

COMPETITION AND REGULATION  
IN THE RETAIL PHARMACY MARKET

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# COMPETITION AND REGULATION IN THE RETAIL PHARMACY MARKET

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# Contents

LIST OF FIGURES AND TABLES	ix
ABBREVIATIONS	x
EXECUTIVE SUMMARY	xi
1 PHARMACY AND REGULATION	1
1.1 Introduction	
1.1.1 Pharmacy – an unusual market?	
1.2 Healthcare/competition/expenditure debates	
1.2.1 Rationale for government intervention	
1.3 Why regulate?	
1.4 A heavily regulated market: global overview	
1.4.1 Price regulation and the role of health insurance	
1.4.2 Non-price regulation	
1.5 Some <i>caveats</i>	
1.6 Outline of paper	
2 RETAIL PHARMACY SECTOR	15
2.1 Profile of the Irish retail pharmacy sector	
2.1.1 Global retail pharmacy sector	
2.2 Irish pharmaceutical distribution sector	
2.3 Operation of the Irish retail pharmacy market	
2.3.1 Nature of demand and supply	
2.4 Value of pharmacy businesses	
2.4.1 Product sales	
2.4.2 Profit margins	
2.5 Conclusions	

3	REGULATORY ENVIRONMENT IN IRELAND	30
	3.1 Regulatory actors	
	3.2 Overview of legislation affecting the sector	
	3.2.1 Pursuit of the pharmacy profession	
	3.2.2 Control and supply of medicines	
	3.3 Regulatory reform in the pharmacy sector	
	3.4 Conclusion	
4	REGULATION OF ACCESS TO THE PROFESSION	37
	4.1 Introduction	
	4.1.1 Access to the pharmacy profession	
	4.1.2 Pre-education registration and post-education training	
	4.1.3 Restrictions on overseas-trained graduates	
	4.2 Regulation of establishment of retail pharmacy businesses	
	4.2.2 Rationale for the 1996 Regulations	
	4.2.3 Reform of the Regulations	
	4.2.4 Legal challenge one: the McSweeney Group	
	4.2.5 Legal challenge two: Dame Street Pharmacy	
	4.2.6 Result of revocation	
	4.3 Regulation of ownership	
	4.3.1 Proposed restrictions on pharmacy ownership	
	4.3.2 GEHE/Unicare merger	
	4.3.3 International ownership restrictions	
	4.4 Relative importance of barriers to entry	
	4.5 Conclusion	
5	REGULATION OF PRICES	57
	5.1 Introduction	
	5.2 Upstream price-setting agreements	
	5.2.1 Price-setting systems	
	5.2.2 Profit control systems	

5.2.3	Difficulties with international comparisons	
5.2.4	Reforming government price regulation in Ireland	
5.2.5	Price regulation in Europe	
5.2.6	Euro-Med-Stat project	
5.3	State payments to pharmacies	
5.3.1	Overall reimbursement arrangements	
5.3.2	Retail margins	
5.4	International regulation of drug prices	
5.5	Breakdown of retail price	
5.6	Analysis of price issues in Ireland	
5.6.1	Guaranteed retail margin	
5.6.2	Cross-subsidisation effect	
5.6.3	Review of Community Drug Schemes	
5.6.4	What scope exists for retail price competition?	
5.7	Conclusions	
6	REGULATION OF SUPPLY	83
6.1	Regulation of supply in Ireland	
6.2	Regulation of supply internationally	
6.3	Prescription versus non-prescription status	
6.4	Regulation of supply: conclusions	
6.5	Internet sales	
7	CONCLUSIONS	91
7.1	Market failure	
7.2	Current competition	
7.3	Regulatory reform	
7.4	Overall conclusions	

8	RECOMMENDATIONS	96
	8.1 Recommendations	
	8.1.1 Statutory framework	
	8.1.2 Controls on entry	
	8.1.3 Drug prices	
	8.1.4 Controls on supply	
	APPENDIX A Applicable legislation	103
	BIBLIOGRAPHY	106



## List of figures and tables

Table 2.1	Pharmacy numbers and density	17
Figure 2.1	Sales per pharmacy (€m) 2000	18
Table 2.2	Share of retail pharmacies in chains, 2001	19
Figure 2.2	USA – retail outlets by type	20
Figure 2.3	USA – pharmacy sales by type of retail outlet	20
Table 2.3	Percentage change in value, volume and prices, 1996 – 2001	26
Figure 2.4	Retail pharmacy sales in Ireland	26
Figure 2.5	Expenditure per person on pharmaceuticals	27
Table 2.4	Profit margins in a typical retail pharmacy outlet	28
Table 4.1	Pharmacy contracts per health board area	50
Table 4.2	Summary of non-price pharmacy regulation in EU and other selected countries	53
Figure 5.1	Relative price trends for pharmaceuticals	62
Table 5.1	Bilateral comparisons of ex-manufacturer prices	62
Figure 5.2	Ex-manufacturer price ratios for all categories, list prices	63
Table 5.2	Breakdown of retail pharmacy charges	69
Box 1	Example	70
Table 5.3	Pharmacy retail margin (%)	71
Table 5.4	Share of final retail drug price (%)	73
Figure 5.3	Price structure – breakdown of the retail price of medicine, 2002 (%)	74
Figure 6.1	Non-prescription medicine sales as % of total pharmaceutical market 2001	84

## Abbreviations

AESGP	Association of the European Self-Medication Industry
CTS	Cosmetics, Toiletries and Sundries
DPS	Drug Payment Scheme
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
GMS	General Medical Services
G10	EU-linked High Level Group on Innovation and Provision of Medicines
HTD	High Tech Drugs Scheme
IMB	Irish Medicines Board
IPHA	Irish Pharmaceutical Healthcare Association
IPOS	Independent Pharmacy Ownership Schemes
LTI	Long Term Illness Scheme
NHS	National Health Service (UK)
OECD	Organisation for Economic Co-operation and Development
OTC	Over the counter medicines
PSI	Pharmaceutical Society of Ireland
RCSI	Royal College of Surgeons in Ireland
TCD	Trinity College Dublin
UCC	University College Cork
VAT	Value Added Tax

## Executive summary

Described in the eighteenth century as the ‘art and mystery of the apothecary’, retail pharmacy is, at the start of the twenty-first century, a billion-euro business. Many of today’s retail emporia would be unrecognisable to the apothecary, with his show globe, compounding dish and bank of wooden drawers. Unfortunately, the antiquated state of current regulation of the sector befits the era of the apothecary – the legislation governing the practice of pharmacy in Ireland at this time is still the Pharmacy Act of 1875.

Much time and energy has been expended trying to explain how the pharmacy business works. This paper is written from a competition perspective, and sets out to get behind the familiar white coat and the medical chemistry, to describe how the retail pharmacy market operates, how it is regulated and the returns to be made from it. Some limitations to the scope of the paper must be noted, particularly regarding (a) the role of parallel trade in medicines, and (b) the trade-off between pharmaceutical price regulation and industry R&D and innovation. It did not prove possible to cover these issues within this paper. There are also well-recognised difficulties in making valid international price comparisons.

The paper draws together data on the operation of the sector in Ireland and the regulatory environment in which it operates – in particular, the way in which that environment shields incumbents from normal competitive forces, facilitating high returns. An increased emphasis on competition and regulatory reform has highlighted the unnecessarily restrictive nature of many of these controls. The paper also presents a new and comprehensive comparison with regulatory environments in other countries showing that the same forces, both market and non-market, also operate elsewhere. Regulation levels are even heavier (in some cases much more so) in many other countries – for example, there are substantial controls on pharmacy ownership in many countries. Nonetheless, heavily regulated environments elsewhere still manage to produce medicine price levels that are, in general, significantly lower than in Ireland. The three defining characteristics of the market worldwide are:

- a) the existence of public or private health insurance cover – this means that consumers' normal price incentives do not generally apply and, therefore, the normal drivers of price competition do not operate
- b) the escalating costs of healthcare prompts governments to intervene with price or profit controls at various levels of the medicine distribution chain
- c) a myriad of non-price regulatory interventions such as controls on medicine supply and sale, as well as severe barriers to entry (chiefly by way of controls on ownership, establishment and location of outlets).

The retail pharmacy sector in Ireland, unlike the wholesale sector, is relatively unconcentrated – for example, the biggest chain in Ireland owns only 4 per cent of all outlets. The value of the market is around 1.2bn euro per annum. Pharmacies are considerably more valuable assets than other forms of retail outlet, reflecting the restrictive regulatory environment in which they operate, and the ensuing high returns to be made by incumbents. Under a long-standing agreement, the Department of Health and Children and drug manufacturers/importers set the maximum wholesale prices of the vast bulk of prescription medicines in Ireland. Retail pharmacies charge a 50 per cent mark-up on medicines supplied to most consumers; this practice has existed for approximately one hundred years, and does not appear ever to have been explicitly agreed, altered or challenged. The effect is that Irish pharmacies benefit from the highest overall retail margin (on average, 33 per cent) on medicines in Europe.

The two most important barriers to entry are the chronic under provision of pharmacy degree course places over the past quarter century, largely as a result of the monopoly on pharmacy education granted during the mid-1970s to Trinity College Dublin (which effectively prevented any other colleges from offering pharmacy training to degree level) – this monopoly was finally revoked in 2002. A second key barrier to entry is the statutory restriction on overseas-trained graduates (including Irish students) that effectively prevents them from ever opening a 'new' pharmacy outlet. The most controversial restrictions affecting the establishment of businesses, introduced in 1996 to control the number and location of outlets, were revoked in 2002 following legal challenges. Although there are no specific controls on

ownership of pharmacy outlets in Ireland, the report of the government-sponsored Pharmacy Review Group (2003) has recommended that such controls be introduced. However, it would seem that legal doubts might prevent the implementation of that recommendation.

There are substantial (and mostly justifiable) restrictions on medicine supply and sale, notably defining those medicines that may only be supplied within a pharmacy with a doctor's prescription. There are also almost complete bans on medicine advertising and public promotion (although promotions to doctors are largely unregulated). Finally, there is a complete ban on medicine sales by mail order or via the Internet – although this must now be modified following the European Court of Justice's 2003 judgement in the *Doc Morris* case.

The paper concludes with a number of recommendations aimed at providing improved access to the pharmacy profession, a reformed approach to price transparency and regulation, as well as liberalisation of the regime applicable to the supply and sale of medicines. The main recommendations include the following.

- 1) A new Pharmacy Act is needed, as a matter of urgency, to provide an appropriate and modern statutory and regulatory framework for the pharmacy sector, and to replace the current Victorian-era legislation. This would provide a proper statutory basis for the Pharmaceutical Society of Ireland, with appropriate oversight and accountability arrangements, modern governance rules (including provision for significant lay representation on its governing council and other boards), enforceable fitness-to-practice provisions and an enforceable code of ethics.
- 2) The 'three-year rule' effectively prohibiting overseas-trained pharmacists from opening their own pharmacy in Ireland should be removed by the Minister for Health and Children with immediate effect. This should be followed by an expansion in the number of available university pharmacy degree places, to facilitate greater entry to the pharmacy profession.
- 3) Publication (by the Minister for Health and Children or one of the bodies under her aegis) of a range of price data relating to prescription medicines in Ireland.

International comparative price data relating to prescription medicines at various levels of the distribution chain should also be published. This would facilitate greater transparency and public debate on the price levels involved.

- 4) The current list of five EU countries against which Irish wholesale prescription medicine prices are benchmarked should be altered or expanded, to better reflect a more realistic set of comparators.
- 5) As recommended by the Brennan Commission, the 50 per cent mark-up paid to pharmacists under the Drug Payment and Long Term Illness schemes should be abolished, and replaced by the same reimbursement arrangement as applies to prescriptions dispensed to medical card-holders, namely a flat-rate professional dispensing fee per item.

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The views expressed in this paper are my own (as indeed are any errors) and do not necessarily reflect those of The Policy Institute or The Competition Authority.





# Pharmacy and regulation

## 1.1 Introduction

The twin issues of regulation and competition have sprung to prominence as a policy issue in recent years in Ireland as witnessed by the establishment of several regulatory agencies, the creation of The Competition Authority and increased public discourse on the role that such policies and agencies play in market-based economies. This debate is particularly intense within the healthcare market. This paper seeks to contribute to this ongoing debate and discussion by focusing on a particular sector within the healthcare market, namely retail pharmacy.

The paper establishes the extent of regulation in the retail pharmacy market in Ireland, considers how Ireland stands in terms of international regulatory comparison, whether, and to what extent, there is scope for more competition in this market, what actions might be necessary to achieve this and how these can be reconciled with the public interest objective of safeguarding and promoting consumer health.<sup>1</sup>

Regulation of this sector is a somewhat controversial issue. It is frequently argued that the health sector is unique and hence it is inappropriate to attempt to apply typical competition policy concepts to it, particularly as regards the supply of professional services. A typically cited rationale for protecting health professionals from competition is that consumers of services often have imperfect information regarding their own needs. Yet this is not unique – many markets and sectors within an economy are characterised by such imperfect information. However, the key goal

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<sup>1</sup> The term ‘regulation’ describes the diverse set of instruments that governments use to regulate the economic and social activities of citizens and organisations. Instruments include Acts of the Oireachtas, statutory instruments, orders, licences, administrative practices and local authority rules. Regulation of economic activity can deliver benefits when it is proportionate and is specifically designed to address market power or some other recognised failures of the market system to produce optimal outcomes for society.

in such markets is to correct for the imperfect information through the *minimum* level of regulation necessary to protect consumers and suppliers of the service. Undoubtedly, the fact that consumers' health is involved (in addition to their financial and/or other interests) does raise special concerns about the quality of service supplied, and who may supply it. While emphasis should certainly be placed on ensuring quality and safety, this can, and should, be done in a way that does not facilitate, or condone, anti-competitive behaviour. Otherwise regulation is self-defeating as the costs to consumers from a lack of competition exceed the benefits achieved by regulation (Competition Authority, 2001).

Recent years have witnessed growing concern on the part of governments worldwide with the retail end of the market for pharmaceuticals, as evidenced by the completion of regulatory reviews in a number of countries including Australia, Norway, Denmark, New Zealand, Germany and the UK, as well as Ireland, and the Organisation for Economic Co-operation and Development's (OECD) Roundtable on *Competition and Regulation Issues in the Pharmaceutical Industry* (2000) in which retail pharmacy featured prominently (OECD, 2001a). The US Federal Trade Commission has also revived its interest, not just in antitrust enforcement, but also in renewed competition advocacy efforts (Levy, 1999).<sup>2</sup>

In general, however, research on the market for pharmaceuticals has been more concerned with cost-containment imperatives and price regulation than with the actual operation of the market, particularly downstream, or indeed with the extent to which regulation is, in fact, necessary or proportionate at the retail level. This paper attempts to redress this imbalance by considering competition and regulatory issues downstream, i.e. at retail level, within the Irish market.

### 1.1.1 Pharmacy – an unusual market?

The retail (or 'community') pharmacy sector is an integral part of the health care system of most developed countries. It is the main

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<sup>2</sup> In 2003, the US Federal Trade Commission and the US Department of Justice held a comprehensive seven-month series of joint public hearings on healthcare issues, including pharmaceutical regulation, at: <http://www.ftc.gov/ogc/healthcarehearings/index.htm>, accessed 3 August 2003, 23 September 2004. This resulted in the publication of a major report *Improving Health Care: a dose of competition* available at: <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> [http://www.usdoj.gov/atr/public/health\\_care/204694.html](http://www.usdoj.gov/atr/public/health_care/204694.html)

distribution network for a wide range of medicines and health care products. Many pharmacies also offer numerous non-pharmacy lines, e.g. cosmetics, photographic services – some larger ones, indeed, now closely resemble niche, and sometimes even general, retailers. Retail pharmacists also provide advice to consumers on the safe and effective use of medicines and on other health care issues.

Retail pharmacists themselves are not always in agreement as to what their real role is. The chief executive of one Irish-owned pharmacy chain says:

Pharmacy is essentially a retail business, and pharmacies are much further behind the other retailers. They are now waking up to the reality of retailing and competing with the pharmacy and retail multiples.<sup>3</sup>

while, according to another:

We are not retailers. We are absolutely not retailers. We are healthcare professionals who have a retailing element to our business.<sup>4</sup>

Retail pharmacies are somewhat unusual enterprises, insofar as they combine professional and retail service functions within the same premises. The Australian National Competition Policy Review of Pharmacy (2000) concluded that, unlike most other professional groups, retail pharmacists do not have a private professional-client relationship based on a fee for service. Instead, the client may simply walk off the street and seek 'free' advice without an appointment. Rather than charge for this advice directly, the pharmacist derives his/her income from the medicines dispensed (including related dispensing fees and product mark-up) and from the other products sold in the pharmacy. The role of the prescriber, the clinical needs of the patient and the responsibility of government to fund the cost of medicines, as well as the operation of price regulation, are key factors in the operation of the market.

Competition principles might be expected to apply with greater force to the delivery of retail pharmacy services than to other professional services, given their direct retail nature. In fact, the opposite is the case, and retail pharmacy turns out, on examination,

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<sup>3</sup> 'Chemically imbalanced', 15 June 2003.

<sup>4</sup> 'Keeping drugs in the family: Firm thrives in the second generation', *Sunday Tribune*, 22 August 2004.

to be one of the most regulated professional services markets in most countries.

## **1.2 Healthcare/competition/expenditure debates**

It is unsurprising that the lively debates occurring in Ireland since the late 1990s in relation to the regulatory environment as it concerns the retail pharmacy sector echo those occurring globally. Many similar positions are adopted, regardless of where the debate is occurring, and there is constant tension and debate between professional, industry and healthcare interests on the one hand, and advocates of competition on the other, with concerned healthcare funders (for example, government) generally finding themselves caught in the middle.

What are these 'similar positions'? Firstly, the pharmacy profession contends that the pharmacy sector – and healthcare generally – is unique and that normal market forces do not, or should not, apply. The notion is rejected that a retail pharmacy business is just that, i.e. a business. Secondly, proponents of market forces argue that the rationale for government intervention in the economic regulation of a sector (involving issues of restrictions on entry, pricing and service), including by direct regulation, must be based on addressing market failure. They argue that pleas that particular economic sectors are 'not suitable for competition' amount to no more than rent-seeking on behalf of an economic interest group, and that many of the restrictions to which the profession/business is subject are totally disproportionate to the health needs of consumers. Thirdly, health funders and insurers note ever-increasing public health expenditure, and see price and other regulation as the ultimate answer to a key problem, namely the lack of incentive for consumers to 'shop around'.

### *1.2.1 Rationale for government intervention*

The principal rationale for many of the regulatory instruments enacted in Ireland to-date of relevance to the retail pharmacy sector is the protection of public health and patients. What is less clear is whether many of these interventions also had the underlying rationale – or at least the effect – of protecting service providers. For example, the underlying rationale for controls on the supply of medicines and restrictions and prohibitions on medicine

advertising – that of protecting public health – is clear and undeniable. What is less clear is how absolute, rigid and all embracing that control needs to be, particularly in relation to medicines that arguably could be made available without prescription and – within that subset – those that ought to be more freely available in non-pharmacy outlets. In relation to controls on price levels, entry to the profession and pursuit of pharmacy, it is even less clear that expressed health-related objectives withstand close scrutiny. In particular, there is no evidence that quantitative controls on entry to the profession are necessary to protect public health. Arguably, the effect of such controls is predominantly to protect and shelter incumbents from competition and actually reduce the availability of services to consumers. Moreover, while the rationale for price controls in this sector is well documented internationally, this paper contends that these can, and should, be eased to allow as much competition as possible without prejudicing patients' health.

This paper argues that the rationale for government intervention, whether by direct regulation or by market-based methods, must be based on addressing market failure or market power. Regulation is often used to deal with the effects of market power, but inappropriate regulation can in itself create market power (Competition Authority, 2002b). 'Good regulating' requires an understanding not only of the particular sector or market involved, but also of the purposes of the regulation. In particular, it requires an assessment and incorporation of the various interests involved, including those of consumers.<sup>5</sup> Building on this, the following could be posited as basic principles in the making of new regulations and, importantly, in the review of existing ones:

- a) economic regulation should be based on a clearly identified market failure
- b) restrictions on competition should be strictly proportionate to an explicit objective
- c) a consumer welfare standard should be adopted in considering whether regulation is appropriate or whether other alternatives would be more suitable.

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<sup>5</sup> This may seem an obvious point, but the danger of 'regulatory capture' whereby those regulating a sector come to represent the industry's rather than consumers' point of view, is well recognised.

This paper uses these principles as a framework to guide its consideration and analysis of the operation and regulation of the Irish retail pharmacy market.

### 1.3 Why regulate?

Regulation emerges for a number of reasons. For example, governments may intervene in markets to pursue objectives such as fairness and equity, macroeconomic stabilisation, the promotion of culture, the maintenance of national security, as well as for reasons connected with environmental, health and safety standards and consumer protection. The set of instruments open to government includes fiscal and monetary policy, primary and secondary legislation and specially appointed regulators and agencies.

In the specific domain of economic regulation (i.e. restrictions on entry, pricing and service), which is this paper's primary concern, the rationale for government intervention should be based on addressing market failure. Market failure can arise *inter alia* for the following reasons:

- information failure, especially asymmetric information
- externalities in consumption or production
- market power (an issue of particular interest from a competition policy perspective).

#### *Information failure*

When buyers and sellers in a market do not have the same information (i.e. there is 'asymmetric information'), the competitive market may fail to produce the socially optimal outcome. In these circumstances, regulation can lead to better outcomes for consumers. For example, legislation that requires the disclosure of prices and quality can protect consumers, as they are likely to have less information about goods than producers. In the case of pharmacy, an example of the use of regulation to rectify market failure would be the obligation to inform consumers of potential side effects arising from the use of particular medicines.

#### *Externalities*

The consumption or production of some goods or services may have a positive or negative spillover effect for third parties. For instance, healthy people not only protect themselves from disease, but also

confer a benefit on other members of society as they help to slow the spread of contagious diseases within society. A pure market-based system, which only captures private benefits, will lead to an under-provision of goods that have external benefits. To overcome this tendency, there may be direct public provision of basic health care. A further example would be the limited protection which may be given to innovators through patent protection, copyright, and other forms of intellectual property legislation.

### *Market power*

Market power is the ability of firms to raise prices above the competitive level and generally leads to reduced output, quality and variety. This involves both a transfer from consumers to producers and an efficiency loss to society as a whole through losses in consumption and production, for which no one is compensated. In addition, firms with market power have less incentive to innovate either in their production methods or in the goods and services they sell. Firms can seek to enhance or protect their market power through collusion, the pursuit of mergers that may result in a lessening of competition, or abuse of a dominant position. Irish competition law, which was strengthened by the enactment of the Competition Act, 2002, is designed to address some of these issues. However, market power can also be created or strengthened by regulation which is either inappropriate *ab initio* or which has become so with the passage of time.

A key element in any discussion of market power is the issue of *inappropriate regulation*, which can lead to substantial costs and inefficiencies. There are five key ways in which regulation can negatively affect a sector (OECD: 1997).

- firms may have less incentive to economise on resources
- lack of competition can result in excess 'rents' (i.e. income in excess of what would accrue in a competitive market, implying that prices in the sector are too high)
- regulations on service and product type can prevent firms from taking advantage of economies of scale and, especially, scope in networking
- regulations can impose high administrative costs on governments, firms and consumers
- there may be less incentive for firms enjoying significant market power to pursue technological innovations in

production or to create or adapt goods and services in response to changing customer needs.

The first and last of these are directly related to market power. To the extent that regulations create market power, they necessarily lower efficiency and may be linked to reduced incentives to innovate. In addition, such regulation can create rents, hinder firms from gaining the advantages of economies of scale and scope and can lead to disproportionate administrative burdens (*ibid*).

### *Rents*

'Rents' arise from a lack of competition, in many cases due to regulations restricting the number of players in a market. The possibility of rents creates an incentive to lobby and work to retain (or even extend) them. These activities are normally referred to as rent-seeking and the rents thus created are often considerable and disruptive of the regulatory process.

## **1.4 A heavily regulated market: global overview**

A considerable array of government regulations applies to the sector worldwide. Taken collectively, they comprise a wide-ranging and formidable series of statutory and non-statutory barriers to entry, restrictions on conduct and ownership, and special government-approved price control regimes.

The most common regulatory features of the market for pharmaceuticals worldwide are the following.

- a) Restrictions on entry:
  - Restrictions on access to the pharmacy profession, often expressed through licensing or registration requirements for pharmacists.
  - A series of non-price restrictions, replicated with minor variations from one country to another. These include restrictions on ownership, establishment, location and sale of pharmacies.
- b) Cost-containment mechanisms by governments or other insurers that reimburse the price of drugs: the most common of these are centrally set (or agreed) price levels applicable to various stages of the distribution chain, for example ex-manufacturer prices, set wholesale margins, set retail pharmacy margins.



- c) Controls on the supply of medicines: the principal restriction of relevance to this paper is the extent to which medicines are restricted to prescription-only status, as opposed to being available over-the-counter either in pharmacies only or more widely (for example, in supermarkets or via the Internet).

Restrictive measures in Ireland encompass both price and non-price regulation. Price regulation includes a government-industry agreement, which fixes, *inter alia*, set industry margins for most drugs. Non-price regulation includes significant under-provision of college training places, a statutory ban on overseas-trained graduates from opening their own outlet in Ireland and restrictions (until very recently) on new openings based on location, viability and effect on competitors.<sup>6</sup>

#### *1.4.1 Price regulation and the role of health insurance*

The demand for prescription drugs is fundamentally influenced by the presence of health insurance (whether public or private), which often pays for all or part of the costs of such drugs (OECD, 2001a). Final consumers generally lack the knowledge to participate actively in the market and decisions to consume (and what, when and how much to consume) are largely taken for them by their agents, in most cases their doctors or pharmacists (Centre for Strategic Economic Studies, 1999).

It is widely argued that consumers are insensitive to changes in prescription drug prices – that consumer demand is inelastic – and several underlying explanations for this have been suggested (Levy, 1999). First, doctors may lack complete information about drug alternatives and otherwise fail to take due account of the cost of prescription drugs. Second, the fact that a third party (an insurer or the State) pays much of the cost inhibits a consumer's incentive to substitute among drug alternatives. Third, private consumers may be willing to pay significant amounts for the treatment of diseases,

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<sup>6</sup> Further restrictions are now contemplated, *viz.* a cap of 8 per cent on the number of outlets owned by a single entity in any one health board area; however, it would seem that legal doubts might prevent their implementation (see Chapter 4 for further detail). While the removal of the current restriction on overseas-trained graduates is also now proposed, this will not occur until primary pharmacy legislation is overhauled.

particularly acute diseases and, as a result, may not be significantly influenced by differences in prescription drug prices. Since insured consumers do not face the full cost, their incentives to curtail their demand are weakened (OECD, 2001a). As a result, health insurers adopt a host of mechanisms to control the quantity and quality of drug expenditures. These mechanisms include the use of co-payments<sup>7</sup>, formularies<sup>8</sup>, and controls on the prices paid for drugs, on pharmacists and on prescribing doctors.

The majority (27 of 29) of OECD countries operate some form of co-payment arrangement (OECD, 2001a, Table A.3.). There is, however, a wide variation between countries with regard to the extent to which such costs are met by individuals directly or through the public purse. In most European countries, the public sector meets over 60 per cent of these costs (and in some cases over 80 per cent) while in the USA only about 15 per cent is met publicly (Centre for Strategic Economic Studies, 1999:6).

#### *Price control*

Most European countries have national health insurance systems, and it is these systems that bear the financial burden of prescriptions most heavily and directly (US General Accounting Office, 1994). The extent of governments' involvement as effective paymasters for much of a nation's drugs' bill means that most countries have in place a system of price controls in relation to prescription drugs or, in some cases, profit controls at upstream industry level and, in yet others, controls over margins throughout the distribution chain. Again, a majority (21 of 29) of OECD countries surveyed in 2000 (including Ireland) have had price controls in place for many years (OECD 2001a, Table A.7). These controls can be either statutorily based, or, as in Ireland, by government-industry agreement. A further six OECD countries (including the UK) place heavier emphasis on the control of upstream industry profits (ibid, Table A.8). In addition to setting price levels upstream, pharmacy *retail* margins are also set or fixed centrally in several countries, although the extent of regulation varies. In Ireland, there are approved prices (or more accurately,

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<sup>7</sup> Co-payments involve the consumer paying some pre-determined component of the final price.

<sup>8</sup> A formulary is a defined list of medications that have been selected for their medical effectiveness, positive results and value.

fixed reimbursement rates) at retail level for most prescription drug transactions, although the amounts vary depending on whether, and to what extent, a level of co-payment applies to the customer concerned.

#### 1.4.2 *Non-price regulation*

Non-price regulation can assume a number of forms including the following.

**(i) Ownership restrictions:** Many countries impose ownership restrictions on retail outlets, for example through the requirement that pharmacies are owned by pharmacist(s), or by preventing a pharmacist from owning more than one pharmacy, or by preventing combinations of pharmacies with other businesses. Ireland and the UK are currently among the exceptions to these restrictions (however, Chapter 3 describes the significant level of regulation to which the Irish retail pharmacy sector is subject). A 1985 European Union (EU) Directive on *Mutual Recognition of Pharmacy Qualifications* contained a derogation enabling Member States to refuse to allow a person trained outside the Member State to own a pharmacy that is less than three years old (the so-called ‘three-year rule’) – this effectively prevents the pharmacist from ever opening a ‘new’ pharmacy. Seven EU countries including Ireland currently avail of this derogation.<sup>9</sup>

**(ii) Location restrictions:** Several EU countries (e.g. UK, France, Spain, Denmark, Portugal) have location restrictions limiting the number of pharmacies based on population size and requirements as to the minimum distances between pharmacies (Office of Fair Trading, 2003: Annex C; OECD 1999; Institut für Höhere Studien, 2003; National Competition Policy Review, 2000). Such restrictions did formerly apply in Ireland, but were revoked in January 2002 following a High Court challenge to their legal validity.

**(iii) Drug supply restrictions:** The sale and supply of drugs and medicines is very heavily regulated worldwide and Ireland is no exception to this practice. However, there is ongoing debate on issues such as whether particular medicines should be prescription-only or

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<sup>9</sup> References throughout this paper to the EU are to the EU 15 (as of April 2004) and do not include the 10 Accession States which joined the EU in May 2004.

available more freely, to what extent (if any) doctors are influenced in their prescribing habits by drug companies and how (and to what extent) Internet medicine sales should be permitted.

### 1.5 Some caveats

It is important to clarify the limitations of the analysis in this paper. The paper focuses on competition and regulation in the retail pharmacy market in Ireland, and this necessarily involves looking more closely at issues such as entry to the profession, practice and business of pharmacy, pricing mechanisms for prescription medicines and the retail supply of such medicines. However, the retail end of the medicines market in Ireland represents only a fraction of a major global industry in which a host of forces operate, many of which ultimately impact on the final consumer. It would take a more extensive paper to address these important issues, particularly in terms of their impact on Ireland, and they warrant further treatment. Examples of these issues include:

- The role of *parallel trade*, resulting from widely divergent national pricing systems. Parallel imports are products imported into one Member State from another and placed on the market in the destination Member State, outside the manufacturer's or its licensed distributor's formal channels. Parallel imports tend to occur when price levels for similar products between two Member States are significantly different, either as a result of national regulations or of manufacturers' policy. That creates an incentive for traders to buy products in the Member State where they are priced lower and sell them in the Member State where they are priced higher, at a price that allows the trader to make a profit. National rules or practices that restrict imports of pharmaceutical products or are capable of doing so are only compatible with the EC Treaty to the extent to which they are necessary for the effective protection of health and life of humans. In particular, such measures must be strictly necessary from the health standpoint and obstruct intra-Community trade as little as possible (European Commission, 2004). The distortions caused by different national pricing regulation regimes has been central to a

number of recent legal cases taken concerning parallel trading and re-export bans on local wholesalers (e.g. *GlaxoWellcome*<sup>10</sup>, *Bayer Adalat*<sup>11</sup>).

- *Research and development (R&D) and innovation* (and the exhaustion of patents) as essential components of the pharmaceutical prices agenda. It is clear that there is a significant trade-off involved here. For example, governments feel under pressure to cap drug prices, however they are continually warned that doing so will, in turn, cap both the willingness and ability of pharmaceutical firms to engage in R&D and drug innovation, and in manufacturing more generally. Instead, the argument is that manufacturers would locate their facilities in those countries not perceived as acting in a 'hostile' manner by capping industry prices. That debate has surfaced most notably in recent times in the USA, Germany and Spain, as governments strive to reform their health care systems, particularly by controlling costs.<sup>12</sup>

A further difficulty is presented by well-recognised problems in international price comparisons, not least because of product heterogeneity, national consumption patterns, and selection bias. These difficulties are highlighted in Chapter 5.2.3 and cannot be underestimated.

Each of these issues requires major analysis in its own right. This paper deals with issues of regulation and competition specifically. The issues above are briefly outlined merely to note the extent of the issues involved in addressing regulatory and competition reform in pharmaceutical markets.

## 1.6 Outline of paper

Chapter 2 describes the structure of the market for pharmaceuticals in Ireland and elsewhere, incorporating the various elements of the

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<sup>10</sup> Commission Decision of 8 May 2001, OJ 2001 L302/1, Case T-168/01 OJ 2001 C275/17 (Appeal to the Court of First Instance pending).

<sup>11</sup> *Bayer AG v Commission*, Case T41/96 23 October 2000.

<sup>12</sup> 'Germany reaches deal on health care reforms', *Reuters News*, 21 July 2003. 'Spain: Health Ministry plans - €300 million saving in outlay on prescription drugs', *El Pais*, 19 July 2003.

distribution chain. It outlines how the retail pharmacy market operates, the number of retail outlets, categories of product sold, the value of pharmacy businesses and the nature of demand and supply in the market.

Chapter 3 provides an overview of the regulatory environment for retail pharmacy in Ireland. The various statutory bodies with functions relating to regulation of the retail pharmacy sector are identified and their roles described, as well as those of non-statutory interest groups active in the area. The Chapter also summarises domestic legislative reforms in the sector to date, as well as the broader and continuing efforts by the OECD, The Competition Authority and others to advocate more fundamental reform.

Chapter 4 identifies and describes the key barriers to entry that exist within this sector, both in Ireland and elsewhere. Chapter 5 describes the various pricing (and price control) systems applicable internationally. The respective roles of the government and the pharmaceutical industry in setting prices at all levels of the distribution chain for prescription medicines are also discussed, and tentative international price comparisons are made, both upstream and at retail level. The justification for fixed retail margins is assessed, as well as their apparent cross-subsidisation effect as between different categories of consumers. Chapter 6 compares the regulatory regime controlling the supply of medicines in Ireland with its international counterparts. The question of prescription-only status for medicines is discussed, as is the emerging issue of Internet medicine sales.

The paper concludes in Chapter 7 with a summary of the conclusions reached throughout the paper with regard to the impact of regulation on competition in the market. Chapter 8 proposes a number of recommendations for consideration to improve access to the pharmacy profession. In summary, it argues for a reformed approach to price transparency and regulation, as well as a liberalisation of the regime applicable to the supply and sale of medicines.

## Retail pharmacy sector

### 2.1 Profile of the Irish retail pharmacy sector

It is important at the outset to get a sense of the nature of pharmacy as a retail business, and the nature of supply and demand, before describing in more detail in later chapters the extent of regulatory overlay that applies to it and the impacts and implications of this for regulation and competition. This chapter sketches a picture of the retail pharmacy sector with regard to: the number of retail pharmacies in Ireland; the products these pharmacies can sell and the suppliers of these products; the key factors in the demand and supply of their products; and finally, considers who consumes and who pays for these products. This chapter also contrasts the situation in Ireland with that worldwide.

According to the Pharmacy Review Group, there were over 1,300 retail pharmacies in Ireland at the end of November 2002 (2003: 22). Of these, 1,250 held a community pharmacy contract with the State which, as shown in Section 2.3, is almost essential to their viability. By the end of 2003, the number of pharmacists holding a State contract had risen to 1,292 (General Medical Services (Payments) Board, 2004a: 18).

Retail pharmacies account for the employment of approximately 80 per cent of the pharmacists in Ireland (OECD, 2001b: 297). Retail pharmacies have traditionally been small, independent, single-location operations, but chains of pharmacies are becoming a more prominent feature of the Irish market.

- There are now four chains controlling over 20 pharmacies each, compared to 1998 when only one chain owned over 20 pharmacies.
- Following a takeover transaction in 2002, Unicare is now, at 55 outlets, the largest chain in Ireland, although its share of outlets (at 7 per cent in Dublin and 4 per cent nationally) is small relative to the overall retail pharmacy sector. Across the EU as a whole, chains have an average share of 6.7 per cent of all pharmacy outlets (Dudley, 2002: 2).

- The second and third biggest chains in Ireland are Boots plc (34 outlets) and the Dutch-owned McSweeney Group (26 outlets). Boots has recently announced its intention to open 12 new outlets (*The Irish Times*, 28 May 2004).<sup>13</sup>
- There are five chains – all Irish-owned – which have between 10 and 20 outlets each. The largest of these is the Hickey chain, with 20 outlets, followed by the McCauley and McCabe chains (15 outlets currently). Each of these chains has exhibited rapid growth in numbers.
- At the end of 2002, 27 per cent of pharmacy outlets with State contracts belonged to a chain of two or more outlets (Pharmacy Review Group, 2003: 23).
- The remaining 73 per cent of pharmacies (n = 907) were sole, independent outlets (*ibid*).

The clear conclusion is that the retail pharmacy sector in Ireland is relatively unconcentrated although there is a noticeable trend towards the growth of chains.

#### 2.1.1 Global retail pharmacy sector

Table 2.1 shows the number of pharmacies throughout the EU, together with indications of their relative density. The table shows that Ireland is – certainly as regards the ratio of pharmacies to population – relatively well served by its pharmacy network, compared to most of its EU partners.

The data in Table 2.1 suggests that sales per pharmacy should generally be highest in those countries with the highest numbers of inhabitants per pharmacy. This is confirmed by Figure 2.1, which shows that pharmacies in Denmark, Sweden and the Netherlands lead the European field with average sales of €3 million or more (Dresdner Kleinwort Wasserstein Research, 2001).

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<sup>13</sup> There has also been speculation that a further UK chain, Superdrugs, is considering entry to the Irish market – ‘Superdrugs to open stores around Ireland’, *Irish Times*, 28 April 2004.



Table 2.1: Pharmacy numbers and density

Country	Number of pharmacies*	Inhabitants per community pharmacy (DKWR) ~	Pharmacies per 100,000 population*
Greece	8,348	<b>1,320</b>	78.8
Belgium	5,273	1,825	51.7
Spain	19,439	2,150	49.3
France	22,689	2,579	38.4
<b>Ireland<sup>e</sup></b>	<b>1,222</b>	<b>3,205</b>	<b>31.2</b>
Italy	16,382	3,600	28.7
Portugal	2,778	3,940	27.8
Germany	21,590	3,800	26.3
UK	12,311	4,758	20.8
Luxembourg	79	5,260	19.8
Finland <sup>a</sup>	796	6,500	15.3
Austria	1,086	7,284	13.4
Netherlands	1,600	10,000	10.1
Sweden <sup>a</sup>	889	10,000	10.0
Denmark <sup>a</sup>	331	17,000	6.2
Canada <sup>d</sup>	7175	4,290	23.3
Switzerland <sup>b</sup>	1,654	44,290	22.7
Norway <sup>c</sup>	490	9,350	10.9
Australia <sup>(f)</sup>	4,926	3,999	25.0

Sources: \* Institut für Höhere Studien, 2003, 340-341, except (a)-(e) ~ Dresdner Kleinwort Wasserstein Research, 2001, 29.

(a) Denmark, Finland, Sweden – Tamro, 2000.

(b) Switzerland – Dresdner Kleinwort Wasserstein Research, 2001.

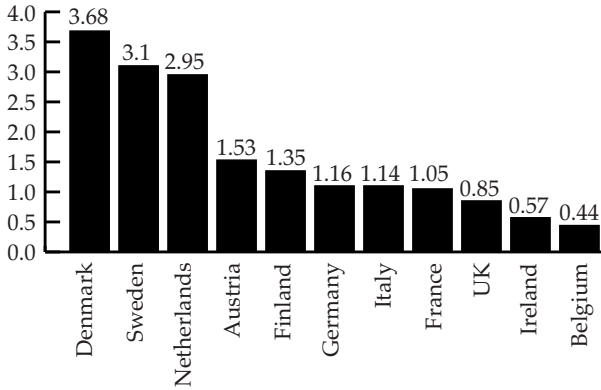
(c) Norway – Apotek1, 2002 (2002 figures).

(d) Canada – Office of Fair Trading 2003, Annex C, citing IMS HEALTH Canada, 2000.

(e) Ireland – 2002 data, Pharmaceutical Society of Ireland and Central Statistics Office Websites, accessed 9 June 2003.

(f) Australia – 2002 data at <http://www.abs.gov.au/Ausstats> and [www.anz.com/Business/info\\_centre/economic\\_commentary/Pharmacy\\_Industry\\_Brief\\_Mar\\_04.pdf](http://www.anz.com/Business/info_centre/economic_commentary/Pharmacy_Industry_Brief_Mar_04.pdf), accessed 23 September 2004.

Figure 2.1: Sales per pharmacy (euro m), 2000



Source: Dresdner Kleinwort Wasserstein Research 2001: 29.

The actual number of outlets has not varied much over time in most of the countries listed in Table 2.1. What is evident, however, is a relatively recent shift in the pattern of distribution and the nature of outlets, reflecting similar movements in retailing generally. Since the late 1990s, there has been a proliferation of pharmacy chains in several countries. Obviously this has only occurred where multiple ownership is actually allowed by law – in Europe this is the case only in Ireland, the UK, Norway, Netherlands, Belgium, Switzerland and Italy (only publicly-owned outlets in this case). In Sweden, one entity (the State) owns 100 per cent of the outlets. Around 7 per cent of Europe's 132,000 pharmacies are in private or public chains – Table 2.2 gives the relevant percentage shares for different countries (Dudley, 2002).

A significant trend is the level of growth in mail order and, more recently, Internet based pharmacies (but again, only in those countries where Internet medicine sales are allowed, i.e. Sweden, UK and the Netherlands). Somewhat similar trends are evident in the USA, where there has been

- a) a noticeable movement away from specialised pharmacy stores to a 'pharmacy corner' in a supermarket or mass merchandiser
- b) a slight rise in the number of pharmacy chain stores
- c) a significant increase in mail order (including Internet) sales.

Table 2.2: Share of retail pharmacies in chains, 2001

Country	% pharmacies in chains
Sweden <sup>a</sup>	100.0
Norway <sup>b</sup>	85.0
UK <sup>c</sup>	50.0
<b>Ireland<sup>d</sup></b>	<b>32.0</b>
Belgium	10.8
Italy	9.8
Netherlands	9.6
Switzerland	3.0
Europe Average	6.7
Canada <sup>e</sup>	
Ontario	48
Western Canada	48
Quebec	85
USA <sup>f</sup>	37 <sup>g</sup>

Sources: Dudley, 2002: 3, except –

- (a) Sweden – State monopoly
- (b) Norway – Tamro, 2004
- (c) UK: Association of the European Self-Medication Industry, 2004a – percentage in chains of 5 or more outlets
- (d) Ireland: The Competition Authority 2002a:16
- (e) Canada – at [www.imshealthcanada.com/htmen/images/graph/graph\\_3\\_2\\_9en.gif](http://www.imshealthcanada.com/htmen/images/graph/graph_3_2_9en.gif), accessed 22 January 2003
- (f) USA: at [http://www.nacds.org/user-assets/PDF\\_files/Retail\\_Outlets.pdf](http://www.nacds.org/user-assets/PDF_files/Retail_Outlets.pdf), accessed 23 September 2004
- (g) The US figure would be 63 per cent if ‘mass merchandisers’ and supermarkets were included.

Figure 2.2 shows the relative decline in the proportion of independent pharmacies in the US over a 10-year period, primarily accounted for by the rise in the number of chain drugstores and supermarkets containing a pharmacy outlet. Figure 2.3 shows broadly comparable changes in actual sales between the various forms of outlet in the same period, with the added extra dimension of the effect of mail order/internet sales on physical outlets.

Figure 2.2: USA retail outlets by type

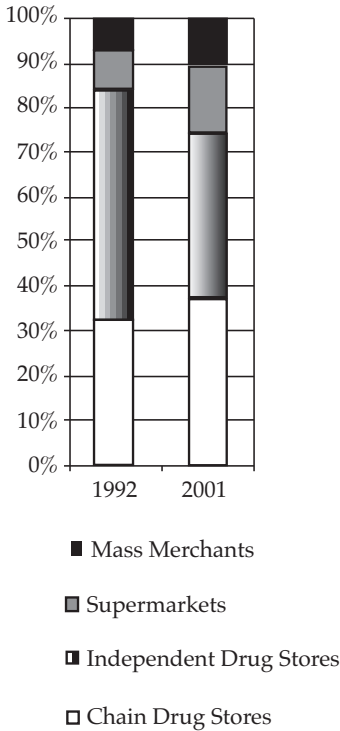
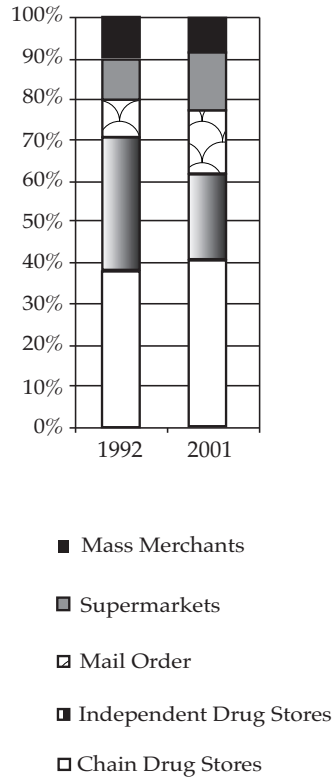


Figure 2.3: USA pharmacy sales by type of retail outlet



Sources: [http://www.nacds.org/user-assets/PDF\\_files/Retail\\_Outlets.pdf](http://www.nacds.org/user-assets/PDF_files/Retail_Outlets.pdf), accessed 23 September 2004.  
[http://www.nacds.org/user-assets/PDF\\_files/Pharmacy\\_Sales.pdf](http://www.nacds.org/user-assets/PDF_files/Pharmacy_Sales.pdf), accessed 23 September 2004.

## 2.2 Irish pharmaceutical distribution sector

While retail pharmacies may occasionally obtain medicines directly from manufacturers (generally this amounts to approximately 8 per cent of their supply), wholesalers are the predominant source of supply.<sup>14</sup> There are three principal full-line wholesalers in the State – United Drug plc, Cahill May Roberts and Uniphar. Combined,

these wholesalers hold over 90 per cent of the market (Dresdner Kleinwort Wasserstein Research, 2001). United Drug plc is the largest of the three principal wholesalers, holding a 44 per cent market share.<sup>15</sup> Uniphar recently announced its intended acquisition of the Whelehan Group, which includes the fourth-largest wholesaler, Boileau & Boyd, and this acquisition has been cleared by The Competition Authority under the Competition Act.<sup>16</sup> This level of concentration is further complicated by the degree of vertical (wholesale-retail) integration in the market.

- Cahill May Roberts also owns the biggest retail pharmacy chain in Ireland (i.e. Unicare with 54 outlets). It is owned by the German-based GEHE AG, one of the biggest pharmaceutical distribution firms in Europe.
- Retail pharmacists hold a substantial level of the shareholding in United Drug (*Sunday Business Post*, 9 December 2001).
- Uniphar is wholly owned by retail pharmacists; almost 40 per cent of all retail pharmacists (approximately equivalent to 450 pharmacists) are shareholders.

Wholesalers to the retail pharmacy business are generally very supportive of pharmacists who wish to purchase their own pharmacy (Brenson and Lawlor 1999) and each of the three main wholesalers has specific financial support schemes in place to finance such purchases (for example, interest-free short-term loans, and deferred interest-free credit on purchases) (Competition

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<sup>14</sup> For completeness, mention should also be made of the emerging trend towards pre-wholesaling. Medicines sold in Irish pharmacies are produced by a large number of manufacturers. Rather than operate their own distribution operation in Ireland, many manufacturers contract this function out to an Irish agent, who provides a full range of services, including storage, marketing, invoicing and delivery. The agent holds a large inventory and distributes it to other wholesalers and to hospitals. This business is known as 'pre-wholesaling'. Pre-wholesalers supply all brands in their respective portfolios to all wholesalers, who in turn supply all pharmacies. In the linear supply chain, this post-production stage arises just prior to wholesaling, and is essentially a method of reducing costs by outsourcing areas such as quality control, warehousing and invoicing. Each of the three main Irish pharmaceutical wholesalers has been increasingly active in this field in recent years (Competition Authority, 2004: 6, 7, 22).

<sup>15</sup> Presentation by United Drug at UBS Global Healthcare Services Conference, February 2004, at [www.united-drug.ie/download/ubs2.pdf](http://www.united-drug.ie/download/ubs2.pdf), accessed 3 July 2004.

<sup>16</sup> 'The Competition Authority clears UniPhar's acquisition of Whelehan Group', Competition Authority Press Release, 15 July 2004 at [www.tca.ie](http://www.tca.ie)

Authority, 2002a). Cahill May Reports reportedly operates such a scheme, while United Drug has been running its own scheme (*Catalyst*) since 2001 and Unipharm advertises its Independent Pharmacy Ownership Scheme (IPOS) on its website ([www.unipharm.ie](http://www.unipharm.ie)). There have been reports that IPOS involves Unipharm actually acquiring ownership of pharmacies, although Unipharm rejects this.<sup>17</sup> If Unipharm does actually control the outlets it acquires, this would of course make it the biggest retail chain (it was reported that a recent transaction ‘brings the number of pharmacies operated by Unipharm to 105’).<sup>18</sup>

Regardless of the matter of ownership, it is obvious that the effect of these schemes can be to tie customers to a particular wholesale supplier for long periods of time. The pervasiveness of these types of agreements at retail level, together with the dominance of just three full-line wholesalers, effectively creates a barrier to entry at wholesale level.

### 2.3 Operation of the Irish retail pharmacy market

Retail pharmacies in Ireland sell four main categories of products.

- 1 Prescription medicines, i.e. a doctor’s prescription is required for purchase; these medicines may only be obtained from a pharmacy.
- 2 Pharmacy-only over the counter (OTC) medicines, i.e. medicines which, while not requiring a prescription, nevertheless can only be sold in pharmacies (whether kept behind the counter or displayed on open shelves)
- 3 Unrestricted OTC medicines, which may be sold in any type of retail outlet, e.g. corner shops, petrol forecourts, supermarkets (e.g. for mild pain and cold symptom relief).
- 4 Non-medicinal cosmetics, toiletries and sundries (CTS); CTS products are also sold by a variety of non-pharmacy retail outlets such as health stores,

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<sup>17</sup> ‘Dispensing a better future to young pharmacists’, *Irish Independent*, 14 August 2003. ‘Phelans reaping €22m from pharmacies sale’, *Irish Independent*, 2 September 2003. ‘Cork pharmacy group sells outlets for over €15m’, *The Irish Times*, 3 September 2003. ‘Pharmacists union keen to curb multinational muscle’, *The Irish Times*, 26 September 2003. ‘UniPharm pays €50m for Walsh pharmacy chain’, *The Irish Times*, 2 July 2004.

<sup>18</sup> ‘UniPharm pays €50m for Walsh pharmacy chain’, *The Irish Times*, 2 July 2004.

department stores, supermarkets et cetera, and retail pharmacies compete with these outlets for their sale.

Prescription medicines are dispensed to consumers either privately or through a variety of State-administered schemes of which the most relevant to this paper are: the General Medical Services (GMS), the Drug Payment Scheme (DPS), the Long Term Illness scheme (LTI) and the High Tech Drugs Scheme (HTD). These are described in Section 5.3.1. In order to participate in these State schemes, a pharmacy must hold a community pharmacy contract (as per the Community Pharmacy Contractor Agreement for Provision of Community Pharmacy Services under the Health Act, 1970) with the appropriate Health Board. Possession of such a contract is almost essential to the viability of a pharmacy business and the vast majority of retail pharmacies in Ireland have such contracts (General Medical Services (Payments) Board, 2003:6). In the case of the GMS, DPS, LTI and HTD schemes, pharmacists are paid a fixed dispensing and/or service fee by the State, as well as the wholesale cost of the medicines. In the case of the DPS and LTI schemes, there are also substantial *extra* payments made to the pharmacist – these are further described in Section 5.3.1. Finally, prescriptions amounting to less than €78 per month and prescriptions dispensed on a purely private basis, i.e. not under any State scheme, are paid for in full by the consumer.

As well as retailing medicinal and non-medicinal products, retail pharmacies holding a community pharmacy contract are expected, under Clause 9 thereof, to supply a range of ancillary professional services to their customers. These include counselling patients about prescription and OTC medicines and maintaining patient medication records. Retail pharmacies may also provide monitored dosage systems to residential nursing homes, cholesterol testing and blood pressure monitoring.

### *2.3.1 Nature of demand and supply*

Demand from pharmacy customers tends to be local in nature as customers are not generally willing to travel long distances to obtain prescription and OTC medicines or CTS products (Competition Authority, 2002a). Factors influencing the consumer's choice of retail pharmacy include the nature of the product required, the degree of urgency with which the customer requires the product, the price and range of OTC medicines and CTS products stocked and, over the long term, the quality of service provided.

Final consumers generally lack the knowledge to participate actively in the market and to respond to financial incentives. Decisions are primarily taken for consumers by their agents (Centre for Strategic Economic Studies 1999). It is the doctor, rather than the patient or the pharmacist, who decides which particular medicine to prescribe. Furthermore, in the case of a significant portion of medicines supplied, the consumer does not pay (and thus may be oblivious of the actual cost). The Irish State pays for over 70 per cent of total pharmaceutical expenditure at final selling price, effectively making the State the largest single buyer of these products from retail pharmacies (McGuinn and Troy, 1998:2). In its December 2001 submission to the Pharmacy Review Group, the Pharmaceutical Society of Ireland (PSI) claimed that this figure was now over 90 per cent. Since insured consumers do not face the full cost, their incentives to curtail their demand are weakened.

These factors have the effect of distorting the normal forces of demand and supply in this particular market. Manufacturers cannot stimulate demand for their products from patients through the usual competitive parameters of pricing, branding and advertising to consumers. Instead, they promote their products to general practitioners through branding, advertising and direct contacts. This market distortion is a key part of the competition mechanism in relation to retail pharmacy and must be borne in mind throughout any analysis of the sector.

## **2.4 Value of pharmacy businesses**

Pharmacies are valuable businesses, selling for amounts in excess of other types of retail outlets. Estimates vary as to the actual amounts involved, although the general basis is a multiple of turnover – a typical estimate would be a valuation of between 1.0 and 1.7 times



turnover (Brenson and Lawlor, 1999:10). Although there appears to have been a sharp fall in the value of outlets immediately after the partial deregulation in 2002, values have now returned to pre-deregulation levels:

Patrick McCormack, joint chief executive of Sam McCauley Chemists, said the value of pharmacies dropped immediately after deregulation from more than twice a pharmacy's annual turnover to 1.2 times its sales, though it was now returning to almost twice the business's turnover.<sup>19</sup>

Pharmacy outlets with high-profile urban locations are considerably more profitable and valuable than others. For example, the GEHE takeover of the Unicare chain in 2002 involved an average valuation of €3.7 million per outlet. The 2003 Hickey takeover of the O'Connell chain in the Dublin area reputedly involved an average price per outlet of €3.6 million.<sup>20</sup> Later on that same year, the average price per outlet obtained by the Cork-based Phelan Group, when it sold 10 of its 12 outlets into Uniphar plc's *Independent Pharmacy Ownership Scheme* was variously reported to be between €1.5 million and €2.2 million.<sup>21</sup> More recently, Uniphar has reportedly paid €3.6 million per outlet for 14 outlets in the Cork and Tipperary areas.<sup>22</sup>

#### 2.4.1 Product sales

Sales by pharmacies have shown large year-on-year increases since the mid-1990s. According to Brenson and Lawlor's analysis of relevant Central Statistics Office figures, retail pharmacies sales increased by 15.6 per cent in the twelve months to October 1998, compared to 10.2 per cent for other retail outlets in the same period (1999:9). Table 2.3 reproduces data from a report carried out for the Pharmacy Review Group, confirming that this trend has been in place over a sustained period.

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<sup>19</sup> 'Chemically imbalanced', Simon Carswell, *Sunday Business Post*, 15 June 2003.

<sup>20</sup> 'Owners of top chemist chain hit jackpot in €25m sell off', *Irish Independent*, 3 May 2003.

<sup>21</sup> 'Phelans reaping €22m from pharmacies' sale', *Irish Independent*, 2 September 2003 and 'Cork pharmacy group sells outlets for over €15m', *The Irish Times*, 3 September 2003.

<sup>22</sup> 'Uniphar pays €50m for Walsh pharmacy chain', *The Irish Times*, 2 July 2004.

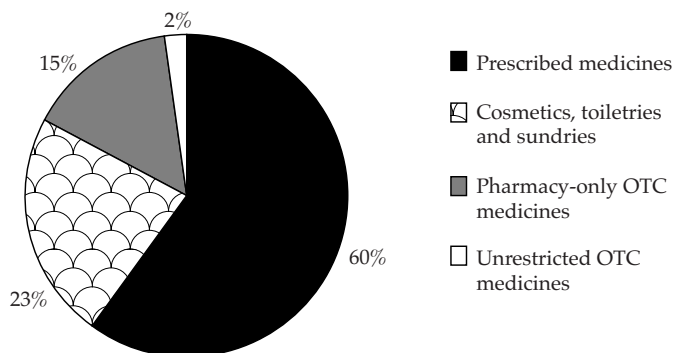
Table 2.3: Percentage change in value, volume and prices, 1996-2001\*

	Value %	Volume %	Prices %
Stores selling pharmaceutical, medical and cosmetic products	+ 119.2	+ 90.8	+ 28.4
Department Stores	+ 75.4	+ 84.3	- 11.8
All Stores	+ 62.7	+ 45.9	+ 16.8

Source: CSO \*Note: Table taken from Indecon International Economic Consultants (2002), *Assessment of the 1996 Regulations*, p. 51, at: [www.doh.ie/pdfdocs/indecon\\_assessment.pdf](http://www.doh.ie/pdfdocs/indecon_assessment.pdf), accessed 23 September 2004.

Figure 2.4 gives an estimate of the respective shares of the four main product categories. It confirms that, typically, the dispensing of prescription medicines forms the core business of pharmacies. For 2001, these estimates correspond to nationwide turnover figures of (a) €702 million, (b) €179 million, (c) €18 million and (d) €253 million for each of the four categories, respectively, or a total of €1.152 billion. According to the Association of the European Self-Medication Industry (AESGP), the medicines components of sales (i.e. categories (a) to (c)) amounted to €950 million in 2001, €1.11 billion in 2002 and €1.32 billion in 2003 (2004b: 13).

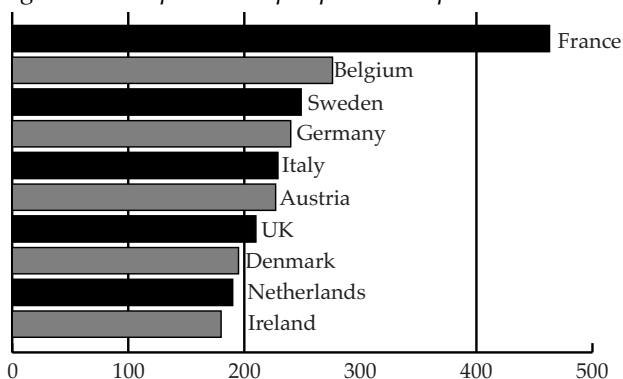
Figure 2.4: Retail pharmacy sales in Ireland, 2000



Source: Competition Authority, 2002a: 13-14.

As a percentage of spending on healthcare, total Irish expenditure on medicines is the second lowest in the EU at 9.6 per cent: Denmark has the lowest, while Portugal has the highest, level of expenditure (24 per cent) (Institut für Höhere Studien, 2003:339). It is not surprising then, that Ireland has the lowest medicine per capita consumption levels in the EU as demonstrated in Figure 2.5.<sup>23</sup> The vast bulk of the expenditure is accounted for by the State. In 2003, more than 43.5 million prescription items were paid for by the State, an increase of over 3.3 million items on 2002 figures (General Medical Services (Payments) Board, 2004a:18).

Figure 2.5: Expenditure per person on pharmaceuticals



Source: United Drug plc, citing IMS World Review 2002 at [www.united-drug.ie/download/ubs2.pdf](http://www.united-drug.ie/download/ubs2.pdf), accessed 23 September 2004. Expenditure includes both retail and hospital pharmacies.

Note: For reasons outlined in Section 5.2.3, international price and expenditure comparisons must be tentative. However, in several broadly similar comparisons of per capita expenditure consulted, Ireland is at, or near, the lower end of the scale in each case.

The EU accounts for approximately 25 per cent of world pharmaceutical market sales (IMS World Review, 2004) and the total EU pharmaceutical market (at retail prices) in 2002 is estimated at approximately €157 billion (Association of the European Self-Medication Industry, 2004; European Federation of Pharmaceutical

<sup>23</sup> While in most European countries, pharmaceutical expenditure *per capita* generally fell in the five years from 1996-2000, in Ireland it rose by over 6 per cent during the same period (Institut für Höhere Studien 2003:337).

Industries and Associations (EFPIA), 2004). Ireland's share of this market is estimated by AESGP at €1.11 billion in 2002 and €1.32 billion in 2003 (2004: 13). Of a total pharmaceutical market value in Ireland of €977 million in 2003 (at ex-factory prices), EFPIA further estimates that sales through retail pharmacy outlets account for 84 per cent. In comparison, the EU average is 79.8 per cent (the highest is Sweden at 90 per cent and the lowest is the UK at 74.4 per cent). The residual percentage values are accounted for by hospitals (in Ireland this equals 14 per cent), and by 'other channels' where these are allowed (in Ireland this equals 2 per cent).

#### 2.4.2 Profit margins

Table 2.4 outlines the estimated gross profit margins for categories of products sold in a typical retail pharmacy.

*Table 2.4: Profit margins in a typical pharmacy outlet*

<i>Product category</i>	<i>Gross profit margin (%)</i>
Prescription medicines dispensed under GMS	19%
Prescription medicines dispensed under DPS and LTI	39%
Private prescriptions	45%
OTC medicines	33%
Cosmetics, toiletries and sundries	33%

*Source:* Brenson and Lawlor, 1999: 9.

In a typical outlet, this would equate to an overall gross profit of approximately 32 per cent. To this however must be added the discounts conventionally obtained by the pharmacist from wholesalers – the general level of these seems to be between 7 to 9 per cent. Ireland has the highest overall retail margin, in any EU country, on prescription drugs across the board at around 33 per cent.

## 2.5 Conclusions

This chapter has provided an overview of the size, scale and operation of the Irish retail pharmacy sector in comparison to

international trends. The key characteristics of the market are outlined below.

- The retail pharmacy sector in Ireland is relatively unconcentrated, with the biggest retail chain (Unicare) controlling approximately 4 per cent of all outlets.
- Ireland is relatively well served by its retail pharmacy network, in terms of pharmacies per 100,000 population.
- A noticeable global trend in recent years is the growth of pharmacy chains, notably in the USA, Canada, Ireland and the UK.
- Involvement by wholesalers extends far beyond the simple supply of goods. The three main wholesalers to the Irish market each have varying, but significant, ownership relationships with the retail sector.
- Retail pharmacies sell four main product categories – prescription medicines, pharmacy-only OTC medicines, unrestricted OTC medicines, and non-medicinal cosmetics, toiletries and sundries.
- Demand for prescription products is driven by a third party, primarily doctors (not the pharmacist or the final consumer) – contributing to a distortion of the normal forces of demand and supply in this market.
- Pharmacies are valuable businesses, selling for amounts considerably in excess of other types of retail outlet.
- Medicine sales in Ireland are showing sustained year-on-year increases, while the retail margin on prescription drugs is, on several estimates, the highest in any country in the EU.

Having thus set the scene, later chapters will describe the extent to which this market is regulated, the kinds of instrument used, and the impact of these on the market.

## Regulatory environment in Ireland

### 3.1 Regulatory actors

This chapter provides an overview of the regulatory environment for retail pharmacy in Ireland. The various statutory bodies with functions relevant to the regulation of the retail pharmacy sector are identified and their roles described, as well as those of non-statutory interest groups active in the area. The chapter also summarises domestic legislative reforms in the sector to date, as well as the broader and continuing efforts by the OECD, The Competition Authority and others to advocate more fundamental reform.

There is a considerable number of key regulatory actors in the retail pharmacy sector in Ireland, including the following.

- The Minister for Health and Children is responsible for Government policy on pharmacy, as well as for the body of legislation governing it.
- The Pharmaceutical Society of Ireland is the regulatory body responsible for overseeing the registration and supervision of retail pharmacists. It performs a number of regulatory functions: (a) it regulates the qualification of pharmaceutical chemist which entitles one to practice pharmacy in Ireland; (b) it regulates the operation of pharmacies for the dispensing of medical prescriptions and sale of medicines; and (c) it ensures that medicines are supplied in accordance with the regulations governing such supply. The Society derives its authority from the Pharmacy Acts 1875, 1890, 1951 and 1962, together with a series of statutory regulations made by the Society with the consent of the Minister for Health and Children.<sup>24</sup> The Society's Governing Council comprises twenty-one members, each of whom is elected by members of the Society – there are no lay or other external members.<sup>25</sup>

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<sup>24</sup> Regulations of the Pharmaceutical Society of Ireland, 1971 to 2002.

<sup>25</sup> Source: PSI website, [www.pharmaceuticalsociety.ie](http://www.pharmaceuticalsociety.ie). Note: at the time of going to print, the Society's website was inaccessible.

- The Irish Medicines Board (IMB) is responsible for licensing the manufacture, preparation, importation, distribution and sale of all medicinal products for human or animal use. It assesses the quality, efficacy and safety of all medicines available in the State, regulates the conduct of clinical trials and inspects the processes of manufacturing and distribution. Its fundamental role is to protect and enhance public and animal health (IMB, 2001:5).
- Health Boards oversee the operation of the various Community Drug Schemes referred to in Chapter 2. The Boards will be replaced on 1st January 2005 by a new Health Service Executive, which will be charged with managing and delivering the health service as a single national entity.
- The General Medical Services (Payments) Board was established under Section 11 of the Health Act, 1970. The Board (on behalf of the Health Boards) pays fees to pharmacists in respect of drug supply to customers under the various state schemes, and reimburses pharmacists in respect of the cost of such drugs.

While at first glance this may seem a complex web of regulatory actors, the quantity of actors is not unusual in this sector – many other professions and sectors also have their own unique ‘cast of regulatory characters’.

### **3.2 Overview of legislation affecting the sector**

Excluding legislation of very general application (such as legislation related to physical planning, employment rights, taxation, et cetera, which apply across a wide range of sectors), a large body of legislation, particularly secondary legislation, applies to the retail pharmacy sector (a full list is contained in Appendix A). Primary legislation in this area has evolved in a piecemeal fashion, with the Principal Act – and the basic regulatory regime underlying it – dating back to the nineteenth century. The past twenty years, on the other hand, have seen the enactment of a considerable amount of secondary legislation governing both the profession of pharmacy and the supply of medicines; these are described in Section 3.2.2. Overall, however, there have been only occasional minor reforms of

the basic regulatory framework and this paper argues that the framework is now in need of a radical overhaul.

The various Acts and statutory and other regulatory instruments regulating this area can be divided into two basic categories:

- those affecting the pursuit of pharmacy as a profession or business
- those affecting the control and supply of drugs and medicines.

### *3.2.1 Pursuit of the pharmacy profession*

The principal legislation affecting the pursuit of the pharmacy profession remains the Pharmacy Act (Ireland) 1875 ('the Principal Act'), as supplemented by amending Acts in 1890, 1951 and 1962, of which only the amending Act of 1962 was of significance.<sup>26</sup> The 1875 Act established the Pharmaceutical Society of Ireland as the regulatory oversight body for pharmacies and pharmacists and provided for a system of examinations and registration for pharmacists by the Society. The Act also entitled registered pharmaceutical chemists to 'sell or keep open shop for retailing, dispensing and compounding of poisons and medical preparations'. In 1890, an amendment to the Principal Act provided that all pharmacies should be personally managed and supervised by qualified pharmaceutical chemists or by 'licentiates of Apothecaries' Hall'.<sup>27</sup> During the 1950s, the Pharmaceutical Society and Apothecaries' Hall agreed that the right of apothecaries to register as pharmaceutical chemists would be terminated; however, apothecaries would continue to have dispensing rights – the terms of this agreement were included in the Pharmacy Act 1962 (Irish Pharmaceutical Union, 2001). While the Pharmacy Act, 1951 made some minor reforms, in reality the only primary legislation of any significance since 1875 affecting the pursuit of pharmacy as a profession was the Pharmacy Act, 1962. Section 2 redefined who could keep open shop for the dispensing of medical prescriptions. Such an 'authorised person' was to be

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<sup>26</sup> See also two sections of the Misuse of Drugs Act, 1977.

<sup>27</sup> The 1875 Act defined such a licentiate as 'a person who had a certificate to keep open shop', 'or to follow the art and mystery of an apothecary under the provisions of the Act of 1791'.



- a) a registered pharmaceutical chemist, or
- b) a registered dispensing chemist and druggist, or
- c) a licentiate of Apothecaries' Hall, or
- d) a registered medical practitioner with a supplementary pharmacy qualification.

If the entity keeping open shop was a body corporate, the shop (and the dispensing of prescriptions) was required to be personally supervised by such an authorised person.

The Pharmaceutical Society of Ireland maintains that it has been demanding a new Principal Act for 'about forty years', claiming that the regulatory structure under which it operates (mainly the 1875 Act) is completely outdated. For example, it claims that the pharmacy profession is unique in not being subject to statutory rules regulating fitness to practise.

For some thirty years the Society, on behalf of the public, has been lobbying for disciplinary procedures for the profession to be introduced but with no success (Pharmaceutical Society of Ireland, 2002:9).

We keep being told they are working on a new Pharmacy Act but we have been told that for years.<sup>28</sup>

The current government's published legislative programme commits to a new Pharmacy Bill 'to update and rationalise the Pharmacy Acts 1875-1977'; however, while publication of this Bill was initially forecast for 2004, it is now forecast for 2005.<sup>29</sup>

### 3.2.2 *Control and supply of medicines*

A large body of primary and secondary legislation controls the supply of medicines. Foremost among these is the Irish Medicines Board Act, 1995, which established the Irish Medicines Board and gave it its functions. A key function of the Board is to advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicines may be marketed or continued in use in the State. This includes advising the Minister as to which medicines should be treated as prescription-only. Where the Board

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<sup>28</sup> 'Public 'at risk' from pharmacists', *The Irish Times*, 13 April 2004.

<sup>29</sup> Department of the Taoiseach, at source: <http://www.taoiseach.gov.ie/index.asp?docID=1703>, accessed 23 September 2004. [www.taoiseach.gov.ie/taoiseachgov/legislation](http://www.taoiseach.gov.ie/taoiseachgov/legislation), accessed 12 April 2003.

so advises, the Minister may make Regulations under the Act regulating, *inter alia*, the sale, supply, placing on the market, advertisement or promotion of the product or products concerned, which the Board then enforces. Legislation also prohibits direct advertising of controlled drugs (e.g. cocaine, morphine, methadone), all prescription-only medicines and medicines to prevent, diagnose or treat certain specified illnesses (e.g. blood pressure, ulcers, depression) to the general public (OECD, 2001a).

### 3.3 Regulatory reform in the pharmacy sector

For over 100 years there was very little reform in this sector. The preceding section has shown that the principal legislation governing retail pharmacy dates back to 1875, that the only reform of any substance was contained in the Pharmacy Act, 1962, and even that reform was relatively minor. However, the past 10 to 15 years have seen a number of forces operating to challenge the *status quo*. These forces have led to change in a number of instances.

Firstly, there has been a surge of new (mainly secondary) legislation of a 'controlling' nature, covering areas as diverse as the control of prescriptions, the advertising of medicines, restrictions on access to the pharmacy profession, and restrictions on setting up a pharmacy business. Secondly, much of this legislation has proved to be controversial and its impacts have been highlighted in two main ways, both of them symptomatic of a greater level of interest in and awareness of economic issues by the Irish media and the general public:

- a) A greater willingness to have recourse to judicial review and other avenues to challenge statutory regulation and Ministerial power.
- b) The issue of competition has assumed greater importance and a higher public profile in Ireland, leading to more open and public debate about the economic effects of much of the new regulation introduced. The Competition Authority has been vocal in relation to competition issues in the pharmacy market in the last number of years, while the Irish Pharmaceutical Union<sup>30</sup> has also been strident in its defence of pharmacy interests during the same period.<sup>31</sup>

It is only in recent years that a consciousness of the need for regulatory reform has begun to emerge.

- The OECD carried out a study on Regulatory Reform in Ireland in 2000/2001, part of which focused on the regulatory environment applicable to pharmacy and this report was highly critical of the restrictions operating at the time (2001b).
- There have been a number of legal challenges to the 1996 Contractor Regulations.
- Legal challenges have also been mounted to test the overseas graduate 'three year rule'.
- The Pharmacy Review Group was established in November 2001 by the Minister for Health and Children to examine the effect of existing regulations and to consider what, if any, regime should replace them.

These developments are explored in greater depth in the following chapters.

### 3.4 Conclusion

The overall dynamic in recent years could be characterised as:

- an archaic overall regulatory regime, beset by analytical criticism
- notwithstanding this, several controversial statutory instruments were introduced during the past ten to fifteen years
- serial private legal challenges to regulation
- a developing public debate about the efficacy of the regulatory environment (involving for example, issues

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<sup>30</sup> The Irish Pharmaceutical Union is the professional association representing retail pharmacists, with a negotiating licence under the Trade Union Acts. It was registered as a Trade Union in 1936 under the name of the Irish Drug Association. Its object was stated to be '... to regulate from time to time and maintain the minimum retail prices to be charged for patent medicines, proprietary articles, drugs, sundries and the compounding of prescriptions....' (*Rules of the Irish Drug Association* on registration as a Trade Union, September 1936. File inspected in Registry of Friendly Societies, Dublin, 11 July 2003).

<sup>31</sup> The IPU President reportedly stated recently that, 'There are elections coming up and we are going to put a lot of pressure on councillors and TDs to act and to act now before it is too late', *The Irish Times*, 2 March 2004.

such as price-fixing of prescription drugs, the growth of retail pharmacy chains, restrictions on overseas pharmacy graduates, the lack of Fitness to Practice Rules, etc)

- a stern defence of the status quo by vested interests.

The following chapters will explore, in turn, the three main components of pharmacy regulation:

- regulation of access to the profession
- regulation of prices
- regulation of medicine supply.

## Regulation of access to the profession

### 4.1 Introduction

This chapter identifies and describes the key barriers to entry that exist within the pharmacy sector, both in Ireland and elsewhere. With respect to Ireland, it shows how the number of pharmacists was constrained for many years by a restriction on the number of degree places available and the persistence of artificial restrictions. It notes that the introduction of yet more artificial restrictions is contemplated. In general, barriers to entry extend far beyond mere legislation, and assume a number of (not always immediately obvious) forms including

- restrictions on access to education
- pre-education registration and post-education training requirements
- restrictions on the practice (within Ireland) of graduates trained overseas
- regulation of establishment of retail pharmacy businesses.

#### *4.1.1 Access to the pharmacy profession*

In all EU Member States, there is only one 'route' to becoming a pharmacist, i.e. completion of a university degree of at least four years duration plus a post-degree 'professional apprenticeship' period varying in length according to the country in which it is undertaken. In eight EU countries, a professional examination is also undergone. Following all of these steps, the next step is to be licensed or registered as a pharmacist. All Member States use this model (Institut für Höhere Studien, 2003:74).

In Ireland it has for many years been difficult to qualify as a pharmacist. This difficulty is primarily attributable to a legal agreement signed in 1977 by Trinity College Dublin (TCD) and the Pharmaceutical Society of Ireland, whereby the latter undertook not to accredit any pharmacy degree course in Ireland other than that

provided by TCD, for the purposes of registration as a pharmacist (Bacon, 1999). This effectively gave TCD a statutory monopoly on pharmacy education at degree level. Furthermore, the number of degree course places available in TCD was for many years limited to fifty, a huge undersupply relative to demand, for example during the late 1990s there were regularly in excess of 1,000 applications for the places available on the Trinity degree course (the number of places available was increased to seventy in 1998: Bacon, 1999). This situation was clearly untenable and, following strong pressure from, among others, The Competition Authority and the Royal College of Surgeons of Ireland (RCSI), the PSI amended its Regulations in 2002, removing the TCD monopoly and allowing for the accreditation of other education providers.<sup>32</sup> RCSI commenced the provision of a pharmacy degree course in 2002. However, University College Cork (UCC), which had long expressed a desire to provide such a degree, had to wait considerably longer. Having first applied for accreditation in 1996, the College failed to gain accreditation despite several attempts during the latter half of the 1990s (despite an announcement by the Minister for Education and Science of fifty new degree course places for UCC in 2001<sup>33</sup>), leading to allegations that the PSI was operating a 'closed shop', a charge rejected by the Society.<sup>34</sup> UCC finally succeeded in having its proposed degree course accredited in 2003. As a result of the limited number of places, the Central Admissions Office entry requirement for pharmacy degree courses is still extremely high. The points level required for entry to the TCD degree course in 2004 was 555, while that for UCC was 560, and the RCSI was 545.<sup>35</sup> Over the years, as a result of this restriction, many hundreds of aspiring pharmacists have been forced to travel abroad to qualify, predominantly to the sixteen undergraduate schools of pharmacy in the UK. While the arrival of new graduates from the new degree courses in RCSI and UCC will ease the situation from 2006 onwards, the overall number of undergraduate places available is, and will be, still limited to an intake of around 150 per annum. This still falls far short of anticipated demand.

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<sup>32</sup> *Regulations of the Pharmaceutical Society of Ireland (Amendment) Regulations, 2002*. S.I. 212 of 2002.

<sup>33</sup> 'UCC cleared to open new pharmacy school', *The Irish Times*, 23 October 2001.

<sup>34</sup> 'Pharmacy group not a closed shop', *Examiner*, 14 October 2002.

<sup>35</sup> At the time of second round offers.

While the supply of pharmacists in Ireland is constrained by, *inter alia*, a shortage of education places in Irish universities and other more direct barriers to entry, Ireland is not alone in experiencing such shortages. For example, a recent report claimed that, while there are currently approximately 11,000 full-time pharmacists in Australia, 14,000 are needed to meet current demand from the community sector and in hospitals – indeed the report’s projections estimated that 17,000 plus pharmacists would be needed by 2010 (Health Care Intelligence, 2003:80). The same trends seem evident in Europe:

Norway, like many countries in Europe, is facing a shortage of pharmacists. Norway is using a familiar tactic to try to overcome its recruitment crisis. Norwegian pharmacist Vibeke Dalen explains: ‘We are increasing the capacity in the education system and bringing pharmacists in from Sweden, Denmark and other countries’, she says.<sup>36</sup>

In the USA, the shortage of pharmacists is so severe that a thriving recruitment sub-sector has grown up, focused on attracting immigrant pharmacists to the US from abroad (e.g. [immigration.com](http://immigration.com)). Financial incentive legislation aimed at encouraging more student enrolment in pharmacy faculties passed the US Senate in November 2003, although it has since stalled in the House of Representatives.<sup>37</sup>

#### 4.1.2 *Pre-education registration and post-education training*

The Pharmaceutical Society requires an aspiring student of pharmacy to obtain (and pay a fee for) preliminary registration with the Society in advance of entering a degree course.<sup>38</sup> It is difficult to see any rationale for this rather unusual requirement, or indeed identify any other profession where it exists. Furthermore, having obtained a degree, graduates must then complete one year of practical training under the supervision of a tutor pharmacist and

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<sup>36</sup> ‘Learn from pharmacy across Europe’, *The Pharmaceutical Journal*, vol. 267, no. 7169: 502, 13 October 2001.

<sup>37</sup> ‘APhA Applauds Senate Passage of S.648: The Pharmacy Education Aid Act of 2003’. Source: [www.aphanet.org/news/03stmt\\_Sentate\\_pass.htm](http://www.aphanet.org/news/03stmt_Sentate_pass.htm), accessed 23 September, 2004.

<sup>38</sup> ‘Education and Training: PSI Regulations governing pre-registration training’, Source: [www.pharmaceuticalsociety.ie/preregregs.htm](http://www.pharmaceuticalsociety.ie/preregregs.htm), accessed 17 April 2003.

take a further Pharmaceutical Society examination or meet requirements for their foreign education to be recognised (ibid). At least six months of this year of training must be spent in a hospital or retail pharmacy. The Pharmaceutical Society supervises the pre-registration year. Having successfully completed all elements of the Society's licence examination, the graduate may apply for registration as a pharmacist. This requirement has a number of significant consequences, particularly for those students forced to obtain their pharmacy degree outside the State, who cannot then undertake the year's pre-registration training required by the Irish Pharmaceutical Society.<sup>39</sup> These graduates must undertake pre-registration training in the country where they have obtained their pharmacy degree and register with the pharmacy registration authority in that country before applying to register in Ireland. Again, it is difficult to see the rationale for this, particularly since one of the express aims of such a pre-registration year is 'to give the graduate a good working knowledge of the practical application of the legislation governing pharmacy and an understanding of the role of the Pharmaceutical Society and other pharmaceutical organisations.'<sup>40</sup> The effect, however, is clear – it is another barrier to entry to the profession.

#### *4.1.3 Restrictions on overseas-trained graduates*

Those who have qualified abroad often encounter an additional obstacle to pursuing the profession in the retail sector when they return to Ireland, because of the manner in which the 1985 *EU Directive on the Mutual Recognition of Qualifications in Pharmacy* (Directive 85/433/EEC of 16/9/1985; Official Journal L253 of 24.9.85:37-42) was implemented in Ireland. This Directive based the right of establishment for pharmacists on the principle of mutual recognition of qualifications. However, a last-minute compromise was inserted in Article 2.2, allowing Member States to derogate from the obligation to recognise EC qualifications in respect of 'new pharmacies' – defined as pharmacies in operation for less than three years. The then Minister for Health (like his counterpart in six other EU Member States) availed of the derogation. The Irish

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<sup>39</sup> 'Registration Information', [www.pharmaceuticalsociety.ie](http://www.pharmaceuticalsociety.ie), accessed 15 April 2003.

<sup>40</sup> Source: PSI website, [www.pharmaceuticalsociety.ie](http://www.pharmaceuticalsociety.ie), Pre-Registration Training Year Information, accessed 30 July 2003.



implementing regulations thus provide that a pharmacist who is professionally trained in another EU or European Economic Area (EEA) country is prevented from ever managing or supervising a pharmacy that is less than three years old.<sup>41</sup> Although foreign-trained pharmacists are free to actually work in the retail pharmacy sector in Ireland, this 'three year rule' effectively prevents an EU/EEA national from ever opening their own pharmacy in Ireland. This includes those Irish nationals who have undertaken their training in other EU states.

According to the Minister for Health and Children, the basis for this restriction lay originally in several attempts made by the European Commission to introduce measures to facilitate the free movement of pharmacists. However, restrictions in most Member States on the freedom of pharmacists to open new pharmacies became a major stumbling block to the adoption of any Directives that would provide for such free movement. Member States with pre-existing restrictions on the opening of new pharmacies were unwilling to remove them, and other Member States, including Ireland, were unwilling to support a measure which would 'impact unfairly' on their home-grown graduates. For example, while Irish graduates would be restricted from opening pharmacies elsewhere, their peers from other Member States would not be restricted from opening pharmacies in Ireland and in other countries with no such controls. Although the Minister conceded that the use of the derogation was not a satisfactory solution in the longer term, he also stated that 'it was decided to defer any change to the regulations dealing with the mutual recognition of qualifications until all legal issues concerning the Health (Community Pharmacy Contractor Agreement) Regulations, 1996 were resolved'.<sup>42</sup>

While the restriction is generally defended on the grounds that it maintains a 'level playing field' between Ireland and those EU and EEA countries with similar restrictions, The Competition Authority and the OECD have been particularly critical of it. The OECD found that the restriction, far from promoting health care delivery, simply restricted entry – and indeed, the economic freedom of pharmacists educated in other EU Member States – with no consumer benefits, and thus had an anti-competitive effect. In

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<sup>41</sup> *European Communities (Recognition of Qualifications in Pharmacy) Regulations, 1987, 1991 and 1994.*

<sup>42</sup> Dáil Debates, 3 April 2001.

particular, it restricted the entry of new pharmacies – those that would have opened if foreign-trained pharmacists were able to open new pharmacies – and employment possibilities for a subset of pharmacists. As the proportion of pharmacists hampered by this restriction increased, the restriction would also serve to raise the market value of pharmacies operating for more than three years above the price of comparable pharmacies operating for less than that. The OECD recommended the removal of the restriction (2001b: 81,106). Within Ireland, The Competition Authority has also strongly criticised this rule, arguing that it has no positive object or effect – indeed, to the contrary, it argues that it has negative effects on both the supply of pharmacists and the retail pharmacy market in Ireland – and that it is particularly restrictive in a sector where there is already an insufficient supply of labour (2001:4). Thus, far from ‘levelling the playing field’, the rule simply operates to the benefit of existing pharmacists. Furthermore, it (a) discriminates against Irish people who, not being able to gain access to one of the limited places available in Irish Universities’ pharmacy degree courses, have thus been forced to travel abroad to study pharmacy, (b) is contrary to the principles of the EU internal market, and (c) is ultimately harmful to consumers as it restricts the supply of pharmacists in Ireland.

The Minister for Health and Children asked the Pharmacy Review Group to review the three-year rule.<sup>43</sup> The Group’s findings and recommendations were presented to the Minister for Health and Children in January 2003 and were published in February 2004 after a 13-month delay. As of September 2004, the Government has still not considered its recommendations, which included the following:

The use of the EU derogation (i.e. the ‘three-year rule’ for overseas-trained pharmacists) should continue until a Pharmacy Act is in place, and then be discontinued. Such Act should be in place within 18 months of the date of the Group’s Report (2003:31-32).

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<sup>43</sup> The Group’s full Terms of reference are on pages 6 and 7 of its final report. See: [www.doh.ie/publications/prgr.html](http://www.doh.ie/publications/prgr.html). The Group was chaired by Professor Michael Mortell (UCC) and comprised representatives from the Departments of Health and Children, Finance, and Enterprise, Trade and Employment, the Southern Health Board, the Pharmaceutical Society, the Irish Pharmaceutical Union, the Consumer’s Association of Ireland and The Competition Authority.

The Group's apparent key concern was that, if the rule were simply removed, pharmacists from other EU Member States would deluge the Irish market. Admittedly, the high margins and asset values applicable to pharmacy in Ireland could indeed attract individuals from elsewhere under a less restrictive immigration policy. However, if this were to happen to any significant extent, it would merely underpin the extent to which the current restriction is anti-competitive. An alternative view would be that an increase in the number of qualified pharmacists entitled to open their own pharmacies would be of positive benefit to consumers. Proponents for retaining the three-year rule also overlook the fact that there is currently no restriction on overseas-trained graduates working in an Irish pharmacy, or managing one that is more than three years old – the restriction is on such graduates managing new pharmacies (and therefore, opening their own outlet). The inescapable conclusion is that the continued existence of the rule amounts to a quantitative limit on entrepreneurship – or, more bluntly, straightforward protection of incumbents.

*Legal challenges to the three-year rule*

In *McCauley*,<sup>44</sup> the plaintiff sought to have the national Regulations implementing Council Directive 85/433/EEC declared invalid on the ground that the Directive gave discretion to Member States as to whether to give full recognition to foreign qualifications, or only to give limited recognition. In availing of the derogation allowing Ireland to implement the three-year rule, it was claimed that Ireland made a policy decision that went beyond mere implementation of EU policy. Rejecting the application, the Court held that the only amendment which the implementing regulations made to existing national legislation was to extend recognition of qualifications to the extent that the State was required to do so under the Directive. The same restrictions were previously challenged in *Young v Pharmaceutical Society of Ireland and Minister for Health*, where the Court had come to the same conclusion, that is to say:

[t]here is no question of derogation from the requirements of the Treaty. What is permitted (subject to review by the Commission or the Council of the operation of the regulation) is to refrain

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<sup>44</sup> *Sam McCauley Chemists v Pharmaceutical Society of Ireland and Minister for Health*, High Court, McCracken J, 31/07/2002, unreported.

from recognising the specified diplomas in relation to a particular range of pharmacies.<sup>45</sup>

#### **4.2 Regulation of establishment of retail pharmacy businesses**

The *Health (Community Pharmacy Contractor Agreement) Regulations, 1996* (SI No. 152 of 1996) (the 'Contractor Regulations') regulated the awarding of General Medical Service contracts to retail pharmacies and were introduced by the Minister for Health and Children as part of an agreement with the Irish Pharmaceutical Union. These Regulations proved highly controversial.<sup>46</sup> In effect, they created another barrier to entry to the sector in that new pharmacies incurred a cost not faced by existing pharmacies in terms of restricted opportunities to obtain a GMS contract (Competition Authority, 2002a). The Contractor Regulations effectively limited the number of GMS-contracted pharmacies. As a GMS contract represents close to half an average pharmacy's revenue (Competition Authority, 2002a:26) and, on average, 42 per cent of a pharmacy's turnover (Brenson and Lawlor, 1999:8), relatively few pharmacies (less than 2 per cent) 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 Regulations included a number of restrictions on where a new retail pharmacy could locate ('the location restrictions').

- a) In urban areas, the distance between a new pharmacy and the nearest existing retail pharmacy had to be at least 250 metres door-to-door. In rural areas, the corresponding minimum distance was five kilometres.
- b) The new pharmacy had to identify a population of 4,000 people (in an urban area or large town) not served by an existing pharmacy. In rural locations not served by an existing pharmacy, the population had to be at least 2,500.

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<sup>45</sup> *Young -v- The Pharmaceutical Society of Ireland and Others* (1995) 2 I.R. 91

<sup>46</sup> Although the tying of the new Regulations to this agreement with the Irish Pharmaceutical Union was not widely publicised at the time of its making, the connection between them has nevertheless since been explicitly acknowledged (Irish Pharmaceutical Union, 2001: 8-9; Pharmaceutical Society of Ireland, 2001: 1; Pharmacy Review Group, 2003: 10).

- c) The promoters of the new pharmacy had to demonstrate that it would be viable.
- d) It also had to be demonstrated that the proposed new pharmacy would 'not have an adverse impact on the viability of existing community pharmacies in the area'.

#### 4.2.2 *Rationale for the 1996 Regulations*

According to the Minister for Health and Children, the Regulations were introduced because of the desire to harmonise regulation of the sector in Ireland with regulations operating across the EU.<sup>47</sup> More specifically, the reasons put forward by the Department of Health for these restrictions were:

- to erect similar controls to those already in place in many EU member countries
- to promote the development of a quality-driven service
- to prevent further clustering of pharmacies in areas already well-served, while promoting the provision of services in rural areas (OECD, 2001a: 301).

However, there was no evidence of market failure and no justification for the new regulations was given at the time of their introduction (Fingleton, 1997). An immediate visible consequence of the introduction of the Regulations was the decline in the number of new pharmacies opening with community contracts (O'Nia and Corrigan, 2000). Prior to the introduction of the regulations (during 1991 to 1996), the growth in contract pharmacies was greater than the growth in population. After 1996, the growth rate in the number of contract pharmacies dropped below that of the population growth rate.

The *quid pro quo* for introducing the Regulations was the introduction of the Community Pharmacy Contract, setting out, *inter alia*, the role and duties expected of retail pharmacists, particularly Clause 9 thereof. This provided for a review by the pharmacist of the medicine therapy of the patient, including screening for any potential drug therapy problems, therapeutic duplication, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions and clinical abuse or misuse. The review was also to include an examination of

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<sup>47</sup>Dáil Debates, 27 February 2001.

the rational and cost effective use of the medicine prescribed, including the choice of medicines and the potential for wastage. It would also include counselling the patient on the importance of compliance with the directions for use of the medicine, techniques for self-monitoring during therapy, the need for patient compliance and the action to be taken in the event of a missed dose. It would be surprising however, if all of these matters did not form an essential part of a pharmacist's professional training in the first instance.

#### 4.2.3 *Reform of the Regulations*

The Contractor Regulations were subject to sustained criticism by The Competition Authority (1997) from 1997 onwards and by the OECD (2001b) on the basis that they were anti-competitive. In addition, the Regulations were subjected to several legal challenges.

The OECD team commented that the logic provided for restricting the location and number of pharmacies was seriously flawed, and recommended:

- a) elimination of the location restrictions
- b) assessment of entry and exit in the sector to be undertaken as well as provision of transparent subsidies to pharmacies that are desirable on the basis of public policy objectives, but are not forthcoming under market conditions (e.g. establishment of pharmacies in sparsely populated rural areas).

Part of the brief of the Pharmacy Review Group was to conduct an *ex post* examination of the effect of the Contractor Regulations with a view to considering what, if any, regime should replace them. The Group ultimately observed that:

the capital value of contracted pharmacies [had] increased greatly under the Regulations, giving a commodity value to the contract, and an increase in the value of contracted businesses, that was never intended (2003:30).

However, barely two months after the Group was established, the Minister for Health and Children revoked the Regulations on 31 January 2002, following a successful High Court challenge by Dame Street Pharmacy Limited (see Section 4.2.5).

#### 4.2.4 Legal challenge one: the McSweeney Group

The 1996 Contractor Regulations were the subject of judicial review proceedings by an existing pharmacy chain, the McSweeney Group (comprising 21 pharmacies located in urban and rural areas), wherein, *inter alia*, the legal authority of the Minister for Health and Children to make the Regulations in the first place was challenged. Although nowhere reported in detail, the *vires* issue likely involved the question as to whether the terms of section 59 of the Health Act, 1970, in fact gave the Minister for Health and Children powers sufficiently wide in scope to encompass the scale of the location restrictions introduced by Regulations under that section made by the Minister. This supposition is given weight by the enactment of the little-known *Health (Miscellaneous Provisions) Act, 2001*. The main thrust of this very short (5-section) Act was a complete re-casting (and a broadening of the scope) of section 59 of the 1970 Health Act to make the Minister's regulation-making power more explicit and detailed. While Ministers piloting the Bill through the Oireachtas never at any stage referred to the *vires* difficulties of section 59, Deputy Gay Mitchell TD did do so at a later stage:

Some questions have been raised about whether regulations made under Section 59 were *ultra vires*. The Minister for Health introduced the Health (Miscellaneous Provisions) Act 2001 and included in that an amendment to put beyond doubt any question of regulations made under Section 59 of the 1970 Act being *ultra vires*.<sup>48</sup>

Deputy Mitchell also observed that, curiously, the Minister '*never actually gave effect to this change*'. According to some press reports, the threat of litigation from the McSweeney Group was one of the factors that ultimately prompted the Minister for Health and Children to deregulate the market.<sup>49</sup> However, a more pressing reason for the revocation of the 1996 Regulations lay in a further legal challenge by Dame Street Pharmacy Ltd.

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<sup>48</sup> <http://www.finegael.ie/PrintNews.cfm?NewsID=21169>[www.finegael.ie/fine-gael](http://www.finegael.ie/fine-gael) [http://www.finegael.ie/fine-gael-news.cfm/News/Id\\_news.cfm](http://www.finegael.ie/fine-gael-news.cfm/News/Id_news.cfm), accessed 23 September 2004.

<sup>49</sup> 'Chemists told more should be invested to improve premises', *Sunday Business Post*, 10 March, 2002.

#### 4.2.5 *Legal challenge two: Dame Street Pharmacy*

The *Dame Street* case involved an applicant who was refused a community pharmacy contract in 2000 and who appealed the decision, challenging the basis of the Regulations. According to the Minister for Health and Children, in the course of that appeal it became clear to him and to the Senior Counsel advising, that the Regulations were *ultra vires* and would collapse. The Minister gave a clear account to the Dáil of the dilemma in which he found himself:

I then sought an opinion from the Attorney General which I received in January on the Monday of the week I decided to revoke the order. The reason for the pressure was that on the Friday following the Monday on which I received the Attorney General's opinion, the *Dame Street* case was back in the High Court. I had to make an immediate decision on whether to continue with a position which I knew in my heart and soul was untenable given that I had been advised these regulations were invalid. The advice was as strong as one could get, so I decided to be up front and say that, as far as I was concerned, the regulations were invalid and I would revoke them. That was our response to that deadline of the court on the Friday. We were in line to be sued by the person concerned.<sup>50</sup>

#### 4.2.6 *Result of revocation*

As a result of the revocation which followed these legal cases, there are now no restrictions on granting new community pharmacy contracts to pharmacists in terms of location, population or viability of existing pharmacies. Notwithstanding the fact that the Minister was forced to revoke the 1996 Regulations early in 2002, he nevertheless appears to have attempted to re-enact them in mid-2002, apparently in the light of fierce opposition by the Irish Pharmaceutical Union to the earlier revocation. According to press reports, the Minister proposed a compromise set of new Regulations to the Union for consideration at its Annual Conference in April 2002.<sup>51</sup> However, the Minister's move was criticised by The Competition Authority, which objected to the non-transparent manner in which the Minister was acting. In the event, the new

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<sup>50</sup> Dáil Debates, 20 February 2002.

<sup>51</sup> 'Martin puts peace package to pharmacy lobby', *Sunday Business Post*, 28 April 2002.



Regulations did not proceed. The overall result is that Ireland is now one of only two EU Member States (Germany being the other) not to apply any distance or population criteria to pharmacy openings (Pharmacy Review Group, 2003). In addition, it is now no longer necessary to prove the viability of the prospective outlet, or to demonstrate that existing outlets (i.e. competitors) will not be adversely affected. The repeal of the regulations has not led to the outcome feared by the pharmacy profession, i.e. a takeover of the sector by multinational operators. In fact, as the figures in Section 2.1 show, the sector is still relatively unconcentrated and the removal of the regulations must be seen as pro-competitive.

### **4.3 Regulation of ownership**

Some countries also regulate ownership of pharmacy outlets, whether by limiting ownership of retail outlets to pharmacists, or by preventing ownership of multiple outlets. While that form of restriction is not yet a feature of the Irish regulatory landscape, there are indications that the Irish government may consider the introduction of such controls, arising from the Report of the Pharmacy Review Group.

#### *4.3.1 Proposed restrictions on pharmacy ownership*

The Review Group's Report included the following recommendations.

- Any pharmacy can hold a community pharmacy contract, subject to quality and service standards.
- A new restriction on ownership: a single entity may only hold up to eight per cent of the total number of community pharmacy contracts in any one health board area.
- Any contracts above this limit must be matched by the operation of contracts (without incentives) in areas designated by the health board Chief Executive Officer as having a significant unmet pharmacy need.
- The Minister for Health and Children should take interim measures immediately to implement the eight per cent limit on the number of contracts that may be held in a health board area.
- This model should be reviewed in five years (Pharmacy Review Group, 2003: 31-32).

The proposed eight per cent cap is particularly significant and Table 4.1 shows how this cap would operate (if adopted) in each Health Board area.

*Table 4.1: Pharmacy contracts per Health Board Area*

<i>Regional Health Authority</i>	<i>Current pharmacy contract numbers</i>	<i>Maximum contracts per entity, based on 8% cap</i>
Eastern Region Health Authority	433	35
Midland Health Board	71	6
Midwestern Health Board	126	10
Northeastern Health Board	112	9
Northwestern Health Board	71	6
Southeastern Health Board	141	11
Southern Health Board	207	17
Western Health Board	131	10

*Source:* General Medical Services (Payments) Board Annual Report, 2003.

Curiously, the Review Group Report does not provide a reasoned basis for the proposed limit or, indeed, any basis at all. The first mention in the Report of any such limit occurs in the list of recommendations.

It is considered appropriate to put a limit on the number of contracts that may be held by any one entity in each health board area, thus opening up competition in the knowledge that a pharmacy act would be in place to underwrite quality and public health in the medium term. It is the majority view that this limit should be 8%. (2003:31)

Nonetheless, it is evident from the written reservations contained within the Report that there were strong opposing views on the matter within the Group. The Irish Pharmaceutical Union President, in a note to Union members, commented:

...strong reservations have been entered by the Chief Pharmacist, DoHC, and the Pharmaceutical Society of Ireland

that the level of the cap is too high, while it is no surprise that the Competition Authority and the Department of Enterprise, Trade and Employment have entered an opposing reservation.<sup>52</sup>

Quite apart from the lack of justification or reasoning for this recommendation, there could also be legal difficulties in putting any such cap in place. For example, it is arguable that existing chains could not be forced to divest any contracts over the 8% threshold that they may currently hold. It is also likely that the Minister for Health and Children could not implement such a cap under existing legislation without introducing new primary legislation. These difficulties could explain why, although the Review Group delivered its Report to the Minister for Health and Children in January 2003, the Report was not published until February 2004 (and publication was not accompanied by any government statement of intended action). The Minister for Health and Children confirmed the legal difficulties to the Irish Pharmaceutical Union in late 2003:

However, as I am sure you are aware, the recommendations raised complex legal issues involving the EU and competition ...<sup>53</sup>

and there has been further recent speculation that the legal difficulties could be of a constitutional nature.<sup>54</sup>

#### 4.3.2 GEHE/*Unicare* merger

While the expressed concern of pharmacy interests was that in the absence of a quantitative limit on outlets in single ownership, the entire sector would be taken over by multinational entities, this does not appear to have transpired to date. When *Unicare* became the biggest chain in Ireland (with 52 outlets) following its takeover by GEHE in early 2002, The Competition Authority investigated the proposed transaction. The Authority reported to the Minister its opinion that, overall, the proposed transaction would not prevent or restrict competition in either the wholesale pharmacy market or in any retail pharmacy market in the State (2002a). In the event, the

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<sup>52</sup> [http://www.pharmacists-at-work.com/focus\\_links.jsp?focusID=99](http://www.pharmacists-at-work.com/focus_links.jsp?focusID=99), accessed 23 September 2004.

<sup>53</sup> Address by Micheal Martin TD, Minister for Health and Children, at the Irish Pharmaceutical Union's 2003 President's Dinner, 12 November 2003.

<sup>54</sup> 'Pharmacy sector criticises report findings', *The Irish Times*, 2 March 2004.

combined entity has acquired only three further outlets in the two years since then, and appears to have abandoned its original intention to acquire 100 outlets.<sup>55</sup> In fact, what has transpired is that smaller Irish chains have been building and expanding. The Hickey Group now controls the fourth-largest chain (20 outlets), and the largest indigenous one, following its acquisition of the seven-outlet O'Connell chain earlier in 2003. The McCauley and McCabe chains have also been expanding in the past two years.

The initial consideration offered in the takeover of Unicare by GEHE was reportedly €152 million (€127 million cash plus a €25 million 'earn-out' clause). Arising from the revocation of the 1996 Contractor Regulations in January 2002, the consideration was reportedly reduced to €110 million or €3.7 million per outlet, following legal action.<sup>56</sup> This reported 28 per cent reduction in valuation appears to reflect the parties' estimate of the value to the pharmacy industry of this particular set of restrictions previously imposed on it by law.

Some property experts expect pharmacy values to fall by up to 30% following deregulation of the sector.<sup>57</sup>

#### 4.3.3 *International ownership restrictions*

Many countries impose ownership restrictions on retail outlets, for example by requiring that pharmacies be majority-owned by an individual pharmacist or by preventing a pharmacist from owning more than one pharmacy, or preventing the combination of pharmacies with other businesses. Within the EU:

- ten of the 15 EU member states limit ownership of pharmacy outlets to pharmacists
- ten EU states have restrictions on multiple outlets owned by the same entity, i.e. there is effectively a ban on chains of pharmacies
- restrictions on the sale of pharmacies operate in eight EU countries.

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<sup>55</sup> 'Cesio quits pharmacy bid trail here', *Irish Independent*, 14 August 2003.

<sup>56</sup> See the following articles in *Irish Independent*, 'GEHE opens case to end deal' (12 March 2002) and 'GEHE eyes up 12 more pharmacies' (9 August 2002).

<sup>57</sup> 'Contract values expected to plunge', *Sunday Business Post*, 10 March 2002.

Table 4.2: Summary of non-price pharmacy restrictions in EU and selected other countries

Restriction on:	Number of openings	Location of openings	Company ownership	Multiple ownership	Sale of pharmacy	Use of EU "3-year rule" Derogation
Austria	Yes	Yes	Yes	Yes	Yes	Yes
Belgium	Yes	Yes	No	No	No	No
Denmark	No	Yes	Yes	Yes	Yes	No
Finland	Yes	Yes	Yes	Yes	Yes	No
France	Yes	Yes	Yes	Yes	Yes	Yes
Germany	No	No	Yes	Yes	No	Yes
Greece	Yes	Yes	Yes	Yes	No	No
Ireland	No	No	No	No	No	Yes
Italy	Yes	Yes	Yes	by private cos.	Yes	n/a
Netherlands	No	No	No	No	No	Yes
Portugal	Yes	Yes	Yes	Yes	Yes	Yes
Spain	Yes	Yes	Yes	Yes	Yes	No
United Kingdom	Yes	Yes	No	No	No	Yes
Australia	Yes	Yes	Yes	Yes	Yes	–
Canada	No	No	No <sup>a</sup>	No	No	–
New Zealand	n/a	Yes	Yes	No	No	–
USA	No	No	No	No	No	–

Sources: For EU Member States – Pharmaceutical Society of Ireland, 2001; Institut für Höhere Studien, 2003; Dudley, 2002. Table excludes Sweden, where a State monopoly owns the entire retail pharmacy network, and Luxembourg.

Australia: OECD 2001a, 159-160, 163.

Canada, Norway and USA: Office of Fair Trading 2003. Note: <sup>a</sup> Quebec, Nova Scotia and Ontario do not allow non-pharmacists to own pharmacies. New Zealand: <http://www.medsafe.govt.nz/hot/PharmLicence/guidelines.htm>, accessed 30 September 2004.

Table 4.2 provides a summary of the ownership restrictions operating in force in EU Member States and a number of other countries. Australia and New Zealand feature strong restrictions on entry, while in the USA and Canada, individual State governments, as opposed to the central Federal Government, largely control entry to the profession. In New Zealand, recent legislation now allows a pharmacist to own up to five pharmacies, but still requires majority ownership by pharmacists.<sup>58</sup> In Australia, each State has different limits on ownership of multiple outlets, ranging from a limit of two per pharmacist in Western Australia and Tasmania, to five in New South Wales.<sup>59</sup> Table 4.2 shows that, despite the restrictions on entry (past and present) in Ireland, most other EU countries are even more heavily regulated in this respect than Ireland. In fact, Ireland is on a par with the most liberal other countries, i.e. Netherlands, Canada, Norway and the USA.

#### 4.4 Relative importance of barriers to entry

In terms of significance, the various barriers described above could be categorised as (a) those affecting initial entry to the profession and (b) those affecting the pursuit of pharmacy as a business.

Those in the first category, i.e. the under provision of education places and the pre-education registration requirement, are indirect barriers, and the effect is difficult to quantify – although the severe under provision of education places is clearly much more serious than forcing aspiring students to register with a professional body before enrolment in a degree course. The result of the disparity between the high entry requirements of the degree course caused by such under provision and the minimum ability required to successfully undertake the study, is that pharmacy has attracted highly qualified (in terms of achieving a high Leaving Certificate standard) school-leavers. Bacon (1999) argues that while this increases the probability that there will be intelligent pharmacists produced, it is a very costly situation from a welfare point of view. First, there is an increased risk that many students will be

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<sup>58</sup> *Medicines (Amendment) Act, 2003*, effective September 2004. <http://www.medsafe.govt.nz/hot/PharmLicence/guidelines.htm>, [http://www.clerk.parliament.govt.nz/Content/Hansard/Final/FINAL\\_2003\\_09\\_11.htm#\\_Toc66856654](http://www.clerk.parliament.govt.nz/Content/Hansard/Final/FINAL_2003_09_11.htm#_Toc66856654), cols 8622, 8636, accessed 6 July 2004.

<sup>59</sup> [www.anz.com/Business/info\\_centre/economic\\_commentary/Pharmacy\\_Industry\\_Brief\\_Mar\\_04.pdf](http://www.anz.com/Business/info_centre/economic_commentary/Pharmacy_Industry_Brief_Mar_04.pdf), accessed 23 September 2004

unfulfilled by the demands of the course and subsequent career. The second loss arises from a resource allocation perspective. Bearing in mind the existence of incentives in modern economies for the most able people to become rent-seekers rather than entrepreneurs, what is happening, therefore, is that the incentives are allocating talent in a sub-optimal manner. The only people gaining entry are those of high ability. While they earn high rewards, this is partly a transfer from the rest of the economy. Bacon concludes that, in effect, the talents of these people are being under-used, and that this type of misallocation imposes a cost on the economy.

Restrictions on ownership and the three-year rule restricting overseas-trained graduates are more direct barriers to entry. While restrictions on ownership are still only putative, if introduced they would have a severe effect on competition, since they would in effect, penalise efficiency by capping chain size. The three-year-rule has already had a damaging effect on the market – the rule is in place now for seventeen years and, by definition, there are currently several hundred Irish-born, UK-educated pharmacists, all of whom are effectively precluded from opening their own pharmacy businesses.<sup>60</sup> The high returns to be obtained from the sector would be ample incentive for these people to enter the market – the fact that they are precluded from doing so effectively acts as a dampener on potential competition.

#### 4.5 Conclusion

The effect of the TCD monopoly on the provision of pharmacy education in Ireland, which was in place until very recently, was to create an artificial shortage of Irish-trained pharmacists. This shortage is costly from a welfare point of view. Those who failed to gain entry to TCD and were educated elsewhere in the EU found, on their return, another barrier to entry – statutory regulations effectively precluded them from opening their own pharmacy (i.e. the three-year rule). This has exacerbated the effects of the pharmacist shortage, thereby restricting competition.

Further restrictions on entry were introduced in 1996, dictating distance and population criteria for the award of State pharmacy

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<sup>60</sup> According to the OECD, the largest number of recent additions to the PSI Pharmaceutical Society register (about half in 1988-1997 and more than two thirds in 1998-1999) gained their qualifications from UK universities; it is reasonable to assume therefore, that many of these graduates are Irish citizens.

contracts (the latter are deemed as virtually essential for the viability of a pharmacy outlet). However, these restrictions were relatively short-lived and were removed following a number of legal challenges. Their removal does not appear to have led to undesirable outcomes. The government-sponsored Pharmacy Review Group has proposed a number of new restrictions, which would place a cap on the number of outlets held by a single entity. It is generally held that such quantitative restrictions on entry penalise efficiency and are therefore anti-competitive. However, it seems that legal difficulties may prevent the introduction of such a quantitative limit.

Ireland is not alone in featuring such barriers to entry. In fact, many other countries go even further, by either (a) restricting ownership of pharmacies to pharmacists or (b) maintaining controls on the sale of pharmacies.



## Regulation of prices

### 5.1 Introduction

Many governments worldwide fix the price of prescription medicines in order to contain public health expenditure. In general, three essential mechanisms (and variations or combinations of them) are used to achieve price regulation of prescription medicines:

- 1 price controls at the level of the manufacturer or importer
- 2 differing levels of co-payment by the consumer
- 3 control over the retail margins of the pharmacist.

The precise mix of instruments used in a particular country will depend on a number of factors, including:

- the size of the State's contribution to pharmaceutical expenditure, and the need to contain public spending
- the extent to which governments wish to recognise the contribution by drug companies to pharmaceutical R&D within their shores
- patterns of medicine prescribing and usage in individual countries.

This chapter explores the various drug-pricing (and price control) systems applicable both in Ireland and wider afield. The respective roles of the government and the pharmaceutical industry in setting prices at all levels of the distribution chain for prescription medicines are also discussed, and limited international price comparisons are made, both upstream and at retail level. The justification for fixed retail margins is assessed, as well as their apparent cross-subsidisation effect between different categories of consumers.

### 5.2 Upstream price-setting agreements

Since the inception of the General Medical Services scheme in 1972, the Department of Health and Children has signed a succession of

multi-year agreements with the drug companies (represented by the Irish Pharmaceutical Healthcare Association – IPHA) outlining agreed prescription drug prices and supply arrangements.<sup>61</sup> The agreements cover all medicines that can be prescribed within the State’s community drug schemes and all medicines supplied to hospitals and health boards. Over-the-counter medicines are not covered. The last such agreement was signed in 1997, has been extended (twice) to July 2004 and is due for review or renewal in 2004. The following are the main provisions of these agreements with the companies (McGuinn and Troy, 1998; Brenson and Lawlor, 1999).

- In the case of each medicine, the core price fixed is the price at which the wholesaler sells to the retailer. This is called the ‘Irish trade price’, or ‘approved trade price’.
- The wholesale margin (on all sales to retailers) is fixed at 15 per cent of the trade price, i.e. 15 per cent of the cost to the retailer, but discounts to retailers of between 7 to 9 per cent are common.
- The ex-manufacturer/importer price is derived from the first two above.
- For a new prescription medicine, the maximum authorised price to wholesalers is the *lesser* of (a) the average of the wholesale prices in five reference countries (Denmark, France, UK, Germany, and the Netherlands), or (b) the UK wholesale price.
- Prices to wholesalers of existing medicines covered by the GMS are frozen for the duration of the agreement.

Section 5.3.2 provides a simple example showing the ultimate impact of these arrangements at retail level.

### 5.2.1 *Price-setting systems*

Health authorities typically use a combination of complex criteria to set the prices for drugs supplied to insured consumers including:

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<sup>61</sup> The IPHA describes itself as ‘representing the international research-based pharmaceutical industry in Ireland. Our members include both prescription medicines companies and manufacturers of non-prescription or consumer health care medicines’ at: [www.ipha.ie](http://www.ipha.ie)

*International reference pricing:* this approach has been used by most OECD countries (including Ireland), with many European countries simply basing their ex-manufacturer prices on a weighted average of other countries' drugs prices. Under this type of scheme, regulators need only to choose the group of countries in the basket, set the weights on each country, and adjust for exchange rate movements (Bloom and Van Reenen, 1998). The list of countries selected for benchmarking in this way is obviously extremely important, since no country would wish to import prices from elsewhere that are higher than appropriate. In Ireland's case, there is an issue as to whether the existing set of reference countries is the correct choice.<sup>62</sup> This is discussed further in section 5.2.3.

*Therapeutic reference pricing:* another approach adopted by a number of European countries (e.g. Germany, Sweden, Netherlands) is to class drugs into therapeutically equivalent groups, and provide government reimbursement only for the cost of the cheapest drug in the group. The theory underpinning this strategy is that prices are driven down towards the lowest price in the group (Jacobzone, 2000).

*Therapeutic value of the drug:* this is taken into account in Australia, Belgium, Finland, France, Japan, Norway, Spain, Sweden and Switzerland (Jacobzone, 2000). In such systems, a panel of doctors typically adjudicates on the therapeutic benefits patients receive and prices are set accordingly (i.e. higher prices for the most 'beneficial' drugs).

*Reference to existing products:* such comparisons have been noted in the case of Australia, Belgium, Canada, Finland, France, Norway, Spain, Sweden and Switzerland (ibid). In Belgium, prices are based on improvement over existing products. In France, final prices are the result of negotiations with companies, which take into account similar products.

*The contribution of pharmaceuticals to the economy:* this is taken into account, to varying extents, in Australia, Belgium, Spain and the UK (Productivity Commission, 2001). For example, the UK government, through its Pharmaceutical Price Regulation Scheme, recognises the

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<sup>62</sup> 'The cost of Irish medicine – a bitter pill to swallow', *Irish Examiner*, 28 June 2004.

cost of research and development (and thus the pharmaceutical industry's contribution to the economy) within the prices paid for NHS medicines (Department of Health [UK], 2003). In Australia, the government compensates pharmaceutical companies participating in its Pharmaceutical Industry Investment Program by paying higher prices on nominated products supplied by the participating companies in return for those companies meeting commitments to undertake certain activities in Australia, including manufacturing and R&D.

To round out the picture, mention might be made of two extremes of the price regulation spectrum. While no OECD country is without *some* form of price limitation mechanism, the USA has less than most. In the USA, most government programmes (e.g. *Medicaid*) have some form of price regulation mechanism such as a mandatory rebate, discount, price cap or limit on price increases (Productivity Commission, 2001). In the private sector, managed care plans directly negotiate rebates from manufacturers based on their ability to use their formularies to steer members toward a particular pharmaceutical. At the other end of the spectrum, Spain takes account of a drug's therapeutic value, the cost of comparable treatments, the economic contribution of the pharmaceutical industry and the price in other countries; manufacturer profits are also controlled by taking industry costs into account in determining prices (Jacobzone, 2000). Governments may exert control by agreeing (or demanding) actual prices at ex-manufacturer level, and/or wholesale level, and/or retail level, and Jacobzone (2000) has shown that at least 20 (21 if Ireland is included) of the 30 OECD Member States control prices in this particular way.<sup>63</sup> Each country has its own variant method.

### 5.2.2 Profit control systems

At least six OECD Member States exert influence on drug prices by controlling profits (as opposed to prices) in the industry.<sup>64</sup> In some cases (Mexico, Spain), both prices and profits are controlled. The UK appears to be the only country using a rate of return or economic

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<sup>63</sup> Australia, Austria, Belgium, Canada, Czech Republic, Finland, France, Greece, Hungary, Italy, Japan, Korea, Luxembourg, Mexico, Netherlands, Norway, Spain, Sweden, and Switzerland and Turkey (Jacobzone 2000: 77).

<sup>64</sup> Czech Republic, Korea, Mexico, Spain, Turkey and the UK (ibid: 78).

regulation system. Under the Pharmaceutical Price Regulation Scheme, firms are prevented from raising the prices of existing drugs without the Department of Health's permission, but they are allowed to price new drugs freely, subject to their total profit constraint (defined as a rate of return on their total NHS capital stock) (Bloom and Van Reenen, 1998).

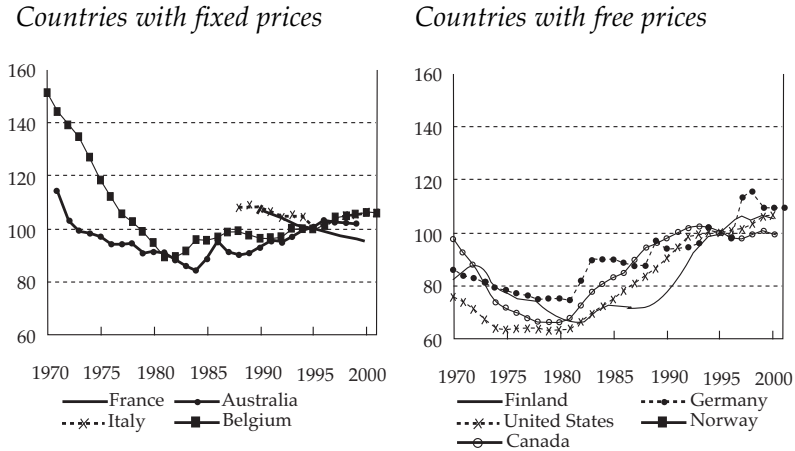
### 5.2.3 *Difficulties with international comparisons*

What effects do these control systems have? An in-depth analysis of cross-country price comparisons is beyond the scope of this paper and with good reason. The literature is permeated with health warnings about the profound difficulties associated with creating such comparisons, due to well-recognised problems with product heterogeneity, national consumption patterns and selection bias (Productivity Commission, 2001). Jacobzone (2000) points out that the complexity of pharmaceutical markets, subject as they are to conflicting policy goals and numerous public interventions, makes it extremely difficult to perform ordinary and reliable price comparisons. Danzon and Furukawa have neatly summed up the problems:

Providing accurate international drug price comparisons is not straightforward, because each country's pharmaceutical market basket is different. Products that are identical across countries in presentation form, strength, pack size, and manufacturer account for a tiny fraction of each country's total sales. This implies a trade-off: comparisons that are restricted to identical products in all countries are severely unrepresentative. Applying less strict matching requirements enables more representative comparisons but with some loss of standardization. Consequently, there is no unique, correct measure of price differences; rather, conclusions depend on unavoidable judgments about sample selection, matching criteria, the measure of price, and the weights attached to individual products in the composite index. We report several comparisons to illustrate the sensitivity of results to these methodological choices (2003: 1).

Having said that, data presented by Jacobzone – see Figure 5.1 – seem to suggest in general that countries using upstream fixed-price controls do not seem to have fared any better from the standpoint of achieving lower price levels in recent years than those who do not use such methods.

Figure 5.1: Relative price trends for pharmaceuticals



Source: Jacobzone, 2002

Table 5.1 compares the ex-manufacturer prices of 150 branded medicines (including branded generics) in the UK with a range of European countries and the USA. This shows that UK prices are considerably below US levels but are considerably in excess of prices in most other EU countries (Germany and Ireland follow much the same pattern as the UK in this regard).

Table 5.1: Bilateral comparisons of ex-manufacturer prices

Country	1998	1999	2000	2001	2002	5 year* average
Spain	71	67	64	67	<b>75</b>	<b>75</b>
France	85	84	80	81	<b>81</b>	<b>81</b>
Austria	81	83	77	81	<b>86</b>	<b>86</b>
Belgium	86	84	78	81	<b>86</b>	<b>86</b>
Italy	81	83	79	82	<b>86</b>	<b>86</b>
Netherlands	n/a	n/a	81	84	<b>88</b>	<b>89</b>
Finland	86	85	83	84	<b>88</b>	<b>89</b>
<b>Ireland</b>	<b>90</b>	<b>88</b>	<b>83</b>	<b>88</b>	<b>93</b>	<b>93</b>
Germany	108	97	91	94	<b>95</b>	<b>95</b>
UK	100	100	100	100	<b>100</b>	<b>100</b>
USA	174	184	209	217	<b>201</b>	<b>204</b>

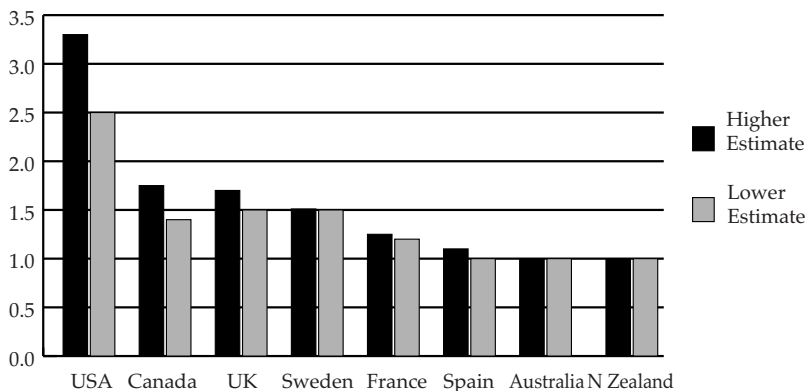
\* Based on 2002 market exchange rates (to Sterling).

Source: UK Department of Health, December 2003: 12.

Figure 5.2 gives an international price comparison based on 150 top-selling medicines, carried out by the Australian Productivity Commission. Again, these were bilateral comparisons, and the Commission urged caution in drawing any conclusions about relative price levels. Nonetheless, they do confirm the trends visible in Table 5.1, and identified elsewhere (see for example, the work of Bloom and Van Reenen, 1998) that, in a global context:

- the USA is a high-price country (at ex-manufacturer level) for pharmaceuticals
- Sweden and the UK are intermediate-price (Ireland would also be an intermediate price country in this context)
- Spain and France are low-price and Australia and New Zealand are also at the cheaper end of the ex-manufacturer price spectrum.

Figure 5.2: Ex-manufacturer price ratios for all categories, list prices



Source: Productivity Commission, 2001: 42 and E10, based on IMS Health price data.

Note: Prices are at average exchange rates for financial years 1998-9 and 1999-2000. Values on left-hand axis are ratios to Australian prices (= 1).

The Productivity Commission found no obvious association between the observed price differences and the types of subsidy or cost-containment mechanisms employed in the comparator countries (2001:73). It suggested that several factors other than

policy regimes also play a role in deciding price differences including factors such as differences in demand conditions, the subsidy status of particular pharmaceuticals, delays due to approval requirements, patent arrangements and the level of competition within therapeutic pharmaceutical groups. This would seem to reinforce the conclusions drawn from Jacobzone's analysis, which compared countries with price-setting systems with those without (see Figure 5.1).

#### *5.2.4 Reforming government price regulation in Ireland*

In Ireland, the Brennan Commission stressed the need for any government reform of the Community Drug Schemes to include the (re-)negotiation of cost-competitive ex-manufacturer drug prices at national level (2003:84). To achieve this, the Brennan Commission recommended that the existing agreement between the Department of Health and Children and the IPHA should be evaluated against international experience with similar agreements (particularly in EU countries) drawing appropriate lessons in containing drug costs and the rate of growth. The results of this evaluation should be used in the negotiation of any further agreement so as to assure value for money. A recent study assessed the effect of the five-country average price system used in setting prices in Ireland.<sup>65</sup> Based on official figures, the study compared the ex-wholesale prices of prescription medicines in Ireland to those in other countries, to determine potential cost savings on the largest community drug scheme if an alternative pricing mechanism were adopted. It was observed that the particular five countries used in the Irish formula tends to reflect a 'northern European price, which is generally higher than the wider European average'. The analysis covered a statistically comparable (and representative) sample of 39 drugs from the GMS list, selected from the top 70 drugs in order of total ingredient cost. The actual comparison was with Danish prices, with a very wide European set of average prices (as used in Denmark),<sup>66</sup> and with UK prices.

The study found that potential cost savings ranged from €20.73 million if a Danish price were adopted, to €16.23 million if an 18-

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<sup>65</sup> Tilson *et al* (2004).

<sup>66</sup> Denmark uses a reference system comprising average prices in the EU-15 (less Spain, Portugal, Greece, Denmark and Luxembourg), plus Norway, Iceland and Liechtenstein.



country European average price was used, to €6.82 million for the UK price. The clear implication is that using a wider set of European countries against which to fix Irish prices would reduce the level of those prices.

### *5.2.5 Price regulation in Europe*

This paper has outlined how Ireland is not the sole country facing the problem of very limited price competition, particularly for prescribed medicines. While the EU Commission has made considerable progress in pursuit of its Single Market goal relating to pharmaceuticals, nevertheless the single and most important item remaining within individual Member States' jurisdiction is the pricing and reimbursement of medicines. Each EU Member State still pursues its own efforts to contain public pharmaceutical expenditure through its own version of price regulation or control. This practice has resulted in a wide variety of pricing and reimbursement schemes across the EU, which is partly attributable to the various ways in which the schemes have historically developed in each Member State.

The sole effort by the Commission to achieve a degree of harmonisation in this area, the 1989 Transparency Directive, achieved a limited degree of success.<sup>67</sup> The Directive required national authorities to adopt transparent, objective and verifiable criteria when deciding on price or profit regulation. It also required Member States using such regulation to publish their lists and prices of approved reimbursable medicines. In reality, however, the Directive was simply a procedural directive setting-out the processes for (national) decision-making and did not serve as a harmonising directive. Member States, who have jealously guarded their subsidiarity rights to control this area, rebuffed several subsequent efforts by the Commission to extend the basic framework of the Directive and the Commission appeared to abandon any hope of further developing harmonisation measures (Joint Research Centre, 1997). However, since the early 2000s the Commission has made a new effort to make progress in converging the regulatory regimes of Member States concerning medicines (EU

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<sup>67</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ No L 40 of 11. 2. 1989 p. 8)

Commission, 2003). It has done this by 'launching a reflection' to identify alternative ways of controlling national pharmaceutical-related expenditure by Member States. Such alternative methods may include the option of letting manufacturers set the prices of new products, while negotiating appropriate safeguard mechanisms for Member States to contain expenditure in compliance with EU competition rules, for example by yearly pay-backs or rebates calculated on the revenues generated by these products on national markets (ibid, 15). The Commission claims that such a system would open the way for the free setting of prices in the market as with any other product. This would allow the emergence of a single EU 'ex-factory' price by allowing companies to have greater control over setting the price of their products while still providing Member States with an adjustable 'safety net' to cap pharmaceutical expenditures.

Obviously, price liberalisation across the EU would be easier to introduce if it was coupled with pharmaceutical budgets in the Member States (Joint Research Centre, 1997). Such budgets would be negotiated with the industry and established by the relevant authorities. A number of Member States have already adopted such measures as part of their national strategies to monitor pharmaceutical spending. Price liberalisation would also increase the scope for generic competition in those product markets where a multiplicity of substitutable treatments exists and where conditions render it feasible. In addition, if the pharmaceutical industry, national governments and EU authorities combined their efforts to address the issues of a single European Trademark and parallel trade in relation to pharmaceuticals, it is possible that a European approach to pharmaceutical pricing could be developed (ibid, 1997).

#### 5.2.6 *Euro-Med-Stat project*

A particularly important initiative to emerge from the EU Commission in recent years is the *Euro-Med-Stat* project, which involves all EU Member States. The aim of the project is to establish a set of indicators for monitoring price, expenditure and use of medicines in Member States. On grounds of practicality, the project group chose the pharmacy retail price as the most comparable price indicator, rather than those at any other level of the distribution chain. The monitoring of price and use in a standardised manner could then be used by each Member State, allowing better

comparison between countries and allowing each country to benchmark its performance against others. The National Centre for Pharmacoeconomics represented Ireland on the project. The project group produced two draft Reports in March 2004.<sup>68</sup> When fully operational, the price information therein should be of enormous help in facilitating informed debate about the level of medicine prices, both in Ireland and elsewhere in Europe. This is because it will, for the first time, provide fully comparable information about such prices, allowing fair comparisons to be made, as well as judgements as to whether current regulatory arrangements offer best value to Irish consumers and the Irish taxpayer.

### 5.3 State payments to pharmacies

In Ireland, the professional dispensing fees payable to pharmacists for dispensing medicines under State-funded schemes are negotiated between the Department of Health and Children and the Irish Pharmaceutical Union. The publicly funded portion of pharmaceutical expenditure has risen dramatically in recent years; from 52 per cent in 1980, to 64 per cent in 1990, to over 80 per cent in 2002 (Jacobzone, 2002; OECD 2004). In 2002, the Irish State paid €818 million to pharmacists for pharmaceutical services under the various schemes, an increase of 21 per cent over the previous year (General Medical Services (Payments) Board, 2003:10). The majority (€601 million) of this amount referred to reimbursement of wholesale drug costs (an average of €481,500 per contracted outlet), and €216 million was in respect of 'fees and mark-up' (an average of €172,800 per contracted outlet). Under the Drug Payment Scheme specifically, the '50 per cent mark-up' component alone accounted for €59 million, an average of €47,200 per contracted outlet.

#### 5.3.1 Overall reimbursement arrangements

The various price reimbursement arrangements for the main drug payment categories met by the Irish State are detailed and summarised in Table 5.2.

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<sup>68</sup> Euro-Med-Stat. The Library of European Union Pharmaceutical Indicators: Draft Report 1 – Price Indicators. Draft Report 2 – Recommendations for national registers of medicinal products with validated ATC codes and DDD values. Pre-Publication Copy. Both documents available at [www.euromedstat.cnr.it/indicators/indicators.asp](http://www.euromedstat.cnr.it/indicators/indicators.asp), accessed 6 October 2004.

Under the General Medical Services scheme, the cost of medicines provided by retail pharmacies free to individuals with medical cards is reimbursed to the pharmacist by the State (approximately 30 per cent of the Irish population are entitled to medical cards) (General Medical Services (Payments) Board 2004a:19). Pharmacists are reimbursed the fixed wholesale cost (i.e. the 'approved trade price') by the Board and paid a standard dispensing fee of €2.98 per item dispensed. There are also higher fees payable for extemporaneous<sup>69</sup> dispensing and compounding, and urgent/late dispensing.

A further 30 per cent of the population (approximately 1.2 million people) are also members of the Drug Payment Scheme.<sup>70</sup> Under this scheme, non-medical cardholders pay for prescription drugs up to a monthly threshold of €78, with any additional expenditure over this amount being met by the State. Above the €78 threshold, the pharmacist is reimbursed the fixed wholesale cost to them of the medicines, plus a standard dispensing fee of €2.59 per item, plus an extra 50 per cent mark-up on the fixed wholesale cost. Higher dispensing fees are available in respect of mixtures, lotions, ointments/creams, powders, and extemporaneous prescriptions.

Medicines are also provided free to all individuals with certain chronic illnesses (e.g. cystic fibrosis, cerebral palsy) regardless of means, under the Long Term Illness scheme. Reimbursement arrangements are exactly the same as for the Drug Payment Scheme, that is both a prescription fee per item and a 50 per cent mark-up applies; the only difference is that there is no qualifying monthly threshold for the consumer.

Some pharmacies provide High Tech Drugs (e.g. anti-rejection drugs for transplant patients, chemotherapy medicines) and the State pays a monthly 'patient care fee' of €49.64 per patient for such services. The pharmacist may also claim varying dispensing fees for mixtures, ointments etc. Health Boards purchase the drugs from wholesalers and distribute them to pharmacies, therefore no retail mark-up is available. Pharmacies participating in the Methadone Treatment Scheme are reimbursed the wholesale cost of the medicine, plus a monthly patient care fee of (a maximum of) €49.59

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<sup>69</sup> An extemporaneous prescription is one that requires the pharmacist to mix or 'compound' the medication in the pharmacy for the specific needs of the patient.

<sup>70</sup> Minister for Health and Children, Dáil Select Committee on Health and Children, 5 December 2002.

per patient (General Medical Services (Payments) Board, 2004a: 38). In each of the above cases, products must comply with the pricing structure of the IPHA Agreement, and the approved trade price is the basis of calculation of payment (by the State) in all cases (General Medical Services (Payments) Board, 2004b: 8).

*Table 5.2: Breakdown of retail pharmacy charges*

GMS	Official fixed wholesale cost + €2.98 dispensing fee + VAT recouped from GMS
DPS (amounts per customer over €78 per month) and LTI (no qualifying threshold)	Official fixed wholesale cost +50% of wholesale cost + €2.59 dispensing fee + VAT recouped from GMS
Private prescription	Free pricing, but 'custom' is to apply a mark-up of 50% of wholesale cost, + dispensing fee + VAT
Over the counter medicines	Free pricing, but 'custom' is to apply a mark-up of 50% of wholesale cost + VAT

*Source:* GMS (Payments) Board Annual Report, 2003, 22.

Box 1 provides a simple example of how the above system works in practice.

*Box 1: Example*

A consumer has not required any medicines in the previous month and comes into a pharmacy with a prescription for one course of tablets. The particular treatment is expensive – suppose the IPHA-Government Price Agreement specifies an Irish trade price of €100 for this. Of this €100, the wholesaler gets €15 and the manufacturer €85. What happens next depends on the status of the end consumer.

If the consumer is a medical card-holder, the price remains at €100, the consumer gets it free of charge, and the pharmacist gets €100 back from the General Medical Services (Payments) Board, plus a dispensing fee of €2.98.

If the consumer is a Drug Payment Scheme or Long Term Illness Scheme member, a 50% mark-up is added, so the invoice price to the consumer is €150. But the consumer only pays €78. The final amount that the pharmacist receives for the transaction is, in this instance, made up as follows:

Wholesale cost to pharmacist	= €100
+ €50 mark-up from the State	= €150
– €78 co-paid by consumer	= €72
+ €2.59 dispensing fee from the State	= €74.59
= Overall re-imburement from State	
Add back in €78 paid by consumer	= €162.59
= Overall amount received by pharmacist	
Pharmacist's margin	= $\frac{(\text{€}162.59 - \text{€}100) \times 100}{\text{€}162.59}$
	= 38.5%

This simple example does not take account of any extra discount the pharmacist may be able to negotiate with his/her wholesaler. Any such discount would, of course, add to the pharmacist's margin.

For purely private prescriptions (i.e. for non-GMS, non-DPS members, and those less than €78 per month for DPS members), consumers pay the full cost of the medicines directly to the pharmacists. Charges to private consumers are not regulated and may vary, but the general charge appears to be the wholesale cost of the product plus a 50 per cent mark-up and a dispensing fee.

### 5.3.2 Retail margins

Table 5.3 outlines the estimated margins achieved by pharmacies at retail level, derived from five published sources. The percentage figures given generally include drugs on which the State or a health insurer has made a reimbursement to the pharmacist, but exclude any wholesale discounts. Over this range of estimates, it is clear that one of the highest retail margins in the EU is achieved in Ireland.

Table 5.3: Pharmacy retail margin (%)

Country	CSES 1998 data	URCH 1999 data	IHS 1999 data	Bacon 1997 data	EU 1997 data	Other <sup>(a)</sup> data
<b>Ireland</b>	<b>n/a</b>	<b>33.0</b>	<b>33.0</b>	<b>33.0</b>	<b>25</b>	
Germany	27.8	31.7	31.7	22.5	28	
Belgium	27.0	31.0	31.0	29.2	27	
Denmark	25.1	25.4	29.2	20.3	25	
Austria	31.0	23.2	28.9	22.6	30	
Finland	29.0	37.0	28.8	29.0	31	
Spain	29.9	27.9	27.9	28.8	28	
France	25.9	26.1	27.6	25.5	25	
Greece	25.0	45.8	25.9	24.0	25	
Italy	25.5	26.7	22.4	25.0	27	
Netherlands	21.4	33.0	21.4	n/a	25	
Sweden	20.0	20.0	20.0	20.1	22	
Portugal	20.0	18.0	20.0	19.0	20	
UK	27.5	15.0	17.3	7.5	26	
Australia	26.0					
Norway		21.9				
Switzerland	33.5	35.4				
USA						22.0

Sources: Centre for Strategic Economic Studies 1999, Table 6, 29.

Urch Publishing, 2001, Appendix Table 4, 192.

EU, 1998, Annex 12,,32.

Institut für Höhere Studien, 2003, 347.

Bacon, 1999, Table 2.2, 11.

<sup>(a)</sup> (US) National Association of Chain Drug Stores.

### 5.4 International regulation of drug prices

Almost all developed countries have well-established systems of health insurance, whether public systems funded by the State or private insurance systems. These systems typically subsidise the retail cost of prescribed medicines via a system of co-payment between the State (or private health insurers, depending on national law and practice) and the consumer. Depending on the system used, pharmacies will be reimbursed either the total cost of medicines supplied (in respect of people eligible for full coverage), or a certain portion of it (leaving the balance to be paid by the consumer). The actual arrangements for reimbursing pharmacies vary widely from country to country, according to which the consumer will pay more or less (towards the cost of the medicines) by way of percentage contribution. The majority of EU countries do not follow a co-payment (France, Italy, Netherlands) system or a set co-payment limit (Belgium, Denmark, Finland, Ireland, Norway, Sweden, UK). In Austria and Spain the co-payment is based on a fee per item – in Germany it is based on a fixed percentage (2 per cent) of income. There is no limit to the co-payment for patients in Greece, Portugal and Spain. Patient co-payment for prescription medicines in Ireland amounted to €95m in 2002 (Barry *et al*, 2004). In 2002, approximately 32 per cent of the Irish population received their prescription medicines free of charge. For other patients (i.e. those under the Drug Payment Scheme) the out-of-pocket co-payment (maximum €78 per month) towards the cost of their medications is amongst the highest in Europe.

Because of the central role of the State in subsidising the retail price of most prescribed medicines, the State is, in fact, the *de facto* single biggest buyer of medicines for the majority of consumers. In cases such as the USA, where private health insurance is more prevalent, it is the insurers (or perhaps, more accurately, health management organisations who perform an intermediary role) who, in effect, are the medicine buyers. It is precisely this central feature that leads to apparent general consumer indifference about the actual cost of drugs. This feature also distorts the price mechanism to the extent that regulation is rendered inevitable, as governments and/or private insurers act to control their exposure by exerting control over the prices charged (and ultimately reimbursed) at various stages in the distribution chain. Thus, the vast majority of OECD countries control drug prices, although a small but significant minority (including the USA and Denmark) do so only to a limited extent.



Pharmaceuticals have been subject to extensive and wide-ranging price-fixing policies in OECD countries, for several decades (Jacobzone, 2000:33).

Of course, in most countries, manufacturers are, in theory at least, formally free to set prices. In practice, however, this freedom is almost completely curtailed by the monopsony status of the State as the single biggest buyer of medicines. This gives governments such a strong hand that formal statutory price control or regulation rarely arises – the most a government has to do is regulate the reimbursement arrangements for a given medicine, thereby forcing the manufacturer to agree to a voluntary price agreement (as is the case in Ireland). References to ‘price-setting’ by States should therefore be seen in this context – a more accurate, if unwieldy, description might be ‘State reimbursement conditions’.

## 5.5 Breakdown of retail price

Table 5.4: Share of final retail drug price (%)

Country	VAT	Pharmacy	Wholesaler	Manufacturer
<b>Ireland</b>	<b>0.0*</b>	<b>33.0</b>	<b>10.0</b>	<b>57.0</b>
Belgium	5.7	29.2	8.5	56.6
Germany	13.8	27.3	7.7	51.2
Spain	3.8	26.8	6.7	62.7
Finland	7.4	26.6	2.6	63.3
France	5.2	26.2	3.8	64.8
Austria	16.7	24.1	7.5	51.8
Greece	7.4	24.0	5.5	63.1
Denmark	20.0	23.4	4.1	52.5
Italy	9.1	20.4	6.7	63.8
Netherlands	5.7	20.2	10.8	63.4
Sweden	0.0	20.0	2.4	77.6
Portugal	4.8	19.0	8.4	67.8
UK	0.0	17.3	10.3	72.4

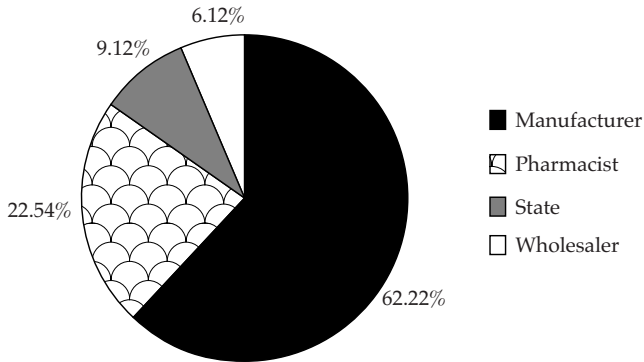
Source: Institut für Höhere Studien, 2003, 349.

Note: \* 0% VAT on oral medicines in Ireland.

Two further elements of the final price at the consumer level should be borne in mind. The first of these is the wholesale price to retailer, and the second is value added tax (VAT). Ireland, Sweden and the UK are the only EU countries with a zero VAT rating for medicines. It is difficult to arrive at reliable data on levels of actual wholesale prices (in view of the variable, but significant, discounting in practice). However, Table 5.4 is a recent effort to represent the final retail price of medicines in EU Member States, in terms of the proportion of that price accounted for by the manufacturer, the wholesaler, the retailer and by VAT. The data is presented in order of decreasing pharmacy retail share of the final price. Again, Ireland is represented at the top of this Table.

Figure 5.3 is an attempt by the European Federation of Pharmaceutical Industries and Associations to show this kind of breakdown graphically on a European-average basis – the reference to ‘State’ is to the payment of VAT, where applicable.

*Figure 5.3: Price structure – breakdown of the retail price of medicine, 2002 (%)*



*Note:* Estimated non-weighted average for Europe

*Source:* European Federation of Pharmaceutical Industries and Associations, 2004: 19.

## 5.6 Analysis of price issues in Ireland

The paper has demonstrated the central role of the State in subsidising (and in the case of the GMS, paying 100 per cent of) the retail price of most prescribed medicines. This effectively removes

the normal incentives for consumers in a competitive market to shop around, and for price to act as the most defining competition characteristic. In practical terms, this also holds true for medicine retailers. Since they are reimbursed in most cases for the wholesale cost of medicines – and also paid a guaranteed 50 per cent mark-up in many cases – the incentive for them to reduce prices to increase market share is reduced. The pharmacist could, in theory, reduce prices, but it would appear that practitioners are so accustomed to a guaranteed reimbursement level that there is no real evidence at present of meaningful price competition.

### *5.6.1 Guaranteed retail margin*

The notion of a guaranteed margin has a long history, pre-dating the Drugs Payment Scheme, GMS and the Health Acts. According to a report by the Fair Trade Commission in 1956, the Irish Drug Association (now the Irish Pharmaceutical Union) said that this had been its principal object on its establishment in 1909. The Association issued an annual list of prices to its members, known as the Index List. For the great bulk of products, the Commission reported that the manufacturers set prices (in agreement with the Association) under resale price maintenance arrangements, and the retailer's margin was 'generally 33% off the price to the consumer' (ibid, 27). Where the manufacturer did not set prices, the Association '... included prices in the Index List which would allow the chemist a margin of 33% off the retail price'. A second stated aim of the Association was the achievement of a position in which a gross profit margin of 33 per cent off the selling price (i.e. 50 per cent on cost) would be accepted as normal and uniform in the trade (ibid, 31). The Commission also reported that, insofar as manufacturers marketed their products through chemists, manufacturers did not take any steps to enforce resale prices, 'There was no need to do so because price-cutting by chemists was stated to be non-existent' (ibid, 33). Against this historical background, it is hardly surprising that today, price-cutting by pharmacists (or as it is also known, price competition) appears practically non-existent, almost 100 years after the foundation of the Irish Drug Association.

The guaranteed margin is effectively embedded in the system at this stage, and is now widely recognised. A press release by the Irish Pharmaceutical Union on 18 June 2003 states in quite straightforward terms that, in relation to the Drug Payment Scheme:

... pharmacists receive a dispensing fee of €2.49<sup>71</sup> per item and they charge an additional 33% margin on the price of medicines dispensed under the Scheme. [emphasis added]

The Minister for Health and Children confirms that the guaranteed margin is a major cost driver in relation to the Drug Payment Scheme:

The other major cost is pharmacists, who obtain a 50% mark-up on every item prescribed under the DPS. That has a significant multiplier effect in terms of driving the costs of the drug payment scheme. That agreement was arrived at after industrial relations issues were resolved and the system was then put in place ... It is built into the system.<sup>72</sup>

### 5.6.2 Cross-subsidisation effect

Overall, it is clear that for a certain portion of their business, pharmacies have for many years been guaranteed a gross profit margin on sales by the State. Such guarantees appear to be unique within the retail sector. The differing payment systems for GMS and other prescriptions are such that, in effect, medicine payment reimbursements to pharmacists under the GMS have, for many years, been cross-subsidised by those consumers who do not qualify for the scheme.<sup>73</sup> In other words, non-medical cardholders, having contributed to the cost of GMS pharmaceutical services via general taxation, are subsidising such costs a second time. Indeed, it could be said that DPS consumers are subsidising not just the GMS, but pharmacists' incomes and profit margins as well. In a further acknowledgement of this issue, the Irish Pharmaceutical Union commented recently:

It's fair to say that if you just had GMS patients, you wouldn't be in the business; that it just wouldn't be enough to support a pharmacy; and that you depend on your private patients to cross-subsidise, to keep both going.<sup>74</sup>

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<sup>71</sup> According to the GMS (Payments) Board Annual Report for 2002, the correct figure is €2.59 per item.

<sup>72</sup> Minister Martin, Dáil Select Committee on Health and Children, 5 December 2002.

<sup>73</sup> This was confirmed by the IPU President at a recent Seminar on Community Pharmacy, *IPU Review*, 1 March 2004: 96.

<sup>74</sup> 'The cost of Irish medicine – a bitter pill to swallow', *Irish Examiner*, 28 June 2004.

Such cross-subsidisation is not uncommon and, in general, private customers in retail pharmacies pay more in order to compensate those for whom prices are bargained down. When the Medicaid extension was established in the USA for example, non-Medicaid consumers had to pay higher prices than before (Jacobzone, 2000).

In summary, in economic terms, the market is characterised by private monopolistic pricing, with prices being set inversely to the demand elasticity of consumers in order to extract the maximum surplus from them. The price strategy of firms also takes into account the level of therapeutic advance embodied in a new product, with higher prices set for products which offer a higher therapeutic improvement and which have less competitors (Lu and Comanor, 1998, as cited in Jacobzone, 2000:40).

### 5.6.3 Review of Community Drug Schemes

The Brennan Commission recently examined the Community Drug Schemes as part of its *Review of Financial Management and Control Systems in the Health Service* (Brennan Commission, 2003). The Commission identified these schemes as the area showing the greatest cost escalation across the Irish health services in recent years. Particular concern was expressed with regard to the operation of the Drug Payment Scheme and the report drew attention to the fact that, 'in accordance with normal commercial practice', retail pharmacies routinely negotiate discounts (in the form of rebates) with wholesalers in relation to the drugs, medicines and appliances they supply under the Scheme. Such discounts are in addition to the dispensing fee and 50 per cent mark-up received by pharmacies on such products, and do not appear to be 'captured' by the State's reimbursement systems. The Brennan Commission concluded that the Scheme needed to be urgently reviewed, to ensure that expenditure thereon was economic, cost effective and provided value for money. Key features of such a review would include:

- influencing/incentivising positive prescriber behaviour
- minimising inappropriate prescribing
- maximising the prescription and dispensing of generic products (2003: 84).

To achieve the above would require the introduction of a system whereby Health Boards would actively monitor and evaluate prescribing patterns by individual prescribers and reimbursement

patterns by individual pharmacists. It would also involve the introduction of incentive schemes for reducing levels of prescribing and drugs costs. It was further recommended that the proposed review would apply across all publicly funded drugs and medicines schemes – the General Medical Services Scheme as well as the Drug Payment, Long Term Illness and High Tech Medicines Schemes.

With regard to generics, much has been written about the role of generic medicines and their potential for moderating price levels. A study of generic prescribing in 2001 found that the proportion of prescriptions dispensed generically under the General Medical Services Scheme (22 per cent) was almost twice the proportion dispensed under the Drug Payment Scheme (12 per cent) (National Centre for Pharmacoeconomics, 2002). Around a quarter of all generics prescribed were branded generics. The Study found that eleven of the top thirty drugs of highest cost to the General Medical Services Scheme, had a generic equivalent, which if substituted could produce savings in the region of €5.65 million.

On the other hand, the potential for savings, arising from more prescribing of generic medicines, appeared to be played down by the Secretary-General of the Department of Health and Children, who stated:

When one begins to strip it down and look at the true potential to make savings through the use of generics, one moves from an intuitive feeling that it is an attractive proposition. When looked at in terms of the availability of generic substitutes, the cost difference for the top thirty items in the GMS and the top items prescribed under the DPS are marginal in many cases. In recent years the significant cost difference that used to prevail between proprietary brands and generics has become marginal. The true potential saving is something to which we are giving active consideration, with a view to taking action in 2003. However, the clinical accountability of certain general practitioners regarding their duty to prescribe what they believe is the best product is also a factor. This matter has a number of different dimensions and it is not easy to deal with. There is some potential for savings, but all of the factors involved mean that is not huge.<sup>75</sup>

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<sup>75</sup> Committee of Public Accounts, Debate on 2001 Annual Report of the Comptroller and Auditor General and Appropriation Accounts. Vote 33 – Health and Children, 16 January 2003.

Finally – and arguably, more significantly – the Brennan Commission recommended that a flat-fee basis for reimbursement of drug costs by the General Medical Services (Payments) Board to pharmacists should apply across all national drug schemes. This would lead to the cessation of payments to pharmacies of the ‘traditional’ 50 per cent mark-up for all non-GMS prescribed medicines – or indeed, any mark-up at all – pharmacists would simply be paid a dispensing fee per item, as they are under the GMS. In addition, the Commission recommended that the State should only reimburse at the rate of the lowest cost for therapeutically equivalent products in all schemes. Not surprisingly, this particular recommendation provoked strong opposition from the Irish Pharmaceutical Union, its Vice-President stating, ‘Under no circumstances will my Members accept a flat fee scheme to replace the current system’.<sup>76</sup>

#### *5.6.4 What scope exists for retail price competition?*

In the case of prescriptions which do not attract public reimbursement (e.g. a prescription presented by a non-medical cardholder who also does not reach the monthly threshold to qualify for the DPS), it might be felt that, on the consumer’s side of the bargain at least, there ought to be an incentive to shop around, as they ought to be sensitive to price.

However, conditions are not conducive to price competition in this case either as there is a complete lack of price transparency in relation to prescription-only medicines. The medicines concerned are never (albeit, perhaps for good reason) kept in public view, nor are prices displayed in any fashion. Thus, the typical consumer has generally no way of knowing what the price of a particular prescription is going to be before the transaction occurs. The only realistic circumstance where the consumer might have this information would be the case of a repeat prescription by a person who (a) does not hold a medical card, (b) is not a member of either the Drug Payment Scheme or the Long Term Illness Scheme – however, even in that case, incentives to shop around would be outweighed by factors such as consumer inertia, fear of embarrassment and (given that the patient is ill to begin with) unwillingness or inability to go elsewhere. In this context, the

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<sup>76</sup> ‘Pharmacists warn that a move to ‘fee per prescription’ in all State drug schemes could lead to collapse of both the GMS and DPS schemes’, IPU press release, 18 June 2003, at [www.ipu.ie](http://www.ipu.ie), accessed 19 June 2003.

Pharmacy Review Group (2003) recommended that there should be increased pricing transparency at the point of sale, including advising of prescription prices in advance of supply, and the price of all dispensed items on labels. This seems a sensible recommendation.

In addition, the scope for a pharmacy to stimulate product demand in ways other than price is severely limited. The next most common demand stimulant (after price) is normally advertising, but this route is not open to pharmacies either, given the extensive prohibitions on medicine advertising described in Chapter 6. In fact, it is the prescribing doctor, rather than the patient or the pharmacist, who decides which particular prescription medicine to demand. Neither can manufacturers use the usual competitive parameters of branding and advertising to consumers, since direct product advertising to the public of prescription-only medicines is also prohibited by law. Of course, product advertising direct to doctors is allowed, but this removes the final consumer from the picture, and arguably contravenes the concept of transparency.

## 5.7 Conclusions

Many governments worldwide have mechanisms in place controlling the prices of medicines (at all levels of the distribution chain), primarily because the State is, in most cases, *de facto* the biggest 'purchaser' of prescription drugs. It is this central feature that leads to apparent general consumer indifference about the actual cost of drugs. It also so distorts the price mechanism that regulation is inevitable, as governments act to control their exposure by controlling the prices charged (and ultimately reimbursed) at various stages in the distribution chain.

Price control systems typically use a combination of complex criteria in setting prices, including international reference pricing, therapeutic value, industry profit controls and contribution of pharmaceuticals to the economy. In Ireland, a Government-Industry Agreement fixes prices, at all levels of the distribution chain. The Brennan Commission has recommended that this agreement be evaluated against international experience and, if necessary, renegotiated on a more cost-competitive basis.

International price comparisons in relation to pharmaceuticals are extremely hazardous (the literature documents this fully). However, countries using upstream controls do not seem, in



general, to achieve lower price levels than those that do not. With regard to ex-manufacturer prices, Ireland is, in general, a high-price country in EU terms. Only the UK and Germany appear to have higher levels. Wider afield, the EU Commission has had to recognise that pricing and reimbursement decisions are the responsibility of each Member State, although it expressed interest in finding alternative ways to control national pharmaceutical-related expenditure by Member States. This includes the option of letting manufacturers set the prices of new products, while negotiating appropriate safeguard mechanisms for Member States to contain expenditure in compliance with EU competition rules.

At retail level in Ireland, the State reimburses pharmacists for pharmaceutical services to consumers under various Community Drug Schemes, most notably the General Medical Services Scheme (for medical card-holders) and Drug Payment Scheme. In all these cases, products must comply with the pricing structure of the Government-Industry Agreement, and the approved trade price is the basis of calculation of reimbursement in all cases. For prescriptions presented by medical card-holders, the State reimburses the pharmacist the fixed wholesale cost (i.e. the 'approved trade price') of the drug; the pharmacist also receives a standard dispensing fee of €2.98 per item dispensed. For prescriptions presented by participants in the Drug Payments Scheme, the consumer pays the first €78 per month, and the pharmacist (as well as the wholesale cost and a standard dispensing fee of €2.59 per item) is paid a 50 per cent mark-up on the fixed wholesale cost. For purely private prescriptions (i.e. for non-GMS, non-DPS members, and below €78 per month for DPS members), consumers pay the full cost directly to pharmacists. Charges to private consumers are not regulated and so may vary, but the general charge appears to be the wholesale cost of the product plus a 50 per cent mark-up on cost, and a dispensing fee. These reimbursement arrangements result in Ireland having one of the highest pharmacy retail margins in the EU, at 33 per cent on average.

The notion of a fixed margin on medicines supplied under certain state schemes is a rather unusual one in retailing nowadays. However, it has a long history, dating back many decades to the foundation of the Irish Pharmaceutical Union. The guaranteed margin is embedded in the Drug Payment Scheme (and beyond) at this stage. The effect is clear – non-medical card-holders, having

contributed to the cost of health services via general taxation, are subsidising such costs a second time, as well as pharmacists' incomes and profit margins. The Brennan Commission recommended the abolition of fixed margins at retail level.

## Regulation of supply

### 6.1 Regulation of supply in Ireland

A comprehensive treatment of the host of legislation governing the manufacture, licensing, wholesaling, supply, sale, advertising and promotion of medicines, both in Ireland and elsewhere is beyond the scope of this paper. This Chapter focuses instead on the control of supply of medicines, including the emerging critical issue of the supply of medicines by mail order, particularly via the internet.

The supply of prescription medicines is controlled by statutory regulations made periodically by the Minister for Health and Children. A number of sets of regulations were made between 1996 and 2002, and these are now consolidated in the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003*. The most important effects of the Regulations are

- to restrict the sale of scheduled prescription medicines to supply on a prescription-only basis
- to provide that most medicines exempt from prescription control may also only be supplied by or under the supervision of a pharmacist
- to prohibit the supply of medicines by mail order; this includes sales via the Internet.

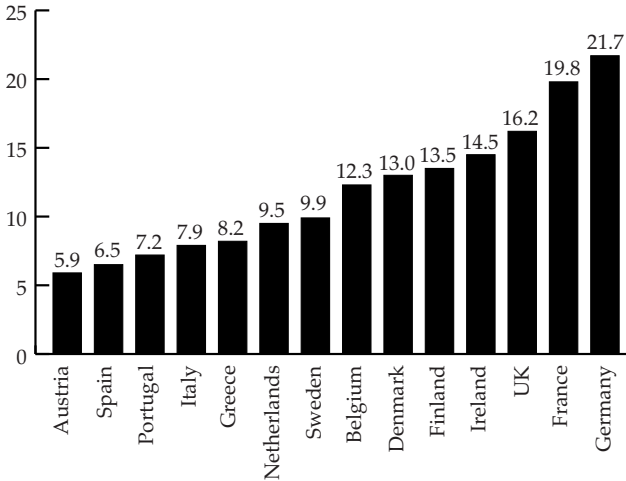
A number of substances are specifically exempted from the pharmacist-supervised sale requirement at (b) above, e.g. aspirin, folic acid and certain vitamins. These substances, listed in a Schedule to the Regulations, may be supplied in non-pharmacy outlets when contained in over-the-counter preparations. There are also limited exemptions for certain low-strength homeopathic medicines.

### 6.2 Regulation of supply internationally

Systems for controlling the supply of medicines vary worldwide, but most make the basic distinction between prescription-only and over-the-counter medicines. Pharmacies have a monopoly on the distribution of over-the-counter medicines in nine of the EU 15

states, while the remainder (Austria, Denmark, Finland, Germany and the UK), generally follow the Irish model, i.e. differentiating between medicines available (a) on prescription-only, (b) over-the-counter, but only in a pharmacy, and (c) over-the-counter in any outlet (Kanavos, 2002). Figure 6.1 gives comparative data on the relative sizes of the prescription and non-prescription drug markets in EU countries; Ireland is at the upper end of penetration of non-prescription (i.e. over-the-counter) versus prescription drugs.<sup>77</sup> Non-prescription medicine sales account for approximately 14.5 per cent of the total Irish pharmaceutical market – only UK, France and Germany demonstrate higher sales in this regard.

*Figure 6.1: Non-prescription medicine sales as % of total pharmaceutical market, 2001*



Source: EU Commission 2003: 50, citing IMS Health.

### 6.3 Prescription versus non-prescription status

Prior to the early 1980s, only a limited range of conditions were considered as suitable for treatment without a doctor's intervention, including mild to moderate pain, coughs and colds, constipation and

<sup>77</sup> Other estimates (e.g. Association of the European Self-Medication Industry, AESGP, 2004b) attribute a higher percentage to non-prescription sales generally, including in Ireland – for Ireland, AESGP suggest a figure of 20.7 per cent.

minor skin problems (Association of the European Self-Medication Industry, 2002a). There is, however, a growing public debate about the extent to which medicines ought to be 'prescription-only' and in recent years governments have begun to actively encourage increased individual responsibility for health by initiating or approving the shift of a growing number of ingredients from prescription-only to non-prescription status. This growing trend has led to continuing tension between, on the one hand, proponents of self-medication who want more medicines to be switched from being prescription-only to being more freely available and, on the other, those who fear for the safety of consumers (and perhaps also for the loss of business to other kinds of retail outlet).<sup>78</sup> The Association of the European Self-Medication Industry has produced several detailed estimates of the potential benefits accruing from a greater degree of over-the-counter self-medication. The Association cites research showing that at least 5 per cent of all prescriptions for medicines are related to the treatment of minor illnesses (2004: 14). Based on a detailed analysis of seven European countries, it estimates that total annual savings resulting from a move of 5 per cent of prescribed medications to self-medication exceed €16 billion (ibid: 6). This would obviously free up a large amount of resources for alternative use in healthcare systems.

Having somewhat skirted around the subject for many years,<sup>79</sup> in 2003 the EU Commission outlined how it proposed to give effect to the recommendations of the G10 Medicines Group<sup>80</sup> in this and other related areas. The G10 Group, recommended, *inter alia*, that

- Member States should review and amend their mechanisms for moving medicines from prescription to non-prescription status
- The Commission and Member States should secure the principle that a Member State's authority to regulate

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<sup>78</sup> For example, the New Zealand Pharmacy Guild has recently criticised the NZ Ministry of Health for allowing the painkiller Ibuprofen (e.g. *Nurofen*<sup>TM</sup>) to be sold in supermarkets from May 2004. The Guild claims that this will be unsafe. The Ministry rejected the claim, pointing out that the decision would merely bring New Zealand into line with Australia, Britain and the United States. Source: 'Supermarket sales of painkiller decried', *New Zealand Herald*, 6 April 2004.

<sup>79</sup> For example, the Commission's 1994 *Communication on health promotion* merely 'endorsed the importance' of self-medication within healthcare systems.

<sup>80</sup> G10 = EU-linked High Level Group on Innovation and Provision of Medicines.

prices in the EU should extend only to those medicines purchased or reimbursed by the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets (G10 Group, 2002: 17–18).

More generally, the Commission fully supports the G10 Group's conclusion that, as a matter of principle, medicines that are neither purchased nor reimbursed by the State should be open to full competition.

#### **6.4 Regulation of supply: conclusions**

The legislation governing the legal classification of medicinal products in Ireland has evolved in a piecemeal fashion over many years and now forms a complex and not easily understood framework (Irish Pharmaceutical Healthcare Association, 2002). This problem has not been solved by the consolidation of the governing Regulations in 2003. In order to establish the legal classification of a particular medicine in Ireland it is necessary to check whether its active ingredient is regulated under the Prescription and Control of Supply Regulations or the Poisons Regulations. The IPHA complains that the whole legal classification and product authorisation system is unduly complex and needs to be simplified to make it more transparent and user friendly. The State can, through its regulatory system, drive the development of self-medication by ensuring that the procedures are in place to facilitate the regular deregulation or 'switching' of products from prescription-only to non-prescription status (a process which would require the periodic amendment of the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003*). This emphasis on switching – insofar as it extended onwards to supermarket sales – would give an obvious boost to competition, since price competition, in particular, is a clear driver of competition in that sector. To be fully effective, however, the question of switching more medicines to over-the-counter status cannot avoid addressing the associated question of reimbursement. In other words, there is little point in switching product status if the automatic result is to remove it from reimbursement coverage under the State drug schemes.

Appropriate regulation and access to information, as well as effective self-medication for the treatment of minor ailments

through the use of non-prescription medicines, can encourage people to take greater responsibility for their own health. In this context, the Irish Pharmaceutical Healthcare Association cites research by the Association of the European Self-Medication Industry suggesting that savings in excess of €75 million per annum could be achieved in Ireland if self-medication was more widely practised (2002:4).

### 6.5 Internet sales

The mushrooming growth of Internet medicine sales is the most significant issue to affect the supply of medicines in recent years and, in general, regulatory agencies are struggling to come to terms with it. Internet sales are a recent phenomenon, first developing in the US during the late 1990s.<sup>81</sup> A recent statistical analysis of 113 online pharmacies distinguished two market segments (Arruñada, 2003: 7-8). Unlike 'rogue sites', which offer very few guarantees and usually sell a very limited range of medicines without prescriptions, many online pharmacies are associated with health insurers, sell the whole range of drugs, require medical prescriptions, and provide information on the use of medicines. The evidence was that

- insurers covered purchases in 20 per cent of all the online pharmacies in the sample
- a minority of online pharmacies (13 per cent) also ran conventional operations
- a doctor's prescription was required by 30 per cent of online pharmacies
- most (70 per cent) were happy to sell in foreign markets
- around a third carried a full range of drugs, in contrast to another third, which carried only one product, with the remaining sites carrying an average of seven products
- more than half the sample (52 per cent) maintained telephone help lines and 35 per cent of them provided

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<sup>81</sup> Drugstore.com, founded by former Microsoft executive Peter Neupert in February 1999, is one example of an apparently booming, and legal, dot.com pharmacy. Neupert says his Web site has served almost 700,000 customers since its start-up and predicts the online drug market will grow to \$15 billion a year by 2004, at: 'Online pharmacies evading regulation: US officials struggle to control prescription drug-dispensing Web sites', Kai Wright, [http://archive.salon.com/health/feature/2000/04/17/internet\\_pharmacy](http://archive.salon.com/health/feature/2000/04/17/internet_pharmacy), accessed 23 September 2004.

- access to a pharmacist
- price lists were provided by 96 per cent of sites, although only 6 per cent offered price comparisons (ibid).

The phenomenon of Internet sales grew rapidly in the USA and by 2003, online and mail order sales accounted for 17 per cent of all prescription drug sales in the US (National Association of Chain Drug Stores, 2004: 4). Traditional, brick-and-mortar pharmacies in the USA are increasingly involved in Internet sales, for example some have formed Internet pharmacies of their own (e.g. CVS Corporation, Walgreens), as have some drug manufacturers, e.g. Merck (Zeman, 2001). A few high profile, well-funded operations, including Drugstore.com and PlanetRx.com, are essentially web-based versions of chain drugstores and mail order houses. At the other end of the spectrum are largely unregulated offshore businesses, selling mysteriously sourced products from unknown addresses.<sup>82</sup>

Importing prescription medication into the USA, even for personal use, is illegal and authorities on both sides of the US-Canada border are trying to deal with the legal uncertainties surrounding the operation of Canadian online/mail-order pharmacies that fill prescriptions for Americans. At least four US states (Arizona, Minnesota, North Dakota and Rhode Island) have passed laws to block the importation of drugs from Canada. The alarm in the USA at the growing influence of online business from Canada is of little surprise, given the US position as a high-price medicine country and the obvious benefits that accrue to consumers who avail of Canadian-based online pharmacies.<sup>83</sup> In Europe, Internet pharmacy was slower to take off, with the first two such operations being established in the UK in late 1999. However, the

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<sup>82</sup> 'Putting The Hex On Rx: How online pharmacies are falling victim to Government regulation'. Virginia Postrel, Reasononline (2000) at <http://reason.com/opeds/postrel052900.shtml>, accessed 23 September 2004.

<sup>83</sup> Canadian online providers claim that Americans usually save between 30 per cent to 80 per cent off the US price – see: 'US Residents can now save up to 80% ordering their prescription drugs from Canada', CanadaPharmacy.com, 22/4/03, at: [http://www.canadapharmacy.com/index.cfm?fuseaction=news\\_article&newsid=12&CFID=455825&CFTOKEN=59df99e-bcafcff0-430c-4582-9224-d5939f918be8](http://www.canadapharmacy.com/index.cfm?fuseaction=news_article&newsid=12&CFID=455825&CFTOKEN=59df99e-bcafcff0-430c-4582-9224-d5939f918be8), accessed 11 June 2003. 'Canadian Prices half that of US', PharmacyChecker.com, 7 April 2003 at [http://pharmacychecker.com/news/news\\_040703.asp](http://pharmacychecker.com/news/news_040703.asp), accessed 11 June 2003.



initial spurt of growth stalled due to regulatory concerns, and only the Netherlands, Sweden and Germany currently permit unrestricted mail order retailing of pharmacy-only medicines.<sup>84</sup> There is no express ban on Internet pharmacy in the UK, but pharmacy-only medicines can only be sold from registered premises. However, this allows some scope for Internet sales. The practice is effectively banned in all other EU Member States.

In Ireland, the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003*, continue a previous prohibition on the supply of medicines by mail order (specifically Regulation 19). This includes any supply made, after solicitation of custom by the supplier, without the supplier and customer being simultaneously present and which involves the use of a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply. Thus, effectively, any form of mail-order sales is prohibited, including Internet sales.

Further growth in Internet sales of prescription medicines in Europe is likely to be hampered by a recent European Court of Justice judgement in the *DocMorris* case (European Court of Justice, 2003). *DocMorris* is a Dutch based online pharmacy, located close to the German border, and German pharmacy representative bodies challenged its right to sell into Germany, despite a prohibition in German law on mail-order medicines sales. *DocMorris* defended the case on the basis of its right to freedom of movement of goods. The German Courts referred the case to the European Court for a ruling. In handing down its judgement, the European Court drew a distinction between prescription-only medicines and non-prescription medicines. While the Court found that Member States were within their rights to apply a national prohibition on Internet sales of prescription medicines, it also found that Article 30<sup>85</sup> of the EC Treaty may not be relied upon to justify a national prohibition on the sale by mail-order of medicinal products which are not subject to prescription control. According to the Chief Pharmacist of the (Irish) Department of Health and Children, the implications of the

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<sup>84</sup> Perhaps partly in response to the (then) impending judgement in the *Doc Morris* case, the German government announced that as part of a series of wider healthcare reforms, Germans would from 1 January 2004 be 'permitted to order medicines by phone and on the Internet', thus allowing firms such as *Doc Morris* to operate in Germany.

<sup>85</sup> Elimination of quantitative restrictions on imports between Member States.

judgement for Ireland are currently being examined, and a possible outcome may be to provide an appropriate exemption for non-prescription medicines (McGuinn, 2004). However, such an outcome seems, not so much possible, as unavoidable, and would represent an important change in the regulatory environment relating to medicine supply. While the facts in the *DocMorris* case would suggest that the opposition of German Pharmacy interests to internet medicine sales was based more on fear of loss of business by incumbent businesses than of any real risk to public health, a more reasonable conclusion would be that online pharmacies are just another form of retail distribution which, if subjected to the necessary safeguards, simply afford consumers an element of retail choice:

It is high time that direct mail dispensing was introduced into the National Health Service along the lines of that available to US patients. If legislation is needed it deserves to be a priority. The European Union may resist, but there is a degree of inevitability here and thus an expectation that the whole of the EU will eventually come into line with US or UK practice (Adam Smith Institute, 2001).

There is no doubt that Internet forms of product distribution are expanding in general. While Internet sales of medicine may have been slower to take off than other products, this trend seems to be reversing itself, and pressure is gradually increasing on the regulatory authorities, particularly in the USA, to loosen the restrictions currently applicable to this form of trading.

In light of the *DocMorris* judgement, it appears that the Irish Government will have to lift its ban on Internet sales of non-prescription medicines. While the judgement will allow the Irish ban on Internet sales of prescription drugs to remain in force, it would be in the interests of pharmacy development, as well as the interests of consumers, to modernise the choice of delivery methods as other forms of retail outlet have done. There appears no reason why internet shopping for prescription medicines cannot be allowed subject perhaps to a requirement that the medicines are dispensed from an identified premises in the State, that qualified pharmacists are used and that both are amenable to supervision by

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<sup>86</sup> Some indication of the level of consumer interest in Internet pharmacies is given by the results of a recent poll conducted by *irishhealth.com* that asked the question: 'Would you consider buying prescription medicines over the Internet?' 29% of respondents said they would, 61% said they wouldn't, while 10% were unsure.

the regulatory authorities.<sup>86</sup>

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## Conclusions

### 7.1 Market failure

In theoretical terms, the retail pharmacy market exhibits a number of the classic symptoms of potential market failure, namely principal-agent problems, information asymmetries and resulting market power. Moreover, the characteristic three-tier demand system – the doctor prescribing the product, the patient taking it and health insurance or the State meeting the cost – produces an important imperfection in the market, which distinguishes it from other markets. The demand for prescribed medicines is not directly controlled by the final consumer but by the doctor who neither pays for the product nor consumes it. The financial costs of consumption for the patient are blurred by the various insurance arrangements, which bear all, or part, of the direct costs of medicines. Furthermore, the consumer's ability to transform information into knowledge is limited. Many types of treatment are not repeated and, as health care is an inherently technical subject, there are few consumers who can 'prescribe' for themselves (although this is slowly changing, with increasing recognition of the merits of self-medication in certain cases).

In regulating medical expenditure, public authorities are playing a double role, often through different bodies:

- As the main implicit buyers of drugs in most countries, they may exert monopsony power to maximise the patients' surplus. They have to obtain the best price for old non-patented products, while putting some limits on the monopoly rents for the producers of very innovative drugs. This inevitably leads to some forms of cost-containment policy. However, at the same time public authorities wish to foster cost-effective innovation.
- As insurers, to arrange for a widespread sharing of the burden of drugs for ill patients, they have to facilitate access to the most vulnerable groups in the population

(Jacobzone, 2000:9).

The role of demand and of 'buyers' is traditionally weak in pharmaceutical markets: OECD countries have willingly limited the traditional role of demand in order to ensure wide access to pharmaceuticals plus reasonable coverage. This has resulted in a rather low apparent price elasticity of demand, once the role of insurance is taken into account. In view of these principles, 'price-setting' has been the traditional answer developed by these countries as, in a market where there was no real demand, a public monopsony had to intervene to 'set' prices. This has not necessarily meant that co-payments would be completely waived for everybody. In some countries, these have been steeply increased and sometimes beyond what simple economic efficiency would advocate to limit excess consumption. On the other hand, co-payments remain limited in many countries (Jacobzone, 2000: 40).

In the case of Irish retail pharmacy specifically, earlier chapters have shown that some of the fundamental conditions necessary for a competitive market are constrained by statutory regulation, namely ease of access and entry to the market, freedom to advertise and incentives to compete on price.

## **7.2 Current competition**

In view of the range of regulatory restrictions and constraints on competition in this market, it might be assumed that there is no competition at all. However, there are some grounds for believing that at least some non-price competition does exist (Competition Authority, 2002a: 34,36,53). GEHE claimed that, in reviewing actual levels of competition between retailers, four dimensions of competition are identifiable:

- 1) pricing
- 2) geographical location
- 3) product selection and availability
- 4) level and quality of retailer service.

It maintained that competition, particularly in relation to product selection and quality of service, was strong among Irish retail pharmacies (Competition Authority, 2002a). The quality service claimed included consultations between pharmacists and targeted patients to discuss their usage of medication dispensed, follow-up telephone calls and consultations, leading to improved patient

adherence to prescriptions, greater understanding by patients of drug treatments and the development of a database relating to medicine. GEHE also provided limited evidence of competition relating to pharmacy opening hours (including matching those hours to local doctors' surgery times). It is difficult to assess the veracity of these claims, in view of their predominantly qualitative nature but, even if they were significant, their impact pales by comparison with the effects of the fundamental restrictions on competition in relation to entry to the profession and on competitive behaviour, particularly in relation to price competition.

### 7.3 Regulatory reform

While there has been a certain amount of international research on the effects of regulation on the market for medicines, this has been confined mainly to academic commentaries and government-sponsored reviews on the rationale and effects of price regulation and control; very little attention has been devoted historically to the rationale and effects of other forms of regulation in the pharmaceuticals market, particularly at retail level. However, since the 1990s, this has begun to change in keeping with more questioning approaches by governments and other bodies generally to issues connected with competition policy and regulatory reform.

Recent years have seen official reviews of retail pharmacy regulation in Australia, New Zealand, Denmark, Norway, Germany and the UK, among others, although not all of these have resulted in substantial reform. The Australian review (which primarily focused on controls on pharmacy ownership and location) ultimately resulted only in the implementation of minor reforms, and has been accused of succumbing to industry lobbying against reform (Greig, 2000). In the UK, the Scottish Executive and the National Assembly for Wales immediately rejected the Office for Fair Trading's recommendation, which called for the abolition of location restrictions on pharmacies.<sup>87</sup> In a later considered response, the UK Department of Health proposed a limited set of reforms that stopped a long way short of

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<sup>87</sup> 'Scotland and Wales reject OFT deregulation call', *Pharmaceutical Journal*, 26 March 2003.

<sup>88</sup> 'Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992', Department of Health [UK], August 2003, at: [http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT\\_ID=4068208&chk=lapHof](http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4068208&chk=lapHof), accessed 3 July 2004.

actually removing the location restrictions.<sup>88</sup> At a wider level, the OECD has been active in calling for reform – its recent reviews of regulatory reform in individual member countries have regularly called for reform of retail pharmacy regulation and it devoted much of a 2000 Roundtable to the subject. In marked contrast, the EU Commission has been very tentative about tackling reform in this area, being generally content to leave issues such as price regulation to Member States.<sup>89</sup>

Returning to Ireland, it seems an extraordinary state of affairs that any sector of a modern economy relies on a basic regulatory regime designed for a bygone age and which, at this stage, is almost a hundred and thirty years old. The amending Acts of 1951 and 1962 made only relatively minor reforms and it is obvious that a radical overhaul is necessary. For example, the Pharmaceutical Society needs a modern regulatory framework, including Fitness to Practise Rules. A new legislative regime also needs to provide a degree of consumer representation on the Council of the Society, in line with norms increasingly applicable to other statutory regulatory bodies in the professional services sector.<sup>90</sup> The Pharmacy Review Group recommended the establishment of a new Pharmacy Act to provide a modern statutory basis for professional standards and practice, to be put in place by July 2004. Such an Act would, among other things:

- a) define the role of pharmacists
- b) define a pharmacy service (what it is, what a pharmacy is, conditions of operation etc)
- c) contain Fitness to Practise provisions, and an enforceable code of ethics
- d) confer specific regulatory powers on the Pharmaceutical Society of Ireland in relation to professional practice and professional policy issues, in line with other statutory professional bodies
- e) provide an appropriate statutory basis for the Society.

As of September 2004, no such Bill has been published.

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<sup>89</sup> Admittedly, in 2003 the EU Commission produced a consultants' study on the economic impact of regulation on selected professions including pharmacy, but it has not announced what, if any, follow-up action it intends to take (Institut für Höhere Studien, 2003).

<sup>90</sup> Such as, for example, the Irish Medical Council, Dental Council, Irish Financial Services Regulatory Authority.

#### **7.4 Overall conclusions**

Where the level of competition is weak, the opportunities for rent-seeking behaviour are greater. A clear example of this situation has been created in relation to retail pharmacy, where over-regulation has created a sector with high returns, sheltered from normal competitive forces (Bacon, 1999). Entry is unnecessarily difficult, ex-manufacturer wholesale prices are fixed (or more accurately, agreed with the government) and retail prices have been too heavily influenced for many years by the 'custom and tradition' of fixed margins at retail level, apparently endorsed by the government through its reimbursement role in the bulk of cases. There are severe controls on medicine supply, and advertising is virtually prohibited. While the extent of regulation – indeed over-regulation – in this market is very extensive, it does not mean that reform is not possible, or that it cannot, or should not, be attempted and a range of recommendations to achieve this are set out in Chapter 8.

Of course, Ireland is by no means alone in having a heavily regulated retail pharmacy sector. Many countries adopt a similar approach, although the particular regulatory instruments chosen vary, to suit local circumstances. Indeed, in some cases (e.g. entry to the retail pharmacy business), the retail pharmacy market in many other countries is even more heavily regulated than in Ireland.

## Recommendations

### 8.1 Recommendations

There is much that could be done to open up this market, and a range of pro-competition reforms that are considered both desirable and possible are outlined in this chapter. None of these prejudice the underlying public interest objective of public health protection. Conversely, they would, individually or collectively, substantially improve the regulatory regime applicable to this sector in Ireland in the overall interests of patients as consumers. A number of areas for further research are also suggested. The recommendations presented in this Chapter identify four principal areas for reform:

- Statutory framework
- Controls on entry
- Price regulation
- Controls on supply.

#### 8.2.1 *Statutory framework*

1. The present statutory framework for pharmacy is in excess of one hundred years old. It is clearly creaking at the seams, and is completely outdated for the modern era. A new Pharmacy Act is needed as a matter of urgency, to provide an appropriate and modern statutory and regulatory framework for the pharmacy sector. Such an Act would:
  - a. Set out a proper statutory basis for the Pharmaceutical Society of Ireland, with appropriate oversight and accountability arrangements (e.g. in relation to reporting, appeals from decisions etc).
  - b. Put in place modern governance arrangements for the Society, in line with trends in other sectors, including provision for significant lay representation on its governing council and other boards, declarations and conflicts of interest, disqualification et cetera.
  - c. Provide for enforceable Fitness-to-Practise provisions and an enforceable code of ethics.



### 8.2.2 Controls on entry

1. Trinity College Dublin had a monopoly on the provision of pharmacy education in Ireland until 2002 and the effect was to create an artificial shortage of Irish-trained pharmacists. This shortage is very costly from a welfare point of view.

The number of available university places should be expanded to facilitate entry to the pharmacy profession. There is clearly no 'correct number', but it is clear that the existing numbers of places (even taking account of recent increases) fall far short of meeting both student demand and the supply requirements of the market (see section 4.1.1 for more detail).

2. The Pharmaceutical Society of Ireland requires an aspiring student of pharmacy to obtain (and pay a fee for) preliminary registration with the Society in advance of entering a degree course. It is difficult to see any rationale for this rather unusual requirement, and the Society should remove it (see section 4.1.2 for more detail).
3. The shortage of degree places in Ireland is exacerbated by the 'three-year rule'. This rule, enshrined in legislation, effectively prohibits overseas-trained pharmacists from opening their own pharmacy in Ireland. The rule is anti-competitive, and should be removed with immediate effect – this could be accomplished by the production and issuing of a one-page regulation by the Minister for Health and Children revoking existing regulations in this area (see section 4.1.3 for more detail).<sup>91</sup>
4. Regardless of whether the 'three year rule' is removed, the Pharmaceutical Society of Ireland should allow Irish students who train overseas to complete their final pre-registration training year in Ireland, since that is the market with which they ought to be expected to be most familiar. This is currently prohibited (see section 4.1.2 for more details)
5. There are currently no controls in Ireland on ownership of multiple pharmacy outlets by one entity. The Pharmacy Review Group has recommended that a quantitative limit be introduced, specifically that a single entity may only hold up

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<sup>91</sup> *European Communities (Recognition of Qualifications in Pharmacy) Regulations, 1987* [S.I. 239 of 1987], as amended by S.I.No. 330 of 1991 and S.I.No.438 of 1994.

to eight per cent of the total number of community pharmacy contracts in each health board area. The Government should, in general, avoid imposing quantitative controls on licences or similar permits to do business – such restrictions on entry penalise efficiency and are therefore anti-competitive. Thus, any controls on multiple ownership of pharmacy outlets should be rejected. Normal competition law rules about market concentration (e.g. merger law) should, of course, continue to apply to this sector as much as to any other (see section 4.3 for more detail)

### 8.2.3 *Drug prices*

Recommendations in relation to drug prices are divided into four categories, namely recommendations relevant to: (i) the issue of price data and transparency; (ii) price agreements at upstream level; (iii) retail prices and (iv) online sales.

#### **Price data and transparency**

1. There is widespread public interest in the cost of medicines in Ireland, and how they compare with prices in other countries. However, reliable comparisons in this area are very difficult to come by, and the difficulties of establishing such comparisons are well documented. It is nevertheless important that such data be available publicly, to facilitate a rational debate about price regulation in this market, and whether Irish consumers are being well served by the regulatory arrangements involved (see Chapter 5 for further discussion on this). Actions that would improve matters in this respect include the following –
  - a. The ex-manufacturer prices negotiated between the Irish Pharmaceutical Healthcare Association and the Department of Health and Children under the current Agreement between them should be published electronically (and the list/prices kept up to date) for all medicines subject to the agreement. This is required under the 1989 EU Transparency Directive. The General Medical Services (Payments) Board does maintain a database on its website<sup>92</sup> on all medicines on the

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<sup>92</sup>At: <http://www.gmspb.ie/search.asp>

approved list for re-imbusement. However, the raw data in the database is restricted to special users, and is not accessible to the public. The GMS Payments Board database should be made accessible for public use, and its existence widely advertised.

- b. The Minister for Health and Children should arrange for the publication of comparative data on ex-manufacturer prescription medicine prices between Ireland and other EU Member States. The appropriate data should be available, assuming that all Member States are observing the 1989 EU Directive.
- c. The *Euro-Med-Stat* project will, in due course, allow valid comparisons to be made about prescription medicine prices at pharmacy (i.e. retail) level, between Ireland and other EU Member States. In the meantime, the Minister for Health and Children should arrange for the publication of such comparative data as is available about retail prices of prescription medicines. The difficulties of making valid international comparisons can, of course, be highlighted, but that should not prevent the ventilation of such data.
- d. The Minister for Health and Children should arrange for the production and publication of data on the degree to which wholesalers discount to the retail sector. The level of such discounting should be taken into account in reimbursing pharmacists under the Community Drug Schemes, such that a proportionate amount of the benefits of such discounting is passed on to the end purchaser (whether that purchaser is *de facto* the State, or a private consumer).
- e. The EU Commission 'launched a reflection' in 2003, to find alternative ways to control national pharmaceutical-related expenditure by Member States. This was to include the option of letting manufacturers set the price of new products, while negotiating appropriate safeguards in compliance with EU competition rules. The Commission's mechanism to address this was to be a Working Group of Member States within the framework of the Transparency Committee (i.e. the Committee set up under the 1989 Transparency

Directive). The Irish government should strongly support these efforts, and publish for debate any proposals emanating from the Commission's initiative.

### **Price agreements at upstream level**

1. The following recommendation of the Brennan Commission should be implemented:
 

The existing agreement between the Department of Health and Children and the Irish Pharmaceutical Healthcare Association should be evaluated against international experience with similar agreements (particularly in countries of the European Union). The results of this evaluation should be used in the negotiation of any further agreement so as to assure value for money (2003:84).
2. For a new prescription medicine, the maximum authorised price to wholesalers is the lesser of (a) the average of the wholesale prices in five reference countries (Denmark, UK, Germany, France and the Netherlands), or (b) the UK wholesale price. However, there is some evidence that the particular (Northern European) set of countries chosen tends to result in higher prices in Ireland than if a wider set of countries was chosen. The reference list should therefore be overhauled, to better reflect a more realistic set of comparators. Based on the work of the National Centre for Pharmacoeconomics (see Chapter 5), there are several options for such a reference list, the most comprehensive being a Europe-wide average price. As an absolute minimum, some lower-price countries should be included in the list, e.g. Spain and Portugal.

### **Retail prices**

1. In Ireland, the pharmacist is reimbursed when a participant in the Drug Payment Scheme or the Long Term Illness Scheme presents a prescription. In these cases, the pharmacist receives from the State (a) the wholesale price fixed under the government-industry agreement, (b) a mark-up of 50 per cent on that price, (c) a standard prescription dispensing fee of €2.59 per item, LESS the first €78 per month per customer (and his family) which the

customer must pay the pharmacist directly. As recommended by the Brennan Commission (2003: 84), the 50 per cent mark-up paid to pharmacists under these Schemes should be abolished. It should be replaced by the same reimbursement arrangement as applies to prescriptions dispensed to medical card-holders, namely a professional dispensing fee per item.

2. Many consumers – principally those covered by the Community Drug Schemes – are not sensitive about the retail price of drugs, as they do not always pay the full retail price. On the other hand, the displaying of retail prices is compulsory in certain other areas, e.g. petrol, alcoholic sales. Consumers – particularly private consumers, as well as those who are members of the Drug Payments and Long Term Illness Schemes – should be facilitated in shopping around in search of price reductions for prescribed medicines, particularly in the case of repeat prescriptions. For their part, retailers should be encouraged to cut prices to win business. The most suitable legal instrument for achieving this appears to be a Prices Display Order by the Minister for Enterprise, Trade and Employment under the Prices Acts, 1958 and 1972. This would require retail pharmacists to
  - a. advise individual consumers, in advance of filling drug prescriptions, of the price(s) they propose to charge, broken down between product price and dispensing fee (if any)
  - b. display on all prescription labels the final price of all dispensed items
  - c. have available, and allow customers to access, price databases for prescribed medicines before purchase (e.g. by touch screen or similar technology).

#### *8.2.4 Controls on supply*

Controls on supply must take into consideration two key issues (i) the prescription versus non-prescription status of particular drugs and (ii) the growing impact of online (Internet) sales on traditional, brick-and-mortar pharmacies.

### Prescription versus non-prescription status

1. The Association of the European Self-Medication Industry estimates that if even 5 per cent of medications prescribed for minor ailments were moved to self-medication, total annual savings across Europe could exceed €16 billion (2004c: 6,14).

This paper recommends that the Irish Medicines Board should implement an annual round (with clear timelines) of switching products from prescription-only status to non-prescription status. This would encourage more pharmaceutical companies to seek to switch products, as they would be able to plan their applications to the Irish Medicines Board with certainty. This needs to be accompanied by a mechanism to ensure that a move to non-prescription status does not automatically result in loss of reimbursement status also. While the Association of the European Self-Medication Industry concedes the inevitability of some products being 'dereimbursed' in this process, it recommends that this should ideally happen by category, and be totally independent from the safety considerations, which make a particular medicine suitable for switching.

### Online sales

1. Mail order and Internet sales of non-prescription medicines are currently prohibited by Regulation 19 of the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003*. In order to comply with the European Court of Justice judgement in the *DocMorris* case, this prohibition must now be lifted.

The amendment required is a simple one, and the Minister for Health and Children should make the appropriate Statutory Instrument without delay.

2. The prohibition on Internet sales of prescription medicines should also be removed, subject to requirements that
  - a. medicines are dispensed from an identified premises in the State
  - b. qualified pharmacists are used for dispensing, and both the premises and the pharmacist are amenable to supervision by the regulatory authorities.

## Appendix A

### Applicable legislation

The main pieces of legislation governing the practice of pharmacy in Ireland are listed below.

#### **Pharmacy profession**

Pharmacy Act (Ireland), 1875

Pharmacy Act (Ireland), 1875, Amendment Act, 1890

Pharmacy Act, 1951

Pharmacy Act, 1962

Regulations of the Pharmaceutical Society of Ireland, 1971-1995

Poisons and Pharmacy Act, 1908

Regulations controlling the purchase and sale of Methylated Spirits

European Communities (Recognition of Qualifications in Pharmacy) Regulations, 1987 [S.I. 239 of 1987]

European Communities (Recognition of Qualifications in Pharmacy) Regulations, 1991 [S.I.No. 330 of 1991]

European Communities (European Economic Area) (Recognition of Qualifications in Pharmacy) Regulations, 1994 [S.I.No.438 of 1994]

#### **Control, advertising and supply of medicines**

Irish Medicines Board Act, 1995

Irish Medicines Board Act, 1995, Commencement Order, 1996

Irish Medicines Board Act (Fees) Regulations, 1996

Irish Medicines Board (Competent Authority) Order, 1998

Medicinal Products (Licensing and Sale) Regulations, 1998

Medical Preparations (Advertising) Regulations, 1993 to 1996

Medical Preparations (Labelling & Package Leaflets) Regulations, 1993 to 1999

Medical Preparations (Wholesale Licences) Regulations, 1993 to 1996

Medical Preparations (Licensing of Manufacture) Regulations, 1993 to 1996

Medicinal Products (Prescription and Control of Supply) Regulations, 2003 [S.I.540 of 2003]

### **Poisons**

The Poisons Act, 1961

Poisons Regulations, 1982 and (Amendment) Regulations, 1983, 1984, 1986 and 1991

### **Misuse of drugs**

Misuse of Drugs Acts, 1977 and 1984

Misuse of Drugs (Safe Custody) Regulations, 1982

Misuse of Drugs Act, 1977 (Controlled Drugs) Declaration Order, 1987

Misuse of Drugs (Exemption) Order, 1988

Misuse of Drugs (Designation) Order, 1988

Misuse of Drugs Act, 1977 (Controlled Drugs) Declaration Order, 1993

Misuse of Drugs (Exemption) (Amendment) Order, 1993

Misuse of Drugs (Designation) Order, 1998

Misuse of Drugs Regulations, 1988 and (Amendment) Regulations, 1993

Misuse of Drugs (Scheduled Substances) (Exemption Order), 1993

Misuse of Drugs (Scheduled Substances) Regulations, 1993

Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1998

Medical Preparations (Control of Amphetamines) Regulations, 1969 and (Amendment) Regulations, 1970.

European Communities (Dangerous Substances) (Classification, Packaging and Labelling) Regulations, 1979 to 1983

European Communities (Dangerous Substances) (Classification, Packaging Labelling and Notification) Regulations, 1982

European Communities (Classification, Packaging and Labelling of Pesticides) Regulations, 1985

### **Veterinary medicines**

Animal Remedies Act, 1993

Animal Remedies Regulations, 1996

Control of Animal Remedies and their Residues Regulations, 1998



**Family Planning**

Health (Family Planning) Act, 1979 and (Amendment) Acts 1985, 1992 and 1993

Health (Family Planning) Regulations, 1980 as amended

**European Legislation**

*Council Directives* 65/65; 75/318; 75/319; 75/320; 78/25; 81/851; 81/852; 83/189; 83/570; 83/571; 85/432; 85/433; 86/609; 87/18; 87/19; 87/20; 87/21; 87/227; 88/189; 88/320; 89/105; 89/341; 89/432; 89/343; 89/381; 90/18; 90/219; 90/220; 91/507; 91/596; 92/25; 92/26; 92/27; 92/28; 92/73; 92/109; 93/39; 93/41; 93/42; 93/73; 94/36; 94/538.

*Council Regulations* 1768/92; 2309/93; 540/95

*Council Resolutions* AP(94)1

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