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Regulation of Pharmacists: A Comparative Law and Economics Analysis

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Abstract

This paper discusses the regulation of pharmacists from an economic perspective, focusing on licensing, price and fee regulation, advertising restrictions and rules on exercise of the profession, and restrictions on business structure. A comparative overview is presented of the most common forms of regulation of pharmacists that are found today in the EU (and to some extent Canada, China and the US) and to investigate whether there is an economic rationale for these rules. Despite the rather strict regulatory frameworks found in all of these jurisdictions, in various countries there is a discussion on how to improve or increase the level of pharmaceutical care. The author suggests in that respect that changes in the reimbursement system may provide a better solution than stricter entry or conduct requirements.

JEL: K21, K32, L44, L51

Keywords: Licensing, Entry barriers, Conduct regulation, Price regulation, Pharmacists.

1. Introduction

The pharmaceutical profession is highly regulated, especially when compared to other professions such as accountants, architects, engineers and lawyers.[1] Some regulation of entry, conduct and price is needed in order to ensure a minimum quality of and adequate access to pharmaceutical services. However, such regulation should not restrict competition more than necessary, especially when it serves private interests rather than the public interest. In other words: regulation should both be justified and proportional.[2] The economic theory of regulation, which focuses on regulation as a means to correct for certain market failures, has provided an excellent theoretical framework for regulators and competition authorities worldwide.[3] Indeed, questions about regulatory reform and deregulation in the professions have received much attention, particularly over the last decade or so. This immediately becomes clear from the long list of academic literature, policy reports, conferences and workshops, and competition cases on professional regulation.

Where overly restrictive entry and conduct regulation exists in self-regulation it can be assessed by competition authorities directly. For example, the European Commission in 2004 imposed a fine of € 100,000 on the Belgian Architects' Association for adopting and making available a scale of recommended minimum fees.[4] This is

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[1] Paterson, Fink, Ogus et al (2003), chapter 3; Competition Bureau (2007); Philipsen (2007), pp. 122-125.

[2] Philipsen (2007), pp. 117-119. Indecon and London Economics (2003, p. iii), present some guiding principles for this concept of proportionality. For a legal study on the application of EU competition law to professional services, see Wendt (2009).

[3] See, for example, Cox and Foster (1990), OFT (2001, 2003), Indecon and London Economics (2003), Paterson, Fink, Ogus et al (2003), European Commission (2004), Competition Bureau (2007) and OECD (2007, 2009).

[4] European Commission, Case COMP/38.549, Commission decision of 24 June 2004.

diffferent when it concerns (self-regulation that follows from) public regulation. In the well-known *Wouters* case from 2002, which dealt with a ban on multidisciplinary partnerships between lawyers and accountants, the European Court of Justice decided that the regulation concerned did not infringe European competition rules, because it "could have reasonably been considered necessary for the proper practice of the legal profession as organised in the Netherlands".[5] In 2009 two similar judgements appeared, this time on ownership regulations of pharmacies as laid down in German and Italian law (to be discussed in section 4.3 below). The result of these cases is that competition authorities – notably the European Commission's Competition DG – have to resort to other strategies like competition advocacy or cooperation with other authorities.[6]

It should be noted at the outset that the aim of this paper is not to give a general introduction into the economic analysis of different types of entry and conduct regulation to be found in the professions. There already is an extensive literature on that topic (including many of my own contributions), to which I refer in footnotes where appropriate. Also, the aim is not to give an in-depth description of each and every restriction to competition that might exist with regard to pharmacists. The objective is rather to present a comparative overview of the most common forms of regulation of pharmacists that are found today and their effect on competition, and to investigate whether there is an economic rationale for these rules.

In the next section I will briefly present the changes that have taken place over the last decades in the market for pharmaceutical services. There is now a strong focus on 'pharmaceutical care', in addition to the traditional tasks in the field of drug distribution. Sections 3 and 4 address, respectively, entry and conduct (including price) regulation in the market for pharmaceutical services. There I will present and analyse – from an economic perspective – the most common forms of regulation found in the EU, with occasional references to other jurisdictions such as Canada, the United States and China. In section 5 the results of a recent ECORYS study into the effects of regulation on performance are presented, this being the first comprehensive empirical study of efficiency of regulation in pharmaceutical services markets.[7] Section 6 concludes.

2. The Market For Pharmaceutical Services

The pharmaceutical profession has been subject to many changes since the middle of the last century. While in the 1950s the tasks of a community pharmacist consisted merely of the compounding and dispensing of drugs (medicines), nowadays pharmacists are considered to be the experts in the field of pharmacotherapy. They not only have a role in the distribution of (now mostly industrially prepared) drugs, but also in the provision of 'pharmaceutical care'. These changes have occurred gradually, under the

[5] Even thought the Court also held that a ban on MDPs is "liable to limit production and technical development". Case C-309/99, *J.C.J. Wouters, J.W. Savelbergh and Price Waterhouse Belastingadviseurs BV v Algemene Raad van de Nederlandse Orde van Advocaten*, 19 February 2002, paras 86-90 and 110.

[6] Http://ec.europa.eu/competition/sectors/professional_services/overview_en.html, visited 24 February 2011.

[7] Volkerink, De Bas, Van Gorp, and Philipsen (2007). Some earlier and smaller- scaled studies exist: see e.g. OFT (2003), Philipsen (2003), Paterson, Fink, Ogus et al (2003) and a number of reports by national competition authorities. However, to my knowledge, there are only very few studies that empirically estimate the effect of regulation strictness on performance in the pharmaceutical sercices market.

influence of the rise of the pharmaceutical industry and the constantly increasing complexity of pharmacotherapy.[8] Important tasks of a pharmacist today include medication control (checking for possible interactions between drugs taken by a patient), monitoring of therapy (primarily double-checking the prescription from the general practitioner or medical specialist), giving advice to patients, supporting local health groups such as lung and diabetes associations, and providing pharmacotherapeutic information and advice to drug prescribers. The first two or three of these tasks are sometimes performed by pharmacists' assistants (technicians), under the supervision of the pharmacist. In some countries pharmacists are also allowed to substitute branded drugs by less expensive generic drugs, under strict conditions such as consent of the patient and physician.[9]

However, the core business of pharmacists – excluding those who work for the pharmaceutical industry, the government, universities, etc - remains the distribution of drugs. There are two channels for the delivery of prescription drugs to patients: via community pharmacies and via hospitals or health clinics. In some countries, general practitioners in remote areas are also allowed to dispense drugs. Furthermore, in some countries selected prescription drugs can be sold in a drugstore (chemist store) or in supermarkets, provided there is a special department supervised by a pharmacist. In other countries, community pharmacies have a monopoly on the sale of all drugs, including not only prescription drugs but also over-the-counter (OTC) drugs. Finally, the sale of medicines via the Internet has increased considerably in recent years.[10]

3. Licensing and other entry barriers[11]

Professional licensing can be defined as the set of regulations that limit service provision to individuals who meet certain government-established criteria.[12] These criteria generally include educational requirements (university diploma), practical experience, and registration in a public register. There is a clear tension between competition law and professional licensing. The former promotes competition, whereas the latter restricts it by creating a 'professional monopoly', an example of which is the monopoly for pharmacists to dispense certain categories of drugs. In addition to licensing, entry into the pharmaceutical profession may also be regulated via establishment restrictions (a minimum number of patients or prescriptions) or mandatory membership of a professional association. These restrictions can only be justified if there are wider public policy benefits, e.g. if they really lead to an improvement in the quality of or access to pharmaceutical services.

In section 3.1 the economic theory of regulation will be applied to the market for pharmaceutical services, focusing on licensing and certification. After that, I will present

[8] Van der Mijn (1989), pp. 107-108.

[9] Philipsen (2003), pp. 59-65; Competition Bureau (2007), p. 99.

[10] Distribution of prescription drugs must still be supervised by a pharmacist and an Internet pharmacy generally needs to have a physicial location. For additional information on internet and mail order pharmacies, see Philipsen (2003), pp. 55-57.

[11] Parts of this section are drawn from Philipsen (2011).

[12] Svorny (2000), p. 296. Licensing may also follow from (conditioned) self-regulation: see Philipsen (2011).

an overview of the actual licensing regimes and additional entry regulation to be found in the EU, Canada, the United States and China.

3.1 Application of theory

From a public interest perspective[13], licensing can be supported if it is used to cure market failures caused by information asymmetry and negative externalities. Indeed, *information asymmetry* between pharmacists and consumers might result in quality degradation of pharmaceutical services. This is the well-known problem of *adverse selection*.[14] While consumers may be able to switch pharmacies in case they are looking for additional services not provided by their current pharmacy (a consultation room, home delivery, etc), it is more difficult for them to judge the quality of the advice they receive. Moreover, consumers generally cannot judge the quality of services such as medication control and monitoring of therapy. Although nowadays these services are performed electronically (by checking in a computer system whether there are interactions with other drugs), something can go seriously wrong if mistakes are made in the dispensing of drugs or if pharmacists fail to notice mistakes in the prescriptions by physicians. In addition, pharmacists should be able to function as an expert of medicines in their relationship with physicans, health insurers and the government. Some regulation of entry (licensing) is therefore warranted to prevent that insufficiently trained pharmacists are active on the market and that the problem of adverse selection occurs.

In some professional services markets, information asymmetry can also lead to the *moral hazard* problem of demand generation. This problem is however not likely to occur in the market for pharmaceutical services.[15] The demand for prescription drugs is (indirectly) determined by general practitioners and specialists and not by pharmacists. Moreover, because of the way pharmacists are paid - in most countries their income is related to the number of prescription drugs sold - they do not have any economic incentives to sell 'extra' services. On the contrary, the supply of services such as drug advice might be too low if these are not paid for.[16]

Negative externalities may appear if the quality of pharmaceutical services is extremely poor. If the drug advice given to patients is incorrect or the wrong drug is dispensed, a contagious disease may spread to other patients or a patient may ultimately die, both of which obviously affects third parties. Regulation of quality is needed to the extent that liabillity rules alone do not have sufficient deterrent effect to prevent these externalities, which can be due to causal link problems or insolvency of the pharmacist.[17] These are, however, rather extreme examples (death, contagious disease). The main argument for regulating the quality of pharmacists through licensing therefore seems to follow from adverse selection rather than negative externalities.

[13] This 'public interest approach to regulation' is discussed in Philipsen (2003), pp. 10-19. See also Van den Bergh and Faure (1991), Arruñada (2006), Stephen (2006), and Philipsen (2010).

[14] As introduced by Akerlof (1970). See also Leland (1979).

[15] There is also no idication of any moral hazard problem of 'consumption-distorting insurance', which may appear in other sectors of health care. See Arrow (1963) and OECD (2005), pp. 27-29.

[16] See also below, section 4.1.

[17] For a general analysis of liability rules versus regulation, see Shavell (1984).

The minimum quality standards required by the licensing system (with respect to educational requirements and registration procedures) should not be set too high from a social welfare point of view.[18] After all, licensing can be used as an entry barrier by interest groups.[19] In addition, there is a risk that consumers are incited to subsitute licensed services by cheaper alternatives, do-it-yourself remedies[20] or services offered on the black market, which may be more dangerous. Suppose, for example, that in the pharmaceutical profession more stringent educational requirements are introduced, which lead to a higher mark-up on the cost price of medicines in a pharmacy. Such an increase in educational requirements can be the result of a policy that aims at improving the advice given to patients by pharmacists. The higher price level of medicines in a pharmacy may cause some consumers to refrain from buying particular medicines or to look for substitutes at the drugstore, where they do not obtain adequate medical information about interactions of this medicine with other medicines, but where the price is lower. In such cases it is doubtful whether licensing will enhance the overall quality level of services, or reduce it because of this substitution effect.[21]

An alternative to licensing would be certification. Whereas licensing excludes certain practitioners from the market, under a certification system non-certified professionals are still allowed to be active on the market. Those who do not have the certification simply may not use the protected title.[22] Economists generally argue that certification is superior to licensing, provided that it can deal sufficiently with the market failure at hand.[23] It follows from this that certification alone does not seem to be suitable in case of serious information asymmetries, as between pharmacists and consumers.

3.2 Licensing in practice

According to the 2005 Directive on the recognition of professional qualifications, individuals in all EU Member States must have a university diploma before being allowed to practice pharmacy. The training should have a minimum duration of five years, including four years of theoretical and practical training at a university and six months as a trainee in a pharmacy or hospital.[24] The actual total duration varies between

[18] Leland (1979) showed by means of economic modelling that professional groups are likely to set too high standards, if they are allowed to do so themselves. Shaked and Sutton (1981) subsequently addressed the specific problem of the suppliers that are excluded from the primary market by licensing.

[19] See also Friedman and Kuznets (1945), Moore (1961) and Stigler (1971). For empirical analyses see e.g. Muzondo and Pazderka (2003) and Pagliero (2005). Also politicians and bureaucrats may derive benefits from the administrative requirements set out in licensing systems. See Ogus and Zhang (2005) and Devas and Kelly (2001).

[20] Carrol and Gaston (1981) found that stricter entry requirements for electricians, leading to lower per capita availability of electricians, are significantly associated with a rise in the rate of death from accidental electrocution.

[21] Philipsen (2011), p. 207.

[22] Curran (1993), p. 53.

[23] E.g. Shapiro (1986), Cox and Foster (1990, pp. 43-46) and Svorny (2000). See also Dingwall and Fenn (1987).

[24] Directive 2005/36/EC, Article 44. Article 45 of this Directive lists a number of activities that pharmacists should be allowed to perform, subject to the requirement, where appropriate, of

five and six years.[25] In some countries entry into the profession can be further limited by restrictions to the number of students (numerus fixus or numerus clausus) laid down in public regulations. In addition, some EU Member States restrict the location and number of pharmacies.[26] Also, pharmacists may have to enter several registers before they are recognised. For example, after the public registration they may have to enter a private register administered by a professional association, subject to continuous education or other conditions laid down in (conditioned) self-regulation [27]

In all EU Member States, prescription drugs can only be sold by community pharmacists who have been granted this monopoly along with the task of controlling the prescription behaviour of physicians. For OTC drugs, which can be obtained without a prescription, the lack of information and dangers of incorrect use are much lower. Nevertheless, many countries have extended the professional monopoly of the community pharmacist to the dispensing of OTC drugs. Only in a minority of EU Member States druggists and/or other stores are allowed to sell OTC-medicines.[28] According to OECD (2000), granting pharmacies a monopoly on the sale of non-prescription drugs is an unnecessary restriction on competition.[29] Finally, it is interesting to note that in four EU Member States, (local) governments can be owners of pharmacies. In Sweden the right to own pharmacies was until recently even exclusive to the government[30], while in Italy, Lithuania and the Slovak Republic both pharmacists and the government can be pharmacy owners.[31]

In Canada, all of the provinces allow pharmacists to self-regulate through governing bodies; in the three territories the government directly regulates pharmacists. These governing bodies (often called boards or colleges) set requirements for registration and licensing of pharmacists, define professional misconduct, set standards of operation and regulate the practice of pharmacy. In order to become a licensed

supplementary professional experience. The Directive also includes minimum educational standards for other health professions and architects.

[25] Volkerink, De Bas, Van Gorp and Philipsen (2007), p. 59.

[26] Philipsen (2003) discusses the establishment policy in Belgium, which includes a moratorium. He also discusses the self-regulation by the national association of pharmacies in the Netherlands, which from 1975 to 1987 contained an establishment policy that served as a guideline for assessing the financial feasibility (viability) of a pharmacy.

[27] Additional rules of entry may exist, such as establishment requirements (minimum number of customers or distance to existing pharmacies) and ownership restrictions. See Volkerink, De Bas, Van Gorp and Philipsen (2007), pp. 37-41 and 59-60. Ownership restrictions are also common in the accounting professions: OECD (2009). See further below, section 4.3.

[28] Volkerink, De Bas, Van Gorp and Philipsen (2007), pp. 38, 52 and 59. Out of the EU25, this was allowed (in 2007) in Austria, Germany, Ireland, the Netherlands, Poland, Portugal and the United Kingdom.

[29] OECD (2000), p. 11.

[30] The monopoly of the state-run company Apoteket AB ended in July 2009. Since deregulation, more than 20 new pharmacy companies have established themselves in Sweden and around 200 new local pharmacies have opened, with applications to open 200 more in the coming years. Also, since November 2009 grocery stores and other retail outlets are allowed to sell certain non-prescription drugs. See *The Local*, 'UK pharmacy Boots set to open in Sweden', 10 January 2011, and related articles at http://www.thelocal.se (visited 24 February 2011) .

[31] Volkerink, De Bas, Van Gorp and Philipsen (2007), p. 59.

pharmacist, individuals must obtain a bachelor's degree in pharmacy from a Canadian university, complete a national examination and obtain practical experience through a training program (apprenticeship or internship). Practical requirements, such as fluency in English or French, vary between provinces. The number of students admitted to the university pharmacy programs is limited. According to the Competition Bureau (2007) the number of places available should be regularly reviewed. The Competition Bureau also recommended that those provinces with high practical experience requirements should look to other provinces to determine whether an acceptable level of quality could be achieved in less time.[32]

In the United States, entry is controlled by state governments. Each state has a board of pharmacy, which is composed of a small number of licensed pharmacists and (in most cases) one or two members representing the public. Licensing requirements and other regulations differ between states and are similar to those that exist in European countries (university diploma, practical experience, payment of a fee).[33] If pharmacists want to work in another state, they need to transfer their existing pharmacist license from their home state or jurisdiction to another, which implies they have to pay a fee and successfully complete the 'Multistate Pharmacy Jurisprudence Examination', which contains federal- and state-specific law questions.[34]

In China[35], due to its former planned economy system, hospitals are still the main distributors of pharmaceuticals. Nearly 80 percent of patients obtain their medication from hospitals.[36] The 'licensed pharmacist system' was introduced only in 1994 with the Provisional Regulation of Licensed Pharmacists. In 1998 the State Drug Administration (SDA) was established in order to enforce the supervision and regulation of drugs.[37] The SDA was also authorised to implement the licensed pharmacist system, which led to the promulgation in April 1999 of the revised edition of the Provisional Regulation of Licensed Pharmacists, extending the licensing sytem to practitioners in medical institutions and introducing a uniform policy regarding curriculum, examinations and registration procedures. Moreover, additional regulations on continuing education were enacted. The practical experience requirements were relaxed and the examination cycle changed from once a year to once every two years.

The Chinese Licensed Pharmacists Association (CLPA) was established in 2003, with the mission to safeguard pharmacists' rights and interests, implement self-discipline, offer services and conduct coordination. It also has an important role in the continuing education of licensed pharmacists.[38] Huang (2007) and Fu et al (2009) argue

[32] Competition Bureau (2007), pp. 99-100.

[33] OECD (2000), pp. 314-315.

[34] Http://www.nabp.net, 24 February 2011. From here the websites of all the State Boards can be accessed, which contain all the specific licensing requirements.

[35] See also Philipsen (2011).

[36] Huang (2007), p. 43.

[37] This was a result of a merger between the Ministry of Health's Department of Drug Administration and the State Pharmaceutical Administration of China (SPAC). In 2003, the SDA was restructured to become the State Food and Drug Administration (SFDA). The SFDA is now officially approved to be a vice-ministry level agency governed by the Ministry of Health Http://www.china-pharma.com and http://www.pharmachinaonline.com, visited 24 February 2011.

[38] Huang (2007), p. 43.

that there is still a huge shortage of licensed pharmacists in community pharmacies or drugstores. Moreover, the distribution of pharmacists is unbalanced: at least until 2006, 80 percent worked in the manufacturing sector and hospitals and less than 10 percent in community pharmacies.[39] One of the solutions would be to enhance the profitability of drugstores by increasing the number of customers. In addition, the government could reduce the cost of continuing education, further improve the pharmacist administration system, and allow drugstores to develop their own methods of pharmaceutical service. Finally, Chinese consumers must be educated to accept services provided by pharmacists.[40] Currently most licensed pharmacists prefer working in hospital pharmacies over working in community pharmacies and hospitals are unwilling to lose their economic interest from drug sales. Services in the field of pharmaceutical care are rarely provided in community pharmacies because they are not profitable.[41]

It follows from the above that licensing systems exist in all jurisdictions, but with varying levels of strictness, i.e. with respect to study duration, practical experience requirements and registration fees. Also the professional monopoly is defined differently across the jurisdictions: some have included the distribution of OTC drugs in the pharmacists' professional monopoly whereas others have not. The fact that pharmacists have different (exclusive) tasks across the various jurisdictions may to some extent explain other regulatory differences between jurisdictions, such as business type restrictions and price regulation.

4. Regulation of market conduct and price

This section addresses forms of regulation other than entry restrictions, focusing respectively on price and fee regulation (4.1), advertising restrictions and rules on exercise of the profession (4.2) and restrictions on business structure (4.3).

4.1 Price and fee regulation

In nearly all EU member states, prices of prescription drugs (or their reimbursement via health insurance) and pharmacists' fees are regulated.[42] Price competition is almost totally excluded. For example, in the Netherlands pharmacists receive a fixed amount per prescription and in Belgium they receive a fixed margin on the sale of drugs.[43] Such tight price regulation takes away some of the possibilities for consumers to choose between different combinations of quality (e.g. additional pharmaceutical services) and price.[44] Moreover, according to the present tariff

[39] Fang, Huang and Yang (2006). Also the distribution over regions was unbalanced: 70 percent worked in East China and only 30 percent in West China.

[40] Fu, Sun, Hua and Jing (2009).

[41] Huang (2007), p. 43.

[42] Volkerink, De Bas, Van Gorp and Philipsen (2007), p. 54. See the table presented there for details on price and fee regulation. It should be noted that with respect to OTC drugs, there are quite some differences between Member States: some do not regulate prices at all, whereas others set either maximum or fixed prices.

[43] Philipsen (2003).

[44] According to Indecon and London Economics (2003, p. iii) fixed and recommended fees in the professions "limit price competition, confer rents on suppliers and reduce social welfare". See in that respect also the Commission Decision on recommended fee scales discussed in section 1 above.

structures, pharmacists are inclined to sell as many prescribed drugs as possible whereas they are generally not rewarded – at least not specifically - for the costly and time-consuming investments in provision of pharmaceutical services such as drug advice. These structures of price regulation might therefore even have adverse effects on the incentives of pharmacists to increase the quality of their services.[45] Philipsen (2003) argued that instead of rewarding pharmacists only with a fixed fee or percentage for every prescription drug dispensed, they could be rewarded separately for specific tasks performed in the field of pharmaceutical care, such as advice to physicians, and for distributional tasks. This would also allow them to specialise further.[46]

Canadian pharmacists also receive a dispensing fee, which is either fixed or consists of a percentage of the price of the prescription dispensed (depending on the jurisdiction).[47] In addition, pharmacists are qualified to provide a small number of specialized services, the fees for which vary widely. Examples of such services are diabetes management, medication management, cholesterol management, and counselling on smoking cessation or weight loss. Most pharmacists however do not charge fees for these services.[48] According to a report from Rogers Publishing (2005), more than half (56%) of Canadian retail pharmacists in 2005 provided some of these special pharmaceutical services to patients. Slightly less than half did not offer these services. Among the reasons cited for not doing so were "lack of time", "lack of staff", and "lack of reimbursement". The Canadian Competition Bureau (2007) noted furthermore that several provincial pharmacy associations have created and promoted 'suggested fee schedules' for professional services. These can "potentially facilitate collusion in price setting, either overtly or tacitly, by signalling acceptable prices and, thereby encouraging pharmacists to set their prices accordingly."[49]

4.2 Advertising restrictions and rules on exercise of the profession

Many EU countries until recently had an almost complete prohibition of advertising for pharmacies.[50] Some countries still have such advertising bans, notably with respect to prescription only products, while others may have specific restrictions, e.g. on comparative advertising or price advertising.[51] From an economic perspective a

[45] See Stichting Farmaceutische Kengetallen (2009), pp. 41-53, for a discussion of the ineffectiveness of the fee system in the Netherlands. See also OECD (2000), p. 10, where it is stated that fixed margins for pharmacists ignore local variation in costs, leading to over-compensation in some areas and under-compensation in others.

[46] Philipsen (2003), 159-165. An interesting development in that respect is the rise of pharmacy chains, where pharmacists can be employed by non-pharmacists (in countries where this is allowed). See also 4.3 below.

[47] Competition Bureau (2007), p. 111.

[48] Rogers Publishing (2005), pp. 21-23. For example, 95% of the respondents to this research (in 1995) stated that they did not charge anything for diabetes care, and 94% did not charge for medication management and drug utilization reviews.

[49] Competition Bureau (2007), p. 112.

[50] In 2004 advertising bans existed in Cyprus, France, Greece, Hungary, Lithuania, Luxembourg, Portugal and Spain, whereas more limited advertising restrictions existed in e.g. Finland, Germany, Netherlands, Poland, Slovenia, Sweden and the U.K. See European Commission (2005), pp. 35-37.

[51] See also Volkerink, De Bas, Van Gorp and Philipsen (2007), p. 54

total ban on advertising, i.e. going beyond a mere prohibition on false and misleading advertising, can hardly be said to serve a public interest goal. On the contrary, if information on e.g. the types of services offered in a pharmacy or pharmacy locations is restricted, information asymmetry problems are increased rather than solved. Economic studies on the effects of advertising restrictions in the professions have generally concluded that the more advertising there is, the lower the fees.[52] Advertising restrictions have been under serious attack from competition authorities. For example, in the Netherlands (where advertising for pharmacies was prohibited in self-regulation until late 2001), restrictions on advertising were not approved by the Dutch Competition Authority NMa.[53] While pharmacists themselves argue that promotion is undignified and unprofessional, competition authorities generally do not follow this line of argumentation.[54]

The exercise of the pharmaceutical profession can be restricted in other ways. Until 2002, the self-regulation by the Dutch pharmacists' association KNMP included provisions on opening hours, the requirement for pharmacies to have a separate room for magistral preparation of medicines, and the requirement to deliver "every sensible prescription". As a result, differentiation in the provision of services (i.e. specialization) was made virtually impossible. This was also the conclusion reached by the Dutch Competition Authority NMa, which based its analysis – indirectly - on the criteria provided in Article 81(3) of the EC Treaty.[55] In Belgium, the sixth professional rule defined by the Order of Pharmacists contained similar requirements. Various EU Member States still have rules on the indoor or outdoor design of the practice, or shelving and storage requirements.[56]

In Canada, the governing bodies of pharmacists regulate the practice of pharmacy. This includes restrictions on price advertising (e.g. a ban on price advertising of a single drug), which has the effect that price comparison between competing pharmacies is made more difficult for consumers. According to the Competition Bureau (2007), competition is inhibited by these provisions, without there being any direct evidence of harm to consumers when pharmacists have been allowed to advertise low prices. Furthermore, in every province comparative advertising is restricted. Pharmacists are generally not allowed to advertise their abilities or services, which leaves them very little room to promote themselves other than by name, contact information and business hours. The Bureau noted that such restrictions may protect relatively inefficient incumbents from competition from new entrants and recommended that all restrictions on advertising going beyond protection against false or misleading advertising should be

[52] For example, Benham and Benham (1975), Bond et al (1980) and Stephen and Love (2000). The relevance of these studies for the pharmaceutical services markets may be limited, because price and fee competition is virtually made impossible (see section 4.1).

[53] Philipsen (2003), pp. 86-87.

[54] See for example European Commission (2005), pp. 21-22, and Competition Bureau (2007), p. 110.

[55] Currently Article 101 (3) TFEU.

[56] Volkerink, De Bas, Van Gorp and Philipsen (2007), p. 54. Examples are Austria, Czech Republic, France, Lithuania and Portugal.

eliminated. [57] Of course, similar points have been made repeatedly in the classic public choice and 'economic theory of regulation' literature.[58]

4.3 Restrictions on business structure

Restrictions on business structure govern who may own and manage pharmacies. Some jurisdictions allow pharmacists only to manage one pharmacy (e.g. Greece, Portugal, Spain, and Nova Scotia in Canada) or require a majority of shareholders or directors in a corporation to be pharmacists. Also there may be a rule requiring pharmacies to be owned by a pharmacist (e.g. Austria, Finland, Germany, Italy, and Spain and Quebec and Ontario in Canada).[59] These rules are designed in order to maintain the independence of pharmacists from other professionals and commercial pressures, however, at the expense of competition. In any case, ownership restrictions do not seem to be designed in order to cure market failures such as information asymmetry or externalities.[60] According to the Austrian Health Institute (2006), such restrictions are rather born out of fear that separation of professional liability and ownership may lead to uncertainty with regard to liability in cases of misconduct or negligence in a pharmacy.[61]

In some jurisdictions, business structure regulation aims at preventing the formation of pharmacy chains, notably when these chains do not only involve horizontal integration, but also vertical integration between pharmacies or chemist stores and wholesalers. Economic theory however suggests that the presence of pharmacy chains may result in cost reductions, due to economies of scale and scope, new management and organisational structures and retail innovations. ECORYS (2009) empirically tested the hypothesis that pharmacy chains have a positive effect on the performance of the pharmaceutical sector, focusing on the main international pharmacy chains active in Europe: Alliance Boots, Celesio, Eurosocial Pharma (EUSP), OPG, Phoenix, Spanhoff and the A.S. Watson Group.[62] The authors conclude that "*in the countries where chains are present* [such as the UK, Ireland, Netherlands, Belgium, Poland, and the Baltic States)*, they are able to realise cost savings and decrease the average price level. Higher profit margins in countries without chains would normally induce entry, in particular by chains, and result in similar profit levels. The fact that this difference in profitability is allowed to exist may, at least partly, be attributed to regulation that prohibits pharmacy chains from forming*".[63]

[57] Competition Bureau (2007), pp. 110-111.

[58] E.g. Olson (1965), Stigler (1971), Pelzman (1976), Buchanan, Tollison and Tullock (1980) and Becker (1983).

[59] Competition Bureau (2007), pp. 112-113; Volkerink, De Bas, Van Gorp and Philipsen (2007), pp. 52-53.

[60] They might be related to (the prevention of) market power created by means of scale economies, notably in the case of chain pharmacies. However, it does seem odd that the pharmacy sector should be treated differently from other sectors; the characteristics of the pharmacy sector do not seem to justify such a distinction. De Bas, Volkerink, Van Gorp and Philipsen (2009), p. 15.

[61] ÖBIG (2006), p. 132.

[62] De Bas, Volkerink, Van Gorp and Philipsen (2009), pp. 11-21.

[63] De Bas, Volkerink, Van Gorp and Philipsen (2011), p. 31.

The Canadian Competition Bureau holds that some of the existing restrictions on business structure force pharmacists into the same business model, facing similar cost structures. This is likely to restrict meaningful competition and prevent entry of new market participants. The only possible public interest rationale for ownership restrictions, so it is argued, is the existence of possible conflicts of interests when drug prescribers such as doctors dispense drugs.[64] Restrictions on pharmacists to manage only one pharmacy, or the requirement that a pharmacy is owned by a pharmacist or pharmacist partnership, go too far.[65] According to the Austrian Health Institute (2006), the removal of establishment rules for pharmacies in European countries usually results in there being more pharmacies, but the new openings predominantly take place in attractive places, such as city centres. With this focus on urban clustering, so it is argued, sparsely populated areas may be neglected. Also, pharmacies that are part of pharmacy chains on the one hand create possibilities for pharmacists to work in employment, while on the other hand they lead to a decrease in the professional freedom of pharmacists and a higher fluctuation of personnel, which would make personal relationships with clients more difficult.[66]

In May 2009 restrictions on pharmacy ownership in Germany and Italy were backed by the European Court of Justice, in its judgements in *Apotherkammer des Saarlandes and others v Saarland* and *Commission v Italy*.[67] In the former, the competent German ministry granted authorisation to DocMorris, a public limited company from the Netherlands (owned by German pharmaceutical company Celesio), to open a branch pharmacy in Saarland. Several German pharmacists and their professional associations challenged this decision before the Administrative Court, arguing that it was not in line with German legislation that restricts ownership and operation of pharmacies to pharmacists only. The latter case was initiated by the European Commission, which asked the European Court of Justice to declare that Italy had failed to fulfil its obligations under the provisions of the EC Treaty on freedom of establishement and the free movement of capital, by keeping in force a legal rule on the exclusion of non-pharmacists. According to the Court, rules according to which only pharmacists may hold and operate a pharmacy indeed restrict the freedom of establishment and the free movement of capital, but these restrictions are justified by overriding reaons in the general interest. Given the risks of medicines "consumed unnecessarily or incorrectly", and given the power accorded to the Member States to determine the level of protection of public health, such rules are justified. The Court drew attention to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. It therefore concludes that "the national legislation at issue is appropriate for securing attainment of the objective of the protection of public health and does not go beyond what is necessary for attaining that objective."[68]

[64] The Austrian Health Institute argued that if non-pharmacists are allowed to own pharmacies, this is likely to lead to vertical integration in the pharmacy sector, e.g. a shift of ownership from pharmacists to wholesalers, which in turn may lead to conflicts of interests. See ÖBIG (2006).

[65] Competition Bureau (2007), p. 114.

[66] ÖBIG (2006).

[67] Joined Cases C-171/07 and C-172/07; and Case C-531/06.

[68] Http://ec.europa.eu/dgs/legal_service/arrets/06c531_en.pdf and cases mentioned supra.

5. Ecorys study

In 2007 ECORYS Nederland BV performed a study on regulatory restrictions in the field of pharmacies, which was commissioned by the Internal Market and Services DG of the European Commission.[69] This study included an empirical analysis of the impact of regulation on the performance of the pharmacy secor in the EU, and therefore deserves a special section in this paper.[70]

As indicators for performance, the authors focus on productivity, allocative efficiency and quality. *Productivity* is defined as the efficiency of drug distribution. More specifically, the authors measured the efficiency of the dispensing of medicines compared 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), on the basis of a data envelopment analysis. They subsequently find, using an analysis of variance[71], that this measure of productivity is negatively influenced by operating restrictions, such as limitations on ownerhsip of pharmacies by non-pharmacists, requirements on the location of pharmacies, and barriers to entry for pharmacists from non-EU Member States.[72] In other words, operating restrictions in the pharmaceutical profession have a negative effect on the efficiency of drug distribution. Also *allocative efficiency* was found to be negatively influenced by these operating restrictions. The proxy used by the authors for allocative efficiency is the operational profit margin of pharmacies: the higher this margin the lower allocative efficiency.

As a proxy for *quality*, service variety is used. Service variety is measured by the percentage of pharmacists offering 'common services', including online ordering of medicines, home delivery, consultations with a pharmacist, and the provision of specialised medication packages. The authors then find that requirements on registration, licensing and obligatory membership of a professional organisation (defined as additional practice requirements, examinations and annual costs) are negatively correlated with service variety. This is in line with predictions made in the economic

[69] Volkerink, De Bas, Van Gorp and Philipsen (2007). Disclaimer: although I was a co-author of this study and still support its conclusions (having been involved *inter alia* in the set-up of the regulation indices and the empirical study), the views expressed throughout this paper do not necessarily match all of the views expressed in the ECORYS study.

[70] An earlier study by the Institute for Advanced Studies (IAS) for DG Competition also included an empirical component. See Paterson, Fink, Ogus et al (2003). However, this empirical analysis more generally concerned the liberal professions and was based on rather crude indicators (e.g. turnover related to population size and GDP). It should therefore be considered as an impetus to further research rather than a fully fledged empirical analysis. For a summary and analysis of this highly interesting IAS report see Philipsen (2010), pp. 210-212.

[71] Analysis of variance, or ANOVA, isa general statistical method for studying sampled-data relationships. In the ANOVA analysis performed by ECORYS, for each category of regulation (structure, registration, professional monopoly, operating, integration, practice, price) EU countries were classified in two groups: those with a high and those with a low regulation index. It could then be determined whether there is a relation between the degree of regulation and the different performance indicators used by the authors for productivity, allocative efficiency and quality/product variety. Volkerink, De Bas, Van Gorp and Philipsen (2007), pp. 77-80.

[72] Note that there are slight differences between the definition of 'operating restrictions' used in the ECORYS study and my classification of regulatory restrictions in sections 3 and 4 above. I filed location requirements and additional entry barriers under 'licensing and other entry restrictions' rather than 'business structure'.

literature, where it is argued that strict licensing procedures can be used to limit enty into the profession.[73] Furthermore, the authors find that educational requirements and regulation of prices and profit margins are both positively (but weakly) correlated with service variety. The first relationship would indicate that minimum education requirements or compulsory practice may indeed have some positive effect on service variety; whereas the second relationship would according to the authors indicate that pharmacists have to compete in service variety if possibilities for price competition are taken away from them.[74]

Restrictions on horizontal and vertical integration, the scope of the professional monopoly (are non-pharmacists allowed to dispense prescription drugs or OTC drugs), and rules on exercise of the profession (advertising, floor space, etc) all were found to have no significant effect on either service variety/quality, productivity or allocative efficiency.[75]

6. Concluding remarks

Compared to other professions, pharmacists worldwide appear to be heavily regulated. Licensing requirements are strictly defined and entry into the market may be further restricted by additional forms of regulation (numerus fixus, establishment policy, etc). This can to some extent be explained as a reaction to the information asymmetries between pharmacists and patients. Applying private interest theories of regulation, however, an additional explanation can be found in the heavy involvement of pharmacists in the formulation and enforcement of regulation.

Despite the existence of all this regulation aimed at quality improvement, in various countries there is a discussion about how to improve or increase the level of pharmaceutical care provided to patients in community pharmacies. The answer to this question may not be related to stricter entry or conduct requirements, as argued by some pharmacists, but to changes in the reimbursement system. Currently there are few financial incentives (there may be non-financial ones) to provide pharmaceutical services, as the pharmacists' income is largely dependent on the number of prescription drugs sold, unless pharmacists are employed by others. In the latter case they can be separately reimbursed for tasks in the field of pharmaceutical care or they can be paid by the hour.

The Canadian example discussed in Section 4.1 indicates that it is possible to allow pharmacists to charge (small) additional fees for specialized services, although it appears that in practice this option has hardly been used. The rise of pharmaceutical chains in Europe (in countries where this is allowed), as discussed in Section 4.3, has shown to be yet another alternative to a system of a fixed fee/margin per prescription, as this generally allows pharmacists to work in employment. However, whether there will be a convergence in Europe of the rules on pharmacists' fees, business types and entry regulation is difficult to predict, when looking at the current differences between jurisdictions that allow pharmacy chains to be formed and others that do not, and when

[73] For example, Friedman and Kuznets (1945); Stigler (1971), pp. 5-6. See also Moore (1961) and Leland (1979).

[74] Volkerink, De Bas, Van Gorp and Philipsen (2007), pp 79-80.

[75] Volkerink, De Bas, Van Gorp and Philipsen (2007), pp. 14-17 and 79-80.

looking at the differences between jurisdictions with regard to the pharmacists' professional monopoly (which may include or exclude the distribution of OTC drugs).

References

Akerlof G. (1970), 'The Market for Lemons: Quality, Uncertainty and the Market Mechanism', *Quarterly Journal of Economics*, **85**, 488-500.

Arrow K.J. (1963), 'Uncertaintly and the Welfare Economics of Medical Care', *American Economic Review*, **53**, 941-973.

Arruñada B. (2006) 'Managing Competition in Professional Services and the Burden of Inertia', in Ehlermann, C. and I. Atanasiu (eds), *European Competition Law Annual 2004: The Relationship between Competition Law and (Liberal) Professions*, Oxford, UK and Portland Oregon, US: Hart Publishing., 51-71

Becker G.S. (1983), 'A Theory of Competition Among Pressure Groups for Political Influence', *Quarterly Journal of Economics*, **98**, 371-400

Benham L., Benham A. (1975), 'Regulating Through the Professions: A Perspective on Information Control', *Journal of Law and Economics*, **18**, 421-447.

Bond R. *et al.* (1980), *Effects of Restrictions of Advertising and Commercial Practice in the Professions: The Case of Optometry*, Washington: Federal Trade Commission.

Buchanan J.M., Tollison R.D., Tullock G. (eds) (1980), *Toward a Theory of the Rent-Seeking Society*, College Station: Texas A&M University Press.

Carroll S.L., Gaston R.J., (1981), 'Occupational Restrictions and the Quality of Service Received: Some Evidence', *Southern Economic Journal*, **47(4)**, 959-976.

Competition Bureau (2007), *Self-Regulated Professions: Balancing Competition and Regulation*, Gatineau QC, Canada: Competition Bureau.

Cox C., Foster S. (1990), *The Costs and Benefits of Occupational Regulation*, Washington: Federal Trade Commission.

Curran C. (1993), 'The American Experience with Self-Regulation in the Medical and Legal Professions', in: Faure, M., Finsinger, J., Siegers, J. and R. Van den Bergh (eds), *Regulation of Professions: A law and Economics Approach to the Regulation of Attorneys and Physicians in the U.S., Belgium, the Netherlands, Germany and the U.K.*, Antwerp: MAKLU, pp. 47-87.

De Bas P. *et al.* (2009), *The Impact of Pharmacy Chains on Sector Performance in the EU*, Rotterdam: ECORYS Nederland B.V. in co-operation with Metro, Maastricht University. Http://www.ecorys.com/rapporten/research-programme-final-outputs/the-pharmacy-sector/download.html

Devas N., Kelly R. (2001), 'Regulation or Revenues? An Analysis of Local Business Licenses, with a Case Study of the Single Business Permit Reform in Kenya', *Public Administration and Development*, **21(5)**, 381-391.

Dingwall R., Fenn P. (1987), 'A Respectable Profession? Sociological and Economic Perspectives on the Regulation of Professional Services', *International Review of Law and Economics*, **7**, 51-64.

European Commission (2004), *Communication from the Commission: Report on Competition in Professional Services*, COM(2004) 83 final, Brussels: Competition DG.

European Commission (2005), *Commission Staff Working Document: Progress by Member States in Reviewing and Eliminating Restrictions to Competition in the Area of Professional Services*, COM(2005) 405 final / SEC(2005) 1064, Brussels: Competition DG.

Fang Y., Huang T., Yang S. (2006), 'Licensed Pharmacists: Practice in Community Pharmacy in China', Asian Journal of Social Pharmacy, **1(1)**, 1-3.

Friedman M., Kuznets S. (1945), *Income from Independent Professional Practice*, New York: National Bureau for Economic Research.

Fu S. *et al.* (2009), 'Lack of Drugstore Pharmacists in China: How to Solve It', *Asian Journal of Social Pharmacy*, **4(3)**, 128-131.

Huang S., 'Licensed Pharmacist System in China', *Asian Journal of Social Pharmacy*, **2(2)**, 41-44.

Indecon and London Economics (2003), *Indecon's Assessment of Restrictions in the Supply of Professional Services*, prepared for the Competition Authority, Dublin/London: Indecon International Economic Consultants and London Economics.

Leland H.E. (1979), 'Quaks, Lemons and Licensing: A Theory of Minimum Quality Standards', *Journal of Political Economy*, **87**, 1328-1346.

Moore T.G. (1961), "The Purpose of Licensing", *Journal of Law and Economics*, **4**, 93-117.

Muzondo T.R., Pazderka B. (2003), 'Income-Enhancing Effects of Professional Licensing Restrictions: A Cross-Section Study of Canadian Data', *Antitrust Bulletin*, **28**, 397-415.

ÖBIG (2006), *Community Pharmacy in Europe*, report commissioned by PGEU, Vienna: Austrian Health Institute.

OECD (2000), *Competition and Regulation Issues in the Pharmaceutical Industry*, Paris: Directorate for Financial, Fiscal and Enterprise Affairs, Committee on Competition Law and Policy.

OECD (2005), *Enhancing Beneficial Competition in the Health Professions*, DAF/COMP(2005)45, Paris: Directorate for Financial, Fiscal and Enterprise Affairs, Committee on Competition Law and Policy.

OECD (2007), *Towards Better Regulation of the Legal Professions*, DAF/COMP(2007)39, Paris: Directorate for Financial and Enterprise Affairs, Competition Committee.

OECD (2009), *Competition and Regulation in Accountancy*, DAF/COMP/WP2(2009)1, Paris: Directorate for Financial and Enterprise Affairs, Competition Committee.

OFT (2001), *Competition in Professions: A Report by the Director General of Fair Trading*, London, UK: Office of Fair Trading.

OFT (2003), *The Control of Entry Regulations and Retail Pharmacy Services in the UK: A Report of an OFT Market Investigation*, **1-3**, London, UK: Office of Fair Trading.

Ogus A., Zhang Q. (2005), 'Licensing Regimes East and West', *International Review of Law and Economics*, **25**, 124-142.

Olson M. (1965), *The Logic of Collective Action: Public Goods and the Theory of Groups*, Cambridge: Harvard University Press.

Pagliero M. (2005), 'What is the Objective of Professional Licensing? Evidence from the US Market for Lawyers', *Job Market Paper*, London: London Business School and Turin: University of Turin.

Paterson I. *et al.* (2003), *Economic Impact of Regulation in the Field of Liberal Professions in Different Member States: Regulation of Professional Services*, study for the European Commission, Vienna: Institute for Advanced Studies.

Peltzman S. (1976), 'Toward a More General Theory of Regulation', *Journal of Law and Economics*, **19**, 211-240.

Philipsen N.J. (2003), *Regulation of and by Pharmacists in the Netherlands in the Netherlands and Belgium: An Economic Approach*, Antwerp/Groningen: Intersentia.

Philipsen N.J. (2010), 'Regulation and Competition in the Legal Profession: Developments in the EU and China', *Journal of Competition Law and Economics*, **6(2)**, 203-231.

Philipsen N.J. (2011), 'Professional Licensing and Self-Regulation in Europe and China: A Law and Economics Perspective', in Faure, M. and X. Zhang (eds), *Competition Policy and Regulation*, Cheltenham, UK and Northampton, MA, USA: Edward Elgar, pp. 205-237.

Rogers Publishing Ltd. (2005), *Trends & Insights 2005*, The Pharmacy Group, Canada. Available at: http://www.mckesson.ca/static/en/pdf/Trends_2005.pdf.

Shaked A., Sutton J. (1981), 'The Self-Regulating Profession', *Review of Economic Studies*, **48**, 843-862.

Shapiro C. (1986), 'Investment, Moral Hazard and Occupational Licensing', *Review of Economic Studies*, **53**, 843-862.

Shavell S. (1984), 'Liability for Harm versus Regulation of Safety', *Journal of Legal Studies*, **13(2)**, 357-374.

Stephen F.H. (2006), 'The Market Failure Justification for the Regulation of Professional Service Markets and the Characteristics of Consumers', in Ehlermann, C. and I. Atanasiu (eds), *European Competition Law Annual 2004: The Relationship between Competition Law and the (Liberal) Professions*, Oxford, UK and Portland Oregon, USA: Hart Publishing, pp. 143-154.

Stephen F.H., Love J.H. (2000), 'Regulation of the Legal Profession', in Bouckaert, B. and G. De Geest (eds), *Encyclopedia of Law and Economics, Volume III: The Regulation of Contracts*, Cheltenham, UK: Edward Elgar, 987-1017.

Stichting Farmaceutische Kengetallen (2009), *Data en Feiten 2009*, Den Haag.

Stigler G.J. (1971), 'The Theory of Economic Regulation', *Bell Journal of Economics and Management Science*, **2**, 3-21.

Svorny S. (2000), 'Licensing, Market Entry Regulation', in Bouckaert, B. and G. De Geest (eds), *Encyclopedia of Law and Economics, Volume III: The Regulation of Contracts*, Cheltenham, UK and Northamption, MA, USA: Edward Elgar, pp. 296-328.

Van den Bergh R., Faure M. (1991), 'Self-Regulation of the Professions in Belgium', *International Review of Law and Economics*, **11**, 165-182.

Van der Mijn W.B. (1989), *Beroepenwetgeving in de Gezondheidszorg*, third edition, Deventer: Kluwer.

Volkerink B. *et al.* (2007), *Study of Regulatory Restrictions in the Field of Pharmacies, study for the European Commission*, Rotterdam: ECORYS Nederland B.V. in co-operation with Metro, Maastricht University. Http://ec.europa.eu/internal_market/services/docs/pharmacy/report_en.pdf.

Wendt I. (2009), *The Tension Between Rules Regulating the (Liberal) Professions and EC Competition Law: Reason and Passion in Discussing Professional Regulation*, Dissertation, Maastricht: Maastricht University.