

Study of regulatory restrictions in the field of pharmacies

Main report

Final

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ECORYS Nederland BV

Dr. Bjørn Volkerink
Patrick de Bas
Nicolai van Gorp

In cooperation with:
Dr. Niels Philipsen (METRO – University of Maastricht)

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ECORYS Nederland BV
P.O. Box 4175
3006 AD Rotterdam
Watermanweg 44
3067 GG Rotterdam
The Netherlands

T +31 (0)10 453 88 00
F +31 (0)10 453 07 68
E netherlands@ecorys.com
W www.ecorys.com
Registration no. 24316726

ECORYS Macro & Sector Policies
T +31 (0)10 453 87 53
F +31 (0)10 452 36 60

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Preface

This report is the result of a study that has been carried out by ECORYS Nederland BV in cooperation with Niels Philipsen (METRO University of Maastricht) from December 2005 to June 2007.

The project team would like to thank all pharmacists, policymakers, national competition authorities and other organisations and experts that contributed to this study through completing our questionnaires, responding to specific questions and providing us with relevant documents and information. We also wish to thank Prof. Leo Sleuwaegen (University of Leuven) for his support to us during the project.

We are also grateful for the constructive cooperation with the European Commission, mainly DG Internal Market & Services and DG Competition. In particular, we wish to thank Mr. Jean Bergevin (Head of Unit), Mr. Salvatore D'Acunto (Deputy Head of Unit) and their team, notably Mr. Jan-Willem Verheijden, from the Services E2 Unit, Internal Market & Services DG, for their comments and support.

We want to stress that the authors take full responsibility for the contents of this report and that the opinions expressed do not necessarily reflect the view of the European Commission.

Executive summary

Objective of the study

This report is the result of a study that has been carried out for the European Commission, DG Internal Market, by ECORYS Nederland BV in cooperation with Dr. Niels Philipsen (METRO) from November 2005 to June 2007.

The aim of the study is to evaluate how the various rules applicable to pharmacies impact on the quality of pharmacy services in the different Member States, and how differing laws regulating pharmacies impact on the effective functioning of the Internal Market, and therefore on the performance of the European pharmacy services sector as a whole.

The study concentrates on community pharmacists in the EU-25.

Policy context

Most Member States, in different ways, restrict, inter alia, the location and number of pharmacies. Usually Member States and stakeholders justify these restrictions in order to ensure the independence of the service provider, the accessibility (in particular, in terms of geography) of the service, and the quality and safe provision of pharmacy services. The OECD in its 2001 report on “Regulatory Reform in Ireland” contested this logic. It argued that the creation of a protected monopoly to cross-subsidise the unprofitable activity was not the right solution. In fact, keeping up with competitors is what usually stimulates quality-improving investments. Therefore, according to the OECD, in contrast to eliminating competition, alternative solutions could be found in transparent subsidies to pharmacies, provided on the basis of sound public interest objectives, in case the activities could not be performed on profitable commercial basis.

A study by IHS, on behalf of DG Competition of the European Commission, on the economic impact of regulation in the field of liberal professions, found some general trends in analysing performance levels set against the degree of regulation in each Member State for the different professions (lawyers, notaries, accountants, auditors, tax advisers, architects, consulting engineers and community pharmacists).¹ It found that relatively higher volumes of turnover (fees) and prices (compared to the number of practising professionals) can be found in countries with high degrees of regulation and vice versa; there is a tendency towards market ‘shake out’ in professions and countries

¹ IHS, *Economic impact of regulation in the field of liberal professions in different Member States, Regulation of Professional Services*, Study for the European Commission, DG Competition, January 2003.

with low levels of regulation, allowing the formation of larger enterprise units; and there is a negative correlation between the extent of regulation and productivity. However, the study indicates that more detailed economic analysis would be needed to measure the strengths of these effects and their statistical significance.

This study represents an evaluation of the impact of rules applicable to pharmacies on the quality of pharmacy services in the different Member States, and on the development of the pharmacy services sector within the EU.

Sources of information and activities undertaken

The analysis presented in this study is based on the following activities that have been undertaken to collect relevant information on the pharmacy sectors of the EU Member States:

- A study of the literature on the relationship between regulation and performance in liberal professions, in particular in the pharmacy sector;
- Collection of quantitative and qualitative information on the regulation and performance of the pharmacy sector from public sources;
- (Web)questionnaires have been sent to the pharmacy representative organisations, policy-makers, national competition authorities and the consumer representative organisations in each of the 25 Member States;
- Meetings with DG Competition, the PGEU, pharmacists and with pharmacy chains.

For each Member State, a country information sheet has been prepared presenting the information on both performance and regulation of pharmacies in each of the Member States. These 25 country information sheets are included as an Appendix to this report.² Although we have tried to gather a complete and fully accurate overview of the regulation and sector performance for each Member State, the amount of information publicly available is limited, and the degree of cooperation from stakeholders was not always optimal.

Outline of the study

Chapter 1 gives the policy context under which this study has taken place and presents the sources of information used and the activities undertaken by the research team. It also presents the methodology and the outline of the report. Chapter 2 describes the characteristics of the pharmacy sector in general. Based on the identified characteristics of the market, we subsequently focus on the reasons for regulating the sector from a theoretical economic point of view. Chapter 3 provides a factual overview of current regulation of the pharmacy sector in each of the EU Member States. This overview contains both statistical information on the sector and on current regulation in the Member States. In that chapter we also quantify regulation and performance. In Chapter 4, we analyse the quantified information on regulation and performance, and present the

² See Appendix 6.

results of our analysis of the impact of regulation on the performance of the pharmacy sector. Additionally, we extrapolate the results to estimate the impact of (de)regulation on the entire EU-25. Chapter 5 concludes.

Methodology

As a framework to describe the regulation in the Member States, we use the Structure-Conduct-Performance paradigm. In this paradigm, a distinction is made between characteristics related to market structure, characteristics related to the conduct of market participants and the performance of the market as a whole. The structure of the market consists of, inter alia, the number and size distribution of firms in relation to the size of the market, the degree of horizontal and vertical integration, and the presence or absence of barriers to entry faced by new firms. Conduct refers to the behaviour of firms, for example, service policies, research and development activities and strategic actions. Performance is commonly measured in terms of productive and allocative efficiency.³ In addition, innovation and quality can be considered as performance indicators. A full description of the SCP-model is presented in Appendix 1 of the report.

According to the economic literature, the structure of the market and the conduct of market participants have an influence on the performance of the market. We have conducted a literature study to identify the relationship (theoretical and empirical) between structure and conduct on the one hand, and performance on the other. In the literature study, we mainly focussed on the literature regarding liberal professions, in particular literature on the pharmacy sector. As a result, we identified the regulation(s) that had or could have an effect on performance. In addition, we drafted a number of hypotheses on the relation between regulation and performance. These hypotheses are schematically presented in Chapter 2 (Figure 2.7).

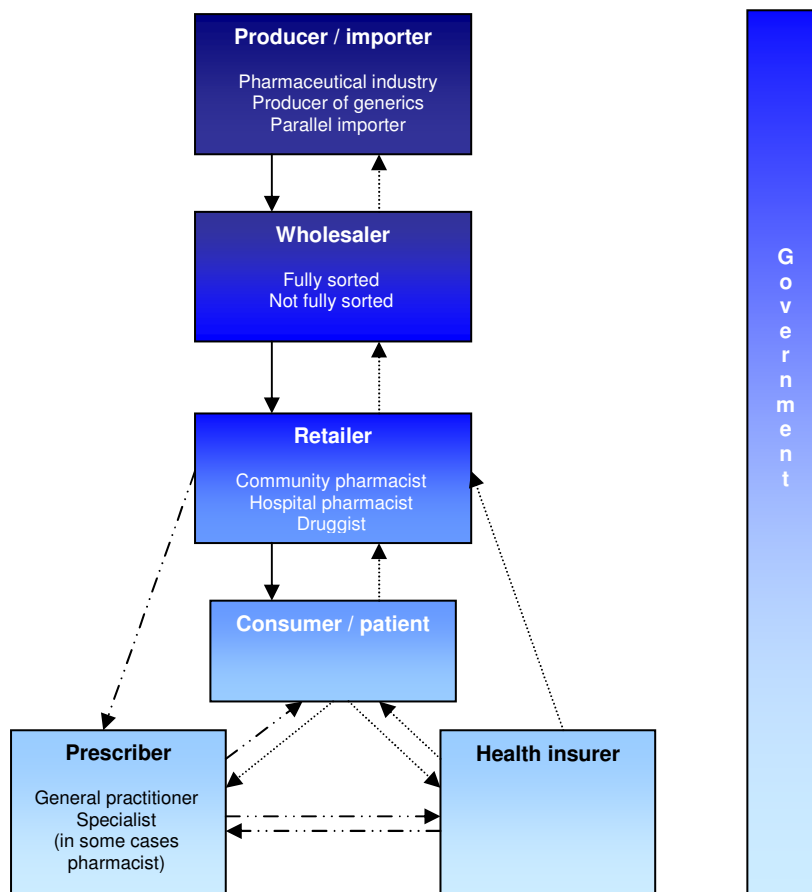
Summary of the main findings and conclusions

The drug market

Pharmacists are active in the market for drugs. The structure of the market for drugs is indicated in the figure below.

³ Allocative efficiency is an economic concept, referring to the maximisation of the sum of consumers' and producers' surplus. In non-economic terms this can be translated as an absence of above-normal profits.

Figure 0.1 The drug market



Source: Philipsen (2003).

At the *production level*, the drug market is characterised by high investments in R&D. This R&D is often protected by patents for drugs developed.

Wholesalers have a strong position in the chain of supply, because retailers (such as community pharmacies) cannot keep everything in stock. This may be either due to limited space or because storage demands special requirements that may be too costly. Wholesalers have been actively engaged in vertical integration, both backwards (with drug producers) and forwards (with community pharmacists).

At the *retail level*, we find community pharmacists and hospital pharmacists. In most countries, the latter are not allowed to dispense drugs extramurally (that is outside of the hospital). In some EU Member States, general practitioners in remote areas are also allowed to dispense drugs. Finally, in some Member States druggists are allowed to sell OTC (over-the-counter) drugs.

Consumers of drugs are mostly dependent on a *prescriber* to determine the need for and enabling access to drugs. In addition, the financial consequences for consumers are usually limited due to the existence of (obligatory) *health insurance*.

Regulation

The retail market for drugs has a number of special characteristics, setting it apart from a prototype market in the economic paradigm. These characteristics are described in Chapter 2. As a result of these characteristics, all Member States have deemed it necessary to regulate the market. There is, however, a significant difference between the level and type of regulation between the Member States.

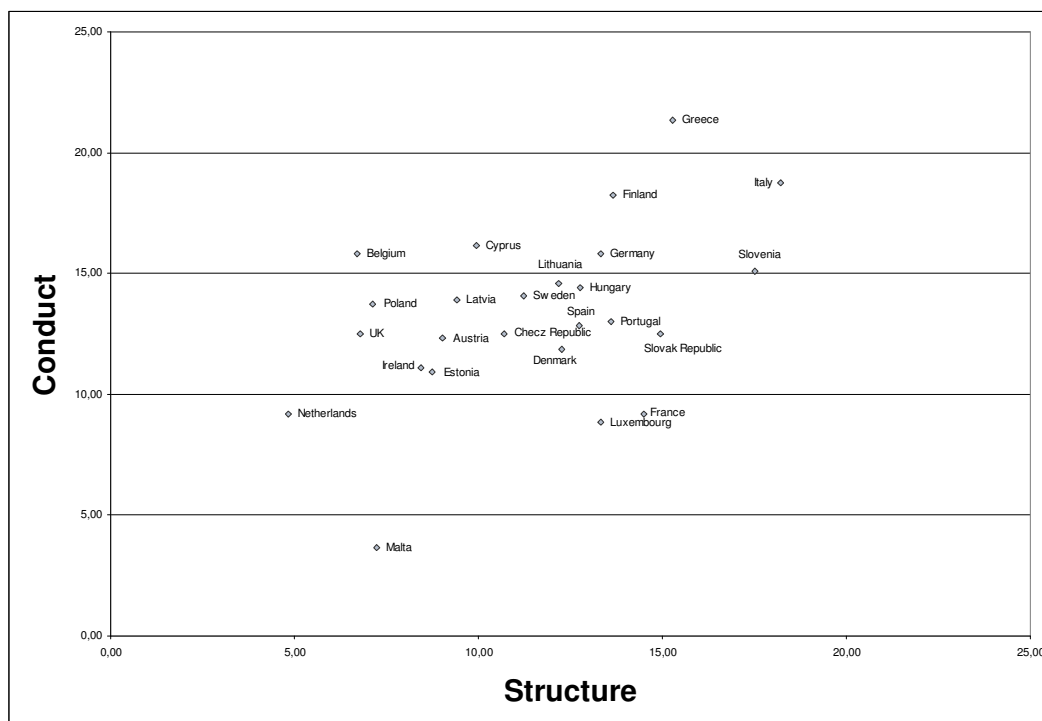
In our report we have categorised regulation in 7 subcategories:

- Educational regulation (for example, mandatory education, limitation on the number of students, duration of the compulsory practice);
- Regulation regarding obligatory registration, licensing or membership of a professional body (for example, additional practice requirements, examinations and annual costs);
- Regulation of the professional monopoly of the pharmacist (which non-pharmacists are allowed to dispense prescription drugs or OTC drugs?);
- Requirements regarding ownership and operating requirements (such as the possibility to incorporate, the possibility to own multiple pharmacies, and restrictions on the location where one can open a new pharmacy);
- Restrictions on horizontal and vertical integration (with wholesalers, producers, druggists, etc.);
- Rules on the practice (for example, rules regarding floor space, indoor or outdoor advertising, the obligatory presence of a pharmacist); and,
- Price regulation (both regulation of prices of prescription medicines and OTCs, and regulation of profit margins).

A full overview of the regulation in each of the Member States is provided in the country sheets that are attached as an Appendix to this report.

We have quantified the degree of regulation for each Member State. Chapter 3 provides the quantification methodology. In addition to the seven subcategories of regulation listed above, we have also analysed two broad categories: ‘structure’ and ‘conduct’. ‘Structure’ consists of the first five subcategories of regulation mentioned above, while ‘conduct’ consists of the latter two subcategories. We have also used a category ‘total regulation’, which is the sum of the scores for structure regulation and conduct regulation. In the figure below, we provide an overview of the scores for each of the Member States on the regulation of structure and the regulation of conduct.

Figure 0.2 Score on structure and conduct (scale: 0-25)



Note: A higher score means a higher degree of regulation. Numbers are based on averages. As not all information on regulation could be obtained, and the scores are non-weighted; the scores in the figure may differ from the true degree of regulation.

Performance

In the economic literature, a number of performance indicators have been developed. These are ‘Production & allocative efficiency’, ‘Progress & innovation’, ‘Equity’, ‘Product variety (choice)’ and ‘Availability’. Some of these indicators, like equity, have a rather political dimension; other indicators, like progress, are hard to quantify. In our study, we have focused on the following performance indicators:

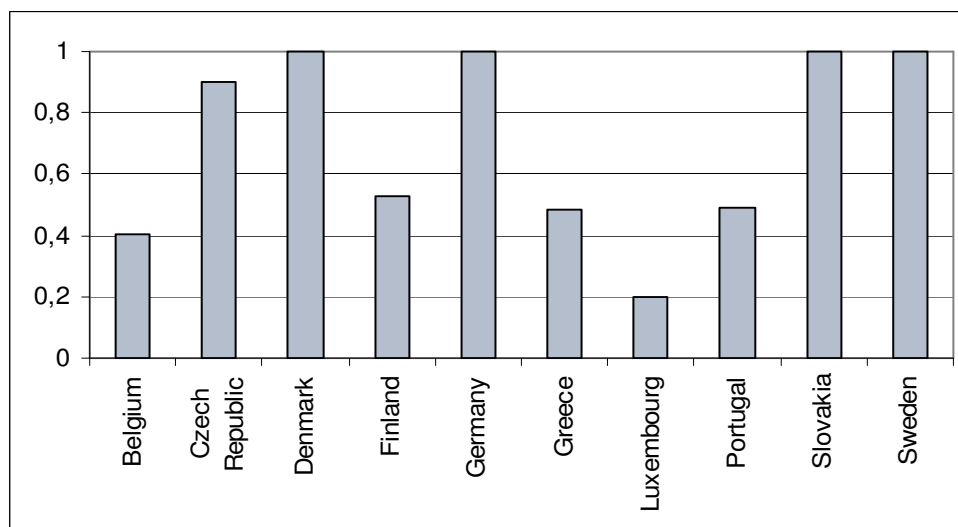
- Productivity;
- Allocative efficiency;
- Quality / Product variety.

Productivity

To measure productivity we have measured how efficient the dispensing of medicines has been by comparing it to the number of outlets (as a proxy for capital used) and the number of employees (as a proxy for the amount of labour used). Productivity is calculated by data envelopment analysis (DEA).

As the required data was not available for all the Member States, we were able to estimate productivity for 10 Member States, based on the data for 2004. The result of the analysis is given in the figure below.

Figure 0.3 Productivity of the pharmacy retail sector in the Member States (year 2004; scale 0-1)



Source: OECD, Eurostat; calculations: ECORYS.

Allocative efficiency

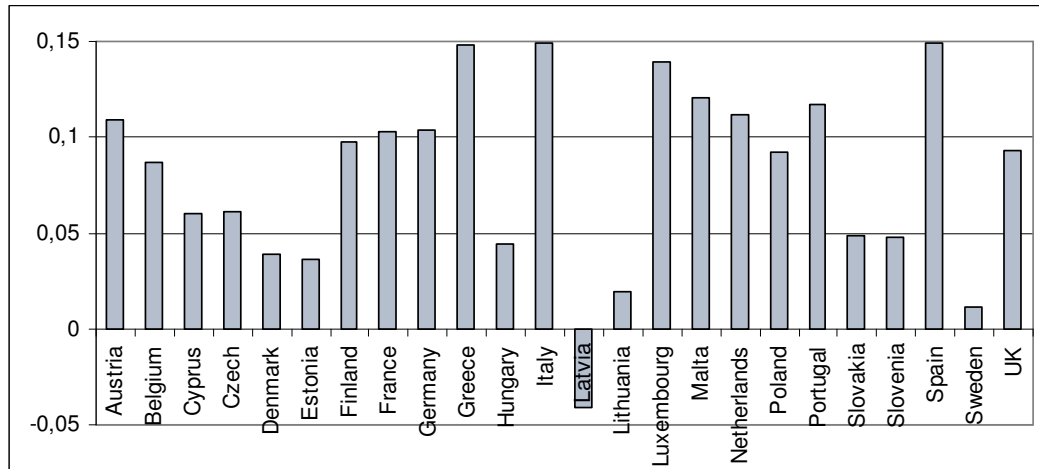
Allocative efficiency is achieved when the production of goods or services is optimised to a degree that the combined welfare of consumers and producers is maximised. As a rule-of-thumb, this is achieved when the above-normal (economic) profits are zero.

The best proxy available for allocative efficiency is the profit margin of pharmacists.⁴ Using accounting data from Eurostat for the year 2004, we have divided the operating result of the pharmacists by their turnover to arrive at the operational profit margin. This margin is the inverse of the degree of allocative efficiency: the higher the margin, the lower the degree of allocative efficiency.

In the figure below, the profit margin for the pharmacy sector in the various Member States is given.

⁴ High(er) profit margins lead to higher prices, which, in turn, leads to lower consumption. Lower consumption equals a reduction in the combined welfare of consumer and producer, as less consumers can derive benefits from the use of the product. As allocative efficiency equals the combined welfare of consumer and producer, this is directly (negatively) related to profit margins.

Figure 0.4 Profit margin of the pharmacy retail sector in the Member States (year 2004)

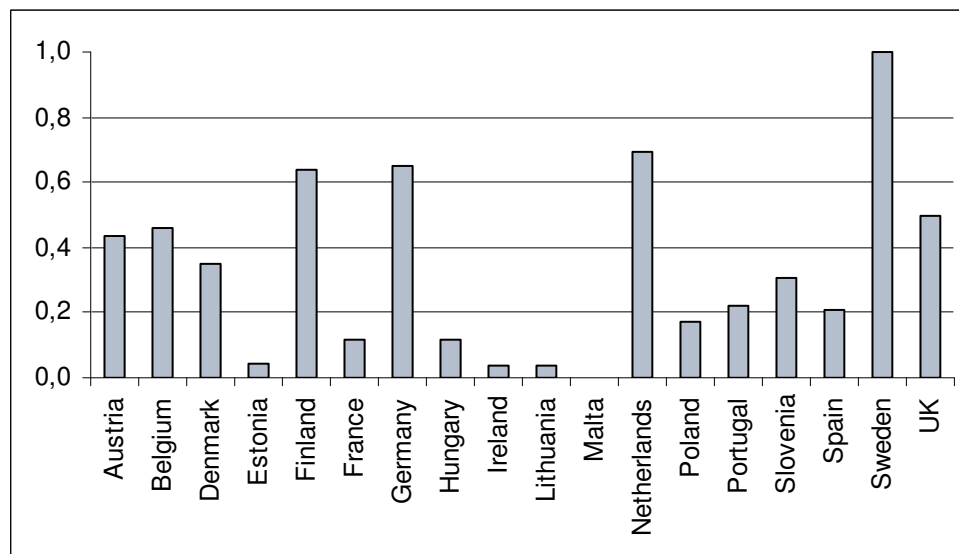


Source: Eurostat, calculations ECORYS.

Quality / Product variety

The third performance indicator we have constructed is the quality of the services provided / product variety. Due to limitations in data availability, we focused on the variety of services provided. The most common services provided – besides dispensing medicines – are online ordering of medicines, home delivery, consultations with a pharmacist, and the provision of specialised medication packages. In the figure below the percentage of pharmacists that offer those particular services is listed.

Figure 0.5 Results of the analysis of quality / service variety (year 2007; scale 0-1)



Analysis of the impact of regulation on performance

To determine the impact of regulation on performance, we have analysed whether a relation can be found between the degree of regulation and the performance of the pharmacy sector.

For each of the categories of regulation (total regulation, structure, conduct and the 7 subcategories) we have clustered the countries in two groups: the Member States with a (relatively) high score and those with a (relatively) low score on those types of regulation. Subsequently, we investigated whether a significant difference in either of the 3 performance indicators between both groups exists. This type of analysis is called analysis of variance (ANOVA).

The results of our ANOVA analysis are given in the table below. When the F-value exceeds one, the differences between both groups can be considered significant, meaning a clear relation between regulation and performance has been identified. These values are presented in bold. The sign between brackets indicates whether regulation and performance are positively correlated (+) or negatively correlated (-). The full results of the analysis can be found in Appendix 8 Results of the ANOVA analysis.

Table 0.1 Results of the ANOVA analysis (F-values and sign)

	Productivity	Allocative efficiency	Quality / Product variety
Total regulation	0.0000 (+)	0.0353 (-)	0.8110 (+)
Structure regulation	3.4001 (-)	3.5123 (-)	0.3195 (-)
Conduct regulation	0.0265 (-)	1.6952 (+)	1.0449 (+)
Subtotal of Education	0.0006 (-)	0.3530 (+)	1.0335 (+)
Subtotal of Registration	0.1601 (+)	0.7640 (-)	1.4884 (-)
Subtotal of Scope of the Monopoly	0.1204 (+)	0.0033 (+)	0.2312 (+)
Subtotal of Operating	3.4001 (-)	3.1509 (-)	0.4444 (+)
Subtotal of Integration	0.1136 (-)	0.4053 (-)	0.1426 (+)
Subtotal of Practice	0.0559 (-)	0.1868 (-)	0.1930 (-)
Subtotal of Pricing	0.4880 (+)	0.5481 (-)	1.1868 (+)

The results indicate that productivity is negatively influenced by regulation(s) setting operating restrictions, that is, inter alia, limitations on ownership of pharmacies by non-pharmacists, requirements on the location of pharmacies, and barriers to entry for pharmacists from other EU Member States. Regulation setting operation restrictions is also a main source of higher profit margins realised by the pharmacy sector, which equals a lower allocative efficiency in comparison to other countries. These results are in line with the findings in the literature.

Finally service variety, as a proxy for quality, is positively correlated with educational requirements and the regulation of prices and profit margins. Requirements on registration, licensing and obligatory membership of a professional organisation are, however, negatively correlated with service variety. All these results are also supported by literature.

Extrapolation of the results to EU25

On the basis of the results of the analysis, we can estimate the effect of changes in regulation on the performance of the pharmacy sector in the EU25. To do so, we have

calculated the difference in average regulation, and the difference in average performance for Member States with a high degree of regulation, and Member States with a low degree of regulation for each of the subcategories of regulation. We consequently calculated the change in performance, assuming the average level of regulation in the EU25 would be reduced to the level of regulation in the Member State with the lowest degree of regulation in that subcategory.

Reducing the operation restrictions from the European average to the lowest level currently found within the EU-25 would result in an increase in productivity of 40.1% (percentage points), boosting the average efficiency from a mediocre 54% to a nearly fully efficient 94%, and an increase in allocative efficiency of 3.2% (percentage points) by reducing the average profit level from 8.1% to 4.9%.

Although the relationships found between regulation and quality/ product variety were weaker than the relationships found between regulation and productivity and between regulation and allocative efficiency, we have also extrapolated the results of deregulation on quality / product variety. A reduction of regulation of educational requirements from the European average to the lowest degree of regulation currently found within the EU-25 would lead to a reduction of the service range of about 33%; while a similar reduction of requirements on registration, licensing and membership of professional organisations would increase the service range with approximately 35%. Finally, reducing the regulation of prices and profit margins from the European average to the lowest level in the EU would lead to an 80% decrease in services provided.

As these estimations are solely based on linear extrapolation of the results obtained from the ANOVA analysis, some caution regarding the interpretation of the results is in place.

Concluding remarks

The study shows that the relationship between regulation of operations – consisting of ownership restrictions for (non-)pharmacists and requirements regarding the establishment of new pharmacies amongst others - and productive and allocative efficiency of the pharmacy sector, is particularly strong. This supports previous findings in the (economic) literature.

A reduction of the restrictions to operations leads to a substantial increase in social welfare (as a result of a reduction of the so-called dead-weight loss) and significantly enhances productivity in the EU. This suggests a societal need for further policies aimed at removing obstacles to the freedom of establishment in the field of pharmacy services. Although this policy increases total social welfare, for some individuals, more specifically pharmacists, this policy may lead to a decrease in welfare.

As the benefits of deregulation of operation requirements for society outweigh the drawbacks for individual pharmacists, from a societal perspective it is desirable to reform certain restrictive elements of national legislation. However, a Pareto welfare improvement would require that such a policy should be accompanied by measures to remedy (part of) the financial setbacks for pharmacists, for instance, through

compensatory schemes. In addition, accompanying measures to safeguard access to medicines in remote areas may be necessary if the market does not provide services in these regions.

1 Introduction

1.1 Objective of the study

This report is the result of a study that has been carried out for the European Commission, DG Internal Market & Services, by ECORYS Nederland BV in cooperation with Dr. Niels Philipsen (METRO) from December 2005 to June 2007. The terms of reference for this study stipulate:

The objective of the study is to evaluate how rules applicable to pharmacies impact on the quality of pharmacy services in the different Member States, and how differing laws regulating pharmacies impact on the effective functioning of the Internal Market, and therefore the performance of the European pharmacy services sector as a whole.

The specific objectives were to:

- Provide detailed updated information on the rules and laws pertaining to pharmacies (except for advertising rules) in the different Member States, in particular the rules concerning the scope of the monopoly for pharmacists, the rules applicable to the opening of pharmacies and the exercising of pharmacy services, the rules concerning ownership of pharmacies and the rules concerning pricing;
- Describe the structure of the pharmacy services sector in 6 EU Member States with different legal frameworks pertaining to pharmacy services;
- Describe the impact of different legal frameworks in the 6 selected Member States on the performance and development of the pharmacy sector;
- Describe for the 6 selected Member States the manner in which regulations applicable to pharmacies may have assisted or restrained the development of highly qualitative (i.e. in terms of skills and qualifications of pharmacists, opening hours, geographical coverage, service provision to the elderly, distance selling provision, etc.) and competitive (i.e. in terms of price margins) pharmacy services;
- Describe the effectiveness of different legal frameworks in realising genuine general interest objectives;
- Describe the impact of diverging rules pertaining to pharmacies within the EU on the integration of the EU pharmacy sector.

The methodology we applied in this study allowed us to involve more than 6 Member States in our analysis. We have therefore extended the analysis to as many Member States as possible instead of restricting ourselves to a selection of 6 Member States, as initially

stated in the specific objectives.⁵ The change in methodology was partly driven by severe problems in getting the sector to cooperate.

As at the start of the study, when the majority of data collection on regulatory restrictions took place, the European Union consisted of 25 Member States, being the current Member States minus Romania and Bulgaria, the study is limited to those 25 countries.

1.2 Policy context

Most Member States, in different ways, restrict, inter alia, the location and number of pharmacies. Usually Member States and stakeholders justify these restrictions in order to ensure the independence of the service provider, the accessibility (in particular, in terms of geography) of the service, and the quality and safe provision of pharmacy services. The OECD in its 2001 report on “Regulatory Reform in Ireland” contested this logic.⁶ It argued that the creation of a protected monopoly to cross-subsidise unprofitable activity was not the right solution. In fact, keeping up with competitors is what usually stimulates quality-improving investments. Therefore, according to the OECD, in contrast to eliminating competition, alternative solutions could be found in transparent subsidies to pharmacies, provided on the basis of sound public interest objectives.

A study by IHS on behalf of the Commission, DG Competition, of the economic impact of regulation in the field of liberal professions, found some general trends in analysing performance levels set against the degree of regulation in each Member State for the different professions (lawyers, notaries, accountants, auditors, tax advisers, architects, consulting engineers and community pharmacists).⁷ It found that relatively higher volumes of turnover (fees) and prices (compared to the number of practising professionals) can be found in countries with high degrees of regulation and vice versa, there is a tendency towards market ‘shake out’ in professions and countries with a low level of regulation, allowing the formation of larger enterprise units; and there is a negative correlation between the extent of regulation and productivity. However, the study indicates that more detailed economic analysis would be needed to measure the strengths of these effects and their statistical significance.

This study represents an evaluation of the impact of rules applicable to pharmacies on the quality of pharmacy services in the different Member States, and on the development of the pharmacy services sector within the EU.

1.3 Activities undertaken

During the project, we have undertaken the following actions:

⁵ See Chapter 4 for our analysis. The number of Member States involved in the analysis ranges from 10 (for the productivity analysis) to 24 (for the analysis of allocative efficiency).

⁶ OECD, Competition and regulation issues in the pharmaceutical industry, February 2001.

⁷ IHS, *Economic impact of regulation in the field of liberal professions in different Member States, Regulation of Professional Services*, Study for the European Commission, DG Competition, January 2003.

- We conducted a study of the literature on the relationship between regulation and performance in liberal professions, in particular in the pharmacy sector;⁸
- We collected quantitative and qualitative information on the regulation and performance of the pharmacy sector from public sources;
- We drafted and disseminated (web)questionnaires to the pharmacy representative organisations, policy-makers, national competition authorities and the consumer representative organisations in each of the 25 Member States;⁹
- We have had meetings with DG Competition, the PGEU and with pharmacists;
- We have analysed the collected information;
- In the reporting period, two coordination meetings were organised between DG Markt and ECORYS;
- We have submitted progress reports, an interim report, a draft final report and a final report.

1.4 Sources of information

In order to undertake this study, we have gathered data and information from a number of sources.

Our sources of information have been:

- Primary and secondary legislation of the various Member States;
- Websites of pharmacists and stakeholders of the pharmacy sector in the Member States;
- Replies to the questionnaires sent to policy-makers and pharmacy representatives;¹⁰
- Reactions of policy-makers and pharmacy representatives to the country sheets we have sent as part of the quality check;¹¹
- Studies and articles.¹²

1.5 Outline of the report

The structure of the rest of this report is as follows.

In *Chapter 2* we investigate the characteristics of the pharmacy sector in general. This investigation is mainly performed on a theoretical basis. Based on the identified characteristics of the market, we then focus on the potential reasons for regulating the sector. The reasons for regulation listed in this chapter are also based on the (economic) literature.

⁸ For a list of literature studied, see Appendix 3 ("List of references").

⁹ For the questionnaires, see Appendix 4 ("Questionnaires").

¹⁰ See Chapter 1 for further information.

¹¹ See Chapter 1 for the performed quality checks.

¹² See Appendix 3 ("List of references") for the list of references.

Chapter 3 provides a factual overview of the pharmacy sector in each of the EU Member States. This overview contains both statistical information of the sector and the current regulation in the Member States.

In *Chapter 4* we analyse the factual information on regulation and performance, and provide the results of our analysis of the impact of regulation on the performance of the pharmacy sector.

Chapter 5 summarises the findings and makes some concluding remarks.

2 The pharmacy sector – conceptual framework

2.1 Introduction

In this chapter, we investigate the characteristics of the pharmacy sector in general.¹³ As our analytical framework for the investigation, we use the ‘Structure-Conduct-Performance’ paradigm. This paradigm describes a sector by focussing on the basic conditions of the market, the structure of the market, conduct of market participants and the performance of the market. For readers who are unfamiliar with the ‘Structure-Conduct-Performance’ paradigm, a detailed explanation of this paradigm can be found in Appendix 1 (“The SCP paradigm”). Appendix 2 (“Regulation of professions: a literature review”) gives general ideas on reasons for and consequences of regulation of professions.¹⁴

To fully comprehend the pharmacy sector we first focus on the drug market as a whole, followed by a description of a typology for the different kinds of drugs (Section 2.2). Next, we analyse the market of community pharmacy services more in depth, in terms of *basic conditions, structure, conduct*, and finally *performance* (Section 2.3).

After identifying the characteristics of the pharmacy sector, we focus on possible reasons for regulating the pharmacy sector in section 2.4. To this end, we use the available economic literature on regulation of liberal professions, in particular the literature on the regulation of the pharmacy sector. A complete list of references can be found in Appendix 3 (“List of references”).

2.2 The market for drugs

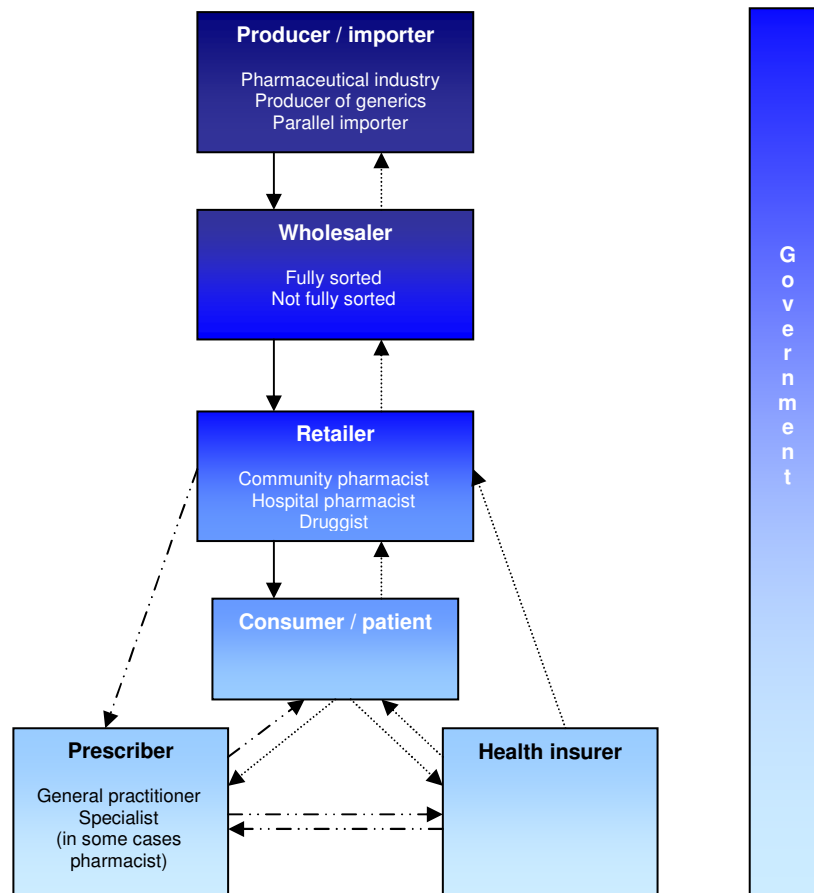
Pharmacists are active in the market for drugs. This market has a number of special characteristics, setting it apart from a prototype market in the economic paradigm. For example, consumers are not fully responsible for the choices made because they are ‘advised’ by prescribers of drugs (who differ from sellers), and because consumers often do not fully pay for the drugs themselves (relying instead on health insurance). In addition, the government intervenes heavily in the market at all levels of the supply chain. The reason being that all levels seem to be hampered by ‘market failures’ that may negatively affect accessibility, price and quality of medicines.

¹³ The actual characteristics of the European pharmacy sector are given in Chapter 3.

¹⁴ It discusses in more detail the public and private interest approach to regulation and elaborates on regulation by law, self-regulation, quality regulation and price regulation.

Figure 2.1 gives a schematic representation of the supply chain of the drug market. By means of arrows it shows how the different players interact with each other.

Figure 2.1 The drug market



Source: Philipsen (2003), p. 48.

In this diagram, the normal arrows represent the flow of medicines, the dotted arrows represent the flow of money, and the broken arrows symbolise other relations between market participants. The government is interacting with all market participants. Below we briefly discuss the production level, the wholesale level and the retail level.

Production

At the production level, the drug market is characterised by high investments in R&D. These investments, if they result in newly-developed and socially-valuable drugs, are protected by means of intellectual property rights. Naturally, in order to attain an 'efficient' level of innovation in the drug market, producers should be able to appropriate some of the social value of their inventions. Without such intellectual property rights (called patents), competitors could 'free ride' on their invention, and no drug producer would be willing to take the risk to invest in R&D and develop new drugs.¹⁵ However,

¹⁵ Note that ideas/inventions are public goods (cf. Appendix 2: "Regulation of professions: a literature review"). Without some kind of intervention in the market, there would be market failure. In this particular case, the introduction of intellectual property rights is the solution commonly found in practice. In theory, subsidising drug producers or production by the government might be another solution, albeit less realistic.

patents impose entry barriers by creating a temporary monopoly for the drug producer. The market power of producers in a monopoly position may lead to inefficient price levels. In many countries, the price received by producers for their drugs is therefore subjected to price regulation (in the form of maximum prices).

Wholesale

Wholesalers have a strong position in the supply chain, because retailers (such as community pharmacies) cannot keep everything in stock. This may be due either to limited space or because storage demands special requirements that may be too costly. Furthermore, direct delivery from producers to pharmacy outlets (sometimes several times per day) may be even more expensive.¹⁶ The wholesale market is characterised by high concentration levels in the market;¹⁷ particularly with regard to the so-called ‘fully sorted’ wholesalers.¹⁸

Wholesalers have been actively engaged in vertical integration, both backwards (upstream) and forwards (downstream). Backward integration refers to integration with drug producers;¹⁹ whereas forward integration refers to integration with community pharmacies. Reasons for backward integration by wholesalers are generally concerned with reducing costs and ensuring supply.²⁰ Forward integration is often engaged in the purpose of setting up a franchise (i.e. a chain of pharmacies working under the same formula) in order for wholesalers to supply directly to customers. Wholesalers are ‘suitable’ candidates to take over a practice, as they have the financial means to do so, may be able to exploit certain synergies that increase technical efficiency (i.e. lower costs), and, moreover, may be able to reduce transaction costs by entering the retail market themselves. Additionally, by setting up a franchise, scale economies (e.g. in advertising and other services) may be exploited, and organisations may become more flexible when pharmacists are on the payroll. This may increase technical efficiency even further, resulting in lower costs.

The effect of the process as described above is that the market for pharmaceutical services is likely to show increasing levels of concentration. This increase in concentration may reduce the competition, for example lead to a decrease quality competition. On the other hand, internal quality control may increase because of quality standards defined by a pharmacy chain. Furthermore, if production and distribution are fully integrated, a conflict of interests may arise, as the independence of the community pharmacists cannot be guaranteed. The Austrian Health Institute (ÖBIG) recently argued that: “[the formation of pharmacy chains] is likely to put a restriction on the professional freedom of pharmacists, in that, as employees, they have to follow the objectives of their superiors, which might include turnover targets and strict regulations on ordering,

¹⁶ Philipsen (2003), p. 53.

¹⁷ Philipsen (2003, pp. 53-54), for example, finds a C4 of 80% in the Dutch wholesale market, and a C4 of 72% in the Belgian wholesale market. ÖBIG (2006, p.8) reports a C3 of 90% in Ireland. These high concentration levels arise, amongst other things, from the fact that the investments for setting up and maintaining a distribution network are substantial. This gives the incumbents an absolute cost advantage and may lead to scale economies.

¹⁸ A ‘fully sorted’ wholesaler offers all medicines available in a country. Wholesalers who are not ‘fully sorted’ sell only the most frequently used medicines.

¹⁹ Particularly to producers of generics.

²⁰ Scherer & Ross (1990), pp. 94-95.

processing and promoting selected products.”²¹ It is however possible to set rules to foresee that a pharmacy chain has a structure that guarantees the independence of pharmacy decisions within a group.²²

Retail

At the *retail level*, we find community pharmacists and hospital pharmacists. The latter are in most countries not allowed to dispense drugs extramurally (i.e. outside of the hospital). In some EU Member States, general practitioners in remote areas are also allowed to dispense drugs. Finally, in some Member States, druggists and other retailers are allowed to sell drugs for which one does not need a prescription – also referred to as Over-The-Counter (OTC) drugs.²³

The *consumers* of drugs are mostly dependent on a *prescriber* to determine the need of access and enabling this access to drugs. In addition, the financial consequences for consumers are usually limited due to the existence of (obligatory) health insurance.

2.2.1 A typology of drugs

Figure 2.2 gives an overview of the different types of drugs. Several categories of drugs may be discerned: pharmaceutical specialties (branded drugs, often protected by a patent), parallel-imported drugs, generic drugs and own preparations. Own preparations are often more costly than prepacked drugs. Most own preparations nowadays entail reducing the doses of prepacked drugs. In addition, prescription drugs and Over-The-Counter (OTC) drugs can be discerned; the difference is that OTC medicines can be obtained without a prescription.

As a result of patenting, if they are not regulated, the prices of drugs might be high along the entire chain. For pharmacists, this might lead to substantial investments in stock.²⁴ In some cases, the drugs need to be prepared on the pharmacist’s premises, meaning that the raw materials required for this preparation need to be stocked by the pharmacist.

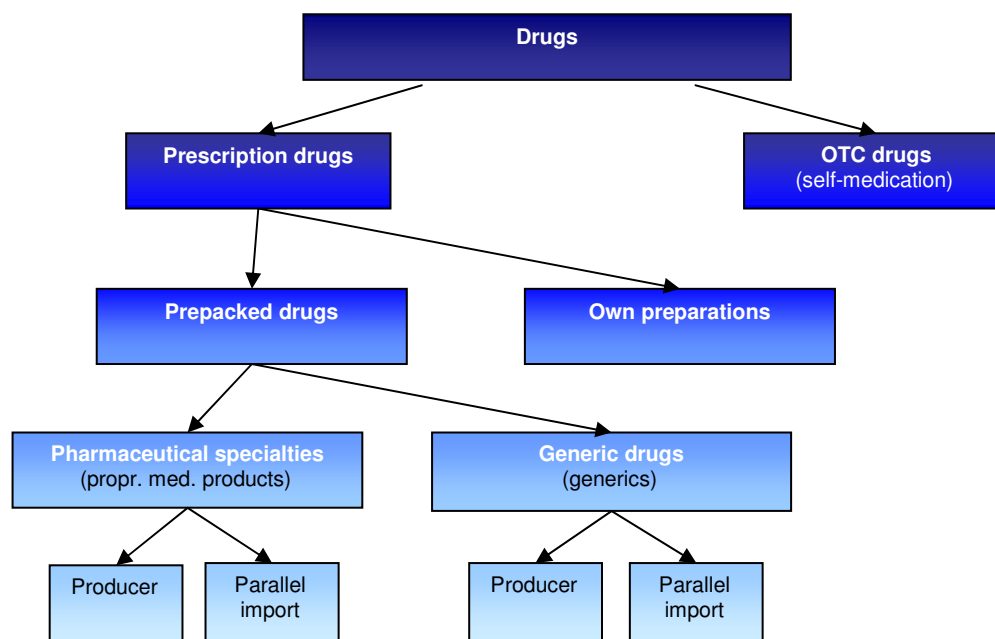
²¹ ÖBIG (2006), pp. 131-132. Concerning the integration trends in Europe, see also pp. 89-91 and 104-106 of that report.

²² For example in the UK, a superintendent pharmacist is required to sit on the Board of Directors and this board member is legally liable for all pharmacy related decisions taken within the organisation.

²³ On this topic, see also ÖBIG (2006), pp. 86-87. In a limited number of Member States, supermarkets are allowed to sell a selection of OTC drugs. For further details, see Chapter 1.

²⁴ The issue of obligatory stock will be addressed later in this chapter.

Figure 2.2 Classification of drugs



Source: Philipson (2003), page 51.

2.3 Characteristics of the pharmacy sector

2.3.1 Basic conditions

With respect to the demand side of the market for pharmaceutical services, the following ‘basic conditions’ are considered to be of importance:²⁵

- Information problems;
- Availability of substitutes (and elasticity of demand);
- Purchase methods;
- Autonomous market growth.

Information asymmetry

The services provided by community pharmacists are ‘experience goods’, of which consumers cannot assess the quality beforehand. The information asymmetry between pharmacists and consumers may lead to quality degradation because of adverse selection.²⁶ In addition, specialised expertise is often required to determine the kind of drugs that are required, for example the expertise of a general practitioner or hospital specialist. Consequently, choices about drug consumptions are typically not made by the consumer himself.

²⁵ Concerning the supply side, those conditions that have not already been discussed in Section 2.2 are not particularly noteworthy.

²⁶ Since consumers cannot recognise good quality beforehand, suppliers have a tendency to supply low-quality services in order to generate cost savings and increase profits (Akerlof, 1970).

Availability of substitutes

As indicated above, the individual consumer lacks the required expertise (information) to identify substitutes for most medicines, particularly for prescription drugs. This means that in the eyes of consumer, there are few substitutes, if any, for the medicine that is prescribed to him/her. Consequently, the demand for drugs is less sensitive (to price) compared to a situation where the consumer himself/herself decides whether or not to purchase a particular drug.^{27,28} This effect is further strengthened by (obligatory) health insurance (see below).

Purchase methods

The demand for drugs is influenced by the extent to which people directly experience the financial consequences of their purchase. In the case of drug purchases, most people are compensated (fully or partially) for their purchase by insurance, and therefore do not experience the full financial consequences of their purchase.²⁹ Furthermore, in most EU Member States, people are required by law to be insured against medical expenses.³⁰ The OECD (2001) concludes that the responsibility to control the quality and quantity of drug expenditures falls to the health insurer. Consequently, it argues that insurance organisations may be granted considerable controlling powers.³¹

The OECD further concludes that “where consumers are insured against the price of pharmaceuticals, they have no incentive to shop at the cheapest pharmacy, and competition between pharmacies cannot be relied upon to ensure efficient and effective delivery of pharmacy services. In these cases, it is necessary to regulate the profit margins of pharmacies. [...] Alternatively it would be possible to tender the right to provide a network of pharmacies in the region.”³²

Both the inability of consumers to identify proper substitutes for particular drugs, and the fact that they do not directly feel the financial consequences of their purchase until now mean that the demand for medicines is not very reactive to price changes.

Autonomous market growth

In addition, some other factors have an influence on the demand of drugs, such as the rise in the ageing population, in birth rates, and in public health. Due to these factors the number of (senior) citizens will increase over time, leading to an increase in the demand for community pharmacy services.³³

²⁷ Among other things, elasticity of demand (the extent to which demand reacts to price changes) is determined by the extent to which consumers regard other products as substitutes.

²⁸ As OTC medicines are usually purchased by the consumer himself/herself, the elasticity of demand for OTC medicines is usually higher than the elasticity of demand for prescription-only drugs.

²⁹ OECD (2001), p. 8.

³⁰ The main reason for mandatory insurance against medical expenses lies in the fact that there are information asymmetries between insurance companies and insured people, which may lead to adverse selection and moral hazards. Without the obligation for people to get insurance for medical expenses, medical insurance would not be provided by the market. For a more elaborate discussion, see e.g. Arrow (1963) and Rosen (2005).

³¹ The health insurer may use various mechanisms to manage pharmaceutical expenditures, such as: co-payment and reimbursement mechanisms, formularies (a list of reimbursed medicines), price controls, and controls on prescribing physicians and pharmacists (guidelines and budgets). See OECD (2001), p. 8.

³² OECD (2001), p. 10. However, the incentive for consumers to pay attention to price have increased significantly in the last few years. In an increasing amount of cases, medicines are not fully reimbursed any more. In particular, OTC may not be reimbursed at all sometimes, meaning that for OTC, consumer do have an incentive to reduce the price of medicine.

³³ OECD (2001), p. 26.

2.3.2 Structure

The most important structural characteristics of the market for pharmacy services are:

- (the extent of) The professional monopoly;
- Horizontal and vertical integration;
- Barriers to entry and exit.

Professional monopoly

Apart from substitutability between medicines, as described in the previous section on basic conditions, the substitutability between suppliers (i.e. community pharmacists, dispensing doctors, druggists or drugstores, supermarkets) is also relevant. In certain situations, it can be useful to provide the right for dispensing drugs to a limited number of suppliers (for example, because advice on using the drugs requires specialised knowledge).³⁴ Substitutability between suppliers is less prevalent when OTC medicines cannot be dispensed by non-pharmacists.

Horizontal and vertical integration

Community pharmacies may also have incentives to integrate horizontally; for example, to obtain economies of scale or scope, or to be able to obtain other (cost) advantages. There may be economies of scope related to the integration between community pharmacies and druggists, or even between community pharmacies and supermarkets.

Vertical integration between general practitioners (prescribers of drugs) and community pharmacists (distributors of drugs) may be induced by economies of scope, such as location synergies, for example.³⁵ Vertical integration between community pharmacists and wholesale suppliers also happens. As indicated earlier, wholesalers are ‘suitable’ candidates to take over a practice, as they have the financial means to do so. Furthermore, efficiency gains can be made due to a reduction in transaction costs and due to the exploitation of scale economies (e.g. in advertising).

Barriers to entry and exit

To open a pharmacy, one needs to make significant investments; for example, investments in the design of the practice and in building up a customer base. These investments can be considerable barriers to entry for new entrants. In addition, entry to the profession might be limited due to regulation.³⁶ There can also be exit barriers, for example, profession-specific investments, such as those in a laboratory.

Both entry and exit barriers lead to a limitation on the number of suppliers of pharmaceutical services.

³⁴ We will deal with the reasons for a professional monopoly in more detail in the next section on regulation.

³⁵ See OFT (2003), Vol. 1. The OFT analysed whether these location synergies may lead to leapfrogging and clustering of community pharmacies in the neighbourhood of prescribers; it did not find such a result.

³⁶ Section 2.4 (on the regulation of the pharmacy sector) elaborates on the reasons for regulating entry.

2.3.3 Conduct

The most important conduct strategies in the market for pharmaceutical services are:

- Pricing strategy;
- Advertising;
- Locations strategy;
- Quality strategy.

Pricing strategy

At all levels of the supply chain, the prices of medicines may be regulated for several reasons:³⁷ to control market power and to control the costs of health insurance (maximum prices); to create incentives for quality competition (fixed prices); or to limit excessive demand (minimum prices).

If the retail prices for drugs are not regulated and consumers are not fully reimbursed, price could become a means of competition. This may be particularly true in cases where other means of competition (on quality) are less successful (for example in cases where consumers cannot assess the quality beforehand).

Advertising

Advertising may increase the demand for drugs (and any non-pharmaceuticals offered) faced by the advertising companies, and consequently may increase profits. However, advertising strategies affect the profitability of a firm not only directly, but also indirectly by imposing entry barriers.³⁸

In the pharmacy sector, advertising is often restricted. In many cases, pharmacies are only allowed to ‘advertise’ their opening hours. In general, the reason to restrict advertising of pharmacies is based on the fear that advertising will degrade the image of the sector. Also practical problems might arise, when competitors are dependent on each other to provide a 24-hours service.

Locations strategy

A third way for pharmacists to compete is to focus on the location(s) of the practice(s). By choosing their locations wisely (given the locations of other pharmacies, general practitioners, (potential) customers, etc.), pharmacists aim to maximize profits.³⁹

The main problem from a social perspective is the issue regarding remote areas. Some regions might not have enough demand for drugs to allow a pharmacist to make a sound financial business case. In those cases, additional rules may be required to guarantee access to drugs for the inhabitants of those regions.

³⁷ The price of drugs typically consists of several elements (costs of production and margins at all levels in the supply chain).

³⁸ Certain strategies, such as advertising or R&D activities, may provide incumbents with an absolute cost advantage, which may increase the market penetration costs for new suppliers – see also Appendix 1: “the SCP Paradigm”.

³⁹ For the general concept of location competition, see Hotelling (1929), pp. 41-57.

The development of Internet and mail order pharmacies lessens the importance of locations from a strategic point of view. Also, the problems concerning supply in remote areas may (partially) be solved by these developments.

Quality strategy

In addition to the three means of competition mentioned above, a pharmacist may also compete on quality. Quality of services provided can consist of quality in the field of pharmaceutical practice, for example checking on any interference between new medicines prescribed and medicines that are already used.

As already indicated above, such a strategy may be rather difficult in cases where consumers are unable to recognise quality beforehand (Akerlof, 1970). In such case a producer may even opt to produce lower-quality goods in order to save costs to better compete on price.

However, for (some groups of) consumers, it is not entirely impossible to observe quality. Especially elderly consumers have a high average level of use of medicines and are thus able to build up experience regarding quality offered. In addition, if these experiences are shared with others, a reputation effect might enter into force.

2.3.4 Performance

The basic performance indications in the SCP-paradigm are:

- Allocative efficiency;
- Production efficiency;
- Rate of technological advance;
- Quality and service.

Allocative efficiency

Allocative efficiency can be measured by profit margins (profit as a percentage of turnover) realised by suppliers. Generally, the presence of market power (often resulting from entry barriers) is regarded as being able to decrease the level of allocative efficiency; that is, it is able to increase profit margins.

Production efficiency

Production efficiency relates to the amount of inputs used to realise a certain output. Translating this to the pharmacy sector, production efficiency can be determined by the amount of labour and (investments in) locations required to dispense a certain number of drugs. In the case of market power, there are fewer incentives for incumbents to strive to improve production efficiency, due to the lack of competitive pressure. Furthermore, scale and scope economies can potentially lead to cost savings; hence, rules limiting the ability to do so potentially prevent improvements in production efficiency.

Rate of technological advance

In the pharmacy sector, technological change is of particular importance at the production stage, and less so at the retail level.

Quality and service

Quality and service levels are indications of how a market performs; after all, more quality creates more value added. Quality can be regarded as being positively related to the intensity of competition. In other words, market power may negatively affect quality. As indicated above, market failure in the form of information asymmetry, if left unaddressed by appropriate incentive schemes, may also lead to socially undesirable low levels of quality.

As the core of the services provided by a pharmacist consists of the distribution of drugs, defining the level of quality and services is not very straightforward. Reviewing the existing literature, we have identified the following quality indicators:

- Security (number of ‘corrections’ and number of ‘accidents’);
- Product and service range;
- Personal care (elderly care, home delivery, consultation areas and consultation time, development of personal medication programs and/or development of chronic disease management packages);
- Opening hours;
- Geographical coverage and supply in remote areas (which will increase when the minimum number of customers needed to operate a pharmacy decreases);
- Number of pharmacies/ists per 1,000 inhabitants;
- Distance-selling (mail order and Internet pharmacies);
- Prices.

2.4 Regulation of the pharmacy sector

In the previous paragraph, we identified a number of characteristics of the pharmacy sector, some of which could lead to potential problems that may require regulation. For a brief discussion on the possible grounds for regulation, see Textbox 1 below. In the remainder of this section, we focus on the way regulation influences the market.

Textbox 1: Justification for regulation

In the (academic) economic literature, the possible justifications for regulation have been discussed extensively, also in the context of professional services. Generally in this literature, a distinction is made between two contrasting approaches to regulation: the public interest approach and the private interest approach. The former looks upon regulation as a possible remedy for so-called market failure. That is, an unregulated market for professional services may not produce efficient outcomes. The latter is less related to justifying regulation but stresses the risk of rent-seeking behaviour by interest groups via lobbying or self-regulation.

The public interest approach argues that in the presence of market failure, government regulation may be needed to improve the efficient working of markets. Market failure may come in four forms: information problems (such as information shortage or asymmetric information); externalities (benefits or costs imposed on third parties); market power (due to scale economies or other entry barriers); and public goods (non-exclusivity and non-rivalry). From the previous section it became clear that the market for pharmacy services is characterised by ‘information asymmetries’ and ‘market power’. In addition, ‘externalities’ play a significant role, as the negative consequences of poor advice may affect people other than the patient and/or the pharmacist. The ‘public good’ argument does not seem to play

a very big role in the context of professional services; the cost of use can be attributed to those making use of the product or service.

A private interest view on the *raison d'être* and the impact of regulation has been formulated by Stigler (1971), who argues that regulation is acquired by the industry, and is designed and operated entirely for its benefit. He stated that every branch of industry which is powerful enough to do so, will lobby the government to erect entry barriers, such as obligatory training or apprenticeships, product requirements, taxes, import quotas, and so on. Naturally, such rules are favourable to the insiders in a market. Likewise, the prohibition of advertising would lead to a less transparent market, where the prices asked could and would be higher than in a market without advertising bans.

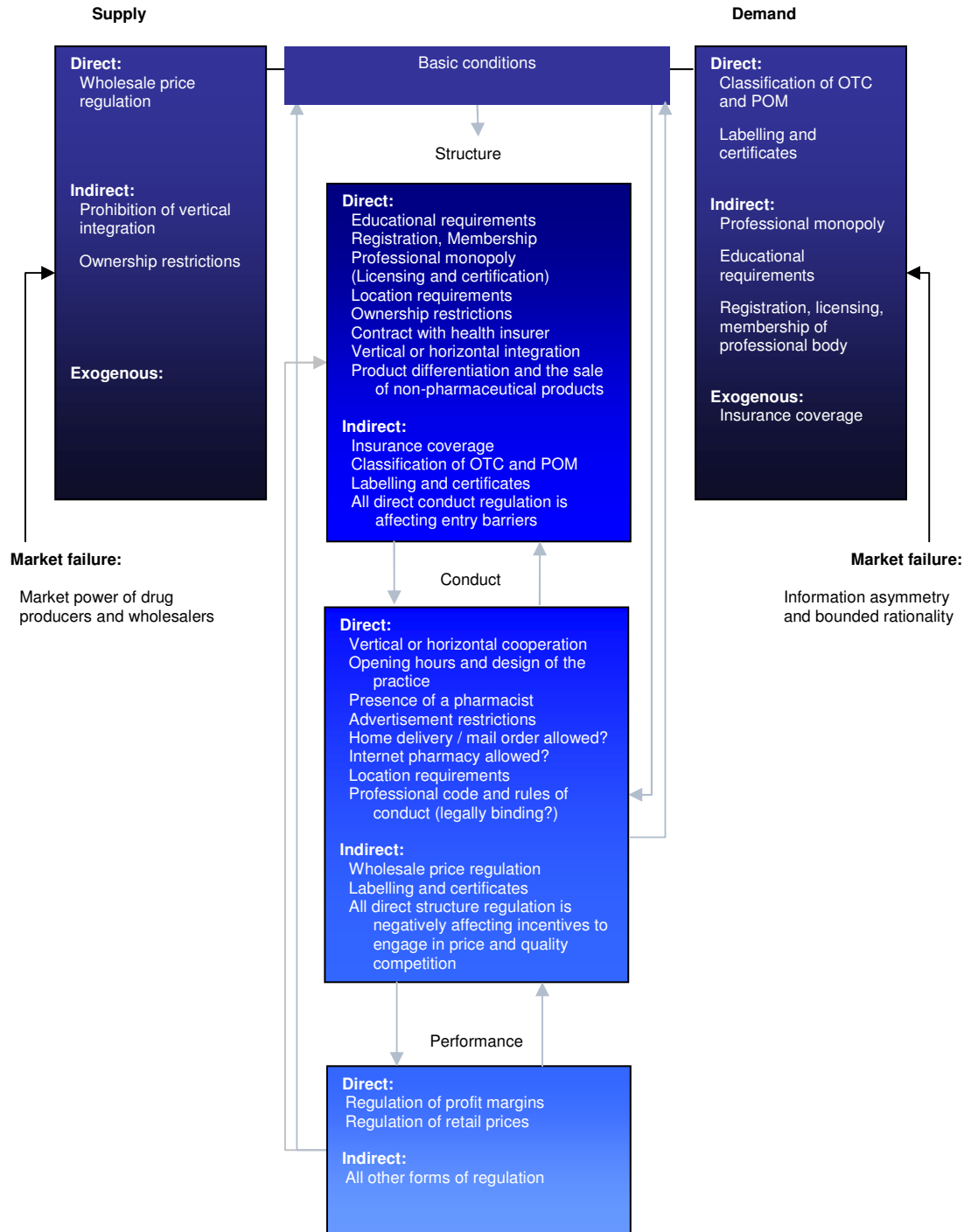
The two approaches to regulation indicate that there are benefits but possibly also costs associated with regulation.

To gain a clearer picture of the direct and indirect effects of regulation, this section will discuss the regulatory framework governing the market for pharmaceutical services in the context of structure, conduct and performance. We have categorised regulation into the following categories:

- Educational requirements;
- Certification;
- Registration and title protection;
- Licensing;
- The required presence of a pharmacist;
- Prohibition of vertical and/or horizontal integration (to preserve independence);
- A professional code (ethics) and rules of conduct.

Figure 2.3 shows how the regulatory framework affects the market for community pharmacies. Certain common forms of regulation and self-regulation are mentioned that relate to basic conditions and/or structure, and/or conduct and/or performance. A distinction is made between, on the one hand, regulation that directly affects any of the elements of the SCP framework; and on the other hand regulation that indirectly does so via the causal relations in the SCP model.

Figure 2.3 Regulations in the market for community pharmacies



Source: ECORYS.

The different forms of regulation in Figure 2.3 are discussed in more detail below. Additionally, it is discussed how the regulatory framework affects the causal relations within the SCP framework (the arrows in Figure 2.3).

Regulation can be formulated either by government, for example, in the form of laws and decrees, or by professional associations. The latter form of regulation is called self-

regulation. Self-regulation exists in many forms, which differ in legal force, and in their degree of autonomy from the government (sometimes it may be legally binding). Public regulatory bodies are usually independent of the interests they regulate, or at least they should be; but such independence is usually absent in the case of self-regulation by professional bodies.⁴⁰ Furthermore, lobbying efforts by professional bodies may successfully steer public regulation to serve private interests.

2.4.1 Structure regulation

The tendency of a totally unregulated market to produce inefficiently low levels of quality (as a result of asymmetric information), and to undersupply remote areas (as a result of scale economies and ‘leapfrogging’)⁴¹ has led to some forms of regulation that directly and indirectly affect the structure of the market by imposing barriers to entry. Examples are: obligations to register, the prohibition of vertical integration, regulation of opening hours, regulation of location choices, etcetera. Figure 2.4 presents an overview of the several forms of regulation that (in)directly affect the structure of the market.

Figure 2.4 Structure regulation

<p>Direct: Educational requirements Registration, Membership Professional monopoly (Licensing and certification) Location requirements Ownership restrictions Contract with health insurer Vertical or horizontal integration Product differentiation and the sale of non-pharmaceutical products</p> <p>Indirect: Insurance coverage Classification of OTC and POM Labelling and certificates All direct conduct regulation is affecting entry barriers</p>
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Source: ECORYS.

Each of the types of regulation from Figure 2.4 will be discussed separately - except for licensing and certification - as these regulatory instruments are connected either to educational requirements, registration with a professional body, or to registration in a public register.

Educational requirements

Before being able to practice pharmacy, individuals in all European Member States must have received a university education.⁴² In addition, some practical experience is required. These educational requirements should guarantee that pharmaceutical services are of a

⁴⁰ Philipsen (2003), pp. 9 and 35. For an extensive discussion of self-regulation, see Ogus (2000).

⁴¹ The OFT (2003) defines leapfrogging as the process “where pharmacies locate between an existing pharmacy and a source of demand, such as a GP’s surgery” (OFT, 2003, Vol. 1, p. 44). The process as described will theoretically result in all pharmacies being located around the source of demand. Leapfrogging thus relates to the tendency of suppliers to cluster near each other in the competitive process, which has been previously explained as ‘Hotelling’s Law’ (supra, note 35).

⁴² According to EU Directive 2005/36/EC. See also ÖBIG (2006), pp. 91-93.

certain minimum level of quality. Moreover, they may generate a feeling of ‘trust’ among consumers about the quality of pharmacists. As such, educational requirements aim to address the problem of asymmetric information (and the related issue of quality degradation).

However, an overly long and difficult period of education may limit entry into the profession. In addition, entry into the profession may be further limited by restricting the amount of students entering that particular course of study.⁴³ Typically, such requirements are laid down in public regulations.

Registration and professional monopoly

The reason behind registration and a professional monopoly is the high degree of knowledge of drugs that is required. Hence, also these forms of regulation address the problem of asymmetric information.

With regard to drugs, an individual consumer lacks the required expertise (information) to identify substitutes for most medicines, particularly for prescription drugs. For that reason, many drugs are only available when prescribed by a general practitioner or a specialist. However, as pharmacology is a highly specialised field of expertise, physicians cannot be expected to have full knowledge of possible side effects when certain drugs are consumed in combination. Hence, prescription drugs can only be sold by community pharmacists who have been granted this monopoly along with the additional public task of controlling the prescription behaviour of physicians (medication control). The lack of information and the dangers of incorrect use of medicines are much less significant for OTC drugs; hence they can be obtained without a prescription. Nevertheless, in some countries the community pharmacist’s monopoly to dispense drugs also extends to OTC medicines.

To become a pharmacist, individuals usually have to fulfil a number of requirements in order to be registered as (community) pharmacists. This public register, as well as the protection of the title ‘pharmacist’, is designed to solve the problem of information, and is intended to create trust among consumers.⁴⁴ However, such procedures also limit entry into the profession. In some EU Member States, pharmacists have to enter several registers before they are recognised.⁴⁵ Once registered, pharmacists enjoy a professional monopoly on the compounding and dispensing of drugs. In some EU Member States, this monopoly extends to prescription drugs only; in others, it also covers OTC drugs. On this topic, the OECD (2001) concludes that “some countries grant pharmacies a monopoly on the sale of non-prescription pharmaceuticals [...] these restrictions [...] appear unnecessary.”⁴⁶ In some EU Member States, pharmacists’ associations have their own private registers (in addition to the public registration), where members can be registered,

⁴³ The reasons for limiting the amount of students may be related to the capacity constraints of the educational facility when a so-called ‘numerus fixus’ applies (i.e. an upper limit on the number of students entering the course of study); or may be related to a quality selection when a ‘numerus clausus’ applies (i.e. selection is based on students’ previous academic performance).

⁴⁴ We need to keep in mind, however, that the level of education is by definition not positively related to the quality of services that is actually provided. Moreover, there is the danger of over-investment in education, if pharmacists try to obtain additional certificates or licenses with the single purpose of signalling high quality levels.

⁴⁵ In some Member States, membership of the professional association is also required by law.

⁴⁶ OECD (2001), p. 11.

for example, as long as they fulfil some conditions of continuous education or other conditions laid down by self-regulation.

Location requirements

Limited access to pharmaceutical services adversely affects public health, and there are negative externalities related to a decline in public health. Considering that scale economies and ‘leapfrogging’ may lead to a clustering of pharmacy outlets in urban areas, and to the insufficient supply of pharmacy services in remote areas; some regulation of pharmacy locations may be necessary.⁴⁷

In some Member States, geographic restrictions apply, concerning the minimum number of patients or neighbouring residents to serve and/or the minimum distance to other pharmacies. These restrictions on the one hand serve the goal of creating “financially viable” pharmacies; while on the other hand, such regulation is obviously limiting entry into the market and creating local monopolies. This may have an adverse effect on the quality of pharmaceutical services. For example, the OFT (2003) found that:⁴⁸

- Pharmacies were more likely to be open before 9 am if they were the closest pharmacy to a GP, and if they faced a higher number of community pharmacists per GP in their locality;
- Pharmacies were more likely to offer a consultation area if there were more supermarket pharmacies in their locality; and
- When a pharmacy faced no other pharmacy within 5 km, it was less likely to offer home delivery.

Ownership restrictions

This category of regulation refers to, for example, limitations on the number of pharmacies that may be owned; and to rules on the takeover of pharmacies. In some EU Member States, only pharmacists are entitled to own a pharmacy. In addition, pharmacists can often only own one or a very limited number of outlets. These regulations prevent, among other things, the formation of pharmacy chains.

The reasons for such restrictions are not clearly related to any of the four market failures referred to in textbox 1 (p. 34). These rules are born out of fear that separation of profession and ownership may lead to uncertainty with regard to liability in cases of misconduct or negligence in a pharmacy.⁴⁹ However, limiting the formation of pharmacy chains may severely limit entry in the market – especially when the amount of financial capital to effect a takeover is significant.⁵⁰ Moreover, rules can foresee that a pharmacy chain has a structure that guarantees the independence of pharmacy decisions within a group. For example in the UK, a superintendent pharmacist is required to sit on the Board of Directors and this board member is legally liable for all pharmacy related decisions taken within the organisation.

⁴⁷ In addition to the danger of insufficient supply in remote areas, the OFT argues that leapfrogging may generally reduce incentives to invest “for fear of being leapfrogged following the investment” (OFT, 2003, vol. 1, p. 44).

⁴⁸ OFT (2003), Vol. 1, p. 44.

⁴⁹ ÖBIG (2006), p. 132.

⁵⁰ Even if takeover prices are restricted, such as in Belgium, numerous ways to circumvent such restrictions are present (Philipsen, 2003, Chapter 4).

Vertical and horizontal integration

Horizontal integration among community pharmacies themselves is restricted in some Member States; while it is permitted in others. Reasons for prohibiting horizontal integration and/or vertical integration may relate to preventing the formation of pharmacy chains in order to preserve the ‘professional freedom of pharmacists’, and in order to have clarity with regard to liability. In relation to the four market failures from textbox 1 (p. 24), it may be argued that integration is not allowed in order to prevent market power (due to scale economies).

However, by not allowing horizontal and/or vertical integration, possible synergies and economies of scope cannot be exploited; this may increase the costs of production. In addition to decreasing productive efficiency, a possible side effect could be that the threshold value to open a community pharmacy outlet (i.e. the minimum number of potential consumers needed to open a business) is higher when integration is prohibited; higher in comparison to a situation where pharmaceutical services would be integrated with, for example, services provided by a druggist. Consequently, entry into the market for community pharmacy services might be impeded, and the problem of insufficient supply in remote areas might be more severe.

Furthermore, by preventing the exploitation of economies of scope, competition from low(er)-cost producers is lessened, which may eventually lead to a lower intensity of quality competition and less choice between quality (service) levels;⁵¹ for example, as mentioned above, the OFT (2003) found that pharmacies were more likely to offer a consultation area if there were more supermarket pharmacies in their locality.

Finally, we would like to point out that vertical integration may lead to lower prices when it prevents double (or even triple) mark-ups. The double-mark-up problem causes an upstream manufacturer’s / supplier’s sales to fall below the integrated profit-maximizing level. This may create incentives for the upstream manufacturer/supplier to integrate forwards.⁵²

Contracts with health insurers

Contracts with health insurers may also pose a barrier to establishing a pharmacy. Even where such contracts are not necessarily required by law, it is often practically impossible to operate a pharmacy without them, or else reimbursement of prescription drugs would not be possible. The structure of the market is affected because entry barriers are created and monopsony power⁵³ is granted to insurance organisations.

⁵¹ This relates to the monopoly non-linear pricing literature, which was mentioned earlier: Mussa and Rosen (1978) and Maskin and Riley (1984). Because products of different qualities are substitutes, a monopolist cannot simultaneously offer each consumer the most efficient quality and also extract his full surplus, even with a fully non-linear tariff. Instead, under standard assumptions, quality to all but those consumers with the highest tastes for quality is distorted downwards. Furthermore, consumers with low preferences for quality may be excluded from the market entirely.

⁵² Alternatively the vertical restraint of resale price maintenance may be imposed, which allows a manufacturer to directly constrain the ability of a downstream retailer to exploit local market power (see Cooper et. al. p. 5).

⁵³ In economics, a monopsony is a market form with only one buyer, called "monopsonist", facing many sellers. It is an instance of imperfect competition, symmetrical to the case of a monopoly, in which there is only one seller facing many buyers.

Related to this issue is the mandatory insurance coverage against medical expenses by consumers. This indirectly affects the structure of the market for community pharmacy services, as demand for drugs will be less elastic (in some cases even inelastic), leaving community pharmacies with some market power.

Product differentiation and the sale of non-pharmaceutical products

In some EU Member States, community pharmacies are only allowed to sell pharmaceutical products. By not allowing community pharmacies to differentiate their product range, they are prevented from enjoying economies of scope. Hence, the analysis presented above – with respect to the effects of such a prohibition on the ‘threshold value’, entry into the pharmaceutical market and quality competition – also applies here.

2.4.2 Conduct regulation

As the structure of a market leads to certain conduct by the incumbents (and potential entrants), structure regulation will also (indirectly) have its effects on conduct by incumbent pharmacists.⁵⁴ There are, however, also many forms of regulation that directly affect conduct. These can be in the form of government law or in the form of self-regulation. Whereas the dangers of rent seeking by the professional association are generally larger in case of self-regulation, self-regulation is likely to lead to better formulated rules than government law, due to information asymmetries between the professionals and government officials. There is no general classification of what rules characterise typical self-regulation or typical public regulation. In some Member States, the rules and code of conduct of the professional association regulate certain forms of behaviour that in other Member States are addressed by public regulation.⁵⁵

In all Member States, one or more professional bodies are actively representing community pharmacists. To various extents, these professional bodies prescribe by means of more or less binding ‘rules of conduct’ how pharmacies should be run.⁵⁶ In the case of self-regulation, it is important to consider how binding these rules are. If membership of the professional body is not compulsory, and the rules are not binding, the effect of such rules may be less than when rules that are less strict but binding to all pharmacies. In the case of public regulation, one may expect that these are binding by definition.

Forms of conduct regulation that commonly apply to community pharmacists (either imposed by the professional association or by the government) are discussed below.⁵⁷

⁵⁴ For example, the professional monopoly inhibits entry in the market and consequently this may have negative incentives for entrepreneurial activities undertaken by the incumbent pharmacists.

⁵⁵ For example, in the United Kingdom, requirements with respect to the design of the practice (such as floor space, outdoor signs, indoor signs, etc.) are laid down in the professional code of the pharmacists’ association (see Section 3 of the Code of Ethics of The Royal Pharmaceutical Society of Great Britain - RPSGB); whereas in the Netherlands, comparative requirements are set out in the Medication Advertising Decree (*Reclamebesluit Geneesmiddelen*).

⁵⁶ Usually, also a so-called ‘professional code’ (also referred to as a code of ethics, code of conduct, or professional norms) is designed to ensure ethical behaviour. Codes of ethics can be imposed by corporations/associations to serve as a management tool for establishing and articulating the corporate/associative values, responsibilities, obligations, and ethical ambitions of an organisation and the way it functions. It provides guidance to employees/members on how to handle situations which pose a dilemma between alternative right courses of action, or when faced with pressure to consider right and wrong.

⁵⁷ The discussion of price regulation will be postponed until the next section, which deals with ‘performance regulation’.

Figure 2.5 represents an overview of all regulation that directly or indirectly affects conduct within the market for community pharmacy services.

Figure 2.5 Conduct regulation

<p>Direct: Vertical or horizontal cooperation Opening hours and design of the practice Presence of a pharmacist Advertisement restrictions Home delivery / mail order allowed? Internet pharmacy allowed? Professional code and rules of conduct (legally binding?)</p> <p>Indirect: Wholesale price regulation Labelling and certificates All direct structure regulation is negatively affecting incentives to engage in price and quality competition</p>
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Source: ECORYS.

Vertical or horizontal cooperation

The reasons for the prohibition of vertical and/or horizontal cooperation are similar to the reasons for not allowing vertical and/or horizontal integration. Also, the analysis of the consequences for the competitive process is rather similar to the analysis of vertical and/or horizontal integration described above.

Opening hours, the design of the practice and the presence of a pharmacist

Generally, restrictions are present in the context of executing one's professional duties. Such rules may vary from general conditions on labour standards, to a prescribed arrangement of the interior space (e.g. a required consultation area), the amount of medicines required to be in stock (e.g. all drugs that may be prescribed must be present at all times), standards on opening hours and service levels, and the required presence of a pharmacist at all times.

These regulations obviously aim to maintain a certain level of quality; hence they try to compensate for the negative consequences of market power and information asymmetry with respect to quality.⁵⁸ However, they may also create entry barriers, for the following reasons:

- Storage of drugs requires large (sunk) investment;
- Prescribed arrangements of the interior space limit the choice of suitable real estate and locations;
- Overly long opening hours in combination with the required presence of a pharmacist may increase threshold values and diminish the availability of pharmaceutical services in remote areas;
- Restricted opening hours may limit the possibility of covering overhead costs.⁵⁹

⁵⁸ On this point, see also ÖBIG (2006), pp. 99-101.

⁵⁹ Generally, however, the required opening hours define a minimum rather than a maximum number of hours.

Advertisement restrictions

Often restrictions apply to advertising one's community pharmacy and to advertising drug prices. The former are usually part of self-regulation (referring to the "ethical behaviour" of pharmacists); whereas the latter mostly follow from public regulations. Such restrictions on advertising increase rather than decrease the information asymmetry between pharmacists and consumers, and moreover restrict competition between pharmacies – so one needs to have good reasons for doing so.

Home delivery, mail order and internet pharmacies

Many characteristics of e-commerce might be expected to increase competition. For example, competition between sellers will tend to be more vigorous when search costs, menu costs and transactions costs are low; and when buyers have a wide choice of suppliers.⁶⁰ To some extent, these arguments do not fully apply to the market for community pharmacy services, as price and fee regulation limits the extent to which price competition can take place (see the following section).

Philipsen (2003), however, mentions that internet pharmacies (as well as mail order pharmacies and home delivery services) may have some additional advantages for consumers:

- Prices, especially of OTC drugs, may be lower;
- Privacy-sensitive medicinal products (e.g. contraceptives, incontinence products, AIDS inhibitors) can be ordered with more anonymity;
- Chronic drug users do not have to go to a pharmacy every time they have to repeat their prescription.⁶¹

Furthermore, mail order pharmacies and internet shops typically form a competitive fringe that requires less sunk investment, even though the distribution must be conducted from a community pharmacy. Naturally, a prescription from physician or specialist is still required for obtaining prescription drugs from a mail order or internet pharmacy.

The long-distance sale of drugs typically diminishes the ability for medication control by a pharmacist.⁶² Consequently, in some EU Member States, drugs may only be sold from a physical pharmacy outlet. Taken to its extreme, a ban on the long-distance sale of drugs (such as through mail order and internet pharmacies) would also prohibit home deliveries (as is the case in Austria, for example).

However, long-distance sale of drugs does not *per se* exclude supervision by a pharmacist. See, for example, the decision of the European Court of Justice in *DocMorris*, where the Court concluded that for non-prescription medicines, there existed no grounds for a prohibition on mail-order sales.⁶³

⁶⁰ OFT (2000), p. 48.

⁶¹ Philipsen (2003), pp. 55-57.

⁶² On the other hand, internet pharmacies are often under legal obligation to undertake such a check *ex ante* before being able to deliver any POM.

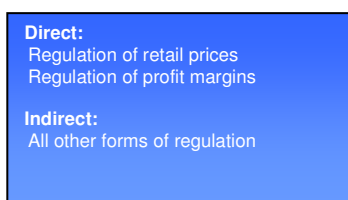
⁶³ European Court of Justice, *Deutscher Apothekerverband v 0800 DocMorris*, 11 December 2003, Case C-322/01.

2.4.3 Performance regulation

The ‘performance’ of the pharmaceutical market can be measured in terms of both quality and price. Quality in this context refers both to the quality of pharmaceutical services (in particular: advice to physicians and patients, medication control, screening services for medicine interferences, monitoring of therapy) and the accessibility of pharmaceutical services (i.e. the number of pharmacies, and the availability of pharmaceutical services in remote areas). Price refers to the pharmacists’ fee and the price of drugs.

Of course, all forms of regulation, as discussed in the previous sections, have an indirect effect on performance. However, here we will only discuss the one form of regulation that *directly* influences performance and that has not been discussed yet: price regulation. This is also depicted in Figure 2.6, below.

Figure 2.6 Performance regulation



Source: ECORYS.

Regulation of retail prices

The retail price charged for a medicine typically consists of several elements:⁶⁴ the cost price of the producer, a profit margin for the producer, a profit margin for the wholesaler (if present), and finally a profit margin for the pharmacist. Prices may be regulated at each stage of the supply chain, in order to allow for the correction of the market power held by drug producers and wholesalers. Most price regulation applies to pharmaceutical specialities (or drugs that are protected by intellectual property rights – see Figure 2.2 above). However, prices of generics may be regulated as well.⁶⁵ Furthermore, the reimbursement by the health insurance is also important, which likewise is regulated by law.

Although price regulation is classified as ‘performance regulation’, we should mention again that it also affects conduct; namely by determining the ‘mode’ of competition: if community pharmacists, as a result of price regulation, have no possibility of engaging in price competition, they will focus on quality competition.

Regulation of profit margins

Pharmacists usually receive a fee related to the number of transactions they conduct. More specifically: they receive a fixed fee or a fixed percentage of the drug price per dispensed prescription drug. This fixed fee is supposed to reimburse pharmacists for their provision of pharmaceutical services. However, the fact that this reimbursement is related

⁶⁴ We exclude value-added tax (VAT) from our discussion.

⁶⁵ See e.g. ÖBIG (2006, pp. 26, 41) for regulations applying in the Netherlands and Norway, respectively. See also Chapter 1.

to the number of prescriptions rather than to the actual provision of pharmaceutical services has been criticised by some authors.⁶⁶ Regulation of OTC margins rarely occurs.

The presence of incentive schemes in some Member States may also have an influence on the pharmacists' profits, as far as the dispensing of prescription drugs is concerned. That is, in some EU Member States, such as The Netherlands, substitution by pharmacists of more expensive by cheaper (generic or parallel-imported) drugs is possible, as long as physicians prescribe under the substance name and not under the brand name.

2.5 Conclusion

The main justification for regulation follows from the market failure called 'information asymmetry'. Indeed, there is an asymmetry of information between pharmacists and their customers, which may lead to the problem of 'adverse selection' – and hence to quality degradation. Some kind of intervention in the market (such as regulation of quality), either by the government or some self-regulating body, is necessary in order to cure this market failure. Additionally, in the absence of some form of quality regulation there may be an externality problem in the pharmaceutical market (adverse health effects on third parties in the case of low-quality services).⁶⁷

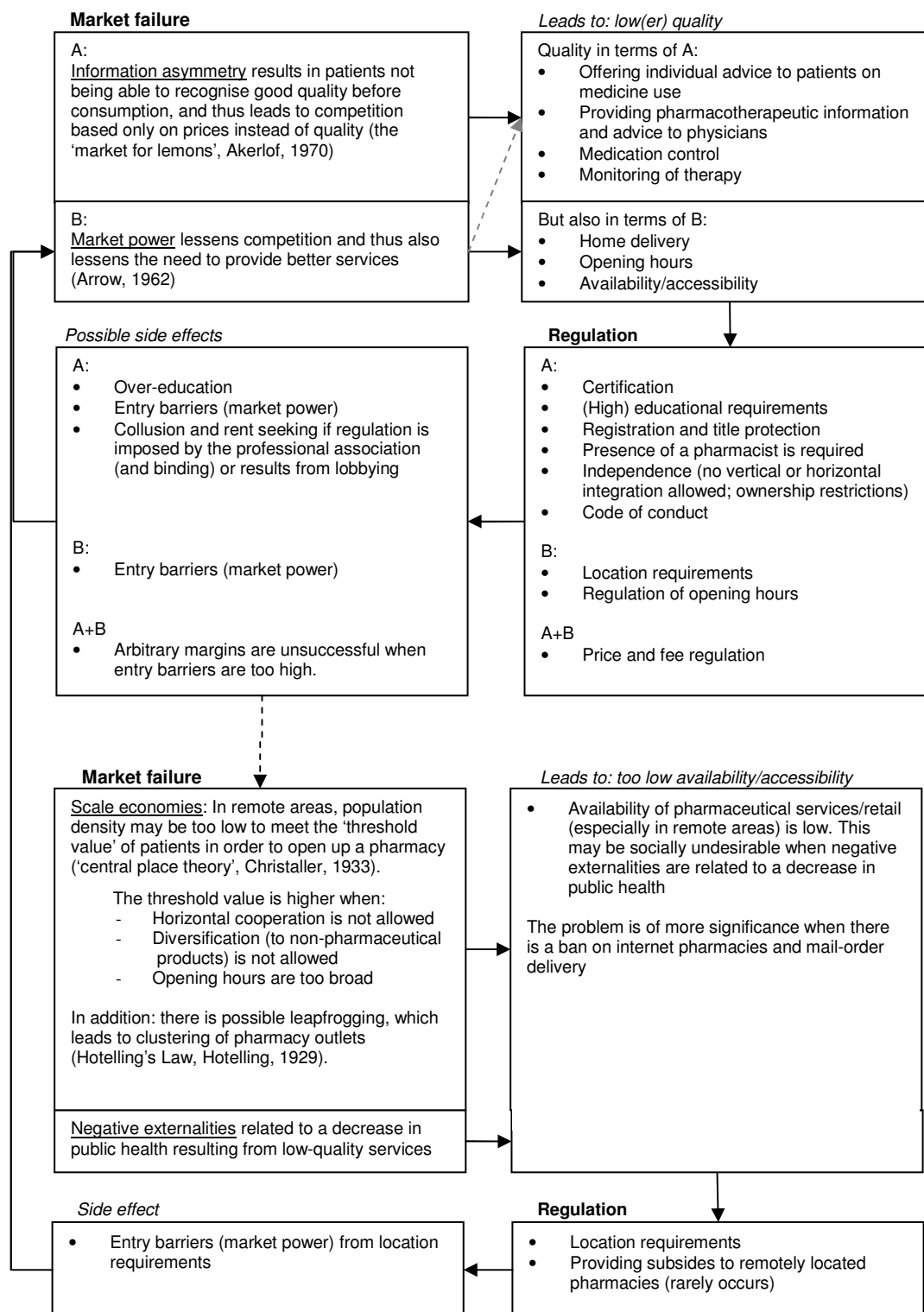
Linked to this discussion of market failure, it is of course necessary to control any (abuse of) market power by, for example, drug producers, wholesale companies and/or health insurers. While competition law is the main instrument for doing so, the presence of market power may also explain to some extent the (sector-specific) price regulation of drugs and profit margins.

Figure 2.7 provides a schematic overview of the arguments presented above, and elsewhere in this chapter. It shows the main forms of market failure that may appear in the pharmaceutical market, as well as the regulation commonly designed by EU Member States to deal with the problems resulting from it. Moreover, the figure shows the possible side effects of such regulation.

⁶⁶ For a critical analysis of the fixed fee/ fixed margin, see e.g. Philipsen (2003), who argues that ideally one would like to have a remuneration system that rewards pharmacists separately for tasks performed in the field of pharmaceutical care, such as giving advice to physicians (in so-called pharmacotherapeutical consultations) and patients on the one hand, and for distributional tasks on the other.

⁶⁷ Sometimes the 'public good' character of health care is used as an additional justification for regulation. However, strictly speaking, the 'public good' problem of free-riding behaviour and insufficient provision of pharmaceutical services (see also Appendix 2: "Regulation of professions: an overview of the economic literature") does not seem to be important in practice. We will therefore not deal with this discussion. The same goes for the 'demand generation' problem resulting from moral hazard (the principal-agent problem).

Figure 2.7 Market failures: effects, regulations and (side) effects



Source: ECORYS.

3 The pharmacy sector – factual information

3.1 Regulation of the pharmacy sector in the Member States – activities undertaken

To obtain information on the regulation of the pharmacy sector in the Member States, we have undertaken the following activities:

- Analysed legal documents;
- Collected information from public sources;
- Conducted a web-questionnaire for policy-makers and the national pharmaceutical representative organisations (PROs);⁶⁸
- Contacted national policy-makers, PROs, competition authorities and consumer representation organisations for additional information.

We sent questionnaires to over 100 organisations. A full list of organisations contacted is given in Appendix 5. In Table 3.1 below, we have listed the pharmacy representative organizations (PROs) and the policy-makers that have cooperated without (web)questionnaires. Only respondents that filled out more than 20% of the questionnaire have been included.

Table 3.1 Response to questionnaires by policy-makers or PROs (only entries with a response of 20% or more to the questions listed)

Country	Organisation	% the questions answered
Austria	Österreichische Apothekerkammer	96%
Hungary	Ministry of Health	96%
Germany	Bundesvereinigung Deutscher Apothekerverbände	83%
Latvia	Ministry of Health	83%
Estonia	Estonian Pharmacists' Union	78%
France	Conseil Central de l'Ordre des Pharmaciens d'officine	78%
Portugal	National Institute of Pharmaceuticals and Medicines	78%
Cyprus	Pancyprian Pharmaceutical Organisation	70%
UK	Department of Health - PPRS	70%
Denmark	Danish Pharmaceutical Association	65%
Italy	Ministero della Salute - Direzione generale dei farmaci e dei dispositivi medici	65%
Slovenia	Ministry of Health	57%

⁶⁸ The questionnaires are presented in Appendix 4 ("Questionnaires").

Belgium	Algemene Pharmaceutische Bond - Association Pharmaceutique Belge	52%
Denmark	Danish Medicines Agency	52%
Ireland	Irish Pharmaceutical Union	52%
Belgium	Orde der Apothekers	48%
Germany	Bundesministerium für Gesundheit	48%
Portugal	Associação Nacional das Farmácias	48%
Estonia	State Agency of Medicines	43%
Greece	Ministry of health	43%
UK	Royal Pharmaceutical Society of Great Britain	43%
Czech	Czech Chamber of Pharmacists	35%
Lithuania	Ministry of Health	35%
Sweden	Apoteket AB	35%

The IHS study and follow-up study by the European Commission suffered from similar low response rates.

Quality checks

We have sent the draft country sheets to the policy-makers and / or the PROs for them to perform quality checks.⁶⁹ In addition, the country sheets have been sent to the Pharmaceutical Group of the European Union (PGEU) and to the European Competition Network (ECN) for a similar check.

The majority of the organisations checked the country sheets and returned them, with corrections in some cases. If the corrections were significant, we resent the corrected country sheet for a final check.

Table 3.2 gives an overview of the quality checks we have performed on our country sheets.

⁶⁹ The policy-makers and PROs in Spain and Greece have not been contacted to perform a quality check, as these organisations refused to cooperate.

Table 3.2 Performed quality check of country sheets as per 4 October 2006

Country	Country Sheet sent?	To	Reply received?	Revised Country Sheet sent?	To	Reply received?
Austria	Yes	- Ministry of Health - Chamber of Pharmacists	Yes	Yes	- Ministry of Health - Chamber of Pharmacists	Yes
Belgium	Yes	- Association Pharmaceutique Belge - Belgian Competition Authority	Yes	Yes	- Association Pharmaceutique Belge	Yes
Cyprus	Yes	- Ministry of Health - Competition authority	Yes	No		
Czech Republic	Yes	- Office for the Protection of Competition - Lekarnici (Association) - SUKL (State Institute for Drug Control)	Yes	No		
Denmark	Yes	- Ministry of Health - Apotekerforeningen - DKMA	Yes	No		
Estonia	Yes	- Estonian Pharmacists Association	Yes	No		
Finland	Yes	- National Agency for Medicines - Finnish Competition Authority	Yes	No		
France	Yes	- Ordre des Pharmaciens	Yes	No		
Germany	Yes	- Bundesvereinigung Deutscher Apothekerverbände - Ministry of Health	Yes	Yes	- Bundesvereinigung Deutscher Apothekerverbände - Ministry of Health	Yes
Greece	No*					
Hungary	Yes	- Ministry of Health - Hungarian competition authority	Yes	No		
Ireland	Yes	- Pharmaceutical Society of Ireland - Irish Pharmaceutical Union	Yes	No		
Italy	Yes	- Ministry of Health	No			
Latvia	Yes	- Latvian Competition Authority	Yes	No		
Lithuania	Yes	- Ministry of Health	No			

Country	Country Sheet sent?	To	Reply received?	Revised Country Sheet sent?	To	Reply received?
Luxembourg	Yes	- Ministry of Health	No			
Malta	Yes	- Ministry of Health	Yes	No		
Netherlands	Yes	- KNMP - Ministry of Health	Yes	No		
Poland	Yes	- Ministry of Health	No			
Portugal	Yes	- Associação Nacional das Farmácias - Instituto Nacional da Farmácia e do Medicamento (Infarmed)	Yes	No		
Slovak Republic	Yes	- Ministry of Health	No			
Slovenia	Yes	- Ministry of Health	Yes	No		
Spain	No*					
Sweden	Yes	- Apoteket	Yes	Yes	- Ministry of Health - Apoteket - Competition Authority	No
United Kingdom	Yes	- Department of Health	Yes	Yes	- Department of Health	Yes

* Cooperation refused

Note: the revised country sheets were only sent in cases where the additions and / or corrections for the first country sheet sent were significant.

For 16 countries, the activities undertaken have led to an almost complete overview of regulation, meaning more than 95% of regulation was identified and checked by stakeholders in those countries. For five countries, it was difficult to obtain a complete overview of the regulation, as stakeholders refused to cooperate. In addition, the legal text was not available in an easily accessible language. For these countries, we did not manage to obtain 95% completion on the regulation. These countries are: Denmark, Greece, Italy, Lithuania and the Slovak Republic. Of these countries, only the sheets of Greece and Slovak Republic are less than 75% complete.

3.2 Regulation of the pharmacy sector in the Member States – results

The information of the regulatory regimes in the different Member States is listed in the country sheets in Appendix 6 of this report. Table 3.3 provides an overview of the scope of the regulation in each of the Member States. The legend for Table 3.3 is given in Table 3.4.

Table 3.3 Overview of regulation in the field of pharmacies in the Member States

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK	
Education																										
Total duration of education	5.5	5.0	n.r.	5.0	5.0	5.0	5.0	6.0	5.0	6.0	6.0	6.0	5.5	5.0	5.5	n.r.	5.0	6.0	5.0	5.5	5.5	5.0	5.0	5.0	5.0	5.0
Duration of education (excl. compulsory practice)	5	4.5	n.r.	4.5	4.5	4.5	4.5	4.83	4	5	5.5	5	5	4.5	5	n.r.	4.5	5.5	4.5	5	5	4.5	4.5	4.5	4.5	4
Duration of compulsory practice	6	6	n.r.	6	6	6	6	14	12	12	6	12	6	6	6	n.r.	6	6	6	6	6	6	6	6	6	12
Limitation on number of students?	413	none	n.r.	300	207	40	100	2990	2650	300	320	85	?	50	?	n.r.	none	none	none	889	none	135	none	200	none	
Continuous training obligatory?	0	0	0	20	0	0	0	0	40	0	20	0	?	0	24	?	0	6	?	24	y	80	0	0	0	
Registration, licensing or membership obligatory?																										
Registration, licensing or membership obligatory?	R.M	R	R.M	R.M	none	R	L	R.M	L.M	R.L. M	R.L. M	R	R.M	R	L	R. L	R	R	R.L. M	R.L. M	M	M	R.M	L	R.M	
Diploma/educational requirements	Y	Y	Y	Y	n.r.	Y	Y	Y	Y	N	Y	Y	?	Y	Y	Y	Y	Y	Y	Y	?	?	Y	Y	Y	
Practice (duration in months)	N	N	Y	N	n.r.	N	N	N	N	Y	N	Y	?	Y	N	N	N	N	N	N	?	?	N	N	N	
Examination	N	N	Y	N	n.r.	N	N	N	Y	Y	N	N	?	N	Y	N	N	N	N	N	?	?	N	N	Y	
Declaration of good conduct	Y	N	N	N	n.r.	N	N	Y	Y	N	N	N	?	Y	N	Y	N	N	Y	N	?	?	N	Y	N	
Language requirement/other	N	N	N	N	n.r.	N	N	N	Y	N	N	N	?	N	N	Y	N	N	Y	N	?	?	N	N	N	
Nationality limitations/obligatory residency	N	N	N	N	n.r.	N	N	Y	Y	N	N	N	?	N	N	Y	Y	N	N	N	?	?	N	N	N	
Costs/year	?	122	17	60	n.r.	0	0	423	150	300	41	404	?	4	0	0	12	0	5	218	?	?	?	0	387	

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK	
Scope of the monopoly																										
POM: Comm. Pharm.?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
POM: Hosp. Pharm?	Y	N	Y	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N
POM: Other Pharm.?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
POM: Other medicals professions?	Y	N	N	N	Y	N	N	N	N	Y	N	Y	N	Y	N	N	N	Y	N	N	N	N	N	N	N	Y
OTC: Comm. Pharm.?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
OTC: Hosp. Pharm?	Y	N	N	N	N	N	N	Y	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N
OTC: Other Pharm.?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N
OTC: Other medical professions?	Y	N	N	N	Y	N	N	N	N	Y	N	Y	N	Y	N	N	N	Y	N	N	N	N	N	N	N	Y
OTC: Druggists?	Y	N	N	N	N	N	N	N	Y	N	N	Y	N	N	N	N	N	Y	N	Y	N	N	N	N	N	Y
OTC: Other stores?	N	N	N	N	N	N	N	N	Y	N	N	Y	N	N	N	N	N	Y	Y	N	N	N	N	N	N	Y
Additional requirements? (licence, education, product min. range)	N	n.r.	n.r.	n.r.	P	n.r.	n.r.	n.r.	E	n.r.	N	?	n.r.	n.r.	n.r.	n.r.	n.r.	L	N	E	?	n.r.	n.r.	n.r.	E	
Operating requirements																										
Ownership restrictions?	M	N	P	N	P	N	P	P	P	P	O	N	PS	PS	N	P	N	N	N	P	N	PS	M	S	O	
Ownership of more than one pharmacy allowed?	M	U	M	U	U	U ⁷⁰	3c	5c	3c	N	Mc	U	N	2c	U	N	U	U	U	N	3c	U	N	n.r.	U	
Restrictions on business form?	A	PL	A	PL	PL	PL	PL	PL	A	PL	A	PL	?	PL	PL	A	PL	PL	PL	PL	S	A	S	n.r.	PL	
Free allocation changes in ownership?	Y	Y(5)	N	N	N	Y	N	Y(5)	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	?	?	N	Y(3)	n.r.	Y	
Internet pharmacies allowed: POM?	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	Y	N	N	?	N	?	Y	Y	

⁷⁰ Note that one pharmacy may own up to 3 subsidiary pharmacies. The number of pharmacy branches owned is unrestricted for owners, however.

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK
Internet pharmacies allowed: OTC?	N	N	N	N	Y	N	N	N	Y	N	Y	Y	N	Y	N	N	N	Y	N	N	?	N	?	Y	Y
Requirements on location of pharmacies																									
Minimum no cust.	N	2500	N	N	?	3000	N	2500	N	?	5000	N	4500	Y	N	5000	N	N	N	4000	N	5000	2800	n.r.	N
Geographical requirements	N	N	N	N	?	1000	Y	N	N	?	275	N	200	N	N	N	N	N	N	500	N	400	250	n.r.	N
Ltd. no pharms	N	N	N	N	?	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	n.r.	N
Econ. needs test	Y	N	N	N	?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	n.r.	N
Contract with insurer	N	N	N	N	?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	n.r.	N
Other	Y	N	N	N	?	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y	N	n.r.	N
Barriers to pharmacists other EU countries																									
3-year clause	Y	N	N	N	N	N	N	Y	Y	?	Y	N	N	N	N	N	N	N	N	N	?	N	N	N	Y
Language requirement	Y	N	Y	N	N	N	N	N	N	?	Y	N	N	N	N	Y	Y	N	Y	Y	?	Y	N	Y	N
Other	N	N	N	N	N	N	N	Y	N	?	N	N	Y	Y	N	N	N	Y	N	N	?	N	N	N	N
Can one operate a pharmacy without a contract with a health insurer?																									
Legally	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	N	Y	Y	Y	Y	?	N	N	n.r.	Y
Economically	Y	Y	Y	Y	N	N	N	Y	Y	N	N	N	N	N	Y	N	Y	N	Y	Y	?	N	N	n.r.	N
Horizontal partnerships/mergers (Integration)																									
Other pharmacies?	Yc	Yc	Y	Y	N	Y	N	Y	Y	?	Yc	Y	?	Yc	Y	Y	Y	Y	Y	N	N	N	N	n.r.	Y
Druggists?	Yc	Yc	Y	Y	N	Y	N	Y	N	N	?	Y	?	Yc	N	Y	Y	Y	Y	N	N	N	N	n.r.	Y
Wholesalers?	Yc	Y	N	N	N	N	N	N	N	?	N	Y	N	Y	N	?	Y	Y	Y	N	N	N	N	n.r.	N
Drug producers?	Yc	Y	N	N	N	N	N	N	N	?	N	Y	N	Y	N	?	Y	Y	N	N	N	N	N	n.r.	N
Insurance companies?	Yc	Y	Y	N	Y	Y	N	N	N	?	Y	Y	N	Y	N	?	n.r.	Y	Y	N	N	N	N	n.r.	Y
General practitioners?	Yc	Y	Y	N	N	N	N	N	N	?	Y	Yc	N	Y	N	N	N	N	Y	N	N	N	N	n.r.	Y
Practice																									
Opening hours?	F	U	F	U	?	U	U	U	F	Min	F	Min	Max	U	U	U	U	U	?	Max	?	Min	U	U	Min

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK
Design of the practice: Floor space?	Y	N	Y	Y	N	Y	Y	Y	Y	?	Y	N	N	Y	Y	Y	N	N	Y	Y	?	Y	Y	Y	Y
Design of the practice: Advertising?	Y	Y	N	Y	N	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	N	N	N	Y	Y
Design of the practice: Outdoor?	Y	Y	Y	Y	N	N	N	Y	N	?	Y	N	Y	Y	Y	Y	Y	N	N	Y	?	Y	N	Y	N
Design of the practice: Indoor?	Y	Y	N	Y	N	N	N	Y	N	?	N	N	N	N	Y	Y	N	N	N	Y	?	N	N	Y	N
Design of the practice: Shelving?	N	Y	N	Y	N	N	Y	Y	N	?	N	N	N	N	Y	N	N	N	Y	N	?	Y	N	Y	Y
Design of the practice: Storage?	N	Y	Y	Y	N	Y	Y	Y	Y	?	Y	N	N	Y	Y	N	Y	N	Y	Y	?	Y	N	Y	Y
Is the presence of a pharmacist required?	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y
Stock?	S	S	S	N	S	T	S	N	S	?	N	N	T	T24	?	N	N	N	S	T24	?	T24	S	S	N
Sale of non- pharmaceutical products allowed?	L	L	L	U	L	L	L	L	L	L	L	U	U	L	?	L	L	Y	N	L	?	L	U	L	U
Provision of diagnostic services?	Y	N	Y	Y	Y	Y	Y	N	Y	?	Y	Y	Y	?	?	N	Y	?	Y	Y	?	N	Y	Y	Y
Consumer registration required: POM?	N	N	N	N	N	N	N	N	N	?	N	N	?	N	?	N	N	?	N	N	?	N	N	Y	N
Consumer registration required: OTC?	N	N	N	N	N	N	N	N	N	?	N	N	?	N	?	N	N	?	N	N	?	N	N	N	N
Price regulation																									
Price of POM regulated?	M	M	M	M	F	M	F	M	F	F	M	F	F	M	M	M	N	M	M	M	M	F. M	F	F	F
Price of OTC regulated?	M	M	M	M	N	M	F	N	N	F	M	N	F	M	M	M	N	N	M	N	M	N	N	F	N
Profit margins regulated?	N	Mp	Mp	Mp	?	Mf. Mp	F. D. Mp	?	Mf	?	Mf. Mp	D.Mp	?	Mf. Mp	?	N	N	D	?	Mf	?	D. Mf	F. Mp	N	Mp

Table 3.4 contains both the legend to Table 3.3 and the score for the regulation when we quantify the regulation. More information on methodology for quantifying regulation is given in Section 3.3.

Table 3.4 Legend and scoring of regulation in the Member States

Category	Answers	Score on 0-1 scale
Duration	<i>Years</i>	Normalisation of number of years
Duration of education (excl. compulsory practice)*	<i>Years</i>	N.a.
Duration of compulsory practice*	<i>Months</i>	N.a.
Limitation on the number of students?	<i>Maximum number of places</i>	Normalisation of inhabitants/number of places
Continuous training (effectively) obligatory?	<i>(Hours/year)</i>	Normalisation of hours/year
Registration, licensing of membership obligatory?	<i>(R, L, M, none)</i>	N.a.
Diploma/educational requirements	<i>Yes/no</i>	Yes = 1, no = 0
Practice (duration in months)	<i>Yes/no</i>	Yes = 1, no = 0
Examination	<i>Yes/no</i>	Yes = 1, no = 0
Declaration of good conduct	<i>Yes/no</i>	Yes = 1, no = 0
Language requirement/other	<i>Yes/no</i>	Yes = 1, no = 0
Nationality limitations/obligatory residency	<i>Yes/no</i>	Yes = 1, no = 0
Costs/year	<i>Annual fee only</i>	Normalisation of the annual fee
Professional monopoly prescription drugs?		
Community pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Hospital pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Other pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Other medicals professions?	<i>Yes/no</i>	Yes = 0, no = 1
Professional monopoly OTC?		
Community pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Hospital pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Other pharmacists?	<i>Yes/no</i>	Yes = 0, no = 1
Other medical professions?	<i>Yes/no</i>	Yes = 0, no = 1
Druggists?	<i>Yes/no</i>	Yes = 0, no = 1
Other stores?	<i>Yes/no</i>	Yes = 0, no = 1
Additional requirements? (licence, education, product min. range)	<i>License (L)</i>	1
	<i>Education (E)</i>	1
	<i>Min. product range (P)</i>	1
	<i>none</i>	0
Ownership restrictions on pharmacies?	<i>State only (S)</i>	1
	<i>Pharmacists only (P)</i>	0.83

Category	Answers	Score on 0-1 scale
Is ownership of more than one pharmacy allowed?	<i>Pharmacists and (local) government only (PS)</i>	0.67
	<i>Pharmacist needs to have majority share (M)</i>	0.50
	<i>Pharmacist needs to be one of the owners (O)</i>	0.33
	<i>Pharmacist needs to be manager (PM)</i>	0.17
	<i>No restrictions (N)</i>	0
	<i>Yes, unlimited (U)</i>	0
	<i>Max ... branches (unconditionally) (#)</i>	0.2
	<i>Max ... branches (conditionally: [condition]) (#C)</i>	0.4
	<i>But minority stake only beyond first pharmacy (unconditionally) (M)</i>	0.6
	<i>But minority stake only beyond first pharmacy (conditionally: [condition]) (MC)</i>	0.8
Are there restrictions to the business form of pharmacies?	<i>No (N)</i>	1
	<i>Allowed are: Sole practitioner (S)</i>	1
	<i>S and Association (A)</i>	0.66
	<i>A and Legal person / private company (P)</i>	0.33
	<i>P and Legal person / private company with limited liability (PL)</i>	0
Free allocation for changes in ownership of pharmacies?	<i>Yes/yes (after # years./no</i>	Yes = 0, yc = 0.5, no = 1
Are there requirements to the location of pharmacies?		
Minimum no. of customers*	<i>Yes (number of customers)/no</i>	Normalisation of the number of

Category	Answers	Score on 0-1 scale
Geographical requirements ⁺	<i>Yes (distance in meters)/no</i>	customers, no = 0 Normalisation of the distance, no = 0
Limited number of pharmacies. ⁺	<i>Yes (number of pharmacies)/no</i>	Normalisation of the inverse of the number of pharmacies, no = 0
Economic needs test	<i>Yes/no</i>	Yes = 1, no = 0
Contract with insurer	<i>Yes/no</i>	Yes = 1, no = 0
Other	<i>Yes/no</i>	Yes = 1, no = 0
Do barriers exist for pharmacists from other EU countries?		
3-year clause	<i>Yes/no</i>	Yes = 1, no = 0
Language requirement	<i>Yes/no</i>	Yes = 1, no = 0
Other	<i>Yes/no</i>	Yes = 1, no = 0
Are internet pharmacies allowed to operate: prescription drugs?	<i>Yes/no</i>	Yes = 0, no = 1
Are internet pharmacies allowed to operate: OTC?	<i>Yes/no</i>	Yes = 0, no = 1
Is co-operation of pharmacies with other professions allowed?		
Horizontal partnerships/mergers allowed: other pharmacies?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Horizontal partnerships/mergers allowed: druggists?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Vertical partnerships/mergers allowed: wholesalers?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Vertical partnerships/mergers allowed: drug producers?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Vertical partnerships/mergers allowed: insurance companies?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Vertical partnerships/mergers allowed: GPs?	<i>Yes/yes, conditionally (yc)/no</i>	Yes = 0, yc = 0.5, no = 1
Can one operate a pharmacy without a contract with a health insurer?		
Legally	<i>Yes/no</i>	Yes = 0, no = 1
Economically	<i>Yes/no</i>	Yes = 0, no = 1
Opening hours?	<i>Unregulated (u)</i>	0
	<i>Minimum hours only (min)</i>	0.33
	<i>Maximum hours (max)</i>	0.66
	<i>Fixed (f)</i>	1
Design of the practice: Floor space?	<i>Yes/no</i>	Yes = 1, no = 0
Design of the practice: Advertising?	<i>Yes/no</i>	Yes = 1, no = 0

Category	Answers	Score on 0-1 scale
Design of the practice: Outdoor?	Yes/no	Yes = 1, no = 0
Design of the practice: Indoor?	Yes/no	Yes = 1, no = 0
Design of the practice: Shelving?	Yes/no	Yes = 1, no = 0
Design of the practice: Storage?	Yes/no	Yes = 1, no = 0
Is the presence of a pharmacist required?	Yes/no	Yes = 1, no = 0
Stock?	Minimum stock(s)	1
	Delivery in time(t;duration)	0.5
	No regulation(n)	0
Product/service differentiation Sale of non-pharmaceutical products allowed?	Yes, unlimited(u)	0
	Yes, limited (l)	0.5
	No	1
Provision of diagnostic services?	Yes/no	Yes = 0, no = 1
Consumer registration required: POM?	Yes/no	Yes = 1, no = 0
Consumer registration required: OTC?	Yes/no	Yes = 1, no = 0
Price POM regulated?	Fixed (f)	1
	Maximum (m)	0.5
	Not regulated (n)	0
Price of OTC regulated?	Fixed (f)	1
	Maximum (m)	0,5
	Not regulated (n)	0
Profit margins regulated?*	Fixed (f)	1
	Dispense fee(d)	1
	Medicine fixed absolute margin (mf)	1
	Medicine percentage (mp)	1
	Not regulated (n)	0

* Not valued to avoid double counting.

+ If multiple criteria were present, the non-weighted average was taken.

If we assess the regulation in the different Member States, we can observe a number of significant differences.

The total duration of the education varies between five and six years, and all are in line with Directive 2005/36/EC, which stipulates education of at least five years' duration, including at least four years of full-time theoretical and practical training and a six-month traineeship in a pharmacy.⁷¹ In most Member States, the duration of the compulsory practice is six months; only a few Member States requiring 12 months of compulsory practice. In France, the compulsory practice is even longer, consisting of 12 months and 10 weeks in total.

Nearly all Member States require either registration, licensing, or membership of a professional organisation for the pharmacists that are active within their territory. The most notable exception is Denmark, which has no registration or licensing requirements at all. For those countries that do have obligatory registration, licensing and / or membership, the most common requirement, in addition to the mandatory educational requirements, is a declaration of good conduct, which is required in seven out of 21 Member States. General language requirements for either registration, licensing, or membership of a professional organisation on the other hand, are only explicitly set in two of the 21 Member States.⁷² These Member States are Germany and Luxembourg.

There is a professional monopoly for prescription-only medicines in all Member States. In seven Member States, physicians are also allowed to prescribe medicines in remote areas where no pharmacy is present within a reasonable distance. In seven Member States the professional monopoly for OTC-medicines extends to druggists and / or other stores. This group of Member States partly overlaps, but is not identical to the group of Member States that have limited the professional monopoly for prescription-only medicines.

In four Member States, (local) governments can be owners of pharmacies. In Sweden, the right to own pharmacies is exclusive to the government; in Italy, Lithuania and the Slovak Republic, both pharmacists and the government can be owners of a pharmacy. Another 12 Member States require pharmacists to play a role in the ownership of a pharmacy, while only nine Member States do not pose any restrictions on who can own a pharmacy.⁷³

Owning more than one pharmacy is allowed in 20 out of the 24 Member States (excluding Sweden). Only in 11 of these Member States is the ownership of multiple pharmacies unlimited. In the other Member States, there are either restrictions on the number of pharmacies one can own, or ownership is restricted to minority stakes in the pharmacies beyond the first one.

Ten Member States do not pose any restrictions on the location of new pharmacies. In all other Member States, there are requirements on the location of pharmacies. The most

⁷¹ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications.

⁷² These are requirements for every pharmacist, domestic or foreign. Some countries do set additional (language) requirements for 'foreign' pharmacists only.

⁷³ Not including possible restrictions to horizontal or vertical integration.

common restrictions are related to a minimum number of customers that is required for a pharmacy, and a minimum distance between pharmacies.

There are still a number of barriers present for pharmacists that want to open a pharmacy in other EU Member States. Five Member States still have the 3-year clause, meaning that pharmacists with a ‘foreign diploma’ cannot open a new pharmacy, and may only own a pharmacy that is at least 3 years old. These Member States are Austria, France, Germany, Hungary and the United Kingdom. In addition, nine Member States have explicit language requirements for ‘foreign’ pharmacists.

Most Member States allow horizontal cooperation. Both partnerships with other pharmacies and integration with druggists are allowed in a majority of the cases. Vertical integration, however, is generally not permitted. Seven Member States allow pharmacists and wholesalers to integrate; while only six Member States allow integration between pharmacists and producers.

In general, pharmacists are allowed to sell non-pharmaceutical products. In seven Member States there are no legal restrictions to the products sold; 15 Member States limit the products that can be sold in a pharmacy to health-related products. Only in Poland, pharmacists are not allowed to sell any non-pharmaceutical products.

Regarding price regulation, only in Malta the government does not regulate prices; yet, prices are set by the wholesaler. All other Member States have regulated prices for prescription-only medicines. In about half of the cases, the prices are fixed, while in the other half of the cases maximum prices are set. A very different situation can be observed if we focus on OTCs. Ten Member States have not regulated the prices of OTCs at all, while ten other Member States only set maximum prices for OTCs.

3.3 Quantifying the regulation of the pharmacy sector in the Member States – methodology

The scope of regulation in Table 3.3 has been transformed on a scale of 0 to 1, where 0 is “relatively unregulated / unrestrictive” and 1 indicates “relatively regulated / restrictive”. Table 3.4 gives a sort of a legend to Table 3.3, explaining the various answers in Table 3.3. In addition, Table 3.4 indicates how these are transformed into quantitative indicators; this is more elaborately explained below.

Numeric scores

Most of the categories in Table 3.3 are questions on whether or not certain regulation exists. The answers to these questions can be formulated as either ‘yes’ or ‘no’. The transformation of these answers to the 0 to 1 scale is straightforward.

A certain number of questions have numeric answers. Examples of these questions are the duration of education, the annual cost per year of registration, licensing of membership of a professional organisation. In these cases, we have normalised these numbers by using the formula:

$$S_n = (\text{value} - \text{avg}) / \text{sd}$$

where:
Sn = normalised score
Value = value listed in Table 3.3
Avg = average of the entries in the category
Sd = standard deviation of the entries in the category

To transform these results onto a scale of 0 to 1, we have used the following formula:

$$\text{Score} = (S_n - S_{n,\min}) / (S_{n,\max} - S_{n,\min})$$

Where:
Sn = normalised score
Sn,min = the lowest value of Sn of the entries in the category
Sn,max = the highest value of Sn of the entries in the category

Cardinal scores

Another category of questions have multiple possible non-numeric answers. Examples of these kinds of questions are ‘ownership restrictions’, ‘restrictions to the business form’ and ‘opening hours’. The results of these categories of questions are treated as ordinal data, meaning we have ordered them from the most restrictive to the least restrictive. After this, we have applied a Likert scale to transform these results into scores, meaning we have scored the least restrictive result as ‘0’, the second-least restrictive result as 1 divided by the number of answer categories minus one, the next least restrictive answer as 2 divided by the number of answer categories minus one, etcetera. As such, the Likert scale gives a value of ‘0’ to the least restrictive result and a value of 1 to the most restrictive result.

Weighing factors and grouping

We have not used any weighing factors to calculate overall scores for the degree of regulation. Any choice of weighing factors is arbitrary, and we have therefore decided not to use any factors at all.⁷⁴ Consequently, this might have led to extreme influences of certain (groups of) regulation on the overall score. For example, incorporating six categories of regulation on the design of the practice would have led to a particularly heavy influence of this regulation on the scoring of the regulation of ‘practice’. To avoid these extremes, we have grouped some very similar regulation into subcategories in the scoring of the regulation.

Missing observations

As there are a number of missing observations, this can result in a discrepancy between the calculated scores on regulation and the actual degree of regulation. To reduce this discrepancy, we have calculated scores on (sub)categories of regulation by taking averages. The effect of this operation is that the missing values are proxied by the average degree of regulation in that (sub)category. We believe that in the method we used, the discrepancy between the calculated scores on regulation and the actual degree of regulation are lower than if we had used alternative methods.⁷⁵

⁷⁴ Letting all scores count as equal is a form of weighing too, of course. As we, however, did not have any indications for weighing factors, we decided to choose the most neutral option, meaning each score has an equal weight in the calculation of overall scores.

⁷⁵ An alternative method would be to just calculate the sum of the categories. However, this would be equal to scoring the missing observations as a ‘0’; thereby (wrongly) regarding it as ‘unregulated’.

3.4 Quantifying the regulation of the pharmacy sector in the Member States – results

Applying the scoring of Table 3.4 to Table 3.3 gives the following score (see Table 3.5) on structure and conduct for the various Member States. As mentioned previously, a high number represents a high degree of regulation.

In Table 3.5, the darker shaded lines are subtotals per category. These are the averages of the subtotal scoring of the regulation listed for each category. The averages of subcategories are given in more lightly shaded lines.

Table 3.5 Overview of regulation in the field of pharmacies in the Member States

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK
Education																									
Total duration education	0.5	0		0	0	0	0	1	0	1	1	1	0.5	0	0.5		0	1	0	0.5	0.5	0	0	0	0
Limitation on number of students?	0.20	0.00		0.55	0.35	0.54	1.00	0.22	0.47	0.62	0.48	0.91		0.84			0.00	0.00	0.00	0.00	0.00	0.07	0.00	0.82	0.00
Continuous training obligatory?	0.00	0.00	0.00	0.25	0.00	0.00	0.00	0.00	0.50	0.00	0.25	0.00		0.00	0.30		0.00	0.08		0.30		1.00	0.00	0.00	0.00
Average education	0.23	0.00	0.00	0.27	0.12	0.18	0.33	0.41	0.32	0.54	0.58	0.64	0.50	0.28	0.40		0.00	0.36	0.00	0.27	0.25	0.36	0.00	0.27	0.00
Registration, licensing or membership obligatory?																									
Registration, licensing or membership obligatory?																									
Diploma/educational requirements	1.00	1.00	1.00	1.00		1.00	1.00	1.00	1.00	0.00	1.00	1.00		1.00	1.00	1.00	1.00	1.00	1.00	1.00			1.00	1.00	1.00
Practice (duration in months)	0.00	0.00	1.00	0.00		0.00	0.00	0.00	0.00	1.00	0.00	1.00		1.00	0.00	0.00	0.00	0.00	0.00	0.00			0.00	0.00	0.00
Examination	0.00	0.00	1.00	0.00		0.00	0.00	0.00	1.00	1.00	0.00	0.00		0.00	1.00	0.00	0.00	0.00	0.00	0.00			0.00	0.00	1.00
Declaration of good conduct	1.00	0.00	0.00	0.00		0.00	0.00	1.00	1.00	0.00	0.00	0.00		1.00	0.00	1.00	0.00	0.00	1.00	0.00			0.00	1.00	0.00
Language requirement/other	0.00	0.00	0.00	0.00		0.00	0.00	0.00	1.00	0.00	0.00	0.00		0.00	0.00	1.00	0.00	0.00	1.00	0.00			0.00	0.00	0.00
Nationality limitations/obligatory residency	0.00	0.00	0.00	0.00		0.00	0.00	1.00	1.00	0.00	0.00	0.00		0.00	0.00	1.00	1.00	0.00	0.00	0.00			0.00	0.00	0.00
Costs/year		0.29	0.04	0.14		0.00	0.00	1.00	0.35	0.71	0.10	0.96		0.01	0.00	0.00	0.03	0.00	0.01	0.51				0.00	0.91
Average registration.	0.33	0.18	0.43	0.16		0.14	0.14	0.57	0.76	0.39	0.16	0.42		0.43	0.29	0.57	0.29	0.14	0.43	0.22			0.17	0.29	0.42

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK	
etc.																										
Scope of the Monopoly																										
Prescription-Only-Medicines																										
POM: Comm.																										
Pharm.?	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
POM: Hosp. Pharm?	0.00	1.00	0.00	1.00	1.00	1.00	1.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
POM: Other Pharm.?	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
POM: Other medical professions?	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00
<i>Average POM</i>	0.25	0.75	0.50	0.75	0.50	0.75	0.75	0.50	0.50	0.50	0.75	0.50	0.75	0.50	0.75	0.75	0.75	0.25	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.50
Over-The-Counter medicines																										
OTC: Comm.																										
Pharm.?	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
OTC: Hosp. Pharm?	0.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
OTC: Other Pharm.?	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
OTC: Other medical professions?	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00
OTC: Druggists?	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	0.00
OTC: Other stores?	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00
Additional requirements? (licence. education. product min. range)	0.00				1.00				1.00		0.00							1.00	0.00	1.00					1.00	
<i>Average OTC</i>	0.29	0.83	0.83	0.83	0.71	0.83	0.83	0.67	0.43	0.67	0.71	0.33	0.83	0.67	0.83	0.83	0.83	0.14	0.57	0.71	0.83	0.83	0.83	0.83	0.43	
Average scope of monopoly (POM+OTC)	0.27	0.79	0.67	0.79	0.61	0.79	0.79	0.58	0.46	0.58	0.73	0.42	0.79	0.58	0.79	0.79	0.79	0.20	0.66	0.73	0.79	0.79	0.79	0.79	0.46	
Operating requirements																										

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK	
Ownership restrictions?	0.50	0.00	0.83	0.00	0.83	0.67	0.83	0.83	0.83	0.83	0.33	0.00	0.67	0.67	0.00	0.83	0.00	0.00	0.00	0.83	0.00	0.67	0.50	1.00	0.33	
Ownership of more than one pharmacy allowed?	0.60	0.00	0.60	0.00	0.00	0.00	0.40	0.40	0.40	1.00	0.80	0.00	1.00	0.40	0.00	1.00	0.00	0.00	0.00	1.00	0.40	0.00	1.00		0.00	
Restrictions on business form?	0.66	0.00	0.66	0.00	0.00	0.00	0.00	0.00	0.66	0.00	0.66	0.00		0.00	0.00	0.66	0.00	0.00	0.00	0.00	1.00	0.66	1.00		0.00	
Free allocation changes in ownership?	0.00	0.50	1.00	1.00	1.00	0.00	1.00	0.50	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00				1.00	0.50	0.00	
Internet pharmacies																										
Internet pharmacies allowed: POM?	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00			1.00		0.00	0.00
Internet pharmacies allowed: OTC?	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	0.00	1.00	0.00	0.00	1.00	0.00	1.00	1.00	1.00	0.00	1.00	1.00			1.00		0.00	0.00
<i>Average internet</i>	1.00	1.00	1.00	1.00	0.50	1.00	1.00	1.00	0.00	1.00	0.50	0.50	1.00	0.50	1.00	1.00	1.00	0.00	1.00	1.00		1.00		0.00	0.00	
Requirements on location of pharmacies																										
Minimum no cust. Geographical requirements	0.00	0.50	0.00	0.00		0.60	0.00	0.50	0.00		1.00	0.00	0.90		0.00	1.00	0.00	0.00	0.00	0.80	0.00	1.00	0.56		0.00	
Ltd. no. of pharms	0.00	0.00	0.00	0.00		1.00		0.00	0.00		0.28	0.00	0.20	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.40	0.25		0.00	
Econ. needs test	1.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	
Contract with insurer	0.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00		0.00	
Other	1.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	1.00	0.00		0.00	
<i>Average location</i>	0.33	0.08	0.00	0.00		0.27	0.00	0.08	0.00	0.00	0.21	0.00	0.35	0.00	0.00	0.17	0.00	0.00	0.00	0.38	0.00	0.57	0.14		0.00	
Barriers to pharmacists from other EU countries																										
3-year clause	1.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00		1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00	0.00	1.00	
Language requirement	1.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00		1.00	0.00	0.00	0.00	0.00	1.00	1.00	0.00	1.00	1.00		1.00	0.00	1.00	0.00	

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK
Other	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00		0.00	0.00	1.00	1.00	0.00	0.00	0.00	1.00	0.00	0.00		0.00	0.00	0.00	0.00
<i>Average barriers</i>	0.67	0.00	0.33	0.00	0.00	0.00	0.00	0.67	0.33		0.67	0.00	0.33	0.33	0.00	0.33	0.33	0.33	0.33	0.33		0.33	0.00	0.33	0.33
Can one operate a pharmacy without a contract with a health insurer?																									
Legally	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00		1.00	1.00		0.00
Economically	0.00	0.00	0.00	0.00	1.00	1.00	1.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	1.00	0.00	0.00		1.00	1.00		1.00
<i>Average insurer</i>	0.00	0.00	0.00	0.00	0.50	0.50	0.50	0.00	0.00	1.00	0.50	0.50	1.00	0.50	0.00	1.00	0.00	0.50	0.00	0.00		1.00	1.00		0.50
Average operating requirements	0.47	0.20	0.55	0.25	0.40	0.30	0.47	0.44	0.28	0.55	0.58	0.13	0.62	0.43	0.13	0.62	0.17	0.10	0.17	0.51	0.35	0.65	0.59	0.44	0.15
Horizontal partnerships/mergers (Integration)																									
Other pharmacies?	0.50	0.50	0.00	0.00	1.00	0.00	1.00	0.00	0.00		0.50	0.00		0.50	0.00	0.00	0.00	0.00	0.00	1.00	1.00	1.00	1.00		0.00
Druggists?	0.50	0.50	0.00	0.00	1.00	0.00	1.00	0.00	1.00	1.00		0.00		0.50	1.00	0.00	0.00	0.00	0.00	1.00	1.00	1.00	1.00		0.00
Wholesalers?	0.50	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00		1.00	0.00	1.00	0.00	1.00		0.00	0.00	0.00	1.00	1.00	1.00	1.00		1.00
Drug producers?	0.50	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		1.00	0.00	1.00	0.00	1.00		0.00	0.00	1.00	1.00	1.00	1.00	1.00		1.00
Insurance companies?	0.50	0.00	0.00	1.00	0.00	0.00	1.00	1.00	1.00		0.00	0.00	1.00	0.00	1.00			0.00	0.00	1.00	1.00	1.00	1.00		0.00
General practitioners?	0.50	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00		0.00	0.50	1.00	0.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00		0.00
Average partnerships/mergers	0.50	0.17	0.33	0.67	0.83	0.33	1.00	0.67	0.83	1.00	0.50	0.08	1.00	0.17	0.83	0.33	0.20	0.17	0.17	1.00	1.00	1.00	1.00		0.33
Practice																									
Opening hours?	1.00	0.00	1.00	0.00		0.00	0.00	0.00	1.00	0.33	1.00	0.33	0.66	0.00	0.00	0.00	0.00	0.00		0.66		0.33	0.00	0.00	0.33
Is the presence of a pharmacist required?	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00
Stock?	1.00	1.00	1.00	0.00	1.00	0.50	1.00	0.00	1.00		0.00	0.00	0.50	0.50		0.00	0.00	0.00	1.00	0.50		0.50	1.00	1.00	0.00
Design of practice																									
Design of the practice: Floor space?	1.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00		1.00	0.00	0.00	1.00	1.00	1.00	0.00	0.00	1.00	1.00		1.00	1.00	1.00	1.00

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK
Design of the practice:																									
Advertising?	1.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	0.00	0.00	1.00	1.00
Design of the practice: Outdoors?	1.00	1.00	1.00	1.00	0.00	0.00	0.00	1.00	0.00		1.00	0.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00	1.00		1.00	0.00	1.00	0.00
Design of the practice: Indoors?	1.00	1.00	0.00	1.00	0.00	0.00	0.00	1.00	0.00		0.00	0.00	0.00	0.00	1.00	1.00	0.00	0.00	0.00	1.00		0.00	0.00	1.00	0.00
Design of the practice: Shelving?	0.00	1.00	0.00	1.00	0.00	0.00	1.00	1.00	0.00		0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	1.00	0.00		1.00	0.00	1.00	1.00
Design of the practice: Storage?	0.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00		1.00	0.00	0.00	1.00	1.00	0.00	1.00	0.00	1.00	1.00		1.00	0.00	1.00	1.00
<i>Average design</i>	0.67	0.83	0.50	1.00	0.00	0.50	0.50	1.00	0.33	1.00	0.67	0.00	0.33	0.67	1.00	0.67	0.50	0.17	0.50	0.83	0.00	0.67	0.17	1.00	0.67
Diversification																									
Sale of non-pharmaceutical products allowed?	0.50	0.50	0.50	0.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.00	0.00	0.50		0.50	0.50	0.00	1.00	0.50		0.50	0.00	0.50	0.00
Provision of diagnostic services?	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00		0.00	0.00	0.00			1.00	0.00		0.00	0.00		1.00	0.00	0.00	0.00
<i>Average diversification</i>	0.25	0.75	0.25	0.00	0.25	0.25	0.25	0.75	0.25	0.50	0.25	0.00	0.00	0.50		0.75	0.25	0.00	0.50	0.25		0.75	0.00	0.25	0.00
Consumer registration																									
Consumer registration required: POM?	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00		0.00		0.00	0.00		0.00	0.00		0.00	0.00	1.00	0.00
Consumer registration required: OTC?	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00		0.00		0.00	0.00		0.00	0.00		0.00	0.00	0.00	0.00
<i>Average consumer registration</i>	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		0.00	0.00		0.00		0.00	0.00		0.00	0.00		0.00	0.00	0.50	0.00

	AT	BE	CY	CZ	DK	EE	FI	FR	GE	GR	HU	IRL	IT	LT	LH	LU	MT	NL	PL	PT	SK	SL	ES	SW	UK	
Average practice	0.65	0.60	0.63	0.33	0.45	0.21	0.46	0.46	0.60	0.71	0.49	0.22	0.50	0.44	0.67	0.40	0.29	0.23	0.60	0.54	0.50	0.54	0.36	0.46	0.33	
Price regulation																										
Price of POM regulated?	0.50	0.50	0.50	0.50	1.00	0.50	1.00	0.50	1.00	1.00	0.50	1.00	1.00	0.50	0.50	0.50	0.00	0.50	0.50	0.50	0.50	1.00	1.00	1.00	1.00	1.00
Price of OTC regulated?	0.50	0.50	0.50	0.50	0.00	0.50	1.00	0.00	0.00	1.00	0.50	0.00	1.00	0.50	0.50	0.50	0.00	0.00	0.50	0.00	0.50	0.00	0.00	1.00	0.00	0.00
Profit margins regulated?	0.00	1.00	1.00	1.00		1.00	1.00		1.00		1.00	1.00		1.00		0.00	0.00	1.00		1.00		1.00	1.00	0.00	1.00	1.00
Average price regulation	0.33	0.67	0.67	0.67	0.50	0.67	1.00	0.25	0.67	1.00	0.67	0.67	1.00	0.67	0.50	0.33	0.00	0.50	0.50	0.50	0.50	0.67	0.67	0.67	0.67	0.67

Note: 1 represents fully regulated, 0 represents not-regulated.

A number of observations can be made when analysing the scores.

The highest score for *education* is for Ireland, as this country both has a long duration of the total education – 6 years – and allows only a relatively small number of student into the educational process annually. A low score for education is realised by Denmark that combines a short duration of the total education – 5 years – with a high number of students that are allowed into the educational process annually.

The highest scores on *registration, licensing and membership of a professional body* is realised by Germany, which has quite a number of requirements for obtaining a licence and becoming a member of the professional organisation. The lowest score is reached by a number of Member States, who in addition to the obligatory educational requirements have no (significant) additional limitations on registration, licensing or membership, and have no or only little costs associated with registration, licensing or membership. These countries are Belgium, Czech Republic, Estonia, Finland, Hungary, the Netherlands and Spain.

For the scope of the *professional monopoly*, there are 13 Member States with a score of 0.79. These Member States have provided an exclusive monopoly for the dispensing of both prescription-only medicines and OTCs to pharmacists; thereby excluding any other organisation from dispensing medicines.⁷⁶ The lowest score for professional monopoly is realised by the Netherlands, where non-druggist are allowed to dispense OTCs, and where physicians and hospital pharmacists are also allowed to dispense prescription-only medicines.^{77,78}

Looking at the scores for *operating requirements*, high scores can be observed for Italy, Luxembourg and Slovenia, all scoring over 0.6 on regulation of operating. For Slovenia especially, the requirements on the location of pharmacies was very high in comparison to the other Member States, scoring 0.57 against an average for the EU25 of 0.11. Low scores for operating requirements were realised by Belgium, Ireland, Lithuania, Malta, the Netherlands, Poland and the United Kingdom. All of these countries have hardly any restrictions related to ownership of a pharmacy, or restrictions on the location of pharmacies.

There are six Member States that have a score of 1 on regulation with respect to *(horizontal and vertical) integration*.⁷⁹ This means that pharmacists in these countries are not allowed to integrate with any other organisation. Ireland has the lowest score in this category; only integration between a pharmacist and general practitioner is subject to the

⁷⁶ In some cases, other organisations may also dispense medicines, albeit in the presence of a pharmacist. See for example the supermarkets in Italy. As presence of a pharmacist is required, the situation can still be considered to be an exclusive monopoly for the pharmacist.

⁷⁷ OTC may be dispensed provided that the distance to the nearest pharmacy, dispensing doctor or drugstore is 3 kilometres or more, a special licence for the dispensing of a restricted range of OTC medicines can be granted as an exception. In practice, this rarely occurs.

⁷⁸ Prescription-only drugs may be dispensed, provided that there is no pharmacy in either the respective community or in the adjacent community.

⁷⁹ Also Greece has a score of 1 on (horizontal and vertical) integration, but as this is based on only one observation, there is a large degree of uncertainty.

condition that the pharmacist is not active in the area of practice of the GP. Also Belgium, Latvia, the Netherlands and Poland manage low scores on regulation of integration.

Scores on *practice* are high for Lithuania, Austria and Cyprus, all scoring over 0.6. The high scores for Austria and Cyprus are mainly the result of a high degree of regulation of opening hours, of the presence of a pharmacist, of stock requirements, and of regulation of the design of the practice. Lithuania scores especially high on the regulation of the design of the practice. A similarly high degree of regulation on the design of the practice can also be found in the Czech Republic, France and Sweden. Low scores of regulation of the design of the practice were found for Estonia, Ireland and the Netherlands.

As already mentioned in Section 3.2, nearly all Member States regulate *prices* or profits. This is also reflected in the scores for price regulation, with nearly all countries scoring between 0.5 and 1. In addition to Cyprus, where prices are set by wholesalers, the lowest scores for price regulation are achieved by Austria and Luxembourg, who both do not regulate profit margins and only set maximum prices for prescription-only medicines and OTCs.

The scores for various categories of regulation are classified into two categories: regulation of the *structure* of the market, and regulations on the *conduct* of market participants. Structure consists of the regulation regarding Education, Registration, Scope of the Monopoly, Operating and Differentiation, Conduct consists of regulation regarding Practice and Pricing. In Table 3.6., the average score for each of the Member States on regulation of structure and conduct is given on a scale of 0 to 25. *Total* regulation (the third column in Table 3.6) is calculated as the sum of structure and conduct regulation, with a maximum of 50. In addition, the degree of completeness of the regulation, defined as the number of cells completed in Table 3.3 divided by the total number of cells, is given for each country.

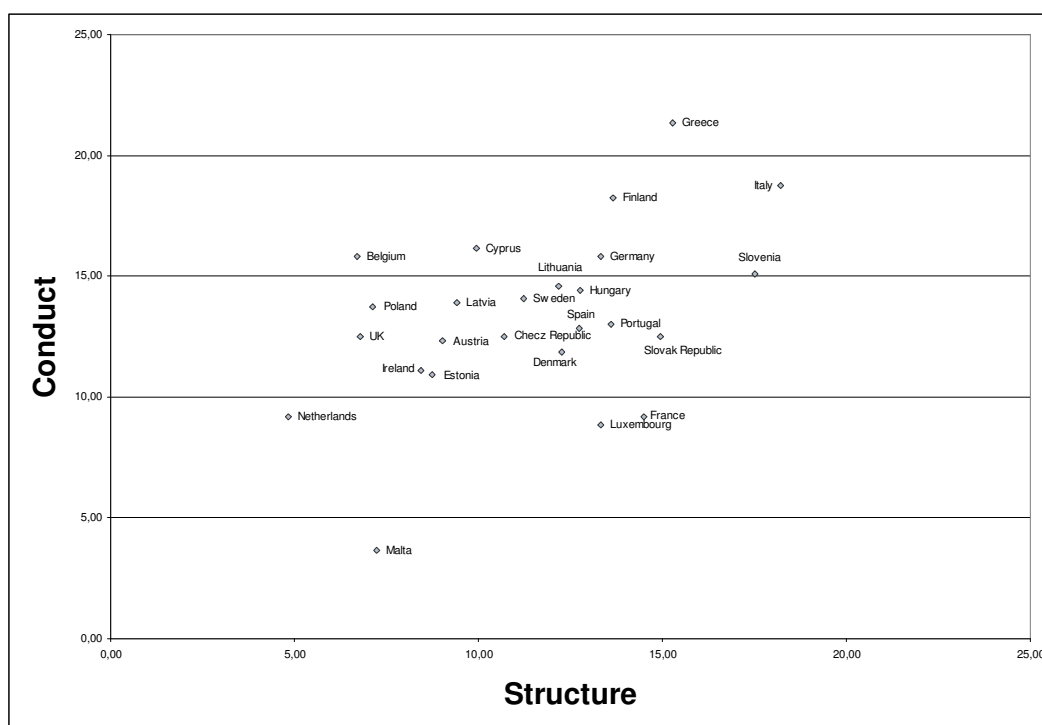
Table 3.6 Scores on regulation of the various Member States (scale Structure and Conduct: 0-25, scale Total: 0-50)

Country	Structure	Conduct	Total	Degree of completeness
IT	18,2	18,7	36,9	76.2%
GR	15,3	21,3	36,6	68.3%
SL	17,5	15,1	32,6	100.0%
FI	13,7	18,2	31,9	100.0%
GE	13,3	15,8	29,1	100.0%
SK	14,9	12,5	27,4	52.4%
HU	12,8	14,4	27,2	92.1%
LH	12,2	14,6	26,8	88.9%
PT	13,6	13,0	26,6	98.4%
CY	9,9	16,1	26,1	100.0%
ES	12,7	12,8	25,6	95.2%
SW	11,2	14,1	25,3	98.4%
DK	12,3	11,9	24,1	87.3%
LU	14,5	9,2	23,7	96.8%
LT	9,4	13,9	23,3	98.4%
CZ	10,7	12,5	23,2	100.0%
BE	6,7	15,8	22,5	100.0%

Country	Structure	Conduct	Total	Degree of completeness
FR	13,3	8,9	22,2	98.4%
AT	9,0	12,3	21,3	85.7%
PL	7,1	13,8	20,9	82.5%
EE	8,8	10,9	19,7	100.0%
IRL	8,4	11,1	19,5	98.4%
UK	6,8	12,5	19,3	98.4%
NL	4,8	9,2	14,0	95.2%
MT	7,2	3,6	10,9	88.9%

The average scores for structure, conduct and total regulation are 11.30, 13.27 and 24.57, respectively. The scores on Structure and Conduct for each of the Member States are graphically presented in Figure 3.1 below.

Figure 3.1 Scores on structure and conduct



In Table 3.7, some descriptive statistics are given for the scores in Table 3.5 and Table 3.6.

Table 3.7 Descriptive statistics of the scoring of regulation (scale Total, Structure and Conduct = 0-25, rest = 0-1)

Regulation	Mean	Highest score	Lowest score	Standard deviation
Total	24.67	36.94	10.89	6.05
Structure	11.38	18.21	4.84	3.50
Conduct	13.29	21.34	3.65	3.59
Subtotal for Education	0.26	0.64	0.00	0.20
Subtotal for Registration	0.33	0.76	0.14	0.17
Subtotal for Scope of the Monopoly	0.66	0.79	0.20	0.18
Subtotal for Operating	0.38	0.65	0.10	0.18
Subtotal for Integration	0.59	1.00	0.08	0.35
Subtotal for Practice	0.47	0.71	0.21	0.14
Subtotal for Pricing	0.60	1.00	0.00	0.23

3.5 Performance of the pharmacy sector in the Member States

The performance indicators as defined by the basic SCP paradigm are: ‘Production & allocative efficiency’, ‘Progress & innovation’, ‘Equity’, ‘Product variety (choice)’ and ‘Availability’.⁸⁰ Some of these indicators, such as equity, have a rather political dimension; other indicators, such as progress, are hard to quantify.

Due to the restrictions on available data, we were forced to proxy some of the performance indicators, based on availability of data with a common denominator across a substantial number of Member States. As performance indicators for our study, we have selected:

- Productivity;
- Allocative efficiency;
- Quality / Product variety.

3.5.1 Productivity

Productivity was measured by performing a DEA (Data Envelopment Analysis). In the text box below, the DEA analysis is explained.

⁸⁰ See also Chapter 2.

Data envelopment analysis (DEA)

Data envelopment analysis (DEA) is an analysis designed to measure determines efficiency levels. The technique is based on linear programming and allows to measure productivity in the case multiple inputs and outputs makes comparisons difficult.

The basic definition of efficiency is:

Efficiency = output / input.

In case of a single input and a single output, measuring efficiency is very simple. In case of multiple inputs and / or outputs, it is more difficult to measure efficiency. If one uses weights for the inputs and outputs, efficiency can be defined are:

Efficiency = weighed sum of outputs / weighed sum of inputs.

One problem is that this assumes a common set of weights to be applied across all units. This immediately raises the problem of how such an agreed common set of weights can be obtained.

DEA takes into account the possibility that units might value inputs and outputs differently. In this analysis each unit is allowed to adopt a set of weights which shows it in the most favourable light in comparison to the other units. For each unit the weights are chosen to maximise efficiency for that unit with the restriction that the efficiency of all the other units with the same weights are equal or smaller to 1 (or 100%).

More elaborate information of DEA-analysis can be found in books on productivity measurement, for example: Coelli, T., D.S. Prasada Rao, en G.E. Battese, *An introduction to efficiency and productivity analysis*, Dordrecht: Kluwer academic publishers, 1998.

In our analysis, we have measured how efficient the dispensing of medicines has been by comparing it to the number of outlets (as a proxy for capital used) and the number of employees (as a proxy for the amount of labour used). Although the number of outlets and the number of employees are far from ideal variables to use to determine efficiency, lack of available data did not leave us with any other option.

Our key formula for the productivity analysis is:

$$P = U / (a * O + b * E)$$

Where

P = productivity
U = the number of daily doses of medicines dispensed annually
O = number of outlets
E = number of employees
a, b = variables

The maximum productivity for each Member State is found by maximizing P for that specific Member State by varying a and b, with the constraints:

a > 0;
b > 0;
P <= 1 (for each MS).

Table 3.8 presents the information we used in the analysis. As performing this analysis requires a complete set of data for each entry, we were only able to perform a DEA for the following ten Member States: Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Luxembourg, Portugal, Slovak Republic and Sweden.

The results of the DEA analysis are given in Table 3.8. The complete results of the analysis can be found in Appendix 7.

Table 3.8 Results of the DEA analysis for productivity

	BE	CZ	DK	FI	GE	GR	LU	PT	SK	SW
Use of medicine	2822.7	4123.0	1634.3	1858.7	24242.3	4387.6	81.7	2318.3	2111.3	4319.0
Outlets	5230.0	2279.3	323.0	802.0	21392.0	8869.0	82.0	2684.0	1389.0	900.0
Employees / pharmacy	3.4	6.4	16.2	9.9	8.3	2.1	9.4	5.0	1.2	12.5
P	0,4033	0,8998	1,0000	0,5276	1,0000	0,4870	0,1970	0,4897	1,0000	1,0000

Source: OECD Health Database 2006 (Use of medicines), Eurostat (outlets, employees), calculations ECORYS (DEA)

3.5.2 Allocative efficiency

To determine the allocative efficiency, we have used the profit margin of pharmacists as a proxy. This margin is calculated by dividing the operating result by the turnover in Euro. For both the operating result and the turnover, we have made use of data from Eurostat. The calculated margin is presented in Table 3.9, below.

Table 3.9 Allocative efficiency (figures of 2004)

Country	Operating result	Turnover (Euro)	Profit margin
Austria	227,304	2,085,495	0.109
Belgium	82,562	950,172	0.087
Cyprus	12,531	206,634	0.061
Czech Republic	28,561	469,260	0.061
Denmark	175,542	4,487,616	0.039
Estonia	25,581	708,372	0.036
Finland	231,671	2,375,312	0.098
France	131,576	1,275,854	0.103
Germany	157,059	1,519,260	0.103
Greece	24,140	162,656	0.148
Hungary	35,451	808,147	0.044
Italy	205,798	1,376,224	0.150
Latvia	-6,667	163,667	-0.041
Lithuania	4,726	246,908	0.019
Luxembourg	368,293	2,641,463	0.139
Malta	35,500	295,000	0.120
Netherlands	259,296	2,322,748	0.112
Poland	30,928	334,710	0.092

Country	Operating result	Turnover (Euro)	Profit margin
Portugal	113,227	964,344	0.117
Slovak Republic	6,623	136,501	0.049
Slovenia	10,484	220,161	0.048
Spain	94,154	629,958	0.149
Sweden	44,889	3,884,333	0.012
United Kingdom	100,172	1,078,818	0.093

Source: Eurostat.

The average profit margin is 8.1%. The range of profit margins is wide, with a maximum margin of nearly 15% realised in Spain, Italy and Greece and a calculated loss of 4% for Latvia. The wide range is also expressed in the high value of 4.90 for the standard deviation.

3.5.3 Quality / Product variety

An important question is how to measure the quality of the services provided by pharmacists. One possibility would have been to use the number of ‘wrong prescriptions’ and / or the number of accidents that are partly the result of mistakes made by a pharmacist. These figures were not available, however.⁸¹

Another performance indicator is the degree of product variety. To this end, we have estimated the average level of services provided by pharmacists. The most common services provided – besides dispensing medicines – are online ordering of medicines, home delivery, consultations with a pharmacist, and the provision of specialised medication packages. To get an idea of the extent to which these services are offered, we performed an Internet search. For each Member State, we randomly selected at least 50 pharmacists, and established checks to determine whether or not one or more of these services were provided.⁸² The results are presented in Table 3.10 below in terms of fraction of the pharmacies that offered the services.

⁸¹ Figures on accidents with medication, and figures on the number of deaths cause by medicines are available; but it was impossible to disaggregate the figures on deaths caused by medicines that were wrongly prescribed by a pharmacist on the one hand, and suicides or other deaths related to medicine use on the other hand.

⁸² The selection was done by looking in the Yellow Pages for pharmacists with a website. Although there is a slight risk of a biased selection by using these methods, the fact that the same method was used for each Member State means that a similar bias is present in the selection of each Member State, which means a significant comparison can still be made.

Table 3.10 Results of the research into quality / product variety

Country	Online ordering	Home delivery	Consultations	Medication packages	Average
Austria	0.5667	0.0000	0.6000	0.5667	0.4333
Belgium	0.8333	0.2667	0.4000	0.3333	0.4583
Cyprus					
Czech Republic					
Denmark	0.2800	0.4800	0.2000	0.4400	0.3500
Estonia	0.0690	0.0345	0.0345	0.0345	0.0431
Finland	0.0000	0.6563	0.9688	0.9375	0.6406
France	0.0000	0.0667	0.1333	0.2667	0.1167
Germany	0.8000	0.6333	0.5333	0.6333	0.6500
Greece					
Hungary	0.0000	0.0000	0.4333	0.0333	0.1167
Ireland	0.0500	0.0000	0.0500	0.0500	0.0375
Italy					
Latvia					
Lithuania	0.0476	0.0000	0.0922	0.0032	0.0358
Luxembourg					
Malta	0.0000	0.0000	0.0000	0.0000	0.0000
Netherlands	0.5667	0.8000	0.8000	0.6000	0.6917
Poland	0.2500	0.3125	0.1250	0.0000	0.1719
Portugal	0.1250	0.0000	0.5000	0.2500	0.2188
Slovak Republic					
Slovenia	0.0000	0.0000	0.8667	0.3667	0.3083
Spain	0.0000	0.0000	0.6923	0.1538	0.2115
Sweden	1.0000	1.0000	1.0000	1.0000	1.0000
United Kingdom	0.2333	0.6333	0.5333	0.6000	0.5000

Source: web search ECORYS.

4 Quantitative analysis

4.1 Introduction

The main goal of this study is to determine the impact of regulation on the performance of the pharmacy sector. In the previous chapter, we identified and quantified the different forms of regulation in the Member States, and we identified and quantified performance indicators. In this chapter, we focus on analysing and interpreting the correlation between regulation and performance.

4.2 Methodology – ANOVA analysis

To determine the extent to which regulation affects the performance of the pharmacy sector, we have used an ANOVA analysis.⁸³ With this form of analysis it is possible to determine whether certain subgroups in a collection of observations have similar characteristics. More information about ANOVA-analysis can be found in the text box below.

ANOVA analysis

Analysis of variance (ANalysis Of VAriance) is a general method for studying sampled-data relationships. The basis of ANOVA is the partitioning of sums of squares into between-class (SSb) and within-class (SSw). The (one-way) analysis is calculated in three steps; first the sum of squares for all samples is calculated, followed by the within-class and between-class cases. These calculations are used via the Fisher statistic to analyse the Null Hypothesis. The Null Hypothesis states that there are no differences between means of different classes, suggesting that the variance of the within-class samples should be identical to that of the between-class samples (resulting in no between-class discrimination capability). It must however be noted that small sample sets will produce random fluctuations due to the assumption of a normal distribution.

Step 1: calculate the sum of the squares for all samples.

The total sum of squares is defined as:

$$SS_t = \sum_{i=1}^S \sum_{j=1}^D (d_{ij} - GM)^2,$$

Where

⁸³ The most obvious type of analysis would be a regression analysis. However, this kind of analysis sets high demands on the quantification of the data that is used. As the number of observations is limited, the available data is not fully complete, and we do not have any reliable weighing factors to build composite indicators (see also section 3.3), a regression analysis is less suitable for analysis than the ANOVA analysis, which has lower demands on the data required.

d_{ij} is the sample for the i th class and j th data point,
 D is the number of data points,
 S is the number of classes, and
GM is the average ($= 1/(S D) \sum_{i=1}^S \sum_{j=1}^D d_{ij}$)

Step 2: Determine the sum of squares for within the class case and for the between-class case.

The sum of squares for the within class case is defined as:

$$SS_w = \sum_{i=1}^S \sum_{j=1}^D (d_{ij} - M_i)^2, \text{ and}$$

$$SS_b = \sum_{i=1}^S D (M_i - GM)^2.$$

Where

M_i is the i th class mean ($= 1/D \sum_{j=1}^D d_{ij}$),

Step 3: Evaluation of the Null Hypothesis

To test the Null Hypothesis the Fisher statistic is used. This statistic is derived from the sum of squares for within the class case and for the between-class case and from the degrees of freedom for both classes. If the value of the F-statistic is (significantly) higher than 1, it is likely that difference between the classes means exist.

In addition to the F-statistic, the results can be tested for statistical significance. This is done with the help of the P-value, which is the probability that a variety would assume a value greater than, or equal to the value observed strictly by chance.

More elaborate information on the analysis of variance can be found in any statistical handbook, for example: Hubert M. Blalock Jr., *Social Statistics*, 2nd revised edition 1988, pages 336 to 379.

ANOVA analysis is a descriptive form of analysis, showing matches in characteristics of observations. It does not explain how and why these characteristics interrelate. These relations are analysed with the help of the literature study we have performed, see Chapter 2.

For Regulation in our analysis we used the score for:

- Total regulation;
- Structure regulation;
- Conduct regulation;
- Subtotal of education;
- Subtotal of registration;
- Subtotal of scope of the monopoly;
- Subtotal of operating;
- Subtotal of integration;
- Subtotal of practice;
- Subtotal of pricing.

For Performance, we used the scores for:

- Productivity;
- Profit margin;
- Quality / Product variety.

For each category of regulation, we have sorted the observations that have a score for both regulation and performance from the highest score to the lowest score on that specific regulation aspect. Next, we divided the set of observations in halves. In cases where of an odd number of observations, we have included the medium score of the group which had a score closest to the median score.⁸⁴

After dividing the complete group of observations into two groups, we performed the ANOVA test on the scores on performance.

4.3 Results of the ANOVA analysis

In this section, we present the results of the ANOVA analysis. We have taken the scores for regulation as presented in section 3.4, and analysed whether these are related to the score on performance as presented in section 3.5. In Table 4.1, the F-statistics of the analyses are presented. The F-statistics in Table 4.1 larger than 1, which indicates a relationship between regulation and performance, are presented in bold. We have also included a sign to indicate whether the relationship is positive or negative.

P-values are presented in square brackets. The P-value is the probability that a variety would assume a value greater than or equal to the value observed strictly by chance. For example, for the F-statistics for ‘operation’ the P-values for productivity and for allocative efficiency are 0.10 and 0.09, respectively; giving a 10% and 9% chance that the value found is the result of chance. The P-values found in the ANOVA analysis are relatively high compared to the ‘usual’ statistical significance intervals of 1% or 5%, due to the limited number of observations that were available for our analysis.

The full results of the analysis can be found in Appendix 8.

Table 4.1 Values of the F-statistic, (sign) and [P-value] of the ANOVA analysis

	Productivity	Allocative efficiency	Quality / Product variety
Total regulation	0.0000 (+) [0.99]	0.0353 (-) [0.85]	0.8110 (+) [0.38]
Structure regulation	3.4001 (-) [0.10]	3.5123 (-) [0.07]	0.3195 (-) [0.58]
Conduct regulation	0.0265 (-) [0.87]	1.6952 (+) [0.21]	1.0449 (+) [0.32]
Subtotal of Education	0.0006 (-) [0.98]	0.3530 (+) [0.56]	1.0335 (+) [0.32]
Subtotal of Registration	0.1601 (+) [0.70]	0.7640 (-) [0.39]	1.4884 (-) [0.24]
Subtotal of Scope of the Monopoly	0.1204 (+) [0.74]	0.0033 (+) [0.95]	0.2312 (+) [0.64]
Subtotal of Operating	3.4001 (-) [0.10]	3.1509 (-) [0.09]	0.4444 (+) [0.51]
Subtotal of Integration	0.1136 (-) [0.75]	0.4053 (-) [0.53]	0.1426 (+) [0.71]
Subtotal of Practice	0.0559 (-) [0.82]	0.1868 (-) [0.67]	0.1930 (-) [0.67]
Subtotal of Pricing	0.4880 (+) [0.51]	0.5481 (-) [0.47]	1.1868 (+) [0.29]

⁸⁴ If the medium score could not be attributed to either the group with high regulation or the group with low regulation in this way, that is both the score directly above and below the medium were equal to the medium score, we looked for the group (high value or low value) that had a value closest to the medium value and added all observation with the medium value to that group.

We now focus on the interpretation of the results of the analysis. Productivity is negatively influenced by types of regulation imposing *operating restrictions*; including a limitation on ownership of pharmacies by non-pharmacists, requirements on the location of pharmacies, and barriers to entry for pharmacists from other EU Member States. The same type of regulation is also the main source of higher profit margins realised by the pharmacy sector, which equals a lower allocative efficiency in comparison to other countries. For both these relationships, we have found high F-statistics and low P-values, meaning the relationship is very strong. The negative impact of regulation imposing operating restrictions on productivity and allocative efficiency is in line with the findings in the (economic) literature. Location requirements and ownership restrictions can (severely) limit entry in the market; entry barriers are generally associated with lower productivity levels and lower levels of allocative efficiency.⁸⁵

We have also found a positive relationship between higher educational requirements and quality / product variety. This relationship is also found in the literature. Educational requirements should guarantee that pharmaceutical services are of a certain minimum level of quality.⁸⁶ The relationship we have found is, although statistically significant, relatively weak compared to the other relationships that were found.⁸⁷

Finally, we found a positive correlation between product variety and regulation of prices and profit margins. The F-statistic and P-value for this relationship indicate a weak relationship. This relationship is also found in literature: in the absence of the possibilities to compete on price, incentives to compete on quality and / or service are high.⁸⁸ High requirements on registration, licensing and obligatory membership of a professional organisation are, however, negatively correlated to the extent of product variety. The low F-statistic, which hardly exceeds the threshold of 1, and the relatively high P-value; indicate that the relationship, although significant, is not very strong. The economic literature indicates that registration procedures may limit entry into the profession, thereby limiting competition and thus also reducing the incentive for service competition.⁸⁹

4.4 Impact of a change in regulation on the EU25

On the basis of the results of the analysis, we can estimate the effects of changes in regulation on the performance of the pharmacy sector in the EU25. Caution is required though, as a straightforward linear extrapolation to estimate the impact on the EU-level is used.

The effect of a reduction in operation restrictions is an increase in productivity and allocative efficiency. In Table 4.2 we present the results of the ANOVA analysis for the

⁸⁵ See section 2.4.1.

⁸⁶ See section 2.4.1.

⁸⁷ The F-statistic for this relationship is relatively low, only exceeding the threshold of 1 by a small margin, and the P-value of this relationship is relatively high, with a 30% chance that the outcome of the analysis is a result of chance.

⁸⁸ See section 2.4.3.

⁸⁹ See section 2.4.1.

relationship between regulation of operation and productivity. The full results are presented in Appendix 8.

Table 4.2 Results of the analysis Operating – Productivity

Group	Average regulation	Average productivity
High regulation	0.5180	0.5403
Low regulation	0.2962	0.8606

The average degree of regulation of the group that is qualified as ‘highly regulated’ on operation regulation is 0.5180; while the score on regulation for the group with a low degree of operation regulation is 0.2962. The score of productivity for each of these groups is 0.5403 and 0.8608, respectively. If we calculate the (linear) relationship between operation regulation and productivity, we find a coefficient of -1.444.⁹⁰ On average, this means that a reduction of the regulation with 0.1 points leads to an increase in productivity of 0.144 points.

Transposing that to the EU25, we find an average score of operation regulation in the EU25 of 0.38.⁹¹ The lowest value can be found in the Netherlands, with a score of 0.10. Reducing the EU25 average to the lowest score found within the EU25 would therefore lead to a reduction of the operation regulation by 0.28 points. Assuming a linear relationship, this equals an increase of productivity of 0.40 points.⁹² For the group of ‘highly regulated’ countries in our ANOVA analysis, an increase of productivity of 0.40 points would mean their average productivity would rise from 0.54 to 0.94. In other words, their efficiency would increase from mediocre to nearly fully efficient.

Table 4.3 presents the results of the ANOVA analysis between regulation on operating restrictions and the allocative efficiency (profit margin).⁹³

Table 4.3 Results of the analysis Operating – Allocative efficiency

Group	Average regulation	Average allocative efficiency (profit margin)
High regulation	0.5415	0.0981
Low regulation	0.2432	0.0642

The effect of a reduction in regulation from the average EU25-level to the level of the least-regulated Member State on allocative efficiency, measured as the gain in terms of reduced profit margins for pharmacists, is 0.032 point in total.⁹⁴ In other words, such a reduction of regulation would reduce the pharmacists’ profit margin by 3 percentage points. Taking the group of ‘highly regulated’ countries as an example, a reduction of the profit margin by 3 percentage points would reduce their profit margin from 9.8% to 6.6%.

⁹⁰ The coefficient is calculated according to the formula: [Performance(high) – Performance(low)] / [Regulation (high) – Regulation (low)]. In the case of operation regulation and productivity, this gives [0.5403-0.8606]/[0.5180-0.2962] = -1.444.

⁹¹ See Table 3.7 for the overview of average and lowest scores of regulation in the EU25.

⁹² Calculated by multiplying 0.28 by -1.444.

⁹³ See Appendix 8 for the full results.

⁹⁴ Calculated by multiplying the coefficient, [0.0981-0.0642]/[0.5415-0.2432], with the reduction in regulation from EU25-average to minimum, [0.38-0.1], leading to a total of 0.032.

Expressed as percentage of the current profit margin, the reduction in profit margin would be slightly over 30%. For the EU25 the reduction in regulation would result in a reduction of the profit margin of pharmacists from 8.1% to 4.9%.

We have calculated the expected impact of deregulation in EU 25 in cases where the average degree of regulation is reduced so as to equal the degree of regulation of the least regulated Member States. The results of these calculations are given in Table 4.4. The impact of a general reduction of total regulation, structure regulation in general, and conduct regulation in general have been eliminated to avoid a double count.

Table 4.4 The impact of deregulation on EU25 (in points)

	Productivity	Allocative efficiency	Quality / Product variety
Subtotal for Education	-	-	-0.111
Subtotal for Registration	-	-	+0.130
Subtotal for Scope of the Monopoly	-	-	-
Subtotal for Operating	+0.401	+0.032	-
Subtotal for Integration	-	-	-
Subtotal for Practice	-	-	-
Subtotal for Pricing	-	-	-0.274

Above, we have already elaborated on the results for deregulating operating restrictions. We will now focus on the more detailed results.

The average score of service range within the EU25 is 0.333.⁹⁵ A reduction in the educational requirements would reduce the service level to 0.222, which would mean a reduction of the average 1.3 service that is currently provided, to an average of nearly 0.9 services after deregulation.

When reducing registration requirements, the score on services provided increases to 0.463. Translating this into the service level, it means that the current service level would rise from the average 1.3 service that is currently offered, to an average of nearly 2 after deregulation.

A similar calculation for deregulating the rules on pricing shows an extreme decrease in the service level of pharmacists. The level of services would decrease from 0.333, which equals 1.3 services on average per pharmacist, to 0.059, which equals an average of 0.2 services per pharmacist.

As these estimations above are based on linear extrapolation of the results from the ANOVA-analysis, we once again stress to be cautious in interpreting the results.

⁹⁵ As we defined service range by the number of services provided out of the four services defined by us, on average a pharmacist offers 1.3 services.

5 Summary and concluding remarks

In this study, we have analysed the impact of regulation on the performance of community pharmacies. For this analysis we compiled a nearly complete overview of regulation of the pharmacy sector in the EU. This information has been supplemented by three (economic) performance indicators (productivity, allocative efficiency and quality / product range). We performed an ANOVA analysis on this (quantified) information to identify whether a relation can be found between regulation and performance of the sector. The literature suggests a clear (negative) relation between the degree of regulation of pharmacies and their performance.

The empirical analysis has revealed support for a number of hypotheses that have been suggested in the literature. In particular, we have found a strong negative relation between operating requirements (notably ownership restrictions for (non-)pharmacists, location requirements for pharmacies and entry barriers for pharmacists from other EU Member States) and productivity. A strong negative relationship was also identified between operating requirements and allocative efficiency. Less strong relationships were found between educational requirements and product range, regulation of prices and product range, and between registration requirements and product range.

It follows those barriers to the freedom of establishment (Article 43 of the EC Treaty) in the field of pharmacy services lead to significant social costs. In particular a reduction of regulation concerning ownership of pharmacies, location of pharmacies and entry for pharmacist from other EU Member States could lead to substantial social welfare increases (a reduction of the so-called dead-weight loss). In addition to the welfare effects, a reduction in regulation hampering the freedom of establishment would significantly enhance productivity in the EU, thereby driving economic growth. A reduction of operating requirements allows new pharmacists and operators from other Member States to develop their activities and offer services across borders. This would at the same time guarantee that the fundamental freedoms provided for by the European Community Treaty, such as the freedom to establish in another Member State, are respected.

There seems to be a need for further policy aimed at removing obstacles to the freedom of establishment in the field of pharmacy services. A process that would encourage reforms by individual Member States would have strong positive effects on both allocative efficiency and productivity. For particular individual groups, however, deregulation might have negative consequences. For instance, a reduction of location and ownership requirements may negatively influence the possibilities for retiring pharmacists to sell their pharmacy. Also access to medicines might come under pressure in some remote areas.

As the benefits for society of deregulation of operation requirements outweigh the drawbacks for individual pharmacists, from a societal perspective there is a clear need for reforms of certain elements of national legislation concerning pharmacy services. However, a Pareto welfare improvement would require that such a policy should be accompanied by measures to remedy (part of) the financial setbacks for pharmacists, for instance through compensatory schemes. In this way the benefits for society are maximised and financial setbacks for specific groups are largely remedied. In addition, accompanying measures to safeguard access to medicines in remote areas might be necessary if the market does not provide services in these regions.