professional bodies provide possibilities for continuous education. The General Council of Pharmacists (CGCOF) develops several training activities such as the National Plan of Continuous Development, health campaigns and the Strategic Plan on Pharmaceutical Care.

Pharmacy assistants are called pharmacy and parapharmacy technicians and have to complete a 2,000 hours formation (two years) including a three months practice training during the last quarter of the formation. The profession of pharmacy assistants is regulated in the Royal Decree 1689/2007. Continuous education is not required (MDE 2011).

The regulatory provisions, which regulate the professional qualifications of pharmacy technicians (Royal Decree 1689/2007, Art. 5), state that pharmacy technicians assist in the dispensing of medicines informing of its characteristics and its rational use. So they may help the pharmacist in the dispensing. The law does not distinguish between POM and OTC (personal communication).

Table 11.4: Spain – Required qualification of pharmacy staff, 2011

Profession	Required qualification	Duration	Practice training required	Continuous education required	Legal basis
Full pharmacists	University, master degree	5 years	Yes, duration 6 months included in the 5 years	Voluntary, but commonly taken out	Royal Decree 1837/2008 of November 8 Order CIN/2137/2008
Pharmacy technicians	Pharmacy and Parapharmacy Technician formation	2 years (2,000 hours)	Yes, 3 months included in the 2 years	No	Royal Decree 1689/2007 of December 14

Source: CGCOF 2011

11.3.1.2 Professional independence of pharmacists

While co-ownership of pharmacies under specific conditions is allowed (cf. section 11.1), multiple ownership as such, permitting the establishment of pharmacy chains is not permitted. Every licensed pharmacist may own one pharmacy (PHIS 2010b, cf. section 11.1). The professional independence of pharmacists is thus total.

11.3.2 Product range

11.3.2.1 Medicines

Medicines, including OTC products, are according to the 2006 Medicines Law only available in pharmacies (cf. sections 11.1 and 11.2.1.1) Self-service of OTC medicines in pharmacies is not explicitly forbidden by law, but it is not practiced in general. Self-service is used, in certain cases, for para-pharamceuticals.

It is common that pharmacies produce medicines (magistral formulas and officinal preparations), most pharmacies therefore have a laboratory or a place to manufacture pharmaceuticals (CGCOF 2011).

11.3.2.2 Non-pharmaceuticals

Medicines are limited exclusively for sale in pharmacies. Only “para-pharmaceuticals” like cosmetic products, medical devices, food supplements, preservatives, phytotherapy, nutraceuticals and other consumer goods are sold through other channels outside pharmacies such as supermarkets, specialist shops and para-pharmacies, which require no license (CGCOF 2011).

11.3.3 Pharmacy services

11.3.3.1 Services provided by pharmacies

Filling prescriptions, dispensing, consulting patients, providing disposal of waste medicines and emergency/night services are services provided by all community pharmacies in Spain. Repeat prescriptions services are available in some regions of the country (mostly electronic prescription services and chronic treatments). Also homecare services, smoking cessation and pregnancy tests are available in some community pharmacies. Additionally measurement of blood pressure, glucose, cholesterol and weight may be provided by some community pharmacies in Spain (PGEU 2010g). Other community pharmacies can provide services such as methadone maintenance, HIV-AIDS test, needle exchange, etc. (information provided by CGCOF).

In Spain the Medication Use Review is part of the pharmaceutical care services provided by some community pharmacies, as part of Pharmacotherapy follow-up service. Similarly, the management of diabetes, asthma, hypertension, and other similar services could be included in the Service of Pharmacotherapy follow up (CGCOF 2011).

11.3.3.2 Pharmaceutical counselling

Pharmaceutical counselling in Spain is associated to three cognitive services: Dispensation (advice on POM), Pharmaceutical Indication for minor ailments (advice on OTC) and Medicines Review with Pharmacotherapeutical follow up (Seguimiento Farmacoterapeútico, SFT). These services were already carried out in the usual day to day in the professional standard practice of the pharmacist at community pharmacies in Spain, although at one time a greater orientation toward the patient and its generalization, as well as proper documentation and uniform protocolization of the actions at national level were deemed necessary.[1]

The pharmacotherapeutic follow-up includes review of the medication, to improve adherence to treatment and to promote the rational use of medicines, but goes beyond medicines use reviews (MUR), is a full service in which the pharmacist must try to identify, assess, and prevent adverse outcomes associated with the use of medications (NMR) as well as identify, evaluate and resolve the problems associated with medication (PRM) which have or which

[1] Although these services were already being carried out at community pharmacies in Spain, the practice differed as several groups have their own protocols. Since 2004 uniform protocols at national level on cognitive pharmaceutical services in community pharmacies in Spain have been developed through the Forum of Pharmaceutical Care, where the General Council together with scientific societies and research networks have been involved. Since then a Strategic Plan of Pharmaceutical Care has been put in place. The generalisation of these protocols is carried out through its dissemination and the development of pilots that show evidence of improved health and quality of life results directly derived from these services. This evidence also shows results in sustainability, in terms of savings to the health system that are being quantified. This Strategic Plan provides pharmaceutical care training programmes involving thousands of pharmacists annually. More information in http://www.portalfarma.com/pfarma/taxonomia/general/gp000030.nsf/vwDocumentos/102D18D0482BCDA0C125717F005663C4?OpenDocument).

may have an impact on the health of the same, through their professional intervention. Also this pharmaceutical follow-up requires collaboration between the different health professionals (Castrillon , Fornos et al. 2006) (CONsigue no year).

Pharmacist counselling is not only about medicines but also pharmacist is qualified for advice in e.g. nutrition, skin care and life styles. Also we could consider pharmaceutical counselling the education for health and the prevention programmes.

The daily visits of community pharmacies in Spain amount up to two million people, the total annual visits represent 577 million visits. One out of three patients requesting an OTC medicine leaves without purchasing. This was estimated to be equivalent to 70 million physician visits, 59 million nursing consultation, and 1.5 million hospital emergency visits, representing 29 percent of acts of primary care, or 25 percent accesses to the national health system. The counselling, pharmacotherapy monitoring and other services besides dispensing undertaken by pharmacists have been estimated as being worth around € 1,740 million (CGCOF 2003).

In order to support this counselling, the General Council of Pharmacists of Spain has developed a IT tool named BOT PLUS: a comprehensive health knowledge database first created 30 years ago in order to meet certain information requirements pharmacists were claiming in order to achieve a better practice. It is implemented virtually in all community pharmacies in Spain. This medicine database is fully integrated in the dispensing pharmacy software. The information comes from official sources such as the Spanish Medicines Agency (AEMPS), Directorate General for Medicines and Medical Devices, pharmaceutical companies, wholesalers, pharmaceutical services from the Autonomous Regions, European Medicines Agency (EMA), international medicines databases, international pharmacopoeias, etc. In 2007 BOT obtained the ISO 9001:2000 accreditations and since June 2009, it has been recognised by the EMA as an official source for medicines information in Spain.

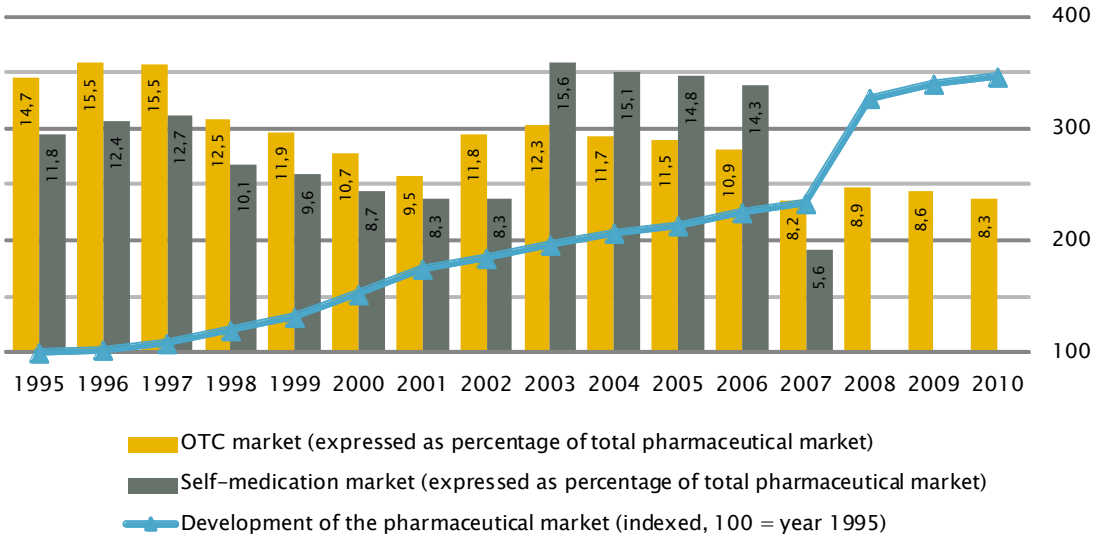
The professional bodies, the General Council of Pharmacists and regional and provincial Chambers, have developed voluntary standards for good counselling in Spain (CGCOF 2011).

11.4 Economics

11.4.1 Market data

While the total pharmaceutical market has more than tripled from 1995 to 2010, the share of OTC medicines has decreased with fluctuations as can be observed from Figure 11.2. The market share of self-medication products has also been very fluctuant, with a downturn from 14.3 percent in 2006 to 5.6 percent in 2007 (cf. Figure 11.3).

Figure 11.3: Spain – Development of the pharmaceutical market, 1995 – 2010



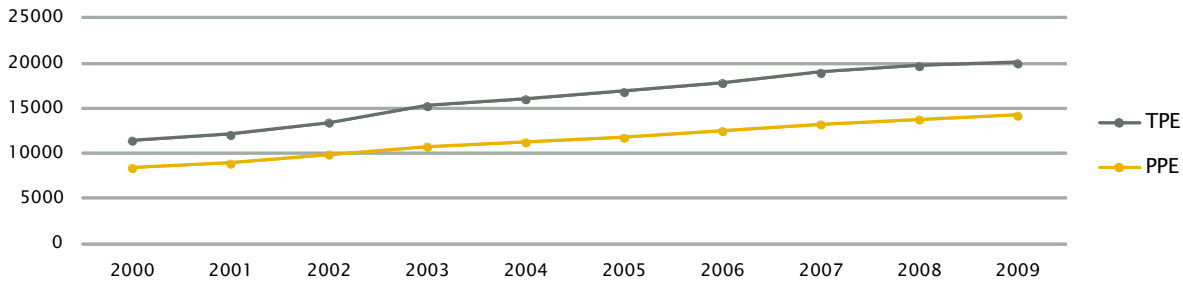
Data indicated as consumer price level

Source: AESGP 1995–2011

11.4.2 Pharmaceutical expenditure

Total pharmaceutical expenditure increased from € PPP 11,458.0 million in 2000 to € PPP 20,021.8 million in 2009. Public pharmaceutical expenditure increased from € PPP 8422.6 million to € PPP 14,230.4 million in 2009 (cf. Figure 11.4).

Figure 11.4: Spain – Total and public pharmaceutical expenditure in million Euro PPP (out-patient), 2000 – 2009



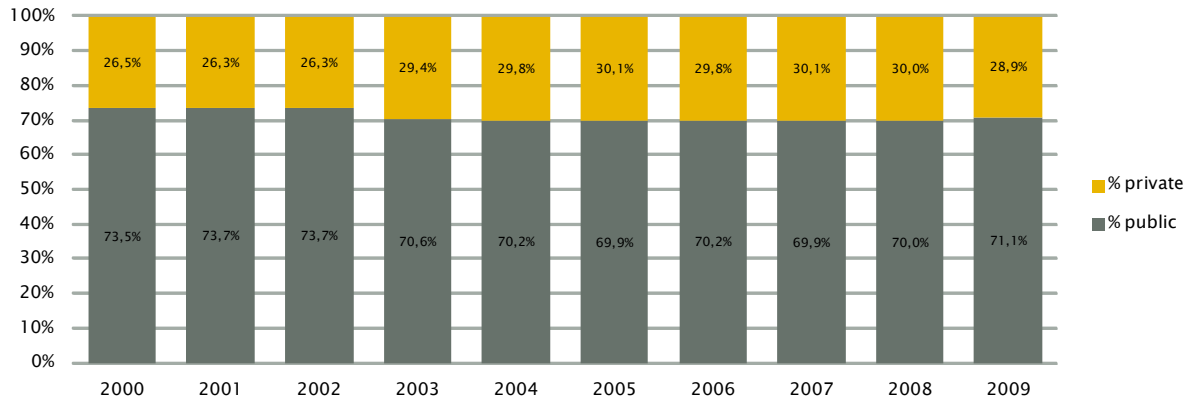
TPE = total pharmaceutical expenditure, PPE = public pharmaceutical expenditure

Source: OECD 2011, PHIS 2011

The public share of the total pharmaceutical expenditure in Spain is high, compared to other countries (PHIS 2011) and has stayed relatively stable from 2000 to 2009. The public share has all in all slightly decreased from 73.5 percent in 2000 to 71.1 percent in 2009. The share

of private pharmaceutical expenditure therefore has slightly increased from 26.5 percent in 2000 to 28.9 percent in 2009 (cf. Figure 1.4).

Figure 11.5: Spain – Share of public and private pharmaceutical expenditure in % of total pharmaceutical expenditure (out-patient), 2000 – 2009



Source: OECD 2011, PHIS 2011

11.4.3 Pharmacy remuneration and turnover

In Spain, margins are fixed statutorily according to the actual Royal Decree 4/2010. These statutory margins are applied to all medicines of human use manufactured industrially excluding magistral formulas. Spain has regressive margins both for wholesale and pharmacy remuneration.

- If the ex-factory price is equal or inferior to € 91.63, the margin for pharmacy is 27.9 percent of pharmacy retail price (PRP) (VAT excluded).
- If the ex-factory price is superior to € 91.63 and below or equal € 200, the margin is € 38.37 per package.
- If the ex-factory price is superior to € 200 and below or equal € 500, the margin is € 43.37 and if the ex-factory price is superior to € 500, the margin is € 48.37.

The latest change of the pharmacy remuneration took place during the emergency laws in response to the global financial crisis. While a part of the pharmacy margin (namely for expensive medicines) was increased, the prices of generics were cut by 30 percent and the prices of original products were subject to a discount (instead of a price cut) which has to be provided to the National Health Service by all pharmaceutical actors, including the pharmacies (Vogler et al. 2011).

In August 2011 (Decree 9/2011), the Spanish Government passed a new package of measures to control the pharmaceutical expenditure. It introduced mandatory INN prescribing (i.e. prescribing by active principle, before indicative) and the dispensing of the lowest priced medicines (in some regions this obligation already existed but now it has been extended at national level). A 15 percent deduction on the price of innovative medicines that have been on the market for ten years, but that are excluded from the reference price system

as there are no generic medicines in their category was introduced. Moreover, a compensation system has been set up for pharmacies in small towns and villages (less than 1,500 inhabitants), modifying the profit margin to compensate for the pharmaceutical services that they provide in these locations (Table 11.6).

Spain applies a claw-back system at pharmacy level. Pharmacies have to make payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices. In July 2010 this system was updated which was also a reaction in reaction to global financial crisis (Kanavos et al. 2011) (cf. Table 11.5).

Table 11.5: Spain – Pharmacy claw-back system (scale of deductions), 2011

Total sales pharmacy retail price	Deduction in €	Percentage
0.00 – 37,500.00	0.00	0,00
37,500.01 – 45,000.00	0.00	7,80
45,000.01 – 58,345.61	585.00	9,10
58,345.62 – 120,206.01	1,799.45	11,40
120,206.02 - 208,075.90	8,851.53	13,60
208,075.91 - 295,242.82	20,801.83	15,70
295,242.83 - 384,409.77	34,487.04	17,20
382,409.77 – 600,000.00	49,479.75	18,20
More than 600,000.01	89,081.17	20,00

Source: CGCOF 2011

For pharmacies with too low turnover a corrective index of its margins is applied (cf. Table 11.6).

Table 11.6: Spain – Corrective index for low turnover pharmacies, 2011

Total sales pharmacy retail price	Percentage	Fixed amount
0.01 – 2,750.00	7,25	0
2,750.01 – 5,500.00	7,75	199,38
5,500.01 – 8,250.00	8,25	412,50
8,250.01 – 10,466.66	8,75	639,37
10,466.67 – 12,500.00	0	833,33

Source: CGCOF 2011

In 2009, the average margin for reimbursable medicines was 22.4 percent of pharmacy retail price, ranging from 26.7 percent on average in pharmacies with a low turnover, which are not subject to the pharmacy claw-back system, to an average 14.9 percent for pharmacies with high turnover (CGCOF 2009).

The VAT rate for pharmaceuticals is 4 percent in Spain (Martinez 2010, PPI 2011).

Table 1.7 shows the development of pharmacy turnover between 1990 and 2011. Medicines account for the largest part of pharmacy's turnover. OTC medicines account for a small part of the pharmaceutical sales. Also non-pharmaceuticals only contribute to the pharmacy turnover.

In 2009 1,196,349 prescriptions were filled and 98,300 OTC medicines were dispensed in Spain. The total number of medicines dispensed therefore was 1,294,549 in 2009 (Farmaindustria 2009). In 2010, the total number of medicines dispensed in Spain was 1,292,000 (CGCOF 2010, cf. Table 11.6).

Table 11.7: Spain – Number of medicines dispensed and pharmacy turnover, as of 1 January 1990 – 2010

Medicines dispensed and pharmacy turnover	**1990**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
Number of medicines dispensed (in million items)	901.5	962	1,045.7	1,163.6	1,170.4	1,271.9	1,275.8	1,288.2	1,292.0
Of which:									
Prescriptions filled (in million items)	515.8	536.2	608.1	776.2	806.4	854	900.9	947.4	969.7
OTC (in million items)	n.a.	n.a.	437.6	387.4	364	417.9	374.9	340.8	322.3
Total pharmacy turnover in million €	n.a.	n.a.	10,750.8	16,037.6	16,979.8	18,331	18,906.1	19,388.8	19,286.5
Of which:									
Turnover of pharmaceuticals	3,670.0	6,014.1	9,114.9	13,579.7	14,235.7	15,370.1	16,011.8	16,514.2	16,490.8
Turnover of OTC medicines	n.a.	370.3	502.7	552.5	523.6	604.6	546.6	541.4	546.9
Turnover on non-pharmaceuticals	n.a.	n.a.	1,636.0	2,457.9	2,744.0	2,960.9	2,894.3	2,874.6	2,795.6

Source: CGCOF 2010

12 Comparative analysis

In this chapter, we present facts and figures about the community pharmacy systems in the nine countries surveyed and discuss their implications in a comparative way. The comparative analysis is based on comprehensive, self-explanatory text tables and the presentation of quantitative data in figures.

We are aware that a comparison is always a simplification, this is necessary for the sake of readability. For further details we advise to consult the country reports in chapters 3 to 11.

The comparative analysis includes all the indicators defined for the analysis, and follows the structure of the three pillars around which the indicators are built: accessibility (section 12.2), quality (section 12.3) and economics (section 12.4). These sections are preceded by an introductory section (section 12.1) comparing the regulatory frameworks in the surveyed countries).

England, Ireland, the Netherlands, Norway, and Sweden are summarized as the group of deregulated (or, alternatively, liberalised) countries, while the “control group” countries, Austria, Denmark, Finland, and Spain, are referred to as regulated countries. In Sweden the deregulation process is called “reregulation” (cf. chapter 7). It should be noted that the process and timing of the liberalisation in the community pharmacy sectors were different across the deregulated countries (e.g. a deregulation in Norway and Sweden versus a more liberal environment for decades in the other countries). In the tables and figures, first the deregulated countries will be presented, followed by the regulated countries.

12.1 Regulatory framework

With regard to the regulatory framework for the community pharmacy sector, establishment and ownership rules are of key relevance. Additionally, community pharmacies might be concerned by a number of regulations (e.g. qualification of staff, rules regarding medicines in stock, space, frequency of dispensing).

During the last decade the community pharmacy sector in several European countries has come under pressure following infringement procedures launched by the European Commission. Two landmark decisions were the rulings of the European Court of Justice (ECJ) in the cases against German and Italian legislation granting the right to own and operate a pharmacy exclusively to pharmacists. The German case involved several pharmacists and their professional associations challenging a decision to allow a Dutch public limited company to operate a branch pharmacy in the German town of Saarbrücken. The Italian case was an action brought by the European Commission alleging that the Italian law contravened EU law.

On 19 May 2009 the ECJ ruled that, while restrictions on ownership and operation of pharmacies constitute a restriction on freedom of establishment and the free movement of

capital, these restrictions can be justified (ECJ 2009a, ECJ 2009b). Each EU Member State has discretion to determine its own level of protection of public health, and thus EU Member States' national legislation may restrict pharmacy ownership and operation to persons having the status of a pharmacist.

These rulings were considered as precedent-setting for the other EU Member States, some of which were facing similar infringement procedures. A ruling of the ECJ as of 1 June 2010 regarding geographic and demographic criteria set by the legislation of the Spanish Autonomous Community Asturia endorsed the principle that measures regulating establishment and ownership can be justified (ECJ 2010a and ECJ 2010b, cf. section 11.1).

On 23 November 2011, European Commission announced the dropping of all charges against Member States regarding the pharmacy sector. This had concerned several countries, also one of those surveyed in this study, Austria (PGEU 2011).

12.1.1 Establishment rules

In the five deregulated countries, there are no statutory establishment rules in place. In Norway they were abolished in 2001 following the deregulation of the pharmacy sector, and in Sweden the establishment of a pharmacy was regulated before 2009 so that the public pharmacy company Apoteket was the sole owner of all pharmacies. In 1996, Ireland introduced establishment rules, comprising demographic and geographic criteria as well as the requirement of not affecting the viability of existing pharmacies, but revoked them in 2001. While there had never been statutory establishment rules in the Netherlands, the Dutch pharmacists association applied its own establishment policies which also considered geographic and viability criteria. After legal proceedings the Dutch pharmacists association was no longer allowed to apply sanctions in their establishment policy from 1987 on, and it was forbidden by the Law on Competition in 1998.

In the four regulated countries statutory establishment rules are applied. While in Austria and Spain a minimum number of inhabitants to be supplied and a minimum distance to the next pharmacy are written in the laws, there are no pre-defined geographic or demographic criteria in the Nordic countries Denmark and Finland. The competent Medicines Agencies in these countries, which are in charge of granting licenses to new pharmacies, base their decisions on the needs of each municipality, consider geographic and demographic characteristics and apply a system of merit among pharmacists applying for vacant licenses. All four regulated countries apply the establishment regulation at national (federal) level. In addition, the Autonomous Communities in Spain, which are granted responsibilities in the organisation of health care, are allowed to adapt the national criteria to their regional peculiarities. This had the effect that in the Autonomous Community of Navarra the establishment rules as defined in the year 2000 were rather liberal compared to the previous regulation which resulted in difficulties regarding the viability of pharmacies due to the opening of several new pharmacies and also in the provision of medicines. In 2008, the establishment criteria were modified in Navarra (cf. section 11.1).

Even in the deregulated countries some restrictions to the opening of new pharmacies are in place. In England, to guarantee viability, a pharmacy needs to dispense state funded NHS

pharmaceutical services. In order to do so, an applicant for a pharmacy must pass the "control of entry test". After deregulation following a study of the competition authority, the Office of Fair Trading (OFT), four types of the pharmacies were exempted (see section 3.1 and the notes to Table 12.1). In the Netherlands, health insurance funds, which, since 1992, are no longer obliged to contract every pharmacy, are interested in the viability of the contracted pharmacies and have therefore become involved in the choice of the location of a pharmacy (i.e. not too close to an existing contracted pharmacy).

Table 12.1: Comparative analysis – Establishment rules for community pharmacies, 2011

Country	Establishment regulation			Criteria for establishment of new pharmacies	
	Y/N	Level	Provision	Geographic	Demographic
England	No[1]	-	-	-	-
Ireland	No[2]	-	-	-	-
Netherlands	No	-	-	-	-
Norway	No[3]	-	-	-	-
Sweden	No[4]	-	-	-	-
Austria	Yes	National	Statutory	Minimum distance of 500 metres to next pharmacy	Minimum number of 5,500 supplied persons
Denmark	Yes	National	Statutory	License system: needs assessment concerning geographic and demographic determinations by authorities	
Finland	Yes	National	Statutory	License system: needs assessment concerning geographic and demographic determinations by authorities	
Spain	Yes	National & regional[5]	Statutory	Minimum distance of 250 metres to next pharmacy	Minimum number of 2,800 inhabitants

1 The viability of a pharmacy is connected to its contract to dispense NHS prescriptions for which a pharmacy owner must apply to the local NHS administration. Four categories of pharmacies are exempt from this "control of entry test" rule (2005 pharmaceutical service regulation): 100 hour pharmacies (the exemptions are proposed to be abolished in 2012 and replaced by local Pharmaceutical Needs Assessments published by Primary Care Trusts), Out-of-Town Shopping Developments, Mail Order or Internet based pharmacies and One-Stop Primary Care Centres.

2 From 1996 to 2001 establishment rules (defining geographic, demographic and viability criteria) were applied.

3 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. Now, 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.

4 Until 2009 all community pharmacies were owned by the public company Apoteket.

5 The general criteria for establishment, as stated in the table, are defined in a federal law. Additionally, at the regional level, the Autonomous Communities (regions) have adjusted these criteria for their own peculiarities.

Source: chapters 3 to 11, data gathering by GÖG FP

12.1.2 Ownership requirements

Table 12.2 provides an overview of the ownership regulation for community pharmacies in the countries surveyed. An overall pattern can be observed: In the regulated countries only pharmacists may own a pharmacy, and multiple ownership (i.e. several pharmacies in the hands of one owner) is forbidden, while other persons and entities than pharmacists may be owners of a community pharmacies and multiple ownership is allowed in the deregulated countries.

It should be noted that even if in the regulated countries only pharmacists may own a pharmacy, co-ownership is allowed in Austria and Spain provided that a pharmacy owner, a pharmacist, holds at least 50 percent (Austria) and 51 percent (Spain) of the pharmacy. The threshold used to be 75 percent in Spain, but was reduced in 2009 (Vogler et al. 2006, CGCOF 2011). In Austria also non-pharmacists may be co-owners provided that it is set up as a partnership and not a stock corporation, and in Spain specific persons and entities, e.g. persons involved in manufacturing and clinical practice of medicine, are not allowed to act as co-owners. In Finland, there are two universities which may own pharmacies, and one is allowed to run several pharmacies.

Among the group of deregulated countries some differences regarding ownership exist. In England and the Netherlands no limitations at all are placed on ownership. In Ireland, Norway and Sweden, doctors are excluded from owning a pharmacy due to their possible conflict of interest as prescribers. Additionally, manufacturers are not allowed to own a pharmacy in Norway and Sweden. Wholesalers are, on the other hand, not excluded in any of the deregulated countries from owning a pharmacy.

Within the group of deregulated countries, limitations on the number of pharmacies in a chain exist only in Norway. In the other deregulated countries the regulatory framework does not contain any provision to prevent market dominance by one or more large pharmacy chains (for details of actual market presence of pharmacy chains see section 12.3.2). In Sweden, where the liberalisation process started two years before this report was carried out, the reregulation consisted of several steps, with a sale of about two thirds of the pharmacies, while leaving the rest in the hands of the public company, Apoteket.

Table 12.2: Comparative analysis – Ownership regulation of community pharmacies, 2011

Country	Owners of pharmacies		Multiple ownership	
	Only pharmacists	Other groups allowed	Allowed	Specifications
England	No	Any individual or legal entity	Yes	No limitation on the number of pharmacies in a chain
Ireland	No	Any individual or legal entity, except prescribers (i.e. doctors) with a practice in the same area	Yes	No limitation on the number of pharmacies in a chain
Netherlands	No	Any individual or legal entity	Yes	No limitation on the number of pharmacies in a chain
Norway	No	Any individual or legal entity, except prescribers (i.e. doctors) and manufacturers	Yes	Limitation on the number of pharmacies in a chain (no chain is allowed to own more than 40% of all pharmacies)
Sweden	No	Any individual or legal entity, except prescribers (i.e. doctors), manu-facturers and companies in which a manufacturer has deciding influence	Yes	No limitation on the number of pharmacies in a chain
Austria	Yes	As a minority due to co-ownership (but a pharmacist has to hold a minimum of 50%)	No	Multiple ownership is not allowed, but a pharmacy may run at maximum one branch pharmacy.
Denmark	Yes	-	No	But pharmacists cooperate in purchasing associations, of which some are constituted as companies.
Finland	Yes	Two universities may additionally run a pharmacy – Helsinki and Eastern Finland	No	Multiple ownership is not allowed, but a pharmacy may run max. three branch pharmacies. The university pharmacy of Helsinki is allowed to own 16 pharmacies and the university pharmacy of Eastern Finland may only own one pharmacy.

Country	Owners of pharmacies		Multiple ownership	
	Only pharmacists	Other groups allowed	Allowed	Specifications
Spain	Yes	As a minority due to co-ownership (but a pharmacist has to hold a minimum of 51%; and people involved in manufacturing and clinical practice of medicine are excluded from co-ownership).	No	Multiple ownership is not allowed.

Source: chapters 3 to 11, data gathering by GÖG FP

12.1.3 Further regulations

In addition to establishment and ownership rules, community pharmacies are affected by a number of regulations. Several of them target staff and their qualification (for further details see section 12.3.1), others enforce EU legislation in national law.

At national level, further requirements might be in place impacting the availability of medicines. Table 12.3 provides an overview of selected regulations. None of the countries surveyed has regulations on the frequency of wholesale deliveries, but the dispensing of medicines is regulated in England, Norway and Sweden, and de facto regulated – not by law, but understood as a rule - in Denmark and the Netherlands. In those countries where it is regulated, it is the 24 hours rule, in Denmark there is a notion of “reasonable time” which is 24 hours at maximum, but usually immediately, while in England more than two days might be considered reasonable for some medicines. Regulation on space is rather rare, only to be found in Austria, the Netherlands (a guideline) and in Spanish regions.

Quite common is a regulation regarding the medicines in stock which is in place in all regulated countries of this study and in Norway. Usually, there are minimum requirements for the medicines in stock, described in terms like “corresponding to usual consumer needs”, only Spain (at federal level and further elaborated at regional level) has defined a list which should be in stock and provides sanctions in case of non-compliance.

Again, Spain displays a regional component with its regulation on medicines in stock and space, where the Autonomous Communities implemented specific regulations on the basis of federal law.

Table 12.3: Comparative analysis – Further requirements for community pharmacies, 2011

Country	Further requirements			
	Medicines in stock	**Requirements concerning space**	**Dispensing within a certain time period**	**Frequency of delivery**
England	No specific regulations.	No specific regulations.	**Regulated.** • Provision to dispense within "reasonable time".	No specific regulations.
Ireland	No specific regulations.	No specific regulations.	No specific regulations.	No specific regulations.
Netherlands	No specific regulations.	Guidelines e.g. with regard to accessibility of the premises, room for consulting, storage space, providing privacy to the patient are laid down in the Dutch Pharmacy Standard.	No specific regulations. • As a rule, but not by law, deliveries to customers need to be done within 24 hours or faster.	No specific regulations.
Norway	**Regulated.** • The amount of medicines, equipment and supplies for administering medicines and dressings must correspond to its usual costumer needs.	No specific regulations.	**Regulated.** • Medicines (also not in stock) have to be available to the customer within 24 hours.	No specific regulations.
Sweden	No specific regulations.	No specific regulations.	**Regulated.** • The medicine has to be available to the customer within 24 hours (this rule does not apply for rural areas).	No specific regulations.
Austria	**Regulated.** • A minimum number of medicines, incl. reimbursable medicines, has to be in stock.	**Regulated.** • A minimum size of 120m^2 of each pharmacy.	No specific regulations.	No specific regulations.

Country	Further requirements			
	Medicines in stock	**Requirements concerning space**	**Dispensing within a certain time period**	**Frequency of delivery**
Denmark	**Regulated.** • The pharmacy must retail all types of medicines and have a suitable and adequate stock in relation to the demand.	No specific regulations.	All medicines should be provided "within reasonable time" (being understood as immediately for most medicines and maximum 24 hours for the rest).	No specific regulations.
Finland	**Regulated.** • The number of medicines in stock has to correspond to usual costumer needs. • If medicines not in stock are demanded, the pharmacy has to provide them.	No specific regulations.	No specific regulations.	No specific regulations.
Spain	**Regulated.** • A general list of medicines to be in stock. • Sanctions if not fulfilled. • Regions may elaborate their own list of legal minimum stock.	Specific regulations depending on the regions (e.g. Aragón establishes a minimum 80 m^2, Cantabria 70 m^2 and The Basque Country 75 m^2).	No specific regulations.	No specific regulations.

Source: chapters 3 to 11, data gathering by GÖG FP

12.2 Accessibility

12.2.1 Accessibility of medicines dispensaries

In all the countries surveyed, community pharmacies are the major dispensaries of medicines, both of prescription-only medicines (POM) as well as of OTC medicines (in particular in the regulated countries). In Spain pharmacies are in fact the sole dispensaries of POM and OTC medicines. Overall, in all countries surveyed community pharmacies and their branch pharmacies are, also in numbers, the main POM dispensaries. In some of the countries they are complemented by POM dispensing doctors mainly to ensure pharmaceutical services in areas with no pharmacy, and to some extent, but usually only in rather rare cases, by the hospital pharmacies. Table 12.4 provides an overview of key dispensaries of prescription-only medicines and OTC medicines.

In Austria, Denmark, Finland and Norway pharmacies are allowed to run branch pharmacies which are under the supervision of the main pharmacies. The branch pharmacies are limited in number in Austria (maximum one branch pharmacy) and in Finland (up to three). In Norway, the Medicines Agency may allow pharmacies to run as a branch if there is no one with a masters in pharmacy (pharmacist) available, and to have it run by a bachelor of pharmacy (prescriptionist). Furthermore, so-called supplementary pharmacy units, also attached to the main pharmacy and operated at its expense, act as dispensaries for POM in Denmark.

In five of the nine countries surveyed (Austria, England, Ireland, the Netherlands, Norway) POM dispensing doctors play a role, in particular for ensuring accessibility in rural areas. Their share is particularly high in Austria where they represent around 42 percent of all POM dispensaries. POM dispensing doctors are also represented to some extent in the Netherlands (20.5 percent) and England (9.6 percent of all POM dispensaries).

Usually, hospital pharmacies are only allowed to dispense to out-patients in special and/or rare cases (e.g. supply after discharge from hospital or for specific treatments and medication like HIV or some hospital-only medicines) (for an overview see Vogler et al. 2010). In two of the surveyed countries hospital pharmacies dispense at a larger scale to out-patients, thus acting as community pharmacies: These are Norway, where all hospital pharmacies offer an out-patient department, and the Netherlands, where more than half of all hospital pharmacies dispense to out-patients. In Sweden a number of community pharmacies located on hospital premises serve out-patients within limited opening hours (personal communication).

Internet pharmacies allowed to dispense POM are rare. This was done by the state-owned pharmacy company Apoteket in Sweden since 2006 till the reregulation. In Denmark, e-commerce of POM is provided by primarily one internet portal, which is run by the Pharmacy Association serving nearly 80 percent of the pharmacies.

With regard to the POM dispensaries, there is no pattern noticeable regarding the deregulated and regulated countries. Each country has its particularities which are usually attributable to historical developments, tradition and culture.

Some pattern is, however, to be observed concerning the sale of OTC medicines. In the liberalised countries, the sale of OTC medicines, or some of them, outside pharmacies is more common. OTC suppliers also include general retail places like supermarkets, groceries or petrol stations. In the regulated countries the sale of OTC medicines outside pharmacies appears to be more regulated: OTC medicines may exclusively be sold in pharmacies in Spain and are mostly sold in pharmacies in Austria. Denmark allows the sale of non-pharmacy restricted OTC medicines in supermarkets and petrol stations as well as in pharmacy controlled or delivered units such as pharmacy outlets, OTC outlets and delivery facilities. In Finland the only OTC medicines sold outside pharmacies are nicotine replacement therapy preparations (NRT). Finland recently (February 2011) allowed internet sale for OTC medicines – and in theory, for POM based on electronic prescriptions.

Table 12.4: Comparative analysis – Key dispensaries of medicines, 2011

Country	Key POM dispensaries	Share of all POM dispensaries	OTC dispensaries
England	Community pharmacies	90.7%)	Drugstores, supermarkets, internet pharmacies[2]
	POM dispensing doctors[1]	9.3%	
Ireland	Community pharmacies	about 90%	Drugstores, petrol stations, supermarkets, internet pharmacies[2]
	POM dispensing doctors	not available	
Netherlands	Community pharmacies	77.0%	Drugstores, supermarkets, internet pharmacies, other OTC dispensaries
	POM dispensing doctors	20.5%	
	Hospital pharmacies	2.1%	
	Internet pharmacies	0.4%	
Norway	Community pharmacies	84.1%	Pharmacy outlets, LUA outlets, located in grocery stores, petrol stations, health stores
	Branch pharmacies	11.7%	
	POM dispensing doctors	1.4%	
	Hospital pharmacies	4.7%	
Sweden	Community pharmacies	99.9%	Supermarkets, petrol stations, apoteket representatives ("apotekombuds"), internet pharmacies
	Internet pharmacies	1internet pharmacy	
Austria	Community pharmacies	57.0%	Drugstores[3]
	Branch pharmacies	1.0%	
	POM dispensing doctors	42.0%	
Denmark	Community pharmacies	72.5% *	Pharmacy outlets, OTC outlets, delivery facilities, grocery stores etc., supermarkets, petrol stations etc.
	Branch pharmacies	21.8% *	
	Supplementary licenses/units	5.7% *	
	Internet pharmacy apoteket.dk	1 portal[4]	
Finland	Community pharmacies	76.1% *	Pharmacy service outlets[5], Internet pharmacies[6] , drugstores, supermarkets
	Branch pharmacies	23.9% (2010)	
Spain[7]	Community pharmacies	100%	-

app. = approximately, LUA = Medicines Outside Pharmacies (Norway), ph. = pharmacy, POM = prescription-only medicine, OTC = over-the-counter

*2010

In this table, community pharmacies are counted excl. branch pharmacies. Branch pharmacies are separately indicated.

This table only contains hospital pharmacies in those countries where more than half of all hospital pharmacies dispense POM to out-patients; this is the case in the Netherlands and Norway. In the other countries dispensing of medicines by hospital pharmacies to out-patients is only done under specific conditions and in specific cases. In these countries (except for Austria to be in line with the national reporting systems), the total of POM

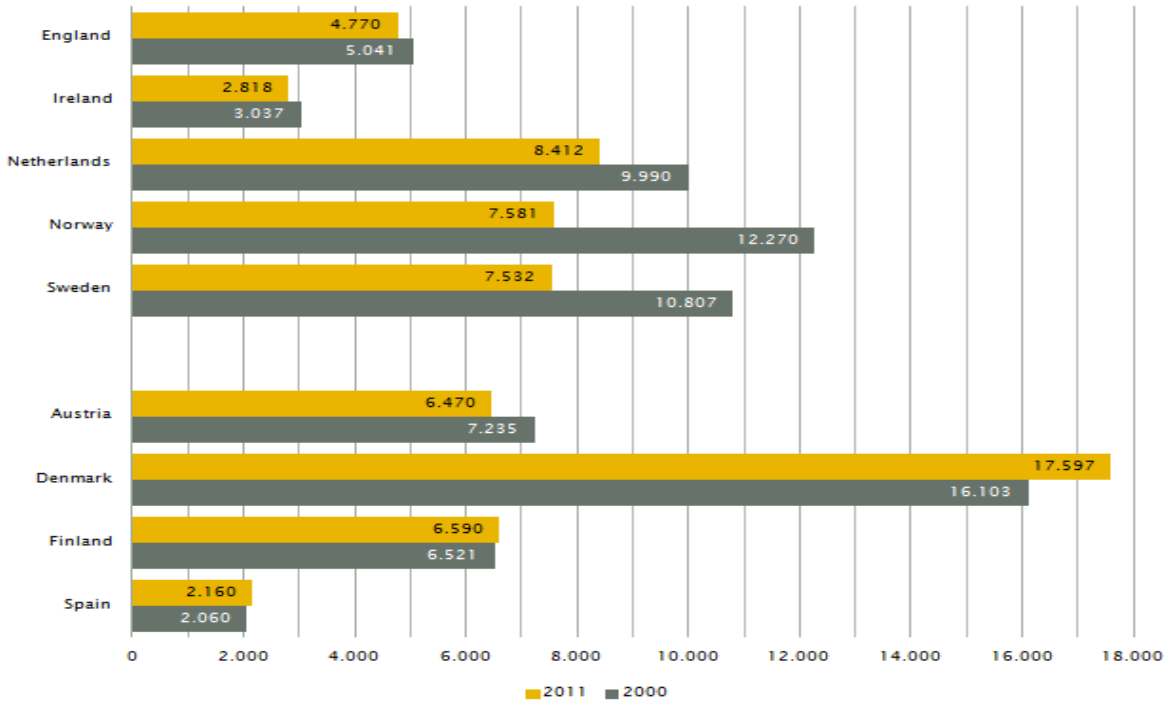
dispensaries does not include hospital pharmacies. In Austria, around ten percent of all hospital pharmacies serve out-patients, corresponding to 0.2 percent of all POM dispensaries.

[1] Doctors may dispense medicines to their patients in a designated rural area only if the patient lives more than 1.6 km from a pharmacy. There were 1129 POM dispensing practices with 5,778 dispensing doctors in England in 2010.
[2] A specific list of medicines that may be sold outside pharmacies is issued by the authorities (General Sales List).
[3] Drugstores in Austria may only sell a very limited number of OTC medicines.
[4] Internet portal serving 245 pharmacies (77.5% of all pharmacies).
[5] Pharmacy service outlets (under the supervision of a pharmacy) have replaced the former medicines chests from February 2011 on. They have more possibilities to supply patients than the disappearing medicines chests. Customers may bring their prescriptions to the service point, where a pharmacist or prescriptionist may be available some days per week.
[6] Internet pharmacies have been allowed to dispense OTC medicines since February 2011.
[7] Farmacia "botiquines" which provide pharmaceutical care in villages with very low numbers of inhabitants are not included in the table as they are very exceptional and rare.

Source: chapters 3 to 11, data gathering by GÖG FP

Figure 12.1 shows the average number of inhabitants who are served by a community pharmacy.

Figure 12.1: Comparative analysis – Inhabitants per community pharmacy, 2000 and 2011



Community pharmacies are counted including branch pharmacies (Norway; Austria, Denmark, Finland) and supplementary units (Denmark).

Finland: 2010 instead of 2011

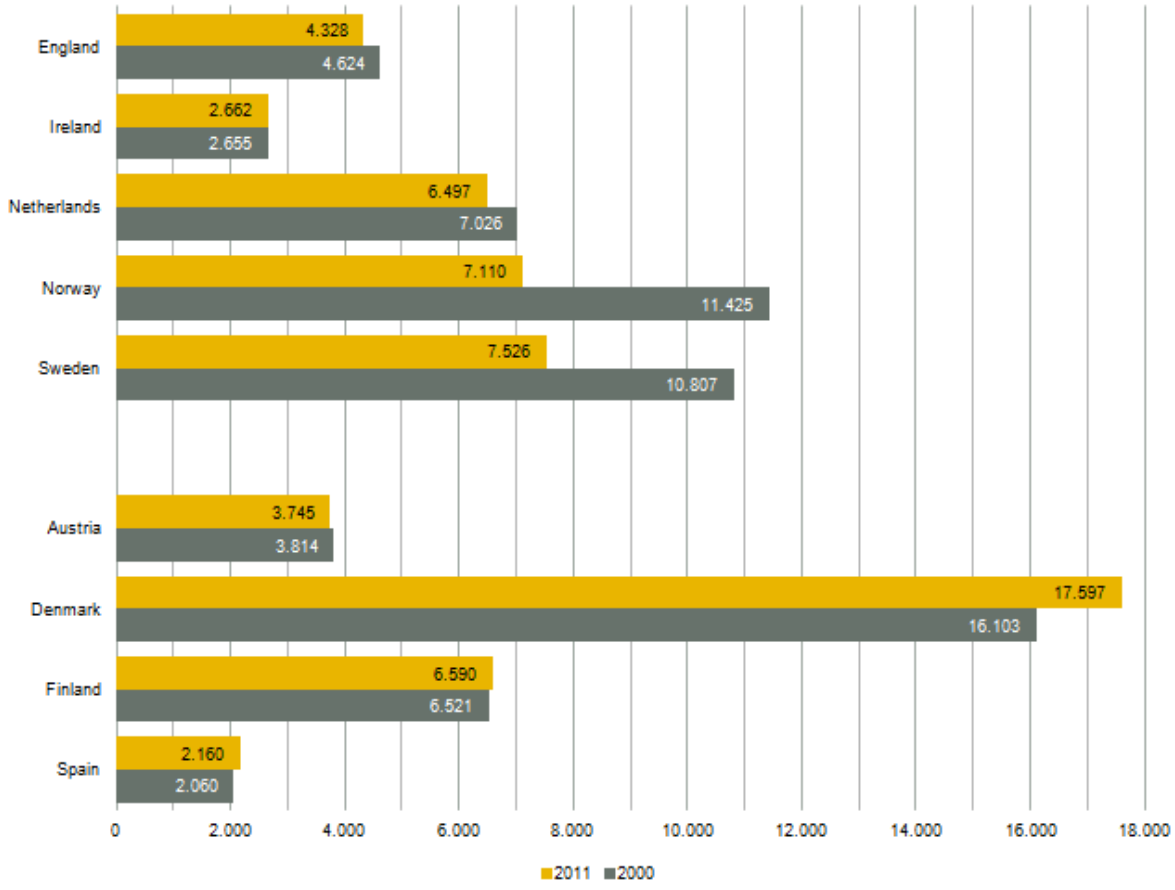
Source: chapters 3 to 11, data gathering by GÖG FP

There are quite considerable variations, ranging between 2,000 and 18,000 inhabitants per community pharmacy. The highest number by far is displayed in Denmark, with 17,460

inhabitants per community pharmacy, followed, at some distance, by the Netherlands, Norway, Sweden and Finland.

Since community pharmacies may be complemented by other POM dispensaries to out-patients, in particular POM dispensing doctors, mainly in rural areas, the ranking, as displayed in Figure 12.2, differs.

Figure 12.2: Comparative analysis – Inhabitants per POM dispensary, 2000 and 2011



POM dispensaries include: community pharmacies counted including branch pharmacies (Norway, Austria, Denmark, Finland) and supplementary units (Denmark), POM dispensing doctors (England – POM dispensing practices are counted; Ireland, the Netherlands, Norway, Austria), hospital pharmacies if their dispensing of POM to out-patients is relevant and considerable (see Table 12.4; Netherlands, Norway; 5 of the 46 hospital pharmacies in Austria; one internet pharmacy in Sweden).

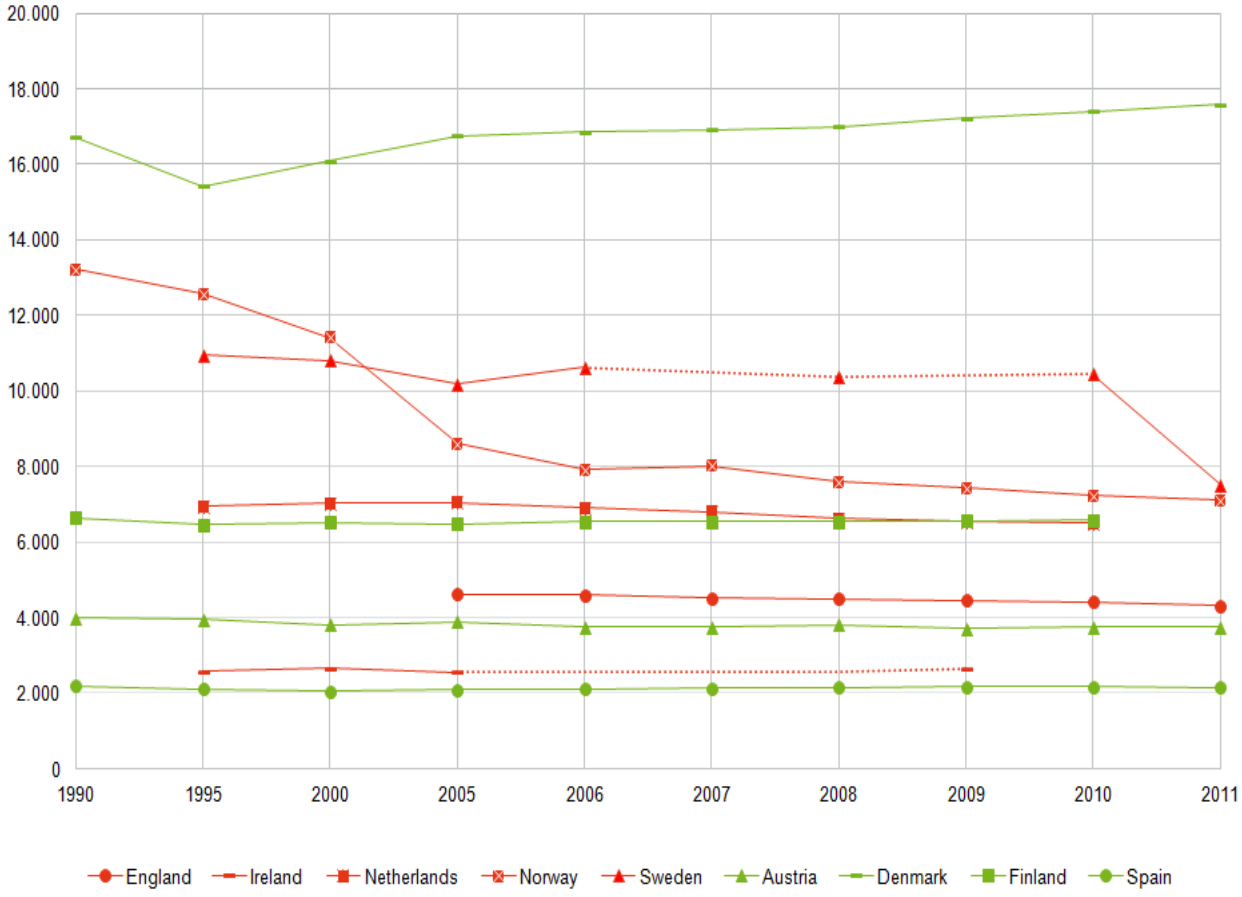
The Netherlands and Finland: 2010 instead 2011; Ireland = 2009 instead of 2011; England = 2005 instead of 2000

Source: chapters 3 to 11, data gathering by GÖG FP

While no difference exists between the number of community pharmacies (including branch pharmacies and supplementary units) in Denmark (internet portal serving pharmacies was not included), Finland and Spain and a minor difference in Sweden (the Apoteket internet pharmacy was considered), there were quite considerable changes in Austria and the Netherlands. Also in Norway and England the POM dispensing doctors do impact the

accessibility to POM dispensaries. Still, Spain continues to display the lowest number of inhabitants per POM dispensary (like per community pharmacies), and Denmark the highest.

Figure 12.3: Comparative analysis – Development of inhabitants per POM dispensary, 2000 – 2011



Sweden: no data for 2007, 2008 and 2009, trend is displayed based on estimation

Methodology: see notes for Figure 12.1 and Figure 12.2

Source: chapters 3 to 11, data gathering by GÖG FP

Figure 12.1 and Figure 12.2 reflect the developments in accessibility of community pharmacies and POM dispensaries during the last decade. Countries with a comparably stable number of inhabitants served per POM dispensary are Spain, Ireland, Austria, England, Finland and the Netherlands. In Sweden and Norway a decrease in inhabitants per POM dispensary can be observed since 1990. Norway was able to increase overall accessibility by lowering the number from about 13,000 inhabitants to about 7,000 inhabitants per POM dispensary. The liberalisation, which had the aim to increase accessibility of pharmacies in both countries, appears to have been successful (for information on the distribution of the new pharmacies see the next section 12.2.2). For an interpretation of the data, the inhabitants per POM dispensary are displayed in a time line analysis. In fact, Norway shows the increase in accessibility directly after the liberalisation,

where a lot of community pharmacies were opened (cf. section 6.2.1.1). For Sweden the time for an evaluation might to be too short, but again the opening of new pharmacies took place after the reregulation (cf. section 7.2.1.1) and is already reflected in the data.

Denmark is the only surveyed country where the number of inhabitants per POM dispensary slightly increased from nearly 17,000 in 1990 to about 17,500 in 2011. Denmark has a relatively low number of community pharmacies, but short distances also in rural areas (cf. section 9.2.1.1).

12.2.2 Accessibility in rural areas

The rationale of establishment regulation is to ensure an equal distribution in the accessibility to community pharmacies. Concerns have been raised that, while a fall of the establishment rules for pharmacies might increase the number of pharmacies (and in fact did, as the examples of Norway and Sweden show), the new pharmacies might be established at attractive locations (e.g. in town centres) where already POM dispensaries are available, while sparsely populated areas (one interview partner from a patients' association referred to them as "vulnerable regions") might be neglected.

Table 12.5 provides indications about the spread of pharmacies in a country as well as the distance to pharmacies. A comparison is very difficult, not only due to missing data but also from a methodological point of view because the concept of "rural area" might be based on different definitions (if any exist) in the countries due to their characteristics.

Further, each country has developed, often based on traditions and history, specific approaches about how to ensure accessibility to rural areas, e.g. via branch pharmacies, POM dispensing doctors, home deliveries or country solution like the Finnish medicines chests which were recently replaced by pharmacy service outlets (for an overview see Table 12.4).

As a trend, urban clustering appears to take place in countries with no establishment and often also no ownership regulation for community pharmacies. Even if data are sparse on this issue, this perception was expressed by several interview partners. In Norway and Sweden, where after the liberalisation several new pharmacies were opened and thus, at first glance contributing to increased accessibility (cf. also section 12.2.1), interview partners could not confirm an improvement of accessibility of community pharmacies in rural areas, but even expressed concerns that the provision with POM dispensaries continues to be poor (personal communication from Sweden).

Table 12.5: Comparative analysis – Accessibility of pharmacies, in general and in urban and rural areas, 2011

Country	Regional spread of pharmacies		Distance to pharmacies	Developments and comparisons
	Urban clustering	Comments		
England	Yes	• Liberalisation is expected to have contributed to pharmacy openings in urban areas.	• 96% of the population in the 10% most deprived areas can reach a pharmacy within 10 minutes by walking or public transport (2007).	• Incentive schemes (subsidisation under the Essential Small Pharmacies Scheme) for establishment in rural areas were abolished.
Ireland	Yes	• Clustering especially concerns the West coast and the islands. • In areas without pharmacies, POM are dispensed by POM dispensing doctors (becoming fewer). • In rural areas high share of individual pharmacies, in urban areas high share of pharmacy chains.	• Very close distances between pharmacies in some (urban) places.	• The number of community pharmacies has increased, but it is not clear in which areas. • The number of POM dispensing doctors is constantly decreasing, POM dispensing doctors are operating mostly in rural areas. • Concerns that the financial crisis might lead to pharmacy closures in "vulnerable", i.e. sparsely populated regions.
Netherlands	Yes	• Especially regions in the North and South-West are sparsely populated and often do not have pharmacies. • In areas without pharmacies, POM are dispensed by POM dispensing doctors. • No incentives for pharmacies to establish in rural areas.	• 91% of the population have a distance of less than 4.5 km to the nearest pharmacy. • The other 9% of the population have a distance of less than 4.5 km to the nearest POM dispensing doctor.	• In 2008 55 of 418 municipalities did not have a pharmacy, this number decreased to 44 in 2010.

Country	Regional spread of pharmacies		Distance to pharmacies	Developments and comparisons
	Urban clustering	Comments		
Norway	Yes	• Clustering is also due to the geographic particularities of the country. • In areas without pharmacies, POM might be dispensed by POM dispensing doctors or by branch pharmacies. • No incentives for pharmacies to establish in rural areas, but a subsidy scheme for rural pharmacies with low turnover. • 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 (based on an agreement, renewal currently under discussion). • Pharmacies in sparsely populated areas are allowed to send POM and OTC to customers who do not have a pharmacy in their immediate vicinity.	• In 2010 250 of 430 municipalities had a pharmacy. • 91% of the population live in a municipality with a pharmacy.	• Establishment of pharmacies in rural areas is not particularly stimulated apart from a subsidy scheme for pharmacies with low turnover in rural areas. • Nevertheless, in the rural, scarcely populated areas, no pharmacy has closed since the pharmacy reform. • The number of pharmacies in each of the 19 Norwegian provinces has increased since 2001.
Sweden	Yes	• 35% of all pharmacies are still owned by Apoteket, the pharmacies that were bought in clusters or individually must be kept in place for 3 years (i.e. till January 2013).	• The average distance to the nearest pharmacy is 3.9 km. • 29% of the population have a distance of less than 1 km to the nearest pharmacy. • More than 50% of the population have a distance of less than 3 km to the nearest pharmacy.	• Before 2009 there were fewer pharmacies (about 250), new entries mainly in cities. • As of mid-2011, the distance to the pharmacy in Sweden has been reduced by an average of 150 metres since the liberalisation started.

Country	Regional spread of pharmacies		Distance to pharmacies	Developments and comparisons
	Urban clustering	Comments		
Austria	No	• More than 50% of all pharmacies are situated in rural areas. • Most pharmacies that opened in the last decade are situated in rural areas, in particular in areas with no pharmacy before. • In areas without pharmacies, POM are dispensed by POM dispensing doctors.	• 92.6% of the population are able to reach a pharmacy within 10 minutes.	• The number of inhabitants per community pharmacy has decreased from 1990 to 2011. • The largest increase in the number of pharmacies (60 new pharmacies) was observed in smaller communities that had not had a pharmacy before.
Denmark	No	• Many small villages have their own pharmacy, an OTC outlet or a delivery facility (OTC outlets which are either attached to a pharmacy or delivered by a pharmacy). • Incentives for pharmacies to establish in rural areas set by authorities. • Equalisation scheme via taxes on pharmacy turnover. • About 60% of all pharmacies receive equalizing subsidies.	• The average distance to the nearest pharmacy is 3.8 km. • More than 40% of the population have less than 1 km to the nearest POM dispensary. • 50% of the population have less than 2 km to the nearest pharmacy. • 60% of the population have less than 2 km to the nearest pharmacy (personal communication). • The average distance to the nearest dispensary is about 1.6 km. • The average distance to the nearest pharmacy in Copenhagen and surroundings is 2 km. • The average distance to the nearest pharmacy in the most rural area of Denmark is 5.3 km. • 75% of the population can collect their medicine in a delivery facility less than 2 km from their home.	• The number of inhabitants per community pharmacy and per POM dispensary is the highest amongst the surveyed countries. • Yet, the distance to a pharmacy is comparably low in spite of differences between urban and rural areas.

Country	Regional spread of pharmacies		Distance to pharmacies	Developments and comparisons
	Urban clustering	Comments		
Finland	No	• No incentives for pharmacies to establish in rural areas, but a pharmacy tax to guarantee equity among pharmacies. • Branch pharmacies support the provision of medicines in rural areas, where the establishment of independent pharmacies is not possible due to a small population. • Pharmacy service outlets replace the previous medicines chests (OTC dispensaries under the provision of a pharmacy).	• 86% of the population live within 5 km of the nearest pharmacy. • 30% of the population live within 1 km to the nearest pharmacy. • 99% of the population live in a community with pharmacy services (full pharmacy or branch pharmacy). 6% of the population have a distance of 10km or more to the nearest pharmacy. • The average distance to the nearest pharmacy is 3.87 km.	• The number of community pharmacies has slightly increased since 1990. • The number of inhabitants per community pharmacy has stayed relatively stable.
Spain	No	• Specific character-istics of the regions are taken into account by each Autonomous Region. • Pharmacies often are the only health service provider in rural municipalities. • Farmacia botiquins can exceptionally support the pharmaceutical provision in rural areas.	• 87% of the population have a pharmacy within 250 m. • 97.3% of the population have a pharmacy at a distance of 5 km or less. • 21.3% of all community pharmacies are established in villages of fewer than 5,000 inhabitants.	• The number of inhabitants per community pharmacy has slightly increased since 2000 from about 2,050 to 2,150 inhabitants per community pharmacy. • Spain has the lowest number of inhabitants per community pharmacy among the surveyed countries.

Source: chapters 3 to 11, data gathering by GÖG FP

Some countries have financial incentives for pharmacies in rural areas. For instance, there is a redistribution for (small) pharmacies in rural areas in Denmark and Finland based on the pharmacy tax for large pharmacies (cf. sections 9.4.3. and 10.4.3). In England, a subsidy scheme which was in place for small rural pharmacies was abolished (cf. section 3.1). In Norway, also granting subsidies, an agreement with the large pharmacy chains provided that they will take over a closing rural pharmacy, or establish a new one in case a pharmacy in a rural area were closed. Sweden chose the approach to oblige the purchasers of the pharmacies to keep them running for at least three years. However there are concerns about a possible closing after the defined three year period (from 2013 on).

12.2.3 Availability of medicines

The availability of (prescription-only) medicines to customers is influenced by the number of medicines held in stock but also by the organization of the supply chain. Table 12.3 provided information on regulations asking for the availability and supply to medicines within a certain time period, and Table 12.6 now provides information about the actual availability of medicines to customers. Standard prescriptions can be filled immediately in most countries. The waiting times for other medicines might be a few hours, supplied on the same day. In England patients might need to wait longer (cf. section 3.2.2). Pharmacies in countries with more frequent deliveries by wholesalers (or emergency deliveries) can make medicines available to customers within a shorter time period. Pharmacies in England, Ireland and Finland are delivered twice a day by the wholesalers, pharmacies in Austria and Spain even three times a day. Pharmacies in Norway are not supplied on a daily basis.

At the qualitative level, concerns have been raised that vertically integrated pharmacies might be focused on the availability of the products they supply, and the financial pressure to be very competitive could induce pharmacies to not supply less frequent medicines. While there was some indication of an increased workload and a possible deterioration in quality (cf. sections 5.3.1.1 – Netherlands and 6.3.3.2 – Norway), no data could be collected to confirm or challenge this thesis.

Table 12.6: Comparative analysis – Availability of medicines, 2011

Country	Availability of medicines	Frequency of wholesale deliveries
England	Following the legal provision to fill prescriptions in a reasonable time, which might vary depending on the kind of product (e.g. for common products on the same or following day).	Twice a day
Ireland	On average 12, but at maximum 24 hours.	Twice a day
Netherlands	Most medicines are dispensed to the patient with 5 to 10 minutes.	Once a day
Norway	Medicines in stock are dispensed directly, others within 24 hours.	4 times a week, in rural areas fewer
Sweden	Rule that the medicine has to be available to the customer within 24 hours (not valid for rural areas).	Once a day
Austria	96% of all customers get their prescription filled at their first visit to the pharmacy; around 80 to 90 percent of all medicines on the market are held in stock of a community pharmacy.	Three times a day, plus emergency deliveries
Denmark	98% to 99%of all dispensed medicines are immediately available, the rest (1-2 percent) within 24 hours.	Once a day, plus "express"-deliveries (immediate deliveries)
Finland	98.4% of all prescription-only medicines are dispensed immediately, 98.5% on the same day.	Twice a day due to only two wholesalers with different products
Spain	On average medicines are available to the costumers within three to four hours.	Three times a day

Source: chapters 3 to 11, data gathering by GÖG FP

12.3 Quality of pharmacy services

12.3.1 Pharmacy staff

Quality of pharmacy services, including dispensing of medicines and counselling and guidance, is ensured through highly qualified staff.

At the heart of pharmacies are the pharmacists trained in university education leading to a Master's degree (current situation after the Bologna process in the EU/EEA countries to harmonize tertiary education). Additionally, some Nordic countries provide Bachelors in pharmacy to complement the "full pharmacists". They are so-called "prescriptionists" and exist in Finland, Norway and Sweden. They may dispense prescription-only medicines; in Norway prescriptionists may be allowed to run a branch pharmacy if no master in pharmacy (pharmacist) is available (cf. section 6.1). Denmark has the concept of "pharmaconomists" who are permitted to dispense prescription-only medicines (cf. Table 12.7). In England, Ireland and the Netherlands, pharmacy technicians (pharmacy assistants) with special vocational training are also allowed to dispense prescription-only medicines, while in Austria and Spain pharmacy assistants may support pharmacists in dispensing, but may not dispense on their own.

Not only in Austria and Spain, but also in some of the other countries surveyed (e.g. Ireland, Sweden) there is further qualified non-dispensing staff in community pharmacies (cf. Table 12.7).

Table 12.7: Comparative analysis – Qualified pharmacy staff, 2011

Country	Phar-macists	Other dispensing staff	Other qualified staff (not allowed to dispense)
England	Y	Y, • Pharmacy technicians with the right to dispense POM	Y, • Medicines counter assistants (MCA) • Dispenser/dispensing assistants
Ireland	Y	Y, • Qualified assistants with the right to dispense POM .they may dispense POM in the temporary absence of a full pharmacist (their training has been abolished however)	Y, • Pharmacy technicians without the right to dispense medicines
Netherlands	Y	Y, • Pharmacy technicians with the right to dispense POM	N
Norway	Y	Y, • Prescriptionists	Y, • Pharmacy technicians without the right to dispense medicines
Sweden	Y	Y, • Prescriptionists	Y, • Pharmacy technicians without the right to dispense POM
Austria	Y	N	Y, • Pharmacy technicians without the right to dispense medicines, called pharma-commercial assistants or qualified pharmacy assistants
Denmark	Y	Y, • Pharmacy technicians with the right to dispense POM, called pharmaconomists	N (except pharmaconomist trainees)
Finland	Y	Y, • Prescriptionists	Y, • Pharmacy technicians with the right to dispense OTC medicines • Pharmacy technicians without the right to dispense medicines
Spain	Y	N	N

N = no, POM = prescription-only medicine, Y = yes

Source: chapters 3 to 11, data gathering by GÖG FP

Given the country-specific characteristics regarding the qualifications of pharmacy staff and missing data, comparisons on pharmacy staff have their limitations at least partially for some

groups. Nonetheless, Table 12.8 provides some indicators on the pharmacy staff in the countries surveyed. We considered the relevance of the prescriptionists (and pharmaconomists in Denmark) in the Nordic countries by also including information on the wider notion of pharmacists.

Table 12.8: Comparative analysis – Pharmacy staff (counted in heads), 2011

Country	At country level		In a pharmacy	
	Full pharmacists[1] per 10,000 inhabit.	Pharmacists[2] per 10,000 inhabitants	Total staff per pharmacy	Full pharmacists[1] per pharmacy
England	n.a.	n.a.	n.a.	n.a.
Ireland[3]	10.22	10.22	n.a.	2.86
Netherlands	1.72	1.72	13.13	1.44
Norway[3]	2.65	4.74	8.84	2.04
Sweden[4]	0.61	n.a[5]	n.a.	0.64
Austria	6.28	6.28	11.55	4.06
Denmark[6]	(0.98) 1.39	(5.58) 5.99	(15.06) 15.76	(1.73) 2.45
Finland	2.62	9.76	10.24[7]	1.73[7]
Spain	9.46	9.46	n.a.	2.04

Inhabit. = inhabitants, n.a. = not available

1 Masters in pharmacy

2 So-called prescriptionists in Finland, Norway and Sweden (bachelors in pharmacy), and pharmaconomists in Denmark

3 2010

4 2008

5 No data on prescriptionists available

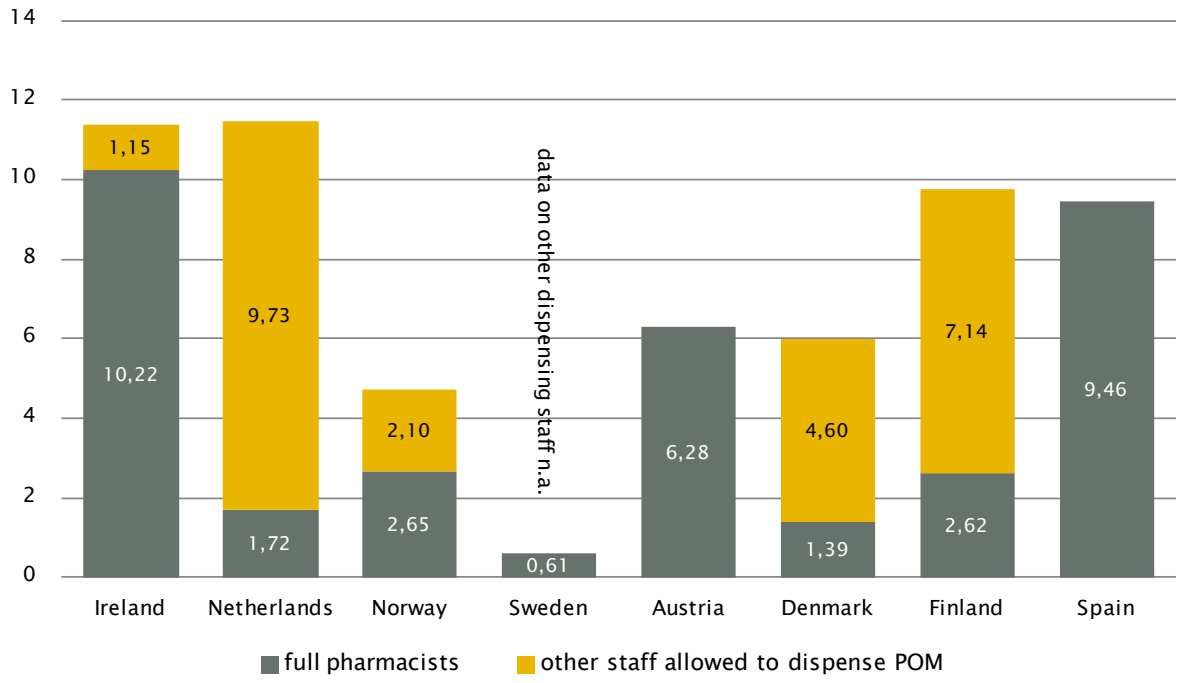
6 Data indicated in full-time equivalents. In Demark, pharmacy owners are not included in the statistics. This table provides indicators for data excl. pharmacy owners (in brackets) and incl. pharmacy owners as part of pharmacy staff (second time)

7 Based on data of the number of pharmacies as of 2010

Source: chapters 3 to 11, data gathering by GÖG FP

At country level, Ireland, Finland and Spain have the highest number of pharmacists (full pharmacists and prescriptionists / pharmaconomists) working in community pharmacies per 10,000 inhabitants (data missing for England and Sweden). Comparability is biased by the fact that data on Denmark are provided in full-time equivalents (FTE) while for the other countries they are counted in heads. Further, statistics on staff data for Denmark usually does not include the pharmacy owners. If they were considered, the numbers would be higher accordingly, as indicated in Table 12.8.

Figure 12.4: Comparative analysis – Dispensing staff per 10,000 inhabitants, 2011



POM = prescription-only medicine

No data available for England; no data on other dispensing staff (prescriptionists) for Sweden

2008 data for Sweden, 2010 data for Ireland and Norway

Data counted in heads except for Denmark (in full-time equivalents)

Denmark: Data on pharmacists includes the pharmacy owners to ensure comparability to the other countries.Other staff allowed to dispense POM include: prescriptionists in Finland, Norway and Sweden and pharmaconomists in Denmark, pharmacy technicians in the Netherlands and qualified assistants (may dispense POM in the temporary absence of a full pharmacist) in Ireland; other staff allowed in AT and ES

Source: chapters 3 to 11, data gathering by GÖG FP

The quantitative dimension of the prescriptionists / pharmaconomists is evident if indicators for full pharmacists and for pharmacists in the broader sense are compared. There are major differences between the number of full pharmacists and of pharmacists weighed per 10,000 inhabitants in Denmark and Finland (cf. Table 12.8). This can also be observed at the level of a pharmacy (cf. Figure 12.4): Three of four pharmacists in Denmark and Finland are prescriptionists. The highest number of dispensing staff can be found the Netherlands (11.44 dispensing staff per 10,000 inhabitants) and Ireland (11.37). While in the Netherlands most of the dispensing staff are pharmacy technicians, the ratio is the other way round in Ireland. Thus, Ireland has the highest number of pharmacists, followed by Spain and Austria.

Analyzing the development of pharmacists, there are no major changes noticeable except for Spain (increase in the 1990s: from 5.1 in 1990 to 8.6 pharmacists per 10,000 inhabitants in 2000, with a moderate continuation of the increase in the last decade), the Netherlands (slight decrease from 2007 to 2009) and Norway.

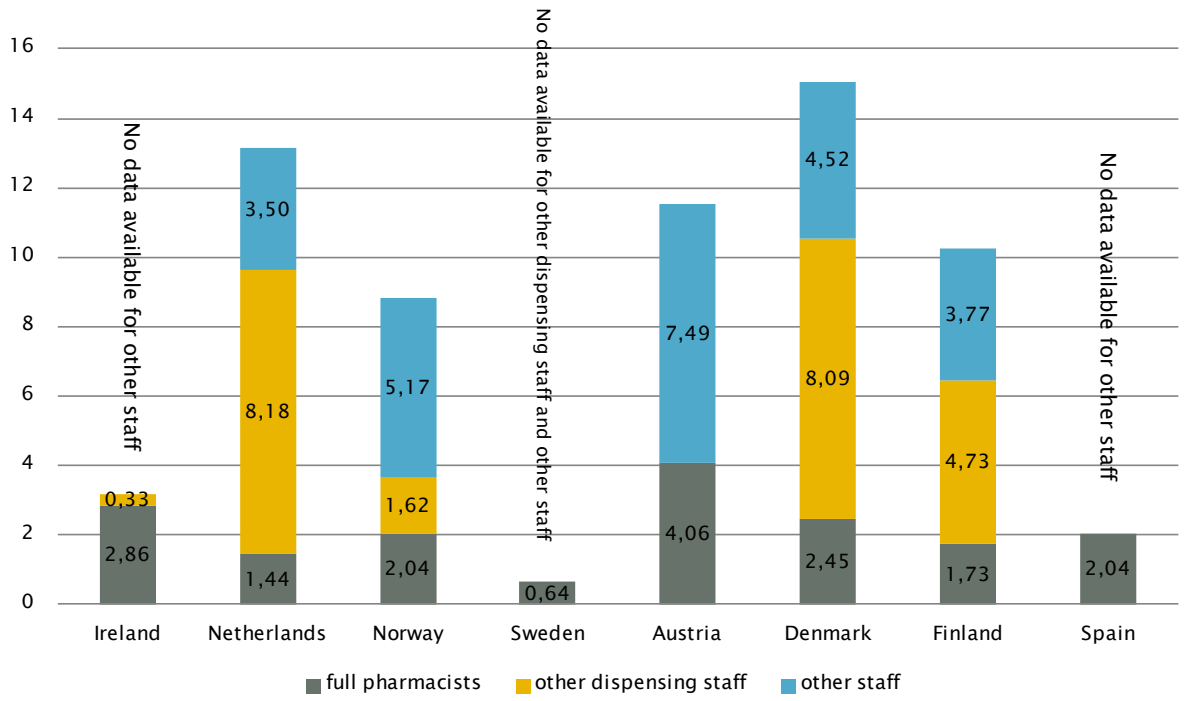
In Norway the number of pharmacists has increased, in particular during the last years (1.92 pharmacists per 10,000 inhabitants in 2000, 2.1 in 2005 and 2.7 in 2010). However, due to

the opening of several new pharmacies, the number of pharmacists (full pharmacists) at the level of pharmacy has sharply decreased after the deregulation (from 2.35 pharmacists per pharmacy in 2000 to 1.81 in 2005). During the last years, a moderate increase in the number of pharmacists per pharmacy could be observed in Norway.

Due to missing data for Sweden and England, we do not know about similar developments in these countries. It appears that organisational changes took place in Swedish pharmacies after the reregulation, with more highly qualified staff working more back-office, which might explain why, according to surveys, consumers perceive a deterioration in the competence in pharmacists (cf. section 7.3.1.1).

Regarding the number of staff per pharmacy Denmark has the highest figure followed by the Netherlands (cf. Table 12.5). The lowest reported number of total staff per pharmacy was found in Norway. It is to be mentioned that neither Spain nor Austria allow staff other than full pharmacists to dispense medicines.

Figure 12.5: Comparative analysis – Pharmacy staff per pharmacy, 2011

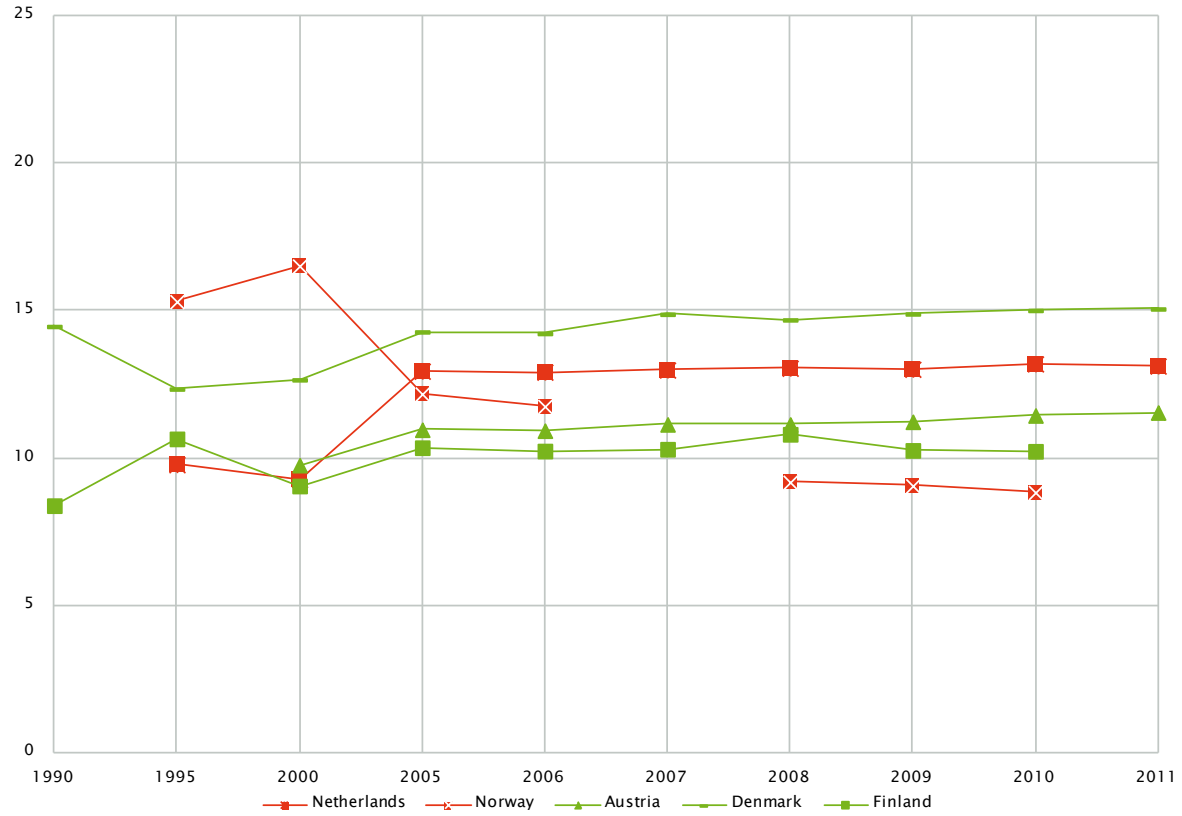


In Austria and Spain there is no other dispensing staff than full pharmacists
No data available for England.

Source: chapters 3 to 11, data gathering by GÖG FP

The number of pharmacy staff per pharmacy stayed relatively stable from 1990 to 2011 in all countries with reported figures (cf. Figure 12.6). The numbers vary between about eight to sixteen persons working in community pharmacies in those countries.

Figure 12.6: Comparative analysis – Pharmacy staff per pharmacy, 1990 – 2011



No data available for England, Ireland, Sweden, Spain

Source: chapters 3 to 11, data gathering by GÖG FP

A decrease in the number of (qualified) staff per pharmacy might lead to an increase in work load, in particular with more tasks to be done (e.g. new pharmacy services), and possibly less work satisfaction. For the Netherlands, an increased work load for pharmacy technicians was indicated by an increased number of prescriptions filled (cf. section 5.2.2).

12.3.2 Professional independence of pharmacists

Professional independence of pharmacists is influenced by the extent to which vertical and also horizontal integration has taken place.

Vertical integration in the community pharmacy sector is the case when pharmacies are owned by other persons and entities of the distribution chain (e.g. wholesalers, manufacturers). As explained in section 12.1.2 (see also Table 12.2), vertical integration is, in principle, not possible in the regulated countries (in Austria, however, no restrictions on the kind of minority co-owners exist), and as a result there is basically no vertical integration in the regulated countries.

As shown in Table 12.2 in section 12.1.2, vertical integration is possible in the deregulated countries (unlimited in England and the Netherlands, exclusions for manufacturers in Norway and Sweden), and in reality the community pharmacy sector in these countries is

considerably vertically integrated. A radical change in the ownership structure and a strong vertical integration took place in Norway after the liberalisation of 2001 leading to the current situation with only every sixth pharmacy still being owned by a pharmacist (not necessarily an individual pharmacist). A considerable number of pharmacies were sold, and further pharmacies were established by pharmaceutical wholesalers. Today 85 percent of all pharmacies in Norway are owned by three large pan-European wholesale companies, and they can and do exercise dominance in the distribution chain. In its reregulation, Sweden did not exclude wholesalers from owning a pharmacy, but the two wholesalers of the country have not bought pharmacies yet. This could be attributed to the single-channel system which is in place in Swedish wholesale, where a wholesaler has the exclusive right to distribute medicines – usually all products – of one manufacturer (WHO CC 2011). In a single channel system the wholesaler is usually more oriented to the manufacturers than to the pharmacies (Vogler/Habl 2003).

In England, Ireland and the Netherlands, large wholesale companies own pharmacies, in particular pharmacy chains. Additionally, companies of the retail sector (e.g. supermarkets) have been increasingly entering the (OTC) market in England, Ireland (e.g. recently Tesco opened two pharmacies) and in Sweden (after the reregulation).

Owning pharmacies offers players of the distribution chain (manufacturers and wholesalers) the opportunity to exercise market control. One interview partner from England, where the new distribution forms like direct-to-pharmacy (DTP) have started, considered these new ways of organizing pharmaceutical distribution as one way of gaining access to information about pharmacies (personal communication, cf. section 3.1).

Table 12.9: Comparative analysis – Vertical integration in the pharmacy sector, 2011

Country	Owners of pharmacies	% pharmacies owned by pharmacists
England	• Most community pharmacies are owned by private persons or entities. • Exceptionally, also Primary Care Trusts (PCTs) own pharmacies. • Vertical partnerships and mergers, i.e. with pharmacy wholesalers and manufacturers, are allowed according to the Competition Act and do take place. • The share of pharmacies owned by so-called multiple contractors (i.e. owners of six and more pharmacies) increased from 59% in 2006 to 65% in 2011.	42% of all community pharmacies are owned by independent contractors (defined as owners of 9 pharmacies or fewer).
Ireland	• More non-pharmacist owners have entered the market in recent years. • In 2011 a supermarket chain (Tesco) opened two pharmacies. • Two of the three large wholesale companies operating in Ireland own pharmacies, they operate the two leading pharmacy chains. • Alliance Boots owns the third largest pharmacy chain.	85% of all pharmacies are pharmacist owned (compared to 90% in 2001).
Netherlands	• The owners of pharmacy chains are mostly wholesale companies. • Two pharmacy chains are owned by pharmacists. • Pharmacies have increasingly been joining co-operations of pharmacies, they are not owned by a chain but are members of a chain.	68%
Norway	• Strong vertical integration since liberalisation. • 85% of the pharmacies are owned by the three large wholesale companies operating in the market. • These are Alliance healthcare, NMD Grossisthandel AS, and Apokjeden Distribusjon (leading pharmaceutical distribution companies in Europe).	Approximately 17%
Sweden	• Major change in the ownership structure, two thirds of all publicly owned community pharmacies were sold in clusters, the rest will be sold to independent pharmacists. • The two wholesalers do not own pharmacies.	n.a.
Austria	• Co-ownership of non-pharmacists is possible, but a pharmacist has to hold at least 50% of the pharmacy ownership. • Co-ownership is the case in nearly 50% of all pharmacies. • Pharmacists are always the (majority) owners of pharmacies.	100% - the majority of the pharmacy is owned by a pharmacist.
Denmark	• Vertical integration is not allowed. • Pharmacists are always the owners of pharmacies.	100%

Country	Owners of pharmacies	% pharmacies owned by pharmacists
Finland	• Vertical integration is not allowed. • Pharmacists are always the owners of pharmacies (with the exception of two universities).	Nearly 100% (apart from the two university pharmacies) are pharmacist owned.
Spain	• Co-ownership of non-pharmacists is possible (unless involved in manufacturing or clinical practice of medicine), but a pharmacist has to hold at least 51% of the pharmacy ownership. • Pharmacists are always the (majority) owners of pharmacies.	100% -the majority of the pharmacy is owned by a pharmacist.

Source: chapters 3 to 11, data gathering by GÖG FP

A strong dominance of big, financially strong companies can limit the independence of pharmacists: Interview partners reported about the problems of independent pharmacists in winning a tender for a pharmacy because the companies usually can offer higher bids (personal communication from UK and Norway). Furthermore, a qualitative study in Sweden shows the reluctance of pharmacists to purchase a pharmacy due to a lot of insecurity, little information by the government about future perspectives and the personal focus on working as a health professional (Bergvist et al 2009).

One approach for pharmacists to react to the challenges in deregulated markets is cooperation, e.g. by forming associations or even pharmacy chains owned by pharmacists. Pharmacy-owned chains are common in Ireland and the Netherlands.

Table 12.10: Comparative analysis – Horizontal integration in the pharmacy sector, 2011

Country	Pharmacy chains	% of pharmacies not part of a chain	% of market share of the 3 biggest pharmacy chains
England	• 61% of all pharmacies are organised in "multiples" (i.e. chains with six pharmacies or more)[1]. • There are nine chains ("multiples") with more than 100 pharmacies[2]. • The "multiples" together account for a market share of 57.9 %[1].	42% (either not part of a chain or part of a chain with 9 or fewer pharmacies)[1].	Approximately 35%[1]
Ireland	• 48% of all pharmacies are organised in chains[2]. • 52% of all pharmacies are run as single shops[2]. • Most of the chains are located in urban areas. • Of the pharmacist owned pharmacies 56% are single shops and 44% are organised in chains[2]. • Of the non-pharmacist owned pharmacies 29% are single shops and 71% are chains[2].	52%[2]	Approximately 79%[2]
Netherlands	• Between 1987 (multiple ownership was first allowed, however only for foundations or sickness funds) and 1999 there were only a few pharmacy chains. • The liberalisation of ownership with regard to non-pharmacists being allowed as owners has lead to an increase in the size of pharmacy chains. • Since 2009, the development slowed down and eventually stopped (due to the economic crisis).	Approximately 54% (excluding pharmacies in membership of a chain).	Approximately 20%
Norway	• No pharmacy chain may own more than 40% of all pharmacies. • There are four major pharmacy chains (3 owned by a wholesale and 1 an agreement based chain involving a wholesaler). • More than 80% of all pharmacies are in the ownership of one of the three large vertically integrated pharmacy chains.	3.7%	Approximately 79%
Norway	• Horizontally the pharmaceutical market in Norway has become very integrated since 2011, because many pharmacies are now owned by the same player.	n.a.	Approximately 83%

Country	Pharmacy chains	% of pharmacies not part of a chain	% of market share of the 3 biggest pharmacy chains
Sweden	• All pharmacies owned by Apoteket till 2009. • In the first selling round of publicly held pharmacies, ApoPharm AB bought 208 pharmacies, Kronans bought 171 pharmacies, Medstop bought 62 pharmacies and Vardapoteket bought 24 pharmacies. • The landscape of pharmacy chains has already slightly changed since the reregulation in 2009.	Approximately 30% of all community pharmacies publicly held in 2009.	n.a.
Austria	• Multiple ownership is not allowed (a maximum of one branch pharmacy under the supervision of the main pharmacy). • No pharmacy chains.	100%	Not applicable
Denmark	• Multiple ownership is not allowed. • No pharmacy chains.	100%	Not applicable
Finland	• Multiple ownership is not allowed (a maximum of three branch pharmacies under the supervision of the main pharmacy). • Only the Helsinki University pharmacy may hold up to 16 branch pharmacies. • No pharmacy chains.	100%	Not applicable
Spain	• Multiple ownership is not allowed. • No pharmacy chains.	100%	Not applicable

[1] Data of 2010

[2] Data of 2009

Source: chapters 3 to 11, data gathering by GÖG FP

In the deregulated countries, around every second pharmacy is organised in a pharmacy chain (cf. Table 12.10). In England, where no data for individual pharmacies are available but "individual contractors" comprise small pharmacy chains with up to nine pharmacies, large pharmacy chains are common. Eleven chains, among those Boots and Health & Beauty, run more than 100 pharmacies. A few large pharmacy chains dominate the market, with only three pharmacy chains concentrating more than 35 percent of the market share (around 80 percent in Ireland and in Norway). Norway is the only deregulated country of this survey that placed a restriction on the number of pharmacies per chain (not more than 40 percent of all pharmacies), nonetheless the market power of the chains is strong. Less than four percent of all pharmacies in Norway are free-standing and independent. In the regulated countries, pharmacy chains do not exist because multiple ownership is not permitted.

Working in a chain pharmacy may have different implications, with regard to workload (cf. section 12.3.1) and to quality of services (cf. section 12.3.4). As discussed in the sections indicated, it is hard to assess the impact of horizontal and vertical integration on these

dimensions. What can be said is that professional independence is seen as a value which is highly appreciated by the pharmacists.

12.3.3 Product range

Medicines are and remain the key products sold in the pharmacies. However, with increasing pressure on the pharmacy margins, the sale of OTC medicines and non-pharmaceuticals has become increasingly important, in particular in the deregulated countries. This trend was confirmed by interview partners in Norway and Sweden. Non-pharmaceuticals might contribute considerably to a pharmacy's turnover, in Ireland and in Norway they account for one quarter of an average pharmacy's turnover (cf. Figure 12.10). Regulated countries tend to have more regulations regarding the sale of non-pharmaceuticals in pharmacies, i.e. in Denmark products sold in a pharmacy must have a natural relationship to the pharmacy, and in Austria the "impression of a pharmacy" should not be disturbed (cf. Table 12.11).

While self-service of non-pharmaceuticals is allowed in all countries surveyed, OTC medicines are usually supplied accompanied by advice in the regulated countries. In the deregulated countries self-service of OTC medicines is permitted in general, at least for general sale products.

A different pattern between the deregulated and regulated countries can be observed with regard to extemporaneous preparations (i.e. pharmacy produced medicines). While in the regulated countries, apart from Denmark, extemporaneous preparations play an important role (not necessarily in terms of turnover but in the professional self-understanding of pharmacists) and nearly all pharmacies have a laboratory to produce these, this is not the case in the deregulated countries. There, the production of extemporaneous preparations is out-sourced to production centres (England, Sweden) or is ensured via cooperation among pharmacies (the Netherlands, Norway). Due to the low relevance of pharmacy-produced medicines, the Norwegian government abolished the rules which had required production facilities in every pharmacy.

Table 12.11: Comparative analysis – Products produced and sold in pharmacies, 2011

Country	Role of pharmacy-produced med.		Non-pharmaceuticals	Self-service allowed for	
	Lab.[1]	Extemporaneous preparations	Role, examples & regulation	OTC med.	Non-ph.
England	A few	"Specials" may be manufactured by pharmacies. Increasingly "specials" are produced by manufacturing companies with a special license.	Commonly sold non-pharmaceuticals include a wide range of health and beauty products, in particular in the big chains Boots and Superdrug. No specific regulations.	N for pharmacy restricted medicines Y for GSL medicines.	Y
Ireland	A few	Not common practice, pharmacies are permitted to produce extemporaneous preparations based on a prescription.	Examples of commonly sold non-pharmaceuticals: Toiletries, dental products, baby products, first aid products, foot care, photo supplies, e.g. films or batteries, perfumes, hairdryers, electric shavers. No specific regulations.	N for pharmacy restricted medicines Y for GSL medicines.	Y
Nether-lands	Some[2]	Decreasing role: 2.1% (2009) and 4.5% of all medicines (2007) were pharmacy-produced. Cooperation among pharmacies for cost reasons[3].	Examples of commonly sold non-pharmaceuticals: bandages, cosmetics, and medical devices. No specific regulations.	Y, but not common practice.	Y
Norway	Some[4]	Minor role.	Examples of commonly sold non-pharmaceuticals: medical devices (e.g. band aids and dressings), skin care products There should be no mismatch in selection of goods in the pharmacy and the public's expectation of what to find in pharmacies.	Y	Y
Sweden	None	Centralised at the state-owned production centre APL (one private production centre is trying to enter the market).	Examples of non-pharmaceutical products commonly sold: health products and cosmetics . No specific regulations. Gaining importance in the recent times.	Y	Y
Austria	All	Very important, mostly made for skin diseases. Already 44% of all prescriptions are magistral preparations. Eye drops and ointments are produced in pharmacies.	Examples of commonly sold non-pharmaceuticals: homeopathic products under certain restrictions, alternative remedies, dressings, tests, nutrition for diets or children or cosmetics . The principle of "health relation" has to be met so that the "impression of a pharmacy" is not disturbed.	N	Y

Country	Role of pharmacy-produced med.		Non-pharmaceuticals	Self-service allowed for	
	Lab.[1]	Extemporaneous preparations	Role, examples & regulation	OTC med.	Non-ph.
Denmark	A few (2 pharma-cies)	0.5% of total pharmacy turnover.	Examples of commonly sold non-pharmaceuticals: food supplements, medical equipment and special skin-care products. Products should naturally belong to a pharmacy.	N	Y
Finland	Most	1% of all medicines are pharmacy-made.	Examples of commonly sold non-pharmaceuticals: vitamins, bandages, tests. Small role for non-pharmaceuticals.	N[5]	Y
Spain	Most	"Magistral formulas" and "officinal preparations" are commonly produced.	N.a.	(Y), Not forbidden, but not practiced.	Y

Lab. = laboratory, GSL = general sales list, med. = medicines, NRT = Nicotine Replacement Therapy, ph. = pharmaceuticals

[1] Number of pharmacies equipped with a laboratory

[2] Not required by law, but the contract with the health insurance states that the pharmacy must take care that manufactured medicines can be delivered

[3] For cost reasons, many pharmacies joined co-operations with centralized manufacturing facilities. In the past years, several central pharmacies that manufacture medicines for other pharmacies were established.

[4] In case of no laboratory, there is often an agreement with another pharmacy that does have a laboratory. The continuously decreasingly role of extemporaneous preparations was a reason for the government to abolish the rules which required production facilities in every pharmacy.

[5] Non-pharmaceuticals have been moved to the self-care section but pharmaceutical advice and guidance is obligatory.

Source: chapters 3 to 11, data gathering by GÖG FP

12.3.4 Pharmacy services

Pharmacies in all surveyed countries provide a range of services for the health care system.

Table 12.12: Comparative analysis – Pharmaceutical counselling, 2011

Country	Quality standards for counselling			Average counselling time
	Y/ N	Nation-wide/ regional	Voluntary/ mandatory	
England	Y	Nation-wide	n.a.	n.a.
Ireland	Y	Nation-wide	Mandatory	n.a.
Netherlands	Y	Nation-wide	Voluntary (by the Royal Dutch Pharmacy)[1]	5 minutes per patient for the first issue of a prescription Less than 5 minutes for repeat dispensing, unless extra information is given
Norway	Y	Nation-wide	Voluntary	n.a.
Sweden	N	-	-	n.a.
Austria	N	-[2]	-	64.4% of all counselling conversations take 4 to 10 minutes 32.2% of all counselling conversations take 1 to 3 minutes 3.1% of all counselling conversations take over 10 minutes
Denmark	Y	Nation-wide	Voluntary[3]	Around 4 minutes in a standard dispensing situation
Finland	Y	Nation-wide	Mandatory (Pharmacy Act)	n.a.
Spain	Y	Nation-wide and regional	Voluntary	n.a.

n.a. = not available

1 From 2012 on, these guidelines will form part of the basis for remuneration of pharmacies by health insurance companies

2 No guidelines for counselling yet, but the integration of community pharmacies into disease management programmes (DMP) is in a pilot phase.

3 Most pharmacies are accredited according to quality model for the National Health System (Danish Healthcare Quality Programme, DDKM)

Source: chapters 3 to 11, data gathering by GÖG FP

In addition to the dispensing of medicines, pharmaceutical counselling is another key activity provided by pharmacies. Pharmaceutical counselling in most countries is subject to quality standards, which are established at regional level. Additional regional quality standards exist in Spain. All surveyed countries except Sweden have mandatory and/or voluntary quality standards for good pharmaceutical counselling. Information on the average counselling time could not be provided by all countries. A standard counselling situation appears to last for around four to five minutes (cf. Table 12.12). Due to the missing data no conclusion on possible differences among countries or groups of countries can be drawn.

Table 12.13: Comparative analysis – Pharmacy services provided by community pharmacies, 2011

Country	Eng-land	IE	NL	NO (2008)	SE		AT	DK	FI	ES
Dispensing Prescriptions	n.a.	All	all	All	All		All	All	All	All
Repeat Dispensing	n.a.	None	All	None	All		None[1]	All	All	Some[3]
Disposal of waste medicines	n.a.	Some	All	All	All		Most	All	Most	All
Medicines Use Review	n.a.	None	Many	Some	Many		None	Many	Some	Some[4]
Provision of emer-gency contraception	n.a.	All	All	None	All		None[2]	All	All	All
Blood pressure meas.	n.a.	Some	Many	Some	Many		Most	Many	Some	n.a
Cholesterol meas.	n.a.	Some	Some	None	None		Most	Some	A few	n.a.
Glucose meas.	n.a.	Some	Most	Some	None		Most	Many	A few	n.a.
Weight measurement	n.a.	Some	A few	Some	Some		Most	A few	n.a.	n.a.
Pregnancy test	n.a.	Some	A few	None	None		None	None	None	n.a.
Smoking cessation	n.a.	Some	A few	Some	Some		Most	Many	A few	n.a.
Diabetes managem.	None	None	Most	None	None		n.a	n.a	n.a.	n.a.[4]
Asthma management	None	None	All	None	None		n.a	Most	Some	n.a.[4]
Hypertension managem.	None	None	A few	None	None		n.a	n.a.	n.a.	n.a.[4]
Vaccination	n.a.	Most	A few	None	A few		n.a	None	A few	None
Homecare services	n.a.	None	Nearly all	None	None		Some	None	None	n.a.
Night services	n.a.	None	Nearly all	n.a.	One		All	Some	One	All
Other services:										
Automatic doses dispensing	n.a.	n.a.	n.a.	n.a.	n.a.		n.a.	All	Many	n.a.
Supply of medicines to nursing homes	n.a.	Some	n.a.	n.a.	n.a.		n.a	n.a	n.a.	n.a
Supervised admin. of methad. & bupren.	n.a.	n.a.	n.a.	Most	n.a.		n.a	n.a	n.a.	n.a
Multidose packaging	n.a.	n.a.	n.a.	Most	n.a.		n.a	A few	n.a.	n.a
Manual dose dispensing	n.a	n.a.	n.a	n.a	n.a		n.a.	n.a	Many	n.a
Individual magistral preparations	n.a	n.a.	n.a.	n.a	n.a		All	A few	n.a	n.a

Admin. = administration, managem. = management, measurem. = measurement, methad. & bupren, = methadone and buprenorphine

[1] Except for private (non-reimbursable) prescriptions (e.g. for contraceptives) which may be repeated up to 5 times

[2] Emergency contraception medication is still POM; however, pharmacists may dispense POM without presentation of a prescription in emergency cases, after interviewing the person on the relevant situation.

[3] Repeat prescriptions services are available in some regions (mostly electronic prescription services and chronic treatments).

[4] In Spain the Medication Use Review is part of the pharmaceutical care services provided by some community pharmacies, as part of Pharmacotherapy follow-up service. Similarly, the management of diabetes, asthma, hypertension, and other similar services could be included in the Service of Pharmacotherapy follow up.

Source: chapters 3 to 11, data gathering by GÖG FP

For historical reasons England, and also the Netherlands, have the lead in pharmaceutical care and other advanced pharmacy services. It is worth mentioning that in England the differentiation into the various kinds of services (essential, advanced and local enhanced) is even reflected in the remuneration system (cf. section 3.3.2.3). In the other countries, the number of pharmacy services has increased during the last decade but according to a large-scale survey of pharmacists involved in pharmaceutical care (Hughes et al. 2010) it is still considered to be limited in the European countries.

Table 12.13 provides an overview about some pharmacy services, however with a lot of missing data (in particular for England). Medicines Use Reviews (MUR) are known to be commonly undertaken in England (cf. section 3.3.2.3), and they have started in some of the other countries (e.g. Spain, cf. section 11.3.3). Point-of-care services (e.g. blood pressure measurement, cholesterol measurement) are regularly provided in several pharmacies in the surveyed countries.

Concerns were raised if deregulation could impact the quality of services. A judgment is hard to give. No consumer surveys have found an improvement of quality due to deregulation. From Ireland and Norway it was reported on an anecdotal basis that the pharmacy chains seem to be the drivers for the quality standards and the enhancement of pharmacy services, but the statement was not confirmed by interview partners of the same and other deregulated countries.

Overall, there appears to be a trend to shift more responsibility to the pharmacists and to involve them as responsible members of the health care system. This may cause tensions between doctors and pharmacists (confirmed by some interview partners). One sensitive issue in this context is the prescribing by pharmacists, which is allowed under specific circumstances in England and is currently done by two to three percent of the pharmacists (cf. section 3.3.2.3).

The involvement in the implementation of generic policies is another field where the competence of the pharmacists is asked for, but it is also an area of possible conflict between doctors and pharmacists: Countries may allow or introduce on a mandatory basis INN prescribing or generic substitution (for the definitions see the notes below Table 12.14). Apart from Austria, all countries of the survey have either INN prescribing or generic substitution in place (cf. Table 12.14). In most countries, it is implemented on a voluntary basis but there appears to be a trend to enforce generic policies on a mandatory basis (Vogler et al. 2011a).

Table 12.14: Comparative analysis – Generic policies, 2011

Country	Generic substitution	INN prescribing
England	Not allowed	Allowed, obligatory[1]
Ireland	Not allowed[2]	Allowed, indicative
Netherlands	Allowed, indicative	Allowed, indicative[3]
Norway	Allowed, indicative	Allowed, indicative
Sweden	Allowed, obligatory	Not allowed
Austria	Not allowed	Not allowed
Denmark	Allowed, obligatory	Not allowed
Finland	Allowed, obligatory	Allowed, indicative
Spain	Allowed, obligatory	Allowed, indicative[4]

Definitions according to the PPRI/PHIS Glossary (WHO CC 2011):
Generic substitution is defined as the practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient(s). In a country, generic substitution by all pharmacists or only by some of them (the ones in the public sector, or the ones in the private sector, etc.), or by other paramedical personnel (e.g. nurses), can be allowed through laws or regulations.

INN prescribing refers to physicians prescribing medicines by their INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory INN prescribing)

1 INN prescribing is indicative, although encouraged and widely practiced

2 Introduction of generic substitution is under discussion

3 Obligatory substitution if the medicine falls under the scope of the preferential pricing policy (exemption: if the prescriber indicates that a medical need exists for other products). The brand name is automatically changed to INN through an electronic prescribing system

4 INN prescribing became mandatory in August 2011, before it was indicative

Source: chapters 3 to 11, data gathering by GÖG FP, PHIS 2011, WHO CC 2011

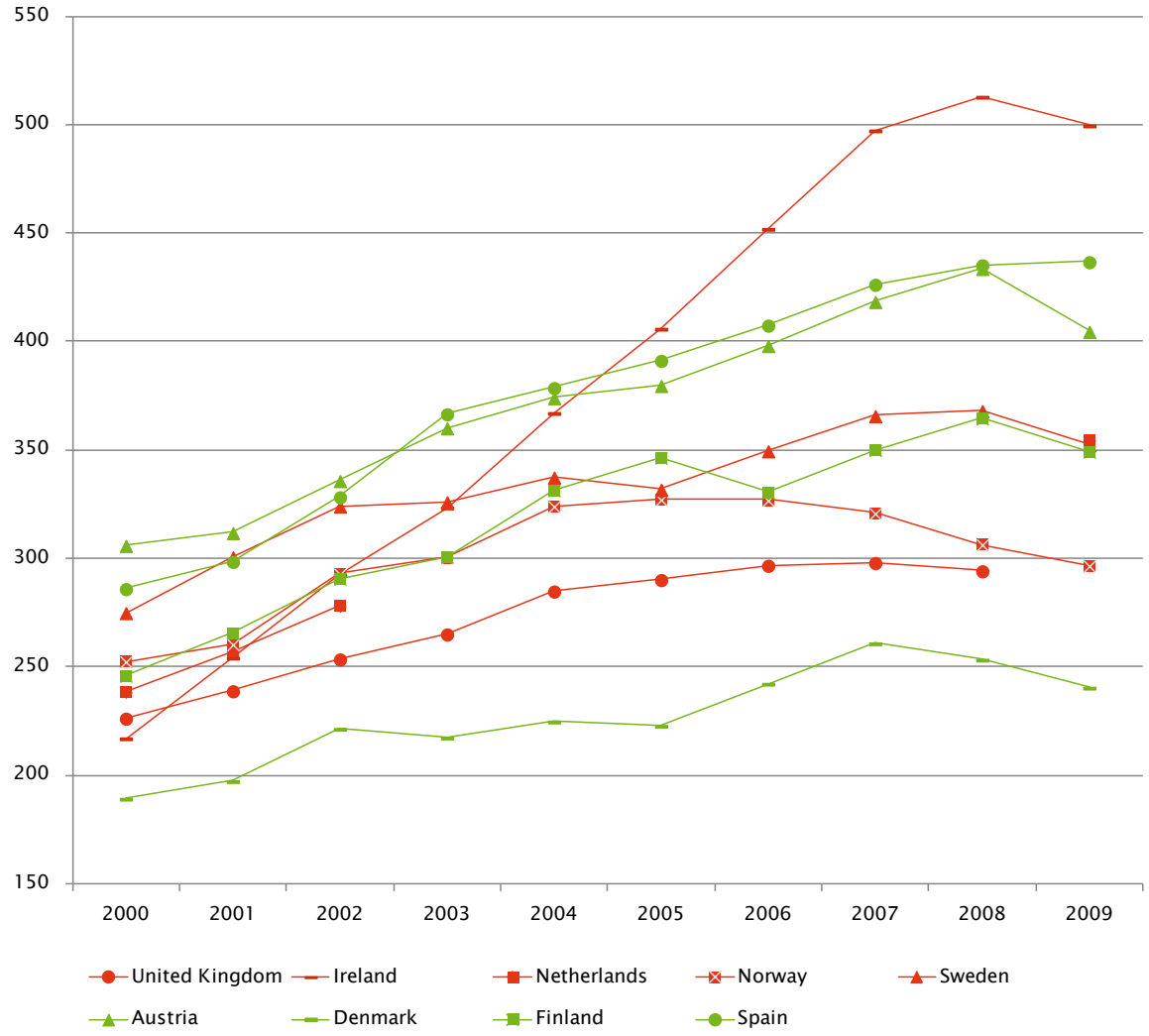
12.4 Economics

12.4.1 Pharmaceutical expenditure

In the countries surveyed, the total pharmaceutical expenditure per inhabitant varied from about € PPP 240.- in Denmark to € PPP 500.- in Ireland. In 2009 the range was rather broader compared to 2000, when it varied from about € PPP 189.- in Denmark to € PPP 306- in Austria.

Data on total and public pharmaceutical expenditure in € Purchasing Power Parities (PPP) are presented in Figure 12.7 and Figure 12.8.

Figure 12.7: Comparative analysis – Total pharmaceutical expenditure per inhabitant in Euro PPP, 2000 – 2009



Note: Data are provided for the whole UK, not only for England.

Please be aware of the currency exchange rate bias for Norway, Sweden and UK.

Source: chapters 3 to 11, data gathering by GÖG FP, OECD 2011

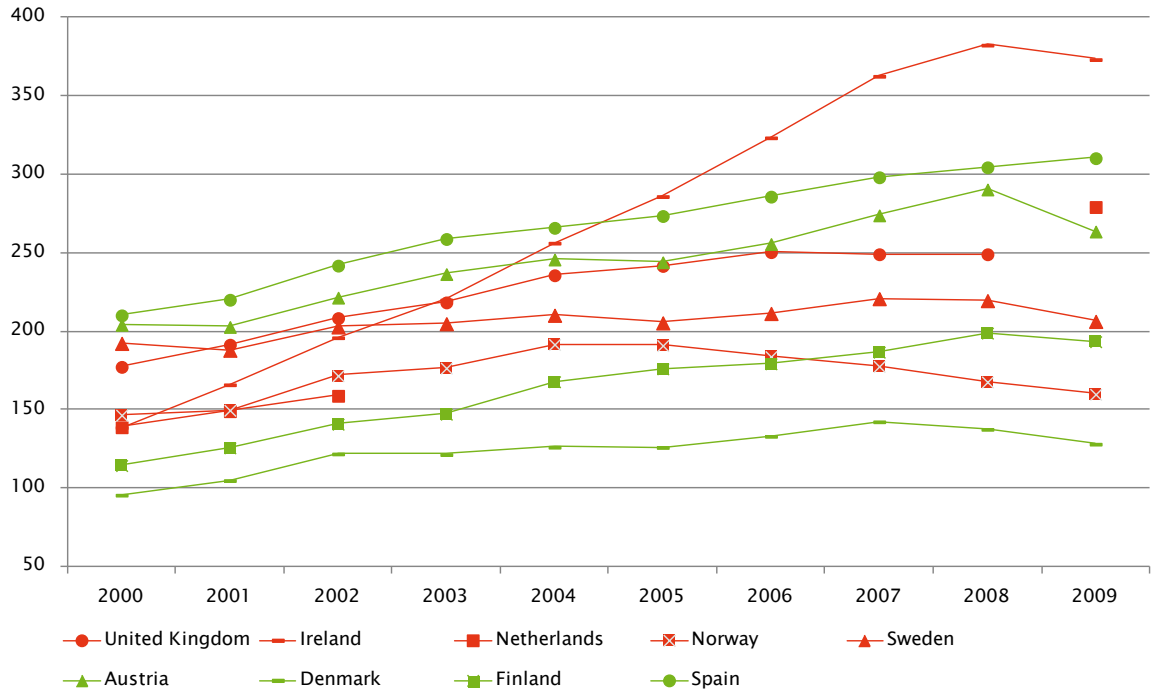
Overall, the countries had rising total pharmaceutical expenditure, sometimes with annual growth rates in double digits, at least in the first half of the decade. At the end, the increases became less and were even negative since 2008 (or 2007) in some countries. This is due to the global financial crisis that forced the countries to introduce strict saving measures. One of the countries strongly hit by the crisis was Spain in 2010, and this was also the time when it reacted with emergency measures for the pharmaceutical sector (Vogler et al. 2011a, Martinez et al. 2011). Till then, pharmaceutical expenditure had been rising (cf. Figure 12.7). Norway's pharmaceutical policies had an impact on total and public pharmaceutical expenditure already earlier, from 2005 on (data in national currency units/NCU display very low and also partly negative growth rates). The Norwegian authorities attribute this to the

country's pricing policies (external price referencing based a well-defined methodology and basket of reference countries), its generics policies (e.g. the "stepped price system") and a good interface management between the hospital and out-patient system (Aanes et al. 2009, Festøy et al. 2011).

The lowest pharmaceutical expenditure data per inhabitant expressed in € PPP have been observed over the years in Denmark (in NCU: no such variations in growth rates as displayed in Euro PPP, but very moderate growth rates).

Ireland had the highest growth in pharmaceutical expenditure and eventually the highest pharmaceutical expenditure per inhabitant in 2009. From 2000 to 2008, total pharmaceutical expenditure more than doubled; after 2008 it decreased.

Figure 12.8: Comparative analysis – Public pharmaceutical expenditure per inhabitant in Euro PPP, 2000 – 2009



Note: Data are provided for the whole UK, not only for England.
Please be aware of the currency exchange rate bias for Denmark, Norway, Sweden and UK.

Source: chapters 3 to 11, data gathering by GÖG FP, OECD 2011

In the European countries on average, two thirds of pharmaceutical expenditure are publicly funded, with major differences between Western and Central and Eastern European (CEE) countries. The share of public funding of pharmaceutical, as well as of health, expenditure is considerably higher in the western European countries, though it has been decreasing over time, compared to the CEE countries (OECD 2011, Vogler 2008, Vogler et al. 2011a). Within the group of western European countries, the Nordic countries display lower shares of publicly funded pharmaceutical expenditure (around 50 percent), while these shares are of

around 70 percent and more for nearly all of the rest of the surveyed countries (cf. Table 12.15).

Table 12.15: Comparative analysis – Pharmaceutical expenditure as percentage of health expenditure and share of publicly funded pharmaceutical expenditure, 2009

Country	Total pharmaceutical expenditure in % of total health expenditure	Public pharmaceutical expenditure in % of total PE
United Kingdom[1]	11.6%	78.4%
Ireland	17.5%	74.7%
Netherlands	9.6%	78.8%
Norway	7.3%	53.9%
Sweden	12.5%	58.6%
Austria	12.5%	65.2 %
Denmark	7.3%	53.3%
Finland	14.3%	55.4%
Spain	18.9%	71.1%

[1] Data are provided for the whole UK, not only for England.

Source: chapters 3 to 11, data gathering by GÖG FP, OECD 2011, PHIS 2011

The level and the developments of public pharmaceutical expenditure of the surveyed countries is, as a result of the high share of public funding, similar to total pharmaceutical expenditure. Again, Denmark has the lowest expenditure per inhabitant and also only moderate increases in public pharmaceutical expenditure; and Norway's pharmaceutical policy succeeded in containing public pharmaceutical expenditure from 2005. At the other end, Ireland displays high increases in public pharmaceutical expenditure, followed by Spain (cf. Figure 12.8). Ireland and Spain also account for the highest share of pharmaceutical expenditure in health expenditure (around 18-19 percent in 2009) among the surveyed countries (cf. Table 12.15).

Expenditure data do not show any pattern with regard to the two defined groups of countries but reflect the impact of wealth and economic developments and overall pharmaceutical policies in the countries.

12.4.2 Pharmacy turnover

A comparison of the pharmacy turnover among the countries is connected with some methodological difficulties, thus we did not compare the average turnover per pharmacy since the size of the pharmacies varies among the countries (cf. Table 12.8). A comparison of turnover per staff, or per pharmacist, could also be biased due to the different composition of staff in pharmacies across the countries.

An analysis of the development of pharmacy turnover across the countries (where data was available) shows that the pharmacy turnover has moderately increased from 2006 to 2010, with not more than 20 percent in total for the four years. In Denmark the pharmacy turnover has even remained more or less at the same level, including a decline from 2007 to 2008.

Finland and Spain also experienced decreases from 2009 to 2010 (cf. Figure 12.9). Unfortunately data for other countries were not available for the time analysis. We know about a decrease in the Netherlands from 2008 to 2009, followed by an increase in the following year. In the Netherlands, the decrease was attributed to the preferencial pricing policies by the sickness funds (Kanavos et al. 2011, Zuidberg 2010, cf. section 5.1).

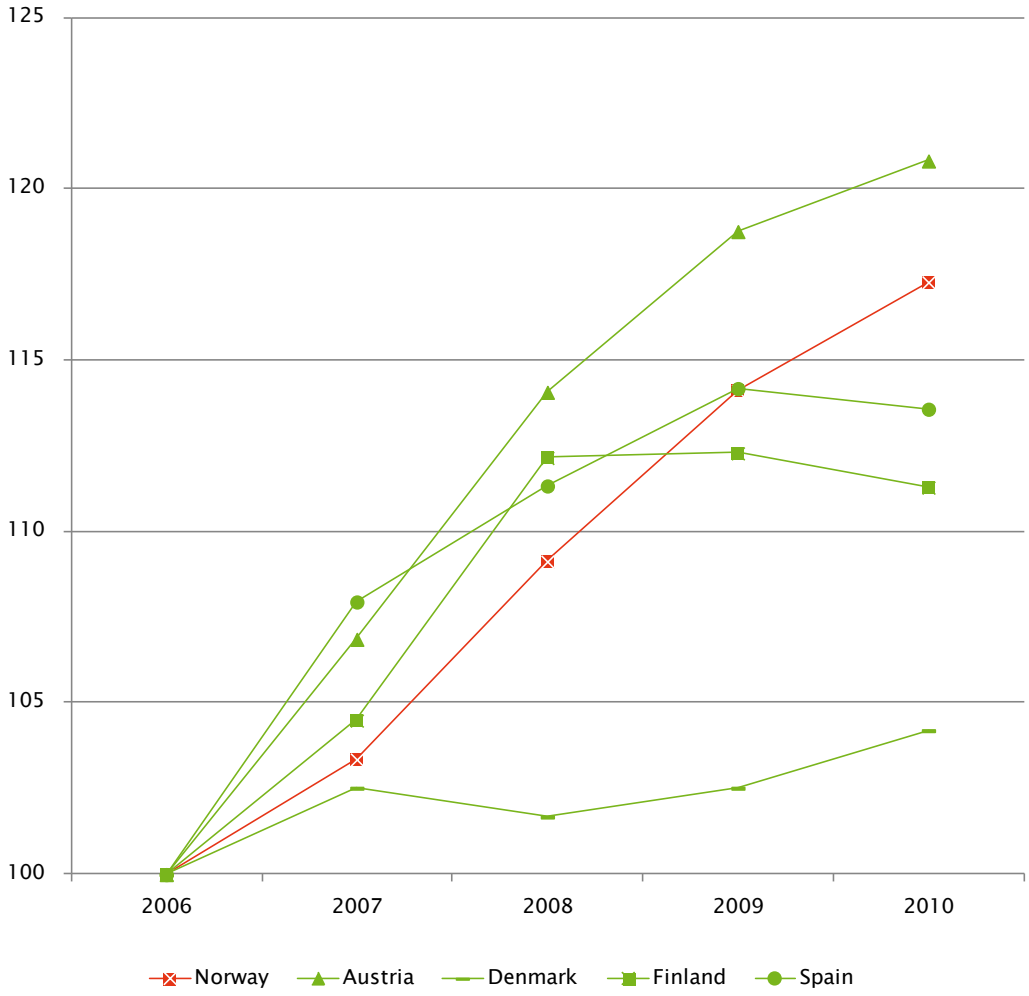
This confirms that the pharmacy turnover can be influenced by policy measures, not only those targeting pharmacies (e.g. margin reductions) but also at other price types (e.g. ex-factory price cuts) and other components of the pharmaceutical expenditure (e.g. prescribing limits/budgets for doctors).

Overall, the increases in pharmacy turnover were rather moderate over the years, in particular in recent times, probably impacted by the global financial crisis.

Looking at the data of the total pharmaceutical markets (from a different data source, see the relevant sections in the country reports), there are no major differences. However, the increases in total pharmaceutical turnover tend to be higher and the data sometimes display breaks (partially to be explained by changes in the price types – from pharmacy purchasing price to pharmacy retail price – this methodological bias being also the reason why the data on pharmaceutical markets were not included in the comparative analysis).

Compared to the developments in pharmaceutical expenditure (cf. section 12.4.1), the pharmacy turnover displays a similar but lower growth. This is particularly evident in the case of Ireland, where total and public pharmaceutical expenditure have increased by five and 3.5. times respectively from 2000 to 2008 (with decreases in the year after, cf. Figure 12.7 and Figure 12.8), but the pharmacy turnover has only doubled in that time period.

Figure 12.9: Comparative analysis – Development of total pharmacy turnover, 2006 – 2010, indexed: 2006 = 100



No data from 2006 to 2010 available for England/UK, the Netherlands and Sweden.

Ireland: data only available for 2000, 2008 (increase of 114 percent compared to 2000) and 2009 (decrease of 1.5% compared to the previous year)

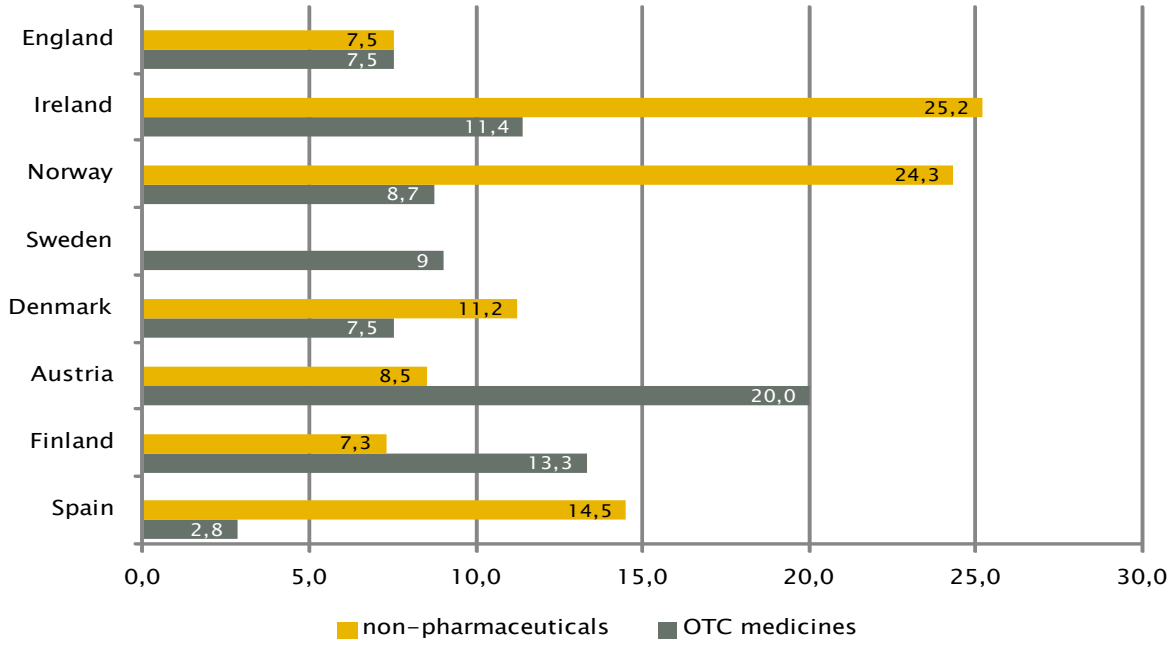
Source: chapters 3 to 11, data gathering by GÖG FP

As discussed in section 12.3.3 the sale of non-pharmaceuticals continues to play an increasingly important role in community pharmacies, in particular in the deregulated countries. In Ireland and Norway the sale of non-pharmaceuticals accounts for about one quarter of the sales of a pharmacy (cf. Figure 12.8). It is worth noting that the shares were 19 percent and 14 percent respectively for the two countries in 2004 (Vogler et al. 2006).

For the OTC medicines there is no clear picture among the countries: The highest share of OTC medicines turnover is in Austria with 20 percent of the total pharmacy turnover, followed by Finland and Ireland, and the lowest in Spain with less than three percent (cf. Figure 12.10). In the deregulated countries often a substantial part of OTC sales is made outside

pharmacies. In the regulated countries the sale of OTC medicines outside pharmacies is allowed only to a limited extent (cf. section 12.2.1).

Figure 12.10: Comparative analysis – OTC turnover and non-pharmaceutical turnover in percent of total pharmacy turnover, 2010



England = estimation; Ireland = data for 2009

Source: chapters 3 to 11, data gathering by GÖG FP

12.4.3 Pharmacy remuneration

The remuneration which pharmacies receive for dispensing medicines is statutorily regulated in all the countries surveyed, at least for the reimbursement and the prescription medicines market.

It is usually regulated in the form of maximum statutory linear mark-ups or regressive schemes, some countries remunerate for the dispensing of medicines via (dispensing) fees (cf. Table 12.16).

Table 12.16: Comparative analysis – Pharmacy remuneration schemes 2011 and average margins

Country	Scope	Type	Average margin	
			Known	In % of PRP
England	Reimbursable[1]	Fees (dispensing fee, additional fees)	N	-
Ireland	Reimbursable	Linear mark-up[2]	N[2]	-
Netherlands	POM	Fees (dispensing fee, additional fees)[3]	N	-
Norway	POM	Regressive mark-up scheme plus fees	N	-
Sweden	POM	Regressive mark-up scheme plus extra fee for generics	Y	21.3% (2008) – total market
Austria	All medicines	Regressive mark-up schemes[4]	Y	18.18% (2010) – reimbursable med.
Denmark	Pharmacy-only med.	Linear gross mark-up (but fixed fee net of turnover taxes)	Y	16.5% (2010) – POM, 21.8% (2010) – total market
Finland	All medicines except NRT	Regressive mark-up scheme	Y	23% (2010) – total market
Spain	All medicines	Regressive mark-up scheme[3]	Y	22.4% (2008) – reimbursable med.

med. = medicines, NRT = nicotine replacement therapy, POM = prescription-only medicine, PRP = pharmacy retail price

1 NHS (National Health Service) medicines

2 Different pharmacy remuneration depending on the Community Drug Scheme, e.g. 20 percent mark-up in the Drug Payment Scheme and Long Term Illness scheme, but no mark-up on the General Medical Service scheme. For all State schemes, pharmacists are paid through a regressive fee structure.
Due to the different Community Drug Schemes, no average mark-ups can be provided.

3 Pharmacy remuneration is reduced by a claw-back system.

4 Two different schemes, one for "preferential costumers" (e.g. sickness funds) and one for private customers.

Source: chapters 3 to 11, data gathering by GÖG FP, PPI 2011, Vogler 2011a, PHIS 2011

Data on average pharmacy margin is increasingly hard to get since not all countries have a policy to publish average margins. For some countries average margins are difficult to be supplied due to the underlying remuneration system (e.g. Ireland – different margin for each Community Drug Scheme but each pharmacy has a different ratio of medicines dispensed under the different schemes).

Information on the average margin could only be surveyed for the regulated countries (and Sweden for the year before the liberalisation). Comparability is limited because the average margins apply to different markets (total, reimbursement, prescription market). The margins range from 16.5 percent for prescription-only medicines in Denmark and to 23 percent for the total market in Finland (cf. Table 12.16).

We were also looking into possible incentives of the pharmacy remuneration to sell more medicines or more expensive medicines but could not get an explicit answer. From a theoretical perspective, regressive mark-ups tend to discourage the sale of expensive medicines compared to linear mark-ups.

In order to compensate for the loss in the margins on prescription-only and/or reimbursable medicines, pharmacies focus on the sale of OTC medicines and non-pharmaceuticals (cf. Figure 12.10).

One expectation which is often connected to the deregulation is a decrease in medicines prices, in particular OTC prices. A price survey was not in the scope of this study. Existing price surveys (Kanavos et al. 2008, Brekke et al. 2008, Kanavos et al. 2010) usually focus on prescription-only and/or reimbursable medicines (also for the practical reason because OTC prices are usually unregulated and thus often not displayed in the national data bases, cf. Leopold et al. 2012). Declines in prices could sometimes be observed but this was a result of policy measures aiming at different price types (e.g. price or margin cuts, change in the methodology of the setting of medicine prices). Only a few studies (Dagens Apotek 2011, Econ Analyse 2004, Danmarks Aptekerforening 2011a, Stargardt 2007, Vogler et al. 2006) are available on the development of the OTC prices, and none of them could confirm a decrease of OTC prices after the liberalisation.

13 Lessons learned

The current chapter draws on the information gained about the community pharmacy sector in the nine countries surveyed. In section 13.1, we summarize key lessons learned in terms of the indicators defined in the three strands on accessibility, quality and economics. Section 13.2 contains key observations with regard to key stakeholders targeted and/or involved. Finally, in section 13.3, we discuss the added value which this study brings to the existing knowledge in this area, and possible limitations of the study.

13.1 Key observations per indicator

13.1.1 Key observations on accessibility of POM dispensaries

Accessibility of community pharmacies and POM dispensaries in general and in rural areas

A major distinction between the deregulated and regulated countries concerns the regulation regarding establishment and ownership rules.

The opening of new community pharmacies is regulated by statutory establishment rules, considering both geographic and demographic criteria, in Austria, Denmark, Finland and Spain. The criteria are set at national level; in addition the regions (Autonomous Communities) in Spain may adjust the criteria to their local peculiarities. In one region, Navarra, rather liberal criteria were introduced, which led to the establishment of new pharmacies in the beginning but eventually forced some pharmacies to close.

The rationale of the establishment rules is to ensure an appropriate provision with community pharmacies, with equitable distribution among the regions, in particular among urban and rural areas: People in sparsely populated regions should be granted equal access to medicines. Additionally, establishment rules aim to prevent the unlimited clustering of pharmacies in popular locations (e.g. town centres), which might harm the viability of the individual pharmacies and negatively impact the quality of pharmacy services due to the financial pressure.

In England, Ireland, the Netherlands, Norway and Sweden no establishment rules are in place. In the deregulated countries new pharmacies were established, especially after deregulation, in urban areas, practically no new pharmacies were opened in rural areas. Overall, with the exception of Denmark, the average number of inhabitants served by a pharmacy has decreased in all surveyed countries, and considerably in Norway after the change in the regulatory framework. Norway had reported a low provision with pharmacies before the deregulation. In Denmark the decrease in the number of pharmacies was decided by the authorities in order to reduce the cost of distribution to society through fewer, but larger pharmacies.

Regarding the provision of medicines in rural areas, all surveyed countries developed individual approaches, often historically based, which take into account their country specific particularities.

Availability of medicines

Regulated countries tend to also have several further regulations in place. For instance provisions on medicines required to be in stock are in place in all the regulated countries but also in Sweden and Norway. There are concerns that deregulation might lead to the lower availability of less frequently used medicines in the pharmacies.

Frequency of wholesale deliveries

The frequency of wholesale deliveries varies to some extent among the countries. A key reason for the differences appears to be the organisation of the wholesale sector. Overall, there are fewer deliveries in the Nordic countries.

13.1.2 Key observations on quality of pharmacy services

Availability of pharmacists and qualified staff in pharmacies

With regard to the number of qualified staff no specific pattern among liberalised and regulated countries is visible.

Several Nordic countries share the characteristics that besides full pharmacists so-called prescriptionists (or in Denmark dispensing pharmacy technicians - “pharmaconomists”) may also dispense (prescription-only) medicines. In Denmark and Finland three of four pharmacists are prescriptionists. In England, Ireland and the Netherlands, pharmacy technicians (pharmacy assistants) with a special vocational training are also allowed to dispense prescription-only medicines, while in Austria and Spain pharmacy assistants may not dispense on their own.

The highest number of dispensing staff can be found in the Netherlands and Ireland (more than (11 dispensing staff per 10,000 inhabitants). While in the Netherlands most of the dispensing staff are pharmacy technicians, the ratio is the other way round in Ireland. Ireland has the highest number of pharmacists per 10,000 inhabitants, followed by Spain and Austria. Regarding the number of pharmacists per pharmacy, the highest numbers were found in Austria (4 pharmacists per pharmacy), Ireland (2.9) and Denmark, while Sweden has by far the lowest number of full pharmacists per pharmacy (0.64). Denmark has the highest number of total staff per pharmacy (more than 15 staff, thereof 10.5 dispensing staff) followed by the Netherlands and Austria.

In Norway, while the overall number of community pharmacists has increased in the last decade, the number of pharmacists (full pharmacists) per pharmacy has, due to the opening of new pharmacies, sharply decreased after the deregulation.

For Sweden no data are available on the staff development after the reregulation. According to a survey consumers had the perception of deterioration in the competence in staff qualification, which might be attributable to the fact that after the reregulation pharmacists and qualified staff tend to work more back-office and are thus less visible for the consumers.

Professional independence of pharmacists

Allowing horizontal integration has led to the establishment of pharmacy chains in all deregulated countries: In the deregulated countries, around every second pharmacy is organised in a pharmacy chain. As a result, a few pharmacy chains can dominate the market, as evidenced in England, Ireland and Norway (around 80 percent of the market share is concentrated on three chains in the last two countries). These pharmacy chains are often vertically integrated large wholesale companies. In Norway, 85 percent of all pharmacies are owned by three large pan-European wholesale companies. In Ireland and the Netherlands, however a majority of the pharmacies are still owned by pharmacists.

Deregulation has in several cases resulted in the loss of the pharmacists' professional independence, which is a high value to them. In tenders for purchasing a pharmacy individual pharmacists stand lower chances against large companies of winning the bid.

Role of tailor-made products

In spite of rather minor economic relevance (i.e. expressed as percentage of the total pharmacy turnover), extemporaneous preparations play a role in some of the countries, i.e. Austria, Finland and Spain. They appear to be relevant in the professional self-definition of pharmacists. Being historically grounded, they are losing their role in the deregulated countries, with "outsourcing" to production centres (England, Sweden) or co-operations among pharmacies (the Netherlands, Norway). In fact, no longer all pharmacies have a laboratory in the deregulated countries.

Focus on medicines

While filling prescriptions is the "core-business" of community pharmacies, the business with OTC medicines and non-pharmaceuticals has continuously been gaining importance for community pharmacies in all countries. This development is considered as a response of pharmacies to cost-containment measures which have, among others, addressed the pharmacy margins. Still, OTC medicines sales usually account for around 10 percent of a pharmacy's turnover (exception Austria: 20 percent). Non-pharmaceuticals may contribute to a considerable extent to a pharmacy's turnover, in particular in Ireland and Norway (currently 25 percent; compared to 19 and 14 percent respectively in 2004).

Relevance of counselling and other pharmaceutical services

Counselling is a key task of community pharmacists and is provided as a part of a pharmacist's work in all the countries. On average, a standard counselling conversation takes four to five minutes (data only available for Austria and Denmark). Typically, counselling is not separately remunerated but as a part of the remuneration for filling

prescriptions. An increased workload can negatively impact the quality and time available for counselling.

In addition to filling prescriptions and counselling, community pharmacies have been providing further services whose number has increased over the years. England has a lead and has frequently been among the first countries providing such services, including pharmaceutical care, often followed by the Netherlands.

Involvement in health promotion and prevention

Independently from the extent of regulation in a country, surveys have confirmed a key role of the pharmacists as a part of the health care system. Pharmacists often act as the first contact point. The increased involvement of pharmacists in health promotion and prevention (e.g. new services like flu vaccinations provided in pharmacies) might be a source of tension between pharmacists and doctors, but there is a potential for further use and expansion.

13.1.3 Key observations on economics

Growth in pharmaceutical expenditure and public pharmaceutical expenditure

During the last decade, policy measures succeeded in containing pharmaceutical expenditure at moderate growth rates in some of the surveyed countries: This was observed for Norway and Denmark which has the lowest level of pharmaceutical expenditure, including public pharmaceutical expenditure, among the analysed countries. At the other end, Ireland had high increases in total and public pharmaceutical expenditure from 2000 to 2008, since then a decrease. From 2008 on countries were hit by the global financial crisis, which is visible in a negative growth in pharmaceutical expenditure in several countries (especially Austria, Netherlands, Finland, Ireland) after this turning point.

Expenditure data do not show any pattern between the deregulated and regulated countries since pharmaceutical expenditure, in particular public pharmaceutical expenditure, is impacted by a mix of policy measures influencing both price (e.g. price control at ex-factory level, pricing procedures such external price referencing and encouraging generic competition, wholesale mark-ups and margins, tax rates and pharmacy remuneration) and volume (e.g. prescription limits for prescribing doctors).

Average pharmacy margin

All surveyed countries have a regulated pharmacy remuneration scheme for dispensing medicines in place. Usually, the remuneration scheme includes counselling while additional services, such as the production of pharmacy-made preparations (extemporaneous preparations), are typically remunerated separately.

Pharmacy margins have increasingly become under pressure. There were changes in the pharmacy mark-ups and margins during the last few years, usually cuts (with the exception of Spain). At the time of this report margin changes/cuts are again under discussion in some

countries. In Sweden, the pharmacy margin is currently reviewed, and it is planned to be changed in 2013, as part of the reregulation process.

Data on average pharmacy margins on medicines are hard to be surveyed. Information could be collected for the different markets (prescription, reimbursement and total market) from the regulated countries (and from Sweden before the liberalisation). The margins range from 16.5 percent (Denmark) to 22.3 percent (Spain) for the prescription and/or reimbursement markets and from 21.8 percent (Denmark) to 23 percent (Finland) for the total markets.

In order to compensate for the loss in the margins on prescription-only and/or reimbursable medicines, pharmacies have been putting more attention to the sale of OTC medicines and non-pharmaceuticals. This has been in particular observed in deregulated countries.

The development of the OTC prices, which are often expected to decline after a deregulation, was not scope of the analysis in this study. Few studies are available on the development of the OTC prices, and none of them could confirm a decrease of OTC prices after the liberalisation.

13.2 Key observations regarding the stakeholders

Key stakeholders targeted by the liberalisation of community pharmacies are pharmacists and consumers; additionally further stakeholders, in particular manufacturers and distribution actors and further authorities, might be addressed and/or play a role.

Pharmacists

- Pharmacists, both pharmacy owners, as well as employees, are strongly hit by deregulation in the pharmacy sector since it usually implies a major change of the business model.

- Liberalisation of the pharmacy sector tends to impact the viability of the individual pharmacies. Clustering was observed at attractive locations (e.g. town centres, in/near shopping centres), and this might eventually lead to the closure of pharmacies.

- Cooperation among pharmacies (e.g. establishing a pharmacy “chain” with pharmacies in membership) is one approach for pharmacists to jointly address the challenges of a more unregulated market.

- Pharmacists as a profession tend to be opposed to a liberalisation of a regulated pharmacy sector because they have a deep professional concern about the impact of the deregulation, especially regarding accessibility to medicines and quality of pharmacy services. They fear a shift in their work from a responsible health professional to an excessive focus on mere retail sales figures.

- Especially experienced pharmacists, being in the job for decades, expressed their concerns about the consequences of a liberalisation on the professional standards.

- Their professional independence continues to be a major value to pharmacists, even in countries which were deregulated years ago. In such markets, the predominance of pharmacy chains, which usually bid at very competitive prices, prevent individual, not financially strong resourced pharmacists to purchase a pharmacy of their own.

- There are indications that after a change in the pharmacy system in some countries the workload for the employed pharmacists and also pharmacy technicians has increased.

- Regarding the quality of pharmacy services, no clear picture could be drawn. While there were concerns that due to liberalisation and increased work load in chains the quality of pharmacy services might be at stake, other interviewees believed in better quality in some chains due to the chain's investment in and implementation of quality standards in all their outlets. In general, most interview partners (pharmacists or other stakeholders) think that in the end quality mostly depends on the individual pharmacists (pharmacy owner, pharmacy manager) and the professional standards outlined by the owner.

- Pharmacists in regulated countries are highly convinced of the benefits of their current system for the consumers.

- Irrespective from the extent of regulation in a pharmacy market, surveys have confirmed the role of community pharmacies (and pharmacists) as major actors in the health care system. This is based on the qualifications and the competencies of the pharmacy staff. This appears to have a potential to be used even more and better throughout the health care system in most countries.

Consumers and patients

- Accessibility to medicines, including to OTC medicines, appears to be of high importance for consumers. Opening hours, waiting times and the distances to the pharmacies and further dispensaries / retailers seem to be major indicators for accessibility from a patient's point of view.

- As a result, consumers tend to be rather in favour of a liberalisation of the OTC medicines sales. The liberalisation regarding OTC medicines sale appears the major, and sometimes sole, aspect of a deregulation process observed and commented on by the consumers.

- Patients tend to not perceive the difference between an individual pharmacy and a chain pharmacy, since patient need is primarily get access to medication and good conselling.

- While consumer associations are aware about the price control for prescription-only medicines, consumers themselves appear to expect lower medicines prices after liberalisation. This might be attributed to public communication that a government announced lower prices as a result of a deregulation process. However, there is no evidence of such price declines.

- However, there was evidence that consumers are willing to pay a higher price for OTC medicines and non-pharmaceuticals charged by a pharmacy compared to other retailers for the same product because they value the counselling service.

Competition authorities

- Competition authorities have been a major driver for the deregulation in the pharmacy sector. However, even in some liberalised countries, they are not entirely pleased with the achieved results for two different reasons: Either they ask for further deregulation (e.g. England, Ireland), or they are concerned of exploitation of a dominant market position resulting from (horizontal and vertical) integration after liberalisation (e.g. Norway).

- Even if pharmacy prices are just one price component, and only one element of pharmaceutical expenditure, competition authorities expect a decrease in the prices of medicines, in particular OTC medicines, as a result of more competition. As a consequence, generics prices and pharmacy margins have been issues addressed by competition authorities in some of the surveyed countries.

- Accessibility issues like urban clustering and/or low availability in rural areas is not in the (primary) scope of competition authorities.

Other public authorities responsible for medicines

- The most relevant area of interest for competent authorities for pharmaceutical pricing is the issue of pharmacy margins. In nearly all countries surveyed, a reduction in the pharmacy margins is currently being politically considered and/or discussed, in several cases as a cost-containment measure in response to the global financial crisis.

- Medicines agencies and other authorities which are in charge of granting (and recalling) pharmacy licences do not appear to be major drivers for liberalisation of the pharmacy sector. However, they tend to be key actors with regard to quality assurance in some countries since they work as inspectorates for quality control. In some countries, they also discuss the further development of quality standards and services with pharmacy representatives – these might be the pharmacy associations, but also big pharmacy chain companies.

Doctors

- In some countries doctors are allowed to dispense prescription-only medicines, usually in sparsely populated areas with no community pharmacy in the neighbourhood. While the number of POM dispensing doctors has been, on general, decreasing and they are rather few in number (with the exception of Austria), tension between POM dispensing doctors and pharmacists has been reported from more than one country.

- A potential source of conflict is generics promotion, in particular generics substitution and prescribing. Some doctors appear to perceive this as interference into their therapeutic freedom.

Wholesalers

- Wholesalers have a predominant role in those countries (Finland and Sweden) in which pharmaceutical wholesale is organised in the form of a single channel system (i.e. the wholesaler has the exclusive right to distribute the full supply of a manufacturer). This is independent from the extent of regulation. In a single channel system, only a few wholesalers operate which, as a result, tend to have high market share.

- Wholesale companies tend to be winners of a deregulation if they are allowed to gain (unlimited) ownership of pharmacies. This was legally possible in all deregulated countries. As a result, in some countries (e.g. Norway), the majority of pharmacies are part of the leading pharmacy chains owned by big wholesale companies, while only a few individual pharmacies are left.

- Wholesalers can be negatively impacted by the new distribution forms, such as direct-to-pharmacy (DTP), agency models and reduced wholesaler arrangements, implemented by large pharmaceutical manufacturers.

Manufacturers

- Piloted and strongly implemented in the UK, manufacturers have been experimenting, also in some other countries, with the new models of distribution, such as direct-to-pharmacy (DTP), agency models and reduced wholesaler arrangements.

- Direct-to-pharmacy is seen as an approach of manufacturers to gain more insight into the pharmacy business as part of their overall marketing strategy.

- Manufacturers have been confronted with a decrease in prices, partly due to statutory price cuts and partly as a result of generic competition. This loss in profit might also impact manufacturers' strategies versus the distribution actors.

13.3 Discussion

The current report offers added value to on-going discussions on deregulation in the pharmacy sectors in Europe. It collects information and data on community pharmacies in several European countries and thus adds to existing and published knowledge. Studies are often focused on a few countries and/or on one aspect (e.g. price development, competition). This study has explored possible differences between deregulated and regulated countries, based on a rather larger basket of nine countries.

In addition to a collection and comparison of hard data, the study design included qualitative interviews with targeted stakeholders. This has allowed the research team to learn about different perspectives and consider them in the analysis.

This qualitative approach helped us to draw conclusions in areas where no hard data were available. In spite of sound research and the cooperation of our contact persons, we have not succeeded in getting data in all areas.

A few biases should be taken in account. For instance, we carefully searched for explanations in some breaks in the market data provided by AESGP. Another limitation concerned the fact that some literature was only available in the country's language, where we often only had access to an executive summary or an oral summary provided by an interview partner. This limited us in assessing the methodology and quality of the studies, and we could gain only limited insight into the results.

Deregulation is often expected to lead to higher accessibility to medicines and lower (OTC) medicines prices. While we analysed accessibility to pharmacies and further POM dispensaries, even with regard to equity and distribution within the countries, the development of the OTC prices was not within the scope of the study. The reason for not defining the price development as an indicator was based on the knowledge about the difficult access to OTC prices in the countries (OTC prices are mostly not statutorily regulated, but may be freely priced by the manufacturer, and are thus usually not included in the price databases). Nonetheless, we considered literature evidence on OTC price development, even if we are aware of methodological limitations in such studies.

The current report about the community pharmacy sector in deregulated and regulated countries has confirmed results from previous research (e.g. Vogler et al. 2006). Some of the developments which were evidenced in the literature to take place after a deregulation can indeed currently be observed in Sweden.

In addition, our study, which surveyed the current situation as of autumn 2011, has brought new findings, since the pharmacy sector – both in deregulated and in regulated countries – was subject to a number of changes (e.g. new distribution forms, e-pharmacy, pharmacy margin cuts) in the last few years.

An evaluation of policy measures tends to be undertaken briefly after a change, but often is not repeated and continued at a later point in time. This study looked at some countries where deregulation in the community pharmacy sector had taken place already years ago, and we could analyse long-term implications. However, for Sweden, the findings and conclusions are preliminary ones, and further developments, in particular after the fall of safeguard clauses, should to be monitored carefully.

In any case, it is recommended to continue surveying and analysing the community pharmacy systems in the future.

14 Conclusions

Based on the findings of our survey and analysis of the five deregulated (England, Ireland, the Netherlands, Norway and Sweden) and four regulated countries (Austria, Denmark, Finland, Spain), we have drawn a number of conclusions (sections 14.1 to 14.6) and propose some recommendations (section 14.7) which can also be generalized beyond the community pharmacy sector.

14.1 Conclusions on the deregulation landscape

- **The community pharmacy systems have been subject to changes and will continue to see further changes**. Some of the changes concern the organisation of the pharmacy sector, in particular the issue of the sale of OTC medicines outside pharmacies. Further, the pharmacy remuneration has caught the attention of policy makers.

- **England, Ireland and the Netherlands have always been liberal countries.** England and the Netherlands have seen several deregulation steps during the last decades, with the latest one for England in 2005 after a report from the competition authority. Ireland, which had never had establishment regulation, introduced statutory rules in 1996 but revoked them in 2001. The Irish Pharmacy Act of 2007 was the first statutory provision after more than hundred years to regulate the quality of the pharmacy services.

- **A decade ago the Norwegian pharmacy sector was radically changed from a regulated to a deregulated system.** Establishment and ownership of pharmacies were deregulated, and the landscape of the community pharmacy sector changed profoundly.

- **The most recent liberalisation of the pharmacy sector was done in Sweden under the title of "reregulation".** The fall of the monopoly of the state-owned pharmacy company Apoteket was accompanied by a deregulation of the sale of OTC medicines.

- **Countries with a regulated community pharmacy sector have been under pressure during the last decade following infringement proceedings of the European Commission.** The European Commission launched infringement proceedings against several Member States regarding the establishment and ownership regulation for community pharmacies. Two landmark rulings by the European Court of Justice in 2009 confirmed that Member States may impose restrictions on ownership and operation of pharmacies if they can be justified for the sake of public health. All charges against Member States regarding the pharmacy sector were dropped in November 2011.

- **Trends for a liberalisation of OTC medicine sales can be generally observed.** Non-pharmacy market players are pushing to get into the sale of OTC medicines, and OTC dispensaries are increasingly permitted, even in the regulated countries.

14.2 Conclusions on accessibility of medicines

- **Deregulation tends to lead to urban clustering.** After a liberalisation new pharmacies are often established, usually in considerable number and rather soon after the change in legislation. However, the pharmacies tend to be opened at attractive locations, e.g. in town centres and shopping zones (“urban clustering”).

- **Deregulation has not improved the accessibility of pharmacies and other dispensaries for prescription-only medicines in rural areas.** There are no indications of an improved accessibility in rural areas in deregulated countries, whereas in some regulated countries it is the strategy to open new pharmacies in places without a community pharmacy.

- **Country-specific approaches ensure accessibility in rural, sparsely populated areas.** Irrespective of the extent of regulation, the surveyed countries have developed solutions such as branch pharmacies or other suppliers under the supervision of pharmacies to deliver medicines in rural areas. Deregulated countries sometimes provide clauses or conclude agreements with pharmacy-owning companies to guarantee a continuation of pharmacy services in rural areas.

- **Deregulation may cause limited availability of less frequently prescribed medicines.** Due to increased financial pressure in a liberalised environment pharmacies might be induced to keep fewer medicines in stock and to focus on “blockbusters”.

- **Vertically integrated pharmacies may be encouraged to align their product range to the supply of their owners.** After deregulation many pharmacies are owned by large companies which have an interest in supplying “their” pharmacies with the products they distribute.

- **Opening hours have, to some extent, been expanded after deregulation.** While in Norway rather limited opening hours were extended after the liberalisation, in Sweden this general trend was counteracted by some limitations (e.g. Apoteket’s 24 hour internet pharmacy was reduced to normal business hours).

14.3 Conclusions on the quality of pharmacy services

- **The quality of pharmacy services appears to be appropriate in all countries regardless of the extent of regulation.** This is due to a high professional standard within the pharmacists’ profession.

- **Counselling is a key task of the pharmacist profession.** Counselling and advice is highly appreciated by patients and consumers who often turn to a pharmacy as first point of reference in the health care system.

- **Deregulation might lead to time constraints and an increased workload of the pharmacy staff.** There were indications of more prescriptions filled per pharmacist and

pharmacy technician after deregulation, and less time for counselling and advice to the patients.

14.4 Conclusions on savings

- **Deregulation in the community pharmacy sector has no direct impact on a country's pharmaceutical, including public, expenditure.** Pharmaceutical expenditure is the product of price and volume. Medicines prices can be regulated at several levels, at the manufacturer, the wholesaler and/or the pharmacy level, and the volume component is influenced by policy measures restricting the number of medicines advertised, prescribed, dispensed and sold. Pharmaceutical expenditure is thus impacted by a range of factors, and the organisation of the community pharmacy system is one of them. Public pharmaceutical expenditure, defining the publicly funded share, is strongly influenced by the ability and willingness of the state to cover costs.

- **Deregulation in the community pharmacy sector cannot considerably influence medicines prices.** Medicines are goods of low price elasticity (i.e. low responsiveness in demand to a price change), and patients will purchase them if needed and affordable (either paid out-of pocket or, as for most prescription medicines, reimbursed by a third party payer). Reductions in the prices of prescription and/or reimbursable medicines, which are statutorily determined, usually result from cuts imposed by the state at the ex-factory, wholesale and pharmacy level. For OTC medicines most European countries allow free pricing (i.e. price freely set by the manufacturer). No study could confirm a decrease in OTC medicines prices after deregulation of the community pharmacy sector.

- **Lower average pharmacy margins are the result of reductions in the statutorily regulated pharmacy remuneration schemes.** Pharmacy remuneration is regulated, at least for prescription and/or reimbursable medicines. Reductions in the pharmacy remuneration have taken place in some countries during the last decade, and, as a result, the average pharmacy margins have decreased over the years.

14.5 Beneficiaries and losers of deregulation

- **Wholesalers are often the winners of deregulation in the community pharmacy sector.** Due to vertical and also horizontal integration large international wholesale companies tend to buy out pharmacies and develop pharmacy chains, thus gaining dominant market positions (oligopoly situation). Their involvement in the pharmacy business is supportive to their activities in pharmaceutical distribution.

- **Independent pharmacists have seen a loss in their professional independence following a deregulation.** Independent pharmacists have come under pressure from the competition of large pharmacy chains and the viability of pharmacies in clustered areas (i.e. many pharmacies in the close neighbourhood) might be at stake. It becomes difficult for independent pharmacists to buy a pharmacy because competing companies are financially stronger.

- **Employed pharmacists and pharmacy staff might experience an increased workload and less work satisfaction in a deregulated environment.** The workload and, as a result, work satisfaction are impacted by the professional standards and (turnover) targets of the pharmacy owners. Concerns were raised that counselling and advice to patients might be reduced at the expense of the retail sales figures.

- **Consumer satisfaction has not necessarily increased after deregulation.** While patients appreciate the longer opening hours of pharmacies in some deregulated countries, surveys did not show an improvement in consumer satisfaction which had been already high before deregulation. Concerns about a possible deterioration in the information provided in pharmacies were reported.

14.6 Expectations and interventions

- **Expectations of the deregulation in community pharmacies are usually not fully met.** A liberalisation in the pharmacy sector is often connected to rather broad aims such as better accessibility and lower medicine prices which, eventually, turn out to be false expectations. The objectives are sometimes not well defined, which complicates a proper evaluation of the liberalisation.

- **Deregulation in the community pharmacy sector does not necessarily lead to increased competition.** Liberalisation might lead to unintended consequences and/or negative side-effects (e.g. market dominance of some market players) which require other regulations in response. Also, for the sake of public health and solidarity considerations, provisions were required, even in deregulated countries, to ensure fair and equitable access to medicines for vulnerable groups and areas.

- **It is sometimes forgotten that the community pharmacy sector is an "atypical" market.** As part of the health care system, the community pharmacy sector is not a traditional supply-and-demand market. A three-tier system (supplier – payer – consumer), a low price elasticity and information asymmetry characterize a public health care system, including the pharmacy sector. Therefore a minimum degree of public regulation is necessary in order to have guaranteed accessibility.

- **The community pharmacy sectors may differ in details between the countries.** The way the pharmacy sector is organised and regulated has been considerably influenced by historic developments, traditions and the culture of a country. What works well in one country is not necessarily successful in another country.

14.7 Recommendations

- **The community pharmacy sectors should not be left to market forces alone.** As part of the health care system, which is not a standard commodity market, the pharmacy sector should be supported by a sound regulatory framework for community pharmacies to support them fulfilling their key tasks (i.e. providing safe medicines to patients, counselling

and advice, involvement in health promotion and prevention). A focus on merely optimizing retail sales should be avoided.

- **Policy measures should contain safeguard measures for vulnerable groups.** In case the deregulation of the pharmacy sector is intended, possible consequences should be considered, and negative implications to public health care and vulnerable groups should be avoided or at least “cushioned”. Conflicts of interest of new pharmacy owners (e.g. wholesalers) and any negative impact, e.g. on independent professional pharmaceutical counselling, should be addressed. Vulnerable groups and rural areas should be ensured good access to (prescription) medicines.

- **Policy measures should include well-defined and measurable objectives and an appropriate implementation and evaluation plan. Any policy measure should be monitored and evaluated.** It is highly recommended to accompany all policy measures by an evaluation. Monitoring and evaluation should be embedded in the planning of policy measures, and should be designed as an integral part of the policy change. Since some effects only come into play some time after the implementation of a measure, the evaluation plan should consider middle- and long-term impact assessments.

- **Benchlearning is important.** Any policy change in pharmacy regulation could possibly benefit from drawing upon positive experiences from other countries. But it must be designed and implemented in respect of each country’s history, culture, goals and preferences. Cross-country comparisons are valuable tools. Their findings should, however, not be copied identically but be understood as “models” for learning. They should be translated into national policies while taking into account country-specific characteristics.

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Annex

Annex 1: Questionnaire

Annex 2: Interview guide

Gesundheit Österreich GmbH

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Questionnaire COUNTRY

This questionnaire was answered by:

Address:

Telephone number:

Fax number:

E-mail:

Please fill/check/add in, as far as possible, *table 1* considering the number of registered community pharmacies and other POM-dispensing outlets in your country. Please provide also information on OTC-dispensaries in *table 1*. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Please fill/check/add in, as far as possible, *table 2* concerning the number of branch pharmacies. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Are there special regulations for branch pharmacies? (multiple answers possible)

- ☐ No.
- ☐ Yes, the opening hours are different:
  _____
- ☐ Yes, a pharmacist has always to be available for the costumer.
- ☐ Yes, a pharmacist has to be the owner of the branch pharmacy.
- ☐ Yes, branch pharmacies are only allowed to dispense POMs.
- ☐ Yes, branch pharmacies are only allowed to dispense special limited POMs.
- ☐ Yes, branch pharmacies are not delivered by wholesalers, but by_____

Please fill/check/add in *table 3* concerning the number and names of chains in your country. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Please check and comment, if necessary, the following paragraph on ownership criteria of pharmacies in your country:

Paragraph on establishment and ownership criteria……

Comments:

What do you consider the most important reforms in the last years concerning ownership criteria of pharmacies in your country ?

Are there any specific establishment regulations for pharmacies in rural areas?

- ☐ No.
- ☐ Yes:
  _____
  __

Are there any incentives for pharmacies to establish in rural areas?

- ☐ No.
- ☐ Yes:
  _____
  __

We are looking for information on accessibility of pharmacies in general and for differences between urban and rural areas, for example:

- the average distance to the nearest pharmacy in total?_____ kilometers.
- the average distance to the nearest pharmacy in urban areas? _____ kilometers.
- the average distance to the nearest pharmacy in rural areas? _____ kilometers.

We are grateful for any other information you can give us on this topic:

Please check, if we found the right information:
_____percent of the inhabitants in our country have a distance less than _____kilometres to the nearest pharmacy.

We would like to have some information on (public) service requirements or obligations regarding availability of medicines in pharmacies. As far as we know…… ODER FOLGENDE 2 FRAGEN:
(Are there regulations on the availability of pharmaceuticals (multiple answers possible)

- ☐ No
- ☐ Yes, a certain amount of medicines has to be on stock: _____
- ☐ Yes, in certain period of time a medicine has to be available to the customer: _____
- ☐ Yes, the pharmacies have to be delivered _____times per day.
- ☐ Yes, further regulations: _____

Normally availability of pharmaceuticals can be provided to the following extent (multiple answers possible):

- ☐ Medicines are available to the customer on average within _____ hours.
- ☐ Pharmacies are on average delivered _____times per day.
- ☐ Other: _____)

Please fill/check/add in *table 4* concerning the number of pharmacists and other pharmacy personnel that are working in
community pharmacies. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Please fill/check/add in *table 5* concerning the required education of pharmacists and other pharmacy personnel. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Is it common that pharmacies produce medicines?
Do you have an idea of how many pharmacies in your country do have a laboratory or a place to manufacture pharmaceuticals?
What percentage of all pharmacies do have a laboratory or a place to manufacture pharmaceuticals?

Please check the **list of pharmaceutical care services**:

Are there regulations concerning the sale of other non-medicines in pharmacies in your country?

- ☐No
- ☐ Yes:_____

Which products can be sold in pharmacies in addition to medicines?

The average counseling time per patient in pharmacies in our country is _____ minutes.

Are there regulations concerning nation-wide quality standards for pharmaceutical counseling in your country?

- ☐ No
- ☐ Yes, voluntary standards:_____
- ☐ Yes, compulsory standards:_____

How is counseling remunerated, as a part of the margin?

Please check, if we found the right answer:
Self-Service of OTCs is allowed/not allowed in our country.

The average pharmacy margin for medicines in our country was _____% of the pharmacy retail price in ____(year)
☐ Of total medicines.
☐ Of reimbursable medicines.
If it is not of the pharmacy retail price, please provide us the margin for another price level:

Could you please fill/check/add in *table 6* concerning the range of non-pharmaceutical products and on the averagenumber of pharmaceuticals on stock/pharmacy. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Could you please fill/check/add in *table 7* concerning the turnover (sales) of pharmacies in your country. If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Are there any incentives for individual pharmacists - in the way how the pharmacy remuneration is organized - to
- ☐ to sell more medicines:
  _____
- ☐ to sell more expensive medicines:
  _____

Do you have suggestions for further readings and material?

Thank you very much for your cooperation!

If you should have any questions do not hesitate to contact us:

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ANNEX:

Table 1: Number of Dispensaries, 1990-2011, as of 1 January

Dispensaries	**1990**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Number of POM-dispensaries [1]										
Community pharmacies										
Of which:										
Private pharmacies (owned by firms or private persons)										
Public pharmacies (owned by units of the state, i.e. cities)										
POM-dispensing doctors										
Hospital pharmacies dispensing POMs to out-patients										
Internet pharmacies dispensing POMs										
Other POM-dispensaries										
Total of POM-dispensaries										
Number of OTC-dispensaries										
Drugstores										
Supermarkets										
Internet pharmacies dispensing OTCs										
Other OTC-dispensaries										
Total of OTC-dispensaries										

[1] Only retailers that are allowed to dispense prescription-only medicines.

SOURCE:

If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Table 2: Branch pharmacies, 1990-2011, as of 1 January

Branch pharmacies	**1990**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Community pharmacies										
Of which:										
Branch pharmacies										

[1] Only retailers that are allowed to dispense prescription-only medicines.

SOURCE:

If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Table 3: pharmacy chains and market share

Name of Pharmacy Chain	**Name of Owner and Category**	**% of market share**	**Number of pharmacies in ownership**	**Number of pharmacies in membership**
		Total:		
		Total:		

To which year do you refer concerning the % of market share?

Table 4: number of Pharmacy staff in community pharmacies, 1990-2011, as of 1 January

Pharmacy Staff	**1990**	**1995**	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Number of pharmacists [1] (counted per head)										
Number of pharmacists [1] (full time equivalent (40hrs/w))										
Of which:										
Full pharmacists *										
Prescriptionists *										
Pharmacy technicians /assistants with the right to dispense pharmaceuticals										
Number of other pharmacy personnel [2]										
Of which:										
Pharmacy technicians /assistants without the right to dispense pharmaceuticals										

[1] This includes active (full) pharmacists, prescriptionists and pharmacy technicians/assistants with the right to dispense medicines (under supervision of a pharmacist). 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.

[2] 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).

SOURCE:

If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Table 5: education of pharmacy staff

Profession	**Required qualification**	**Duration** (years)	**Practice training required** (yes/no)	**Continuous education required** (yes/no)	**Legal basis**
Full pharmacists	e.g., university				
Prescriptionists					
Pharmacy technicians /assistants with the right to dispense pharmaceuticals					
Pharmacy technicians /assistants without the right to dispense pharmaceuticals					

Table 6: Non-pharmaceutical products and pharmaceuticals on stock, 1990-2011, as of 1 January

	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Non-pharmaceutical products on the market										
∅ number of pharmaceuticals on stock /pharmacy[1]										

∅ = average
* As of 1 January

SOURCE:

If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Table 7: Number of medicines dispensed and pharmacy turnover, 1990-2011

	1990	1995	2000	2005	2006	2007	2008	2009	2010	2011
Number of medicines dispensed										
Of which:										
Prescriptions filled (in items)										
OTCs (in items)										
Total pharmacy turnover										
Of which:										
Turnover of pharmaceuticals										
Turnover of OTC										
Turnover on non-pharmaceuticals										

SOURCE:

If you do not have the accurate numbers, please provide an estimation and identify the estimated figures with *. Please do not forget to quote the sources.

Questionnaire – Assessment of deregulation (deregulated countries)

Which were the key liberalization trends in the pharmacy sector during the last 5 years? With regard to ownership / establishment rules?

Which were the reasons for the changes? Which actors asked for the changes? Were these national decisions and due to EU infringement procedures / discussions?

(What has exactly changed?)

Do you see an impact of the change?

- With regard to accessibility to (prescription) medicines
- to affordability and solidarity (rural areas)
- to the quality of the pharmacy service,
- to costs (savings)?

Who would you consider as beneficiaries of the changes, and who as losers (ask explicitly about the patients) – and why?

Have the changes impacted the professional independency of pharmacists?

Has there been any accompanying review been undertaken? Suggestions for literature and further persons to talk to (contact details)?

Questionnaire – Assessment of current situation (regulated countries)

Have there been any key liberalisation trends in the pharmacy sector during the last 5 years in your country as well – or any discussion?
With regard to ownership / establishment rules?

Which were the reasons for the proposed changes / discussion? Which actors asked for the changes? Were these national decisions and due to EU infringement procedures / discussions?

What are the advantages of your current system? Which risks would your country incur in case of a change of the system?

- With regard to accessibility to (prescription) medicines
- to affordability and solidarity (rural areas)
- to the quality of the pharmacy service,
- to costs (savings)?

Who would you consider as beneficiaries in case of changes, and who as losers (ask explicitly about the patients) – and why?

Has there been any accompanying review been undertaken? Suggestions for literature and further persons to talk to (contact details)?

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