# Impact of pharmacy deregulation and regulation in European countries

Summary Report

Gesundheit Österreich
Forschungs- und Planungs GmbH

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Vienna, March 2012

Commissioned by Danmarks Apotekerforening (Association of Danish Pharmacies)

Gesundheit Österreich
Forschungs- und Planungs GmbH

ISBN-13 978-3-85159-164-4

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# Acknowledgements

We would like to express our thanks to several people and institutions who contributed to this study through their experience and their sharing of data and information.

First, we would like to thank the contact persons within the national pharmacy associations for their continuous cooperation: Gareth Jones (National Pharmacy Association, UK), Pamela Logan (Irish Pharmacy Union), Th(Dick)FJ Tromp (EuroPharm Forum, President), Oddbjorn Tysnes and Jon A. Anderson (Apotekforeningen / Norwegian Pharmacy Association), Thony Björk (Apoteket International AB, Sweden), Mag. Leopold Schmudermaier und Mag. Josef Fasching (Österreichische Apothekerkammer / Austrian Chamber of Pharmacists), Sirpa Peura (Apteekkariliitto / Association of Finnish Pharmacies), Sonia Ruiz Morán (Consejo General de Colegios Oficiales de Farmacéuticos / General Council of Pharmacists of Spain).

They contributed to the filling in of the questionnaire, checked available information and provided data. Additionally, they were available for several follow-up questions, for clarifications and discussions and for the reviewing of the draft country reports. We highly appreciate their inputs which have definitively contributed to the quality of this report.

Further, we thank all our 16 interview partners from different institutions (public authorities, consumers associations, interest associations, researchers) for agreeing to an interview which was often followed-up by the submission of additional relevant material. The interviews helped us to gain insight into the national community pharmacy systems and to learn about the different perspectives of the stakeholders.

Finally, we would like to thank the Association of Danish Pharmacies (Danmarks Apotekerforening) for commissioning us to undertake this survey and for being available for methodology discussions, for helping us in identifying and contacting resource persons within the national pharmacy associations. We welcomed their review of the draft report. In particular we thank Per Nielsen, Head of Analysis, for the excellent cooperation throughout the whole project.

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# 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 nine European countries. The project started in July 2011, and GÖG FP (Gesundheit Österreich Forschungs- und Planungsgesellschaft GmbH) submitted the final report to the commissioning party in December 2011. In March 2012 the report was published under the title "Impact of pharmacy deregulation and regulation in European countries".

The evaluation of the impact of pharmacy deregulation and regulation was based on in-depth country profiles for the nine countries selected. Selected were five countries with a rather liberal community pharmacy sector (England, Ireland, the Netherlands, Norway, and Sweden) and four countries with a regulated community pharmacy sector (Austria, Denmark, Finland, and Spain).

The 250 page full report contains

» nine country reports with facts and figures about the community pharmacy systems described according to a homogeneous outline,
» a comparative analysis in which fifteen indicators developed for assessing the impact of the community pharmacy system with regard to accessibility, quality and economics were benchmarked and discussed for the nine countries, and
» concluding chapters (lessons learned, with key observations per indicator and regarding key stakeholders, and conclusions).

This summary report provides the brief summary, the executive summary and the detailed conclusions including recommendations of the full report.

# 2 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 (over-the-counter medicines) 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.

# 3 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".

## 3.1 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 "re-regulation" 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 3.1 provides an overview of the key features of the community pharmacy systems of the nine countries surveyed, while Table 3.2 discusses the indicators selected in the sample of surveyed countries.

Table 3.1:
Executive Summary – Characteristics of the community pharmacy systems in the nine countries surveyed, 2011

**England**

- 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**

- 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.

**Netherlands**

- 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

- 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.

### Sweden

- 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.

### Austria

- 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**

- 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 reasonablely 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.

**Finland**

- 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**

- 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 medicines, 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 the study "Impact of pharmacy deregulation and regulation in European countries" 2012

## 3.2 Key findings per indicator

### 3.2.1 Accessibility of medicines

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.

### 3.2.2 Quality of pharmacy services

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.

Table 3.2:
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. |

| Indicators | Deregulated countries | Regulated countries |
|---|---|---|
| **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.<br>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).<br>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.<br>With regard to pharmacists in a pharmacy, Austria has the lead among the surveyed countries (4 pharmacists per pharmacy). |
| 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.<br>The highest number of dispensing staff per pharmacy (10 people: pharmacists and pharmacy technicians) is found in the Netherlands.<br>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.<br>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.<br>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. |

| Indicators | Deregulated countries | Regulated countries |
|---|---|---|
| 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. |
| 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 study "Impact of pharmacy deregulation and regulation in European countries" 2012

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 (over-the-counter) 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.

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.

### 3.2.3 Economic impact

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.

## 3.3 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.

# 4 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 4.1 to 4.6) and propose some recommendations (section 4.7) which can also be generalized beyond the community pharmacy sector.

## 4.1 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.

## 4.2 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).

## 4.3 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.

## 4.4 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 phar-

macy remuneration have taken place in some countries during the last decade, and, as a result, the average pharmacy margins have decreased over the years.

## 4.5 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.

## 4.6 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.

## 4.7 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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