Do You Believe in Magic: Improving the Quality of Pharmacy Services Through Restricting Entry & Aspirational Contracts, the Irish Experience

Paul K Gorecki[*]

Economic and Social Research Institute, Dublin

A constant refrain of policy makers and public representatives is the necessity of improving the quality of public health services. In this paper two inter-related policies designed to raise the quality of pharmacy services in Ireland are considered. The first was to restrict the opening of new pharmacies, the second, to increase the quality of pharmacy services through contract specification. While the first policy restricted entry and raised returns to existing pharmacies, there is no evidence it raised service quality. Equally, the second policy appears to have had little effect on the quality of pharmacy services. The contractual provision itself is largely unenforceable, does not recognize the conflicting motivations of a pharmacist and results in no measurable output. Drawing on this experience several lessons as presented as to how service quality can be improved, which are likely to have application beyond Ireland.

Key words: pharmacy; pharmacist; 1996 Pharmacy Regulations; 1996 Community Pharmacy Contract; definite public health need; economic regulation; prescription drugs; GMS; drug reimbursement.

JEL Codes: I11, L43, L84, L98,

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1. Introduction

A constant refrain of policy makers and public representatives is the necessity of improving the quality of public health services. In this paper two inter-related policies designed to raise the quality of pharmacy services in Ireland are considered: restricting the opening of new pharmacies; and, contract specification. These policies are assessed in Sections 2 and 3, respectively, drawing on a series of official reports together with an examination of published data. Section 4 draws some lessons from the Irish experience and considers whether these have wider applicability.

2. Licensing Pharmacies: the 1996 Pharmacy Regulations

The purpose of the Health (Community Pharmacy Contract Agreement) Regulations, 1996 ("the 1996 Pharmacy Regulations")[1] was to increase the quality and accessibility of pharmacy services in Ireland by only granting a community pharmacy contract when there was a definite public health need. These definite public health need criteria were, according to the Chief Pharmacist of the Department of Health and Children ("Department of Health"), intended to ensure that "the quality of the pharmacy service in the various local areas is not unduly reduced by over-competition" (Pharmacy Review Group, 2003, p. 11). The 1996 Pharmacy Regulations were revoked on 31 January 2002 following legal advice from the Attorney-General sought by the Minister for Health and Children ("Minister for Health") on foot of a court challenge to the regulations.[2]

Importance of a Community Pharmacy Contract

Although there was no legal bar on establishing a new pharmacy or limitation on the number of pharmacies,[3] the operation of the 1996 Pharmacy Regulations created a de

[1] S.I. No 152/1996 - Health (Community Pharmacy Contractor Agreement) Regulations, 1996, which are reproduced in Pharmacy Review Group (2003, Appendix 3).

[2] For details see Pharmacy Review Group (2003, p. 7), Purcell (2004, pp. 48-49) and Department of Health (2002)

[3] Apart that is from regulations concerning possession of professional pharmacy qualifications.

facto restriction on the number of new pharmacies.[4] These regulations set the criteria by which the State would award a new community pharmacy contract to a pharmacy to supply drugs to those persons eligible under various government community drug programmes, the most important of which is the General Medical Services ("GMS"). In 2002 it paid €550.89 million to pharmacies for 29.5 million prescription items. All persons below an income threshold were eligible for GMS coverage as were those over 70 years of age. There was no co-payment.[5]

There was – and is – acceptance that it is vitally important, although not absolutely essential, for the commercial viability of a pharmacy to have a community pharmacy contract. A survey by undertaken by Indecon (2002, Table 6.3, p. 42 and Table 6.7, p. 44)[6] found that in 2001/02 community drug schemes accounted, on average, for 72.3% of the value of total prescription drugs sold by a pharmacy and 40% of total pharmacy turnover.[7] There was relatively little variation in the 72.3% figure by whether or not the pharmacy was located in a city (71.4%), large (72.2%) or small (73.2%) town or a rural area (75.2%).[8] Purcell (2004, p. 44) observes that "… relatively few pharmacies (less than 2%) would be viable without such a contract. Indeed the lack of a GMS contract is likely to restrict a pharmacy's sales by an even greater amount, because a GMS contract brings other 'footfall' business with it."

The 1996 Pharmacy Regulations: Description

[4] Note that these restrictions on opening a new pharmacy applied to the creation of a new retail pharmacy at location x, irrespective of whether or not it was opened by a new entrant or an existing pharmacy. Existing pharmacies were grandfathered under the 1996 Pharmacy Regulations. However, there were limitations on the degree to which a pharmacy could switch location.

[5] For details of the community drug schemes see Barry et al (2004, Table 1, p. 191).

[6] The survey undertaken covered both contractor pharmacists and employees, with a response rate of 14% yielding a sample size of 371 pharmacists. The Indecon survey was part of the review of the 1996 Pharmacy Regulations that was envisaged in 1996. For details see Pharmacy Review group (2003, pp. 11-12).

[7] The 40% figure is consistent with other estimates. See Purcell (2004, p. 44).

[8] For details see Indecon (2002, Table 6.4, p. 43).

Under the 1996 Pharmacy Regulations a new community pharmacy contract would only be awarded if there was a "definite public health need," defined cumulatively in terms of the:

- catchment area served by a new community pharmacy (i.e., urban and large towns a population of 4,000 for most of the year; other locations population of not less than 2,500);
- minimum distances between pharmacies (i.e., 250 metres in the case of urban and large towns; five kilometers in rural area); and,
- new pharmacy "will not have an adverse impact on the viability of existing community pharmacies in their respective catchment areas to the extent that it will affect the quality of pharmacy services being provided."

There were other conditions, including: (i) "the proposed supervising pharmacist shall have at least three years recent post registration experience in the practice of community pharmacy … "; (ii) "the proposed supervising pharmacist shall have a high degree of professional competence including the ability to effectively manage the community pharmacy."; and, (iii) "the proposed pharmacy has a reasonable prospect of being viable in the context of the pharmacy services to be provided and that there is a long term commitment to the catchment areas which it is intended to serve."

In order to be awarded a new community pharmacy contract, the 1996 Pharmacy Regulations set up an administrative procedure. The applicant had to make a detailed description of how they met the criteria necessary to be awarded a community pharmacy contract such as viability. A public notice was to be placed in newspapers so that observations could be made by interested parties, including pharmacists whose viability might be adversely affected. An assessment board was created in each health board to evaluate the application and any observations and make recommendations to the chief executive officer of the relevant health board.[9] The procedures allowed for

[9] The health boards were replaced by the Health Services Executive ("HSE"), which came into operation in 2005, when the functions of the health boards were subsumed into the HSE.

the opportunity for an exchange of views between the assessment board and the applicant on the former's view as to whether there is a definite public health need. The health board chief executives' decision as to whether or not to award a community pharmacy contract could be appealed to the Minister for Health.

1996 Pharmacy Regulations: Did They Restrict the Opening of New Pharmacies?

In order to determine whether or not the 1996 Pharmacy Regulations led to decline in the number of new pharmacies, absent the regulations, three inter-related questions are posed.

Are the 1996 Pharmacy Regulations Inherently Restrictive?

The 1996 Pharmacy Regulations are likely to be a binding constraint that limited the opening of the number of new pharmacies, given that one of the objectives of the regulations was to ensure the quality of pharmacy service is "not unduly reduced by over-competition."[10] The criteria to establish a new community pharmacy are inherently restrictive.[11] If pharmacists, as private parties, had agreed collectively to the 1996 Pharmacy Regulations they would almost certainly be guilty of a breach of section 4 (1) of the Competition Act 2002, which prohibits agreements whose object or effect is to restrict competition.[12] The 1996 Pharmacy Regulations favour the status quo by allowing incumbents to object to new entrants.

The costs of entry were raised by the regulations. These costs include the necessity of meeting the requirements set out above to the satisfaction of the assessment board and

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[10] Pharmacy Review Group (2003, p. 11).

[11] For example, while the 1996 Pharmacy Regulations place minimum distances between pharmacies of 250 metres in urban area/large towns and five kilometres in rural areas, the Competition Authority (2002, p. 57; pp. 62-63) use 1 mile and 15 miles, respectively, distance radius, in defining separate geographic markets for pharmacy services.

[12] Section 4 (1) of the Competition Act 2002 prohibits agreements that have as their object or effect the prevention, restriction or distortion of competition. Section 4 specifically prohibits the sharing of markets or customers. However, section 4 (5) allows otherwise restrictive agreements if, broadly speaking, the benefits outweigh the costs. The discussion below concerning service quality is relevant to these issues. These provisions of the Competition Act 2002 mirror Article 81(1) and 81(3), respectively of the European Treaty. For further discussion see Whish (2009, pp. 81-169).

the chief executive of the health board combined with the uncertainty of the process,[13] given that incumbent pharmacies could object to the opening of a new pharmacy on the grounds, among others, that the new entrant would undermine their viability. The latter reflect criteria that are not related to the practice of pharmacy as such, but rather are economic in nature.[14]

Did the 1996 Pharmacy Regulations Discourage the Opening of New Pharmacies?

In order to determine whether or not the 1996 Pharmacy Regulations led to a reduction in the number of new pharmacies, absent the regulations, a number of different pieces of evidence are examined.

First, the refusal rate for applications for community pharmacy contracts, between 1996 and 2001, was 42%-47%.[15] The refusal rate was similar in both urban and rural areas (Pharmacy Review Group, 2003, p. 13). Such a high rate of refusal is consistent with the view that there was considerable uncertainty surrounding the application of the criteria set out in the 1996 Pharmacy Regulations for awarding a community pharmacy contract. With clarity and certainty the refusal rate should be much lower, if not zero.

Second, legal proceedings were instituted by two separate pharmacies: a judicial review of the 1996 Pharmacy Regulations was taken by McSweeney Group, which consisted of 21 pharmacies; and, Dame Street Pharmacy challenged the basis of the 1996

[13] This uncertainty is reflected in the variance of reasons used by the Health Boards to refuse to grant a community pharmacy contract. One would expect that, other things equal, the reasons for rejecting an application for a new community pharmacy would be reasonably consistent across the health boards. However, what is striking is the variance across the health board. For example, Health Board 2 rejected 56% of applications for 'other reasons.' None of the other six health board used this reason, bar one and then it only accounted for 5%. This variance is not altogether surprising since it is not usually within the competence or expertise of a health board to evaluate the commercial viability of a pharmacy and/or long term commitment of a pharmacy to a location. The author will provide details on request.

[14] In other words, the assumption is made that if a pharmacy can show that its viability is adversely affected by entry then given the stated concern with over-competition, it is assumed that it follows that quality is assumed to fall, even though, as we shall see below, there is evidence to suggest that competition increases service quality.

[15] Indecon (2002, p. 24) claim it is 47% while, based on the same data, the Pharmacy Review Group (2003, p.13) argue for 42%.

Pharmacy Regulations after they had been refused a community pharmacy contract.[16] If the 1996 Pharmacy Regulations were not restrictive then it is unlikely that such actions would have been taken.

Third, if the 1996 Pharmacy Regulations were effective at restricting entry then, other things equal, the net change in the number of pharmacies with community pharmacy contracts should be reduced. The 1996 Pharmacy Regulations restrictions on awarding a community pharmacy contract lasted from 1996 to 31 January 2002. The change in the total number of community pharmacy contracts before, during and after that period is presented in Table 1 as well as the number of persons per community pharmacy contract.[17] As expected there is a marked decline in the rate of increase in the number of community pharmacy contracts during 1996-2001. The rate increased after 2002 reflecting the fact that some of those who were unsuccessful in applying between 1996 and 2001 subsequently acquired a community pharmacy contract while pharmacists who decided not to apply for a community pharmacy contract between 1996 and 2002 - because they knew that they were unlikely to be successful – decided to apply for a community pharmacy contract. Comparing 1991-95 to 1996-2001 suggests that the rate of opening of new pharmacies was reduced by 50% by the 1996 Pharmacy Regulations.[18]

[16] For details of these two cases see Purcell (2004, pp. 47-48).

[17] In the early 2000s Ireland had, compared to other EU Member States, a low number of persons per pharmacy at 3205, with only France (2579), Spain (2150), Belgium (1825) and Greece (1320) recording a lower number. In contrast, Italy (3600), Portugal (3940), Germany (3800), UK (4758), Luxembourg (5260), Finland (6500), Austria (7284), Netherlands (10000), Sweden (10000) and Denmark (17000) all had a higher number. For details see Purcell (2004, Table 2.1, p. 17).

[18] A corollary of this pattern of new pharmacy openings – given that the population of Ireland grew throughout the period 1991 to 2007 – is that, other things equal, the number of persons per pharmacy with a GMS contract is likely to decrease (or may be increase) at a much slower rate between 1996-2001, than either the previous or subsequent period. This is consistent with Table 1.

Table 1

Number and Net Change of Pharmacies with GMS Contracts, Ireland, Selected Periods, 1991-2005

Period	Annual Average Number of Pharmacies with GMS Contracts	Annual Average Net Change in Number of Pharmacies with GMS Contracts (Min-Max) (%)	Average Annual Number of Persons per Pharmacy with a GMS Contract (Start Year – End Year)
1991-1995	1,115	1.51 (0.73-2.53)	3201 (3252-3129)
1996-2001	1,177	0.75 (-1.52-2.86)	3167 (3145-3198)
2002-2007	1,403	4.47 (3.17-7.28)	2940 (3136-2734)

Source: HSE (2008c, p. 10); Indecon (2007, Table 2.8, p. 17); Central Statistics Office.

It could be argued, however, that demand might have fallen considerably between 1996 and 2001 compared with both prior and subsequent periods. In other words, the change in the annual net change in the number of pharmacies merely reflects changes in demand, rather than the effect of the 1996 Pharmacy Regulations.[19] In order to test for this, the annual increase in the overall cost of GMS medicines was estimated for each of the periods in Table 1, deflated by the consumer price index with 1996=100: [20]

Period Annual Average Increase in Overall Cost of GMS Medicines

[19] Studies of entry typically find that entry is positively related to growth in demand. See, for example, Baldwin & Gorecki (1987).

[20] The overall costs of medication are taken from HSE, *Statistical Analysis of Claims and Payments*, various years and General Medical Services (Payments) Board, *Annual Report 1998* and *Financial and Statistical Analysis of Claims and Payments*, various years.

1991-1995	4.88 %
1996-2001	10.46%
2002-2007	11.94%

The pattern of demand does not reflect the pattern of the net change in the number of pharmacies. There is a substantial increase in demand in 1996-2001 compared with the earlier period, which is maintained if not exceeded in 2002-2007.[21] Hence based on 1991-1995, if demand increased by a factor of slightly more than two then, other things being equal, the net change in the number of pharmacies should have been 3.24% rather than 0.75%, suggesting the impact of the 1996 Pharmacy Regulations was to reduce entry by around 75%.

Fourth, the discussion so far has been limited to the opening of new pharmacies *with* a community pharmacy contract. The restrictive nature of the 1996 Pharmacy Regulations is likely to result in more areas where a pharmacy may be viable *without* a community pharmacy contract; although for reasons set out above this is very much likely to be the exception rather than the rule. In order to test the hypothesis that there is likely to be an increase in the number of pharmacies opening *without* a community pharmacy contract, the ratio of non-GMS pharmacies to all pharmacies for 1996 and 2001 was compared to 1991-1995 and 2002-2007. If the hypothesis is correct then, other things being equal, this ratio should be higher during the period when the 1996 Pharmacy Regulations were in effect and lower prior to and subsequent to 1996-2001.[22] The results in Table 2 are consistent with the prediction, with the ratio of non-GMS

[21] The total number of persons eligible for GMS does not explain these movements in overall demand. The eligible number of persons increased between 1990 and 1995 from 1.221 m to 1.277 m, before declining from 1.252 to 1.199 between 1996 and 2001, and then increasing from 1.169 m in 2002 to 1.276 m in 2007. These data are from the same sources as the prior footnote.

[22] One of the things that were not equal was the state of the economy. Economic growth, measured as annual average change in GNP at constant market prices, increased from 4.6% over 1991-1995, to 9.0% for 1996-2001, before declining somewhat to 5.5% for 2002-2007. Thus during 1996-2001 economic conditions were particularly propitious for opening a new business or a new branch of an existing business.

contract pharmacies to all pharmacies increasing from 2.6% in 1991-1995 to 4.1% in 1996-2001, before declining to 2.6% in 2002-2007.[23]

Table 2

Number of Pharmacies with & without GMS Contracts, Ireland, Selected Periods, 1991-2007

Period	All Pharmacies[1] (Annual Average No)	GMS Contract Pharmacies (Average Annual No)	Non-GMS Contract Pharmacies (Annual Average No)	Ratio of Annual Average No. Non-GMS Contract to Average Annual No All Contract Pharmacies
1991-1995	1,145	1,115	30	2.6
1996-2001	1,227	1,177	50	4.1
2002-2007[2]	1,465	1,434	31	2.1

1. All pharmacies as recorded by the Pharmaceutical Society of Ireland.
2. Data for 2002 not available.

Source: Indecon (2002, Table 5.3, p. 23); Pharmaceutical Society of Ireland ("PSI"), *Annual Reports*, various issues, Table 1 above and information supplied by the PSI.

In sum, the evidence strongly suggests that the 1996 Pharmacy Regulations were effective in reducing the number of new pharmacies with a community pharmacy contract.

Did the 1996 Pharmacy Regulations Result in Community Pharmacy Contracts Acquiring Value?

[23] Over the period prior to 1996 the ratio falls, after 1996 it increases, while there appears to be no clear trend after 2002.

Regulations that limit entry while demand is expanding typically result in the creation of rents, which become capitalized. The Pharmacy Review Group (2003, p. 24) commented, "… the capital value of contracted pharmacies increased greatly under the [1996 Pharmacy] Regulations, giving a commodity value to the contract, and an increase in the value of contracted businesses, that was never intended." The Indecon survey of pharmacists referred to above, found that in 2001/02, 81% of pharmacists were in favour of retention of the restrictions contained in the 1996 Pharmacy Regulations and 74% felt that their profitability would fall if there were no restrictions on granting community pharmacy contracts.[24]

Evidence presented by Purcell (2004, p. 52) suggests that possession of a community pharmacy contract increased the value of a pharmacy by 40%. The estimate is derived from a natural experiment similar to an event study. A chain of pharmacies was sold for €152 million on the expectation that the 1996 Pharmacy Regulations would continue. However, subsequently the 1996 Pharmacy Regulations were unexpectedly revoked in January 2002. Following legal action the acquisition price was reduced to reflect the changed circumstances to a reported €110 million, implying that the 1996 Pharmacy Regulations increased the value of a pharmacy by 40%.[25]

Impact of the 1996 Pharmacy Regulations on Quality

The stated purpose of the 1996 Pharmacy Regulations was to increase the quality and accessibility of pharmacy services in the State by restricting the operation of market forces.[26]

<u>Restricting Entry: Is There a Valid Rationale?</u>

[24] Indecon (2002, Table 4.2, p. 16, and Table 8.8, p. 74).

[25] A survey of the views of pharmacists on this issue conducted by Indecon (2002, p. 77) puts the figure at 57.1%.

[26] See Pharmacy Review Group (2003, pp. 11-12) for more details.

It is not clear that reduced competition, by ensuring that pharmacies are shielded from market forces, will lead to a better quality of patient care. According to Fingleton (1997, p. 91), "[T]here was no evidence of market failure and no justification for the new regulation was given." Nevertheless, subsequently some justifications have been advanced.

First, in justifying the 1996 Pharmacy Regulations reference is specifically made to 'over-competition' as a rationale. This has echoes of excessive or destructive competition, which was used as the rationale for much regulation in the 1930s.[27] This can be a valid justification for introducing regulation.[28] It has been characterized as follows:

> It is the very intensity of competition, which, it is argued, has to be subject to controls over entry and/or price to protect the firms in the industry and their customers. In the absence of regulation, an industry … might operate for a loss for long periods; consumers might suffer through degradation in the quality of the goods or service; and, for some products or services, safety standards may be reduced to a dangerously low level.
>
> 'Excessive' competition may be the result of a cyclical downturn in demand or of a longer term trends tending to increase substantially the industry's production potential relative to demand. … The chief prerequisites for destructive competition are substantial excess capacity and rigidities that retard the reallocation of capital and labour (Economic Council of Canada, 1979, p. 47).

However, such a characterization of pharmacy in Ireland in the early 1990s is untenable.

Pharmacists in Ireland had high wholesale and high retail percentage mark-ups on prescription drugs compared with elsewhere in EU (Indecon, 2007; Bacon, 1999, Table 2.2, p. 11; Indecon, 2002, Table 8.1, p. 66). There was already limited competition between pharmacies. There were substantial restrictions on entry of persons into pharmacy, both from within Ireland, through limited training places at Trinity College Dublin, and from other EU Member States, due to the so-called three year rule (Bacon,

[27] See Breyer (1982) for a discussion of this in the context of the airline and trucking industries in the US.

[28] For a discussion of this rationale for regulation see Noll and Owen (1983, pp. 53-58).

1999; Purcell, 2004; Pharmacy Review Group, 2003, pp. 13-15).[29] Advertising was severely restricted. There was no evidence of a sudden increase in the number of pharmacies being awarded community pharmacy contracts in the early 1990[30] or of a dramatic decline in demand that would result in excess capacity and render many pharmacies unprofitable, at least judging by the growth of the GMS scheme for pharmacy services prior to the introduction of the 1996 Pharmacy Regulations[31] and subsequently (see discussion above).

Second, the theory underlying the rationale for restriction on competition was tested in a series of US studies, all of which predated the 1996 Pharmacy Regulations. However, instead of restrictions on entry, restrictions on advertising were examined. These studies found that increased competition in markets such as eyeglasses, optometry, drugs, and legal services led to *lower* not *higher* prices with *no* change in the quality of service.[32] As the Chairman of the Federal Trade Commission, Tim Muris (2003, p. 37), stated, "[R]estrictions on truthful and nondeceptive advertising harm competition, because they make it more difficult for consumers to discover information about price and quality of goods or services, thereby reducing competitors' incentives to compete with each with respect to such features."

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[29] Fingleton (1997, p. 91) argues that the 1996 Pharmacy Regulations, "appears to have resulted from an increased supply of qualified pharmacists, itself a result of EC measures to increase labour mobility." However, the three-year rule referred to in the text limited the ability of pharmacists trained outside of Ireland (even if they were Irish citizens trained in another EU Member State such as the UK) from competing with existing pharmacies since such persons: were *not* entitled to act as a pharmacist in Ireland in a pharmacy less than three years old; and, *could not* open a pharmacy in their own right, or work (except under the supervision of an Irish trained pharmacist) or manage any pharmacy that is less than three years old. It was introduced because of a concern over an alleged influx of pharmacists from other EU Member States (Pharmacy Review Group, 2003, pp. 14-15). The three year rule was not abolished until 2008. See Department of Health (2008).

[30] See Indecon (2007, Table 2.8, p. 17).

[31] The overall cost of medicines under GMS increased each year from 1990 to 1996. In inflation adjusted terms the increase was from €162.1 million to €216.1 million or 33.3%. Based on General Medical Services (Payments) Board, *Financial and Statistical Analysis Claims and Payments*, various issues.

[32] These studies are cited in Muris (2003, footnote 52, pp. 38-40) and include Bond et al (1980). The restriction that these studies examined was advertising restrictions. They typically compared US states where there were restrictions on advertising with those US states where such restrictions did not exist.

Third, in an examination of the relationship between the degree of local competition and service quality among a sample of UK pharmacies, the Office of Fair Trading ("OFT") found that greater local competition resulted in *higher* not *lower* service quality.[33]

Restricting Entry: Did Service Quality Improve?

The 1996 Pharmacy Regulations were designed to improve the service quality provided by pharmacies by "encouraging the greater involvement of pharmacists in the discharge of their professional responsibilities," thus "reducing the involvement of pharmacists in activities which were not related to their professional responsibilities" (Pharmacy Review Group, 2003, p. 11). In other words, if the commercial imperative was reduced then pharmacists could devote more of their time to patient care, rather than selling cosmetics or buying more pharmacies.

A number of points can be made about this argument. *First*, in principle, the objective of pharmacists allocating more of their time to professional health care tasks is sensible. Pharmacists are highly trained and knowledgeable experts that can enhance patient welfare. Given that in early 1990s most pharmacies were owner operated, in that the ratio of pharmacists to pharmacies in 1993 was 1.1, one of the lowest in Europe (Bacon, 1999, Table 2, p. 10), removal of the competitive/commercial imperative might have led to pharmacists spending more time advising patients and less on commercial and other activities.[34]

The 1996 Pharmacy Regulations do not provide an incentive for the pharmacist to allocate more time to their professional duties nor was any evidence adduced to demonstrate that the pharmacist was devoting too little time to patient advice and care.

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[33] For details see OFT (2003, P. 44). The OFT cautioned that given the sample size that these findings "should be treated as indicative rather than providing precise results." (p. 44).

[34] Indecon (2002, Table 9.13, p. 96) found that pharmacists spent on average 67% of their time on professional activities in 2001/02.

Furthermore, if competitive pressures were reduced on pharmacists because the 1996 Pharmacy Regulations restricted entry, it is not at all obvious that pharmacists[35] would devote more time to their professional duties. Pharmacists might decide to take more leisure. Each pharmacist was under the 1996 Pharmacy Regulations protected to some degree from competition from rival pharmacies. As Sir John Hicks famously observed in the 1930s, "[T]he best of all monopoly profits is a quiet life …" Equally, since pharmacists are small businesses selling non-prescription drugs and other items such as cosmetics in competition with other retail outlets such as supermarkets and convenience stores, the pharmacist might decide to develop this aspect of their pharmacy business.[36]

Second, the 1996 Pharmacy Regulations are likely to result in an increase the demand for professional services per pharmacy, since overall demand is increasing while the opening of new pharmacies was reduced drastically. This is likely to lead to an increase in the ratio of pharmacists to pharmacies. As a result, it could be argued, that not only will larger pharmacies be able to realize economies of scale, but there may also be some specialization, with some of the business development aspects of the pharmacy being left to non-pharmacists, thus releasing pharmacists' time for professional duties. Furthermore, larger pharmacies are likely to stay open for longer hours, thus benefiting the consumer.

There is no increase in the rate of growth of the number of prescriptions dispensed per pharmacy comparing 1996-2001 to prior or subsequent periods. Instead there appears to be a gradual decline in the rate of growth of the number of prescriptions dispensed per pharmacy comparing 1990-1995 (6.61 thousand to 7.98 thousand or 20.7%) with 1996-2001 (9.4%) and 2002-2007 (0.6%) (Table 3). Thus there would appear to be no pronounced change occasioned by the period 1996-2001. This is a puzzling result.

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[35] This applies particularly to pharmacy owners.

[36] Indecon (2002, Table 6.5, p. 43; Table 9.17, p. 99) found that 39% of the turnover of a pharmacy is from OTC non-prescription drugs and other goods and services, while of the average pharmacy only 33.8% of the square footage was devoted to prescription drugs, with 24.1% allocated to OTC non-prescription drugs and 42.1% to other goods/services.

Table 3

Average Number of GMS Prescriptions Dispensed per Pharmacy, Selected Periods, 1990-2007.

Year	No. of GMS Pharmacy Contracts	Total No. Prescription Forms (000s)	Average No Prescription Form Dispensed per Pharmacy (000s)	Items per Prescription Form (Number)	Adjusted[1] Total No. Prescription Forms (000s)	Average Adjusted No. Prescription Forms Dispensed per Pharmacy (000s)
1990	1,079	7,136	6.61	2.05	7,136	6.61
1995	1,151	9.191	7.98	2.05	9,191	7.98
1996	1,153	9,160	7.94	2.09	9,334	8.09
2001	1,203	10,454	8.69	2.44	12,440	10.34
2002	1,249	11,551	9.25	2.55	14,369	11.50
2007	1,587	14,780	9.31	3.00	21,623	18.43

1. Adjusted for the number of items per form as follows: Total No. Prescription Forms x ((Items per Prescription Form for i =1995, 1996, 2001, 2002, 2007)/ Items per Prescription Form 1990).

Source: General Medical Services (Payments) Board, *Financial and Statistical Analysis of Claims and Payments*, various issues and HSE, *Statistical Analysis of Claims and Payments*, various issues.

However, these estimates weigh each prescription equally. This is inappropriate in that the number of items per prescription has increased from 2.05 in 1991 to 3.00 on 2007 (Table 3). More items per prescription is likely to require the pharmacist to spend more

time dispensing the prescription since, for example, the likelihood of adverse interactions that need to be monitored increase more than proportionately as does the advice needed to be given to the patient.[37] Table 3 takes into account the number of items per prescription to estimate the 'adjusted' number of prescriptions dispensed per pharmacy. When this is done there is pronounced increase in the rate of growth number of prescriptions dispensed per pharmacy between1996-2001 compared to the prior and subsequent five year periods:

1990-1995	20.7%
1996-2001	27.8%
2002-2007	18.4%

It thus appears that the 1996 Pharmacy Regulations raised the number of prescriptions dispensed per pharmacy substantially.

There is some evidence that the number of pharmacists per pharmacy increased, but it is somewhat tentative. The ratio increased from 1.1 in 1993, as noted above, to 1.95 in 2002 (Indecon, 2002, Table 9.10, p. 94). However, the numbers are not directly comparable.[38] Nevertheless, there are other indicators that suggest the pharmacy size has increased: in terms of employees, for example, from 5.5 in 1995 to 9.2 in 2002 (Indecon, 2002, Table 9.10, p. 94). This growth was also explained by the entry and expansion of pharmacy chains that are likely to have a different business model than a single operator pharmacy (Competition Authority, 2002; Pharmacy Review Group,

[37] If there only two drugs per prescription then there is only one interaction that has to be considered; if there are three drugs there are three interactions that have to be considered. Thus a 50% increase in the number of drugs per prescription leads to a 200% increase in the number of interactions that have to be monitored. However, if the patient is taking non-prescription medicines then the increase will be different, but the point remains valid. For example, if the increase is from three to four drugs, then the increase in the number of drugs is 33.3%, but the increase in the number of possible interactions goes from three to six or a 100% increase.

[38] Indecon (2002, fn. 15, p. 95) says that the 1.95 refers to full-time pharmacists and that such data was not available for 1995 on a comparable basis.

2003, pp. 22-23). It may also explain the slight increase in pharmacy opening hours recorded between 1996 and 2001/2. [39]

Thus there is some evidence consistent with the view that the 1996 Pharmacy Regulations encouraged larger pharmacies, with more pharmacists per pharmacy and greater specialization.[40] This is likely to have resulted in pharmacists allocating more of their time to their professional duties. However, absent these regulations, the entry and expansion of pharmacy chains would have had a similar effect.[41] Indeed, it could be argued that since the 1996 Pharmacy Regulations restricted entry that they retarded the development of chain pharmacists and thus greater provision of pharmacy services.[42]

It is difficult to come to a definitive conclusion on whether or not pharmacists allocated more of their time to professional duties, over and above what would be expected taking into account the ongoing increase in demand, supply side constraints referred to above and the increasing importance of pharmacy chains. In terms of the time allocation of pharmacists the evidence suggests that despite these factors, between 1996-2001, that only 42% of pharmacists increased the time spent on their professional duties, with 50% either experiencing a decrease or no change (Indecon, 2002, Table,

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[39] There was a "small" increase in pharmacy opening hours per week from 52.2 to 55.6 between 1996 and 2002, which may not be statistically significant (Indecon, 2002, Table 9.8, p. 93). Even if it is statistically significant this could be explained as a result of the growth of chain pharmacies since work done in the UK suggests that such pharmacies open for longer hours than do community pharmacies (OFT, 2003, pp. 50-51). In discussing non-price competition in pharmacy the Competition Authority (2002, p. 53) report that two pharmacy chains remarked on how they opened late, with some of their pharmacies opening on a Sunday. In other words, the increase in pharmacy opening hours could have occurred independently of the 1996 Pharmacy Regulations.

[40] For example, if pharmacies become managed by professional managers and pharmacists specialise in performing their professional duties then the time allocated to such duties will increase.

[41] The Pharmacy Review Group (2003, p. 18) estimate the proportion of new pharmacies that are opened by an existing pharmacy as opposed to a new entrant. For the July 1996 to July 2001 the percentage is 67%; for the nine months following the revocation of the 1996 Pharmacy Regulations, the ratio was 66%.

[42] Another positive impact of chain pharmacies is that employed pharmacists are less likely to be motivated by over-selling, given that the latter are paid by a salary rather than obtaining all the return from selling a product (Competition Authority, 2002, p. 58).

9.15, p. 98). Thus it is not at all clear that was an increase in pharmacy services measured by time, as a result of the 1996 Pharmacy Regulations.[43]

3. Raising Quality Standards: the 1996 Pharmacy Contract

While the 1996 Pharmacy Regulations did not contain any explicit reference to the quality of professional practice and care of patients, the 1996 Community Pharmacy Contract ("the 1996 Pharmacy Contract"),[44] negotiated between the Department of Health and the Irish Pharmaceutical Union ("IPU") did. This was a quid pro quo for the introduction of the 1996 Pharmacy Regulations (Purcell, 2004, p.45). The 1996 Pharmacy Contract is currently extant, although a new contract is in the process of being negotiated.

Clause 9 of the 1996 Pharmacy Contract states that contractors – pharmacists – are to review a patient's drug regimen, including the examination of the rational and cost effective use of medicines.[45] Furthermore, the pharmacist shall offer to discuss with the patient "all such matters as the pharmacist, in the exercise of his/her professional judgment, deems significant …." The Pharmacy Review Group (2003, p. 12) stated that, "Clause 9 provides an emphasis on professional knowledge and expertise, with its direct effect on patient care and its reliance on proper and appropriate communication between pharmacist and patient."

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[43] These results on how pharmacist's allocated their time is difficult to square with the finding by Indecon (2002, Table 9.3, p. 89) that 79% of contract pharmacists and 46% of employee pharmacists thought that quality of service had improved between 1995 and 2001. Quality was not defined and Indecon did not report the results of any additional follow-up questions on the issue. While contract pharmacists have an obvious incentive to bias their responses upwards this is less so for employee pharmacists and hence their views may be more accurate. However, in the absence of any definition of quality of service the results are somewhat ambiguous.

[44] The 1996 Pharmacy Contract is reproduced as Appendix 2 of the report of the Pharmacy Review Group (2003). The Irish Pharmaceutical Union is the professional body representing pharmacists. For details see: www.ipu.ie. Accessed 6 November 2009.

[45] Pharmacy Review Group (2003, p. 12) provides a summary.

A number of points can be made concerning the 1996 Pharmacy Contract with respect to Clause 9. *First*, Clause 9 is largely unenforceable, it is aspirational. The Department of Health would appear to have no method of measuring and/or monitoring to ensure compliance which could have been employed by the health boards that were charged with administering the 1996 Pharmacy Contract.[46]

Second, in assessing whether or not a pharmacist is likely to comply with Clause 9, attention needs to be paid to the compatibility between the objects of Clause 9 and pharmacist's economic incentives. The pharmacist is not only a provider of health services but also a small business person interested in maximizing profits. Thus if Clause 9 results in professional practice at variance with the pharmacist's economic interest, it is not clear such practice will be followed. Under Clause 9 pharmacists, for example, agreed to review a patient's drug regimen, including an examination of the rational and cost effective use of medicines. However, if such an examination were to lead to recommending lower priced generic brands or lower priced but equally effective drugs, then this would directly conflict with the economic incentives of the pharmacist since returns are linked to percentage mark-ups.[47] At the same time patient safety is not compromised if the higher priced brand/drug is dispensed.[48]

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[46] There was, for example, no benchmarking of key indicators of professional practice and care. One indicator might have been the incidence of non-compliance with supplying medicines in excess of maximum legal quantities. According to an RGDATA survey conducted in 2001, only 2% of pharmacists surveyed refused to sell a researcher an amount of paracetamol in excess of the legal maximum, while of those that sold paracetamol in excess of the legal maximum only 14% gave any advice to the customer on taking the paracetamol (Competition Authority, 2001, p. 16).

[47] For the GMS prescriptions the pharmacists was paid a flat dispensing fee, while for the Drug Payment Scheme, the second most important community drug programme, the pharmacist receives not only a flat dispensing fee but also a 50% mark-up on the gross wholesale cost (Purcell, 2004, Table 5.2, p. 69). However, for all prescriptions pharmacists received a 7-8% wholesale rebate thus favouring the dispensing of the higher priced brands/drugs (Brennan Report, 2003, pp. 80-81; Indecon (2007, p. 25). Recently the wholesale margin has been reduced (Department of Health, 2009a).

[48] While this incentive incompatibility no doubt contributes to the fact that Ireland has the lowest generic penetration across 16 EU Member States, with generic market shares of 13 per cent by value and 35 per cent by volume (European Commission, 2009, p. 62), there are other more important factors. These include the fact that a pharmacist cannot select a different brand from that prescribed by the physician except with the latter's permission and that there is no onus on physicians to prescribe lower priced brands.

Third, if Clause 9 is to have any meaning then it implies that it will result in professional services being supplied that would not normally be supplied by the pharmacist or else the Clause 9 serves little purpose. Although there appears to be no evidence on what professional services were supplied prior to Clause 9, many of the duties required of the pharmacist in Clause 9 appear to have been no more than what would be expected of a pharmacist in the performance of their professional duties, judging by the Pharmaceutical Society of Ireland's *Code of Conduct for Pharmacists*, which seems to embody much of what is in Clause 9 (PSI, 2009a).

4. Conclusions: Lessons for the Future

Lessons from the experience of the 1996 Pharmacy Regulations and the 1996 Pharmacy Contract can be drawn in two respects; first, the efficacy of economic regulations designed to limit entry so as to improve quality; and second, improving service quality through contractual specification. In each case government is trying to improve the welfare of consumers through better regulation and public procurement. There are a number of lessons that can be drawn from the Irish experience:

Lesson #1: Avoid Regulatory Capture **-** government intervention should promote consumer welfare and be consistent with the better regulation agenda.[49]

Lesson #2: A Valid Rationale **-** regulatory intervention requires a valid rationale such as market power, externalities or information asymmetries that is consistent with the facts.

Lesson #3: Contracts Should be S.M.A.R.T. **-** a contract between a purchaser, such as the health board, and provider, such as a pharmacy, should be well specified. They should be SMART: Specific; Measurable; Attainable; Realistic; and Timely.

[49] The better regulation agenda commenced following an OECD review of regulation in Ireland (OECD, 2001). For details see: http://www.betterregulation.ie/eng/. Accessed 4 November 2009. There is some evidence that in Ireland this lesson has been learned with efforts to remove the rents that government intervention bestowed on pharmacies. See, for example, Dorgan et al (2008), Department of Health (2009b), and HSE (2008a, 2008b).

Lesson #4: Incentives Count, So Don't Ignore Them **-** regulatory regimes or contracts for services should ensure that these are incentive compatible with the motivation of the provider.[50]

Lesson #5: Markets Do Work: Working with Rather than Against the Market **–** new entrants typically supply new ideas, new ways of doing things, with the result that productivity and innovation increase.[51] Competitive markets are able to provide improved service in terms of prices and other non-price aspects that are valued by consumers such as opening hours, home delivery and so on. [52]

It could, of course, be objected that the lessons from the Irish experience are likely to be of limited relevance. However, this is a mistaken view. *First*, the issues surrounding the 1996 Pharmacy Regulations and Clause 9 of the 1996 Pharmacy Contract are as relevant today as they were over a decade ago. The Pharmaceutical Society of Ireland, for example, has recently called for, "[R]estrictions on new pharmacy openings should be considered and a methodology that optimizes fair access for patients and ensures that pharmacies are located where need is identified, should be developed" (PSI, 2009b, p. 2). *Second*, it is important in the aftermath of the financial crisis which resulted in many calling for more restrictive regulation to ensure that the failure of regulation in one, albeit very important market, is not used an excuse to reintroduce inappropriate restrictive regulation in another completely unrelated market. *Third*, other EU Member States have restrictions on pharmacies similar to those analyzed for Ireland (Pharmacy Review Group, 2003, pp. 9-10; OFT, 2003, Table 3, p. 23). In some instances, such as the UK, these restrictions have been a relaxed with

[50] There are a number of ways that the incentives of the pharmacist could be better aligned in terms of dispensing lower priced brands such as a flat dispensing fee and associated measures, some of which were recommended previously by the Brennan Report (2003, p. 84).

[51] On the issue of entry in general see Kay (2009b); on how entrants are more productive that the firms they replace see Baldwin and Gorecki (1991).

[52] Kay (2009a) draws this distinction in regulating safety in airlines, arguing that safety should be regulated and that service provision should be left to market forces. Efforts to control the market in order to ensure quality were a failure.

positive results for consumers (OFT, 2010). Thus it seems the results of this paper are likely to have a wider applicability.

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