

Delivery of Pharmaceuticals in Ireland

Getting a Bigger Bang for the Buck

Paul K. Gorecki
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The Authors

Paul K. Gorecki is a Research Professor, Anne Nolan is a Research Officer, Aoife Brick is a Research Analyst, and Seán Lyons is an Associate Research Professor at the Economic and Social Research Institute (ESRI). All have adjunct positions at the Department of Economics, Trinity College Dublin.

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Abbreviations

ACE inhibitor	Angiotensin-converting-enzyme inhibitor
APMI	Association of Pharmaceutical Manufacturers of Ireland
ATC	Anatomical Therapeutic Chemical
BNF	British National Formulary
CDS	Community Drug Schemes
CMR	Cahill May Roberts Group Limited
CPI	Consumer Price Index
CSO	Central Statistics Office
DHB	District Health Board
DoH	Department of Health
DoHC	Department of Health and Children
DP	Drug Payment
DTP	Direct-to-Pharmacy
DTS	Dental Treatment Services
EEA	European Economic Area
EHB	Eastern Health Board
EMA	European Medicines Agency
EPO	European Patent Office
EU	European Union
EU-15	Fifteen EU Member States prior to enlargement in 2004 and 2007
EU-27	Twenty-seven EU Member States following enlargement in 2004 and 2007
FEMPI	Financial Emergency Measures in the Public Interest Act 2009
FTC	Federal Trade Commission
GMS	General Medical Services
GP	General Practitioner
HAA	Health (Amendment) Act 1996 Scheme
HIQA	Health Information and Quality Authority
HQ	Headquarters
HSE	Health Service Executive
HTA	Health Technology Assessment
HTD	High Tech Drugs
ICGP	Irish College of General Practitioners
IDTS	Indicative Drug Targeting Scheme
IMB	Irish Medicines Board
IMF	International Monetary Fund
IMO	Irish Medical Organisation
Independent Body	Independent Body on Pharmacy Contract Pricing
INN	International Non-Proprietary Name
IPHA	Irish Pharmaceutical Healthcare Association
IPOS	Independent Pharmacy Ownership Scheme
IPU	Irish Pharmaceutical Union/Irish Pharmacy Union
ISD	Integrated Services Directive
LSP	Logistics Service Provider
LTI	Long Term Illness
MAC	Maximum Allowable Cost
MT	Methadone Treatment
NAO	National Audit Office

NCE	New chemical entities
NHS	National Health Service
NMIC	National Medicines Information Centre
NPCE	National Centre for Pharmacoeconomics
NPS	National Prescribing Service
ODB	Ontario Drug Benefit
OECD	Organisation of Economic Co-operation and Development
OTC	Over-the-counter
PBC	Practice Based Commissioning
PCA	Prescribing Cost Analysis
PCRS	Primary Care Reimbursement Service
PDF	Pharmaceutical Distributors Federation
PHARMAC	Pharmaceutical Management Agency of New Zealand
PHO	Primary Health Organisations
PI	Parallel Imports
PIP	Practice Incentives Program
PPIs	Proton Pump Inhibitors
PSI	Pharmaceutical Society of Ireland
PSO	Public Service Obligation
QALY	Quality Adjustment Life Years
QOF	Quality and Outcomes Framework
R&D	Research & development
SKUs	Stock Keeping Units
TFEU	Treaty of the Functioning of the European Union
TILDA	The Irish Longitudinal Study on Ageing
UK	United Kingdom
Uniphar	Uniphar Group plc
United Drug	United Drug plc
VAT	Value Added Tax
Working Group	The Working Group on Reference Pricing and Generic Substitution
1996 CPC Agreement	Community Pharmacy Contractor Agreement for the Provision of Community Pharmacy Services under the Health Act 1970

Executive Summary

The Irish health care system is under severe budgetary pressure. Pharmaceutical expenditure is no exception. During the 2000s Ireland experienced one of the highest annual growth rates in pharmaceutical expenditure of any OECD country. In 2009 Ireland spent more on pharmaceuticals per capita than any other OECD country (with the exception of the US, Canada and Greece).

The onset of the financial crisis has seen a number of austerity budgets, which will continue to at least 2015. Public expenditure is being tightened. Households, whose incomes are being squeezed, are likely to be asked to make greater out-of-pocket contributions towards pharmaceuticals. Budget 2012, for example, raises the monthly threshold for the Drugs Payment Scheme by €12 to €132 and retains the 50c charge per prescription item for medical card patients, which was introduced in October 2010.

One way of alleviating the pressure on government and household budgets arising from expenditure on pharmaceutical products is to address the following questions:

- Can the pharmaceutical delivery system be improved?
- Can better value for money be achieved?

The purpose of this report is to examine these issues, by analysing policy in relation to the major participants in the pharmaceutical delivery system including the manufacturer, wholesaler, pharmacist, prescriber and the Health Service Executive (HSE).

In designing ways of achieving better value for money, the proposals in this report are based on evolution, rather than revolution. In part this approach has been driven by the observation that variation within health care systems is much greater than between them. Thus by reforming the current model of pharmaceutical delivery, better value for money can be realised, while at the same time the costs and unintended consequences of large changes can be prevented. This minimises the chances that there will be an adverse impact on security of supply.

In Ireland much valuable research has already been conducted and policy reform introduced. The prices of new pharmaceuticals and those that no longer have patent protection have been significantly reduced. Wholesale mark-ups have been halved. Pharmacist mark-ups have been reduced for the State schemes, although the extent to which this has influenced the cash paying patient is unclear. Nevertheless, despite

these undoubted improvements more can and should be done. Relatively little attention has been devoted to the demand side in terms of, for example, examining the role of prescribers.

Prices of *new pharmaceuticals*, subject to patent protection, could be reduced further by setting the ex-factory price with reference to the lowest priced comparator Member State. An examination of data for the last number of years suggests that prices would decline by 20 to 25 per cent if such an approach were adopted. Measures should also be taken to ensure that when a new pharmaceutical is introduced it does not displace, for particular uses, equally effective but lower priced alternatives. It should be confined to those indications for which it provides value for money. Economic evaluation of new interventions is crucial in this regard. Risk-sharing arrangements between the HSE and individual pharmaceutical firms are proposed to address this issue.

Parallel imports of new products – pharmaceuticals that are imported to Ireland from another Member State where the price is lower and without the authorisation of the patent owner – is legal. Indeed, it is an imperative of the EU single market. These lower price parallel imports are important, in some instances accounting for as much as 20 to 25 per cent of the sales of leading new pharmaceuticals in Ireland. However, consistent with experience in other Member States, these lower prices are not reflected – except to a small degree – in either the price that the HSE or the cash paying patient is charged. This needs to change if expenditure is to be reduced and value for money obtained. The HSE and the cash paying patient should share in the benefits of lower price parallel imports. It is proposed that, initially at least, the difference between the price of the parallel imported product and the price charged by the patent owner in Ireland should be shared 50:50 between the parallel importer and the HSE/cash paying patient.

Once patent protection for a pharmaceutical expires, in particular for high volume products, generic competitors supply *interchangeable products* at a lower price. This increased competition should benefit both the HSE and the cash paying patient. These benefits are likely to increase as a series of blockbuster pharmaceuticals lose patent protection in the near future. However, at the moment there are barriers that prevent full realisation of the benefits from competition. A series of proposals are made to correct this situation. Interchangeability will be determined by an expert body, such as the Irish Medicines Board. For high volume interchangeable pharmaceuticals the price should be set by competitive tendering. The HSE and the cash paying patient should only pay the lowest price for an interchangeable product. For higher priced interchangeable products – typically the brand name – to be paid for by the HSE the prescriber should specify the reason and write in their own hand

'no substitution' on the prescription. This will provide useful feedback to the HSE and the agency charged with determining interchangeability. These ideas, it is anticipated, will inform the debate concerning forthcoming legislation on reference pricing and generic substitution.

The *wholesale function* is an important bridge between the manufacturer and the pharmacist. The evidence suggests that there is vigorous competition between the three full-line wholesalers. The market appears to work well. While it is the case that the current recession and HSE policy moves have placed wholesalers under financial pressure, this is insufficient reason to change the wholesalers' current business model. Many other sectors are experiencing falling profits and demand. However, there are some issues that might raise concerns over the Direct to Pharmacy (DTP) distribution model. Under this model the brand name manufacturer sets the quality standards for the wholesale function (e.g. frequency of deliveries) and pays the distributor a fixed distribution fee. DTP has limited but rising penetration in Ireland. Nevertheless, we recommend that the HSE actively monitor the importance and service levels offered by DTP brand name manufacturers. If the service levels fall below acceptable levels to the HSE, then minimum quality standards should be set.

The *pharmacy market* is marked by a lack of information available to patients on not only pharmaceutical prices, mark-ups and dispensing fees, but also the services supplied by pharmacists. These services have been expanding with the administration of the seasonal influenza vaccine and the dispensing of emergency hormonal contraception. In other professions such as dentistry and medicine in Ireland, as well as pharmacy in other jurisdictions, patients are provided with information that assists them in deciding which provider to choose. The same should apply for pharmacy in Ireland. Dispensing fees, services offered and mark-ups should be posted in pharmacies, and pharmacists should have the option of using media to disseminate such information. New forms of retailing such as the internet should – under the appropriate regulatory conditions – be considered by the HSE, perhaps on a trial basis. The result should be a more competitive, efficient and vibrant pharmacy sector that is more responsive to patient preferences and needs.

The *prescriber*, typically the family doctor, acts on the patient's behalf in making decisions concerning the appropriate course of treatment in addressing the patient's condition. This may involve selection of a pharmaceutical. The report suggests that in writing a prescription that the international non-proprietary name – atorvastatin, rather than Liptor, fluoxetine rather than Prozac – be used by the prescriber. In other words, the prescriber selects a particular pharmaceutical rather than a particular supplier or brand. There are likely to be exceptions, as discussed in the report, such as that referred to above in the discussion of no-substitution prescriptions. Proposals

are also made concerning the development of protocols and clinical guidelines so that the quality of prescribing will be improved. At the present time the HSE is providing tools whereby prescribers can compare their prescribing patterns for selected products with their peers. These proposals take the debate a stage further.

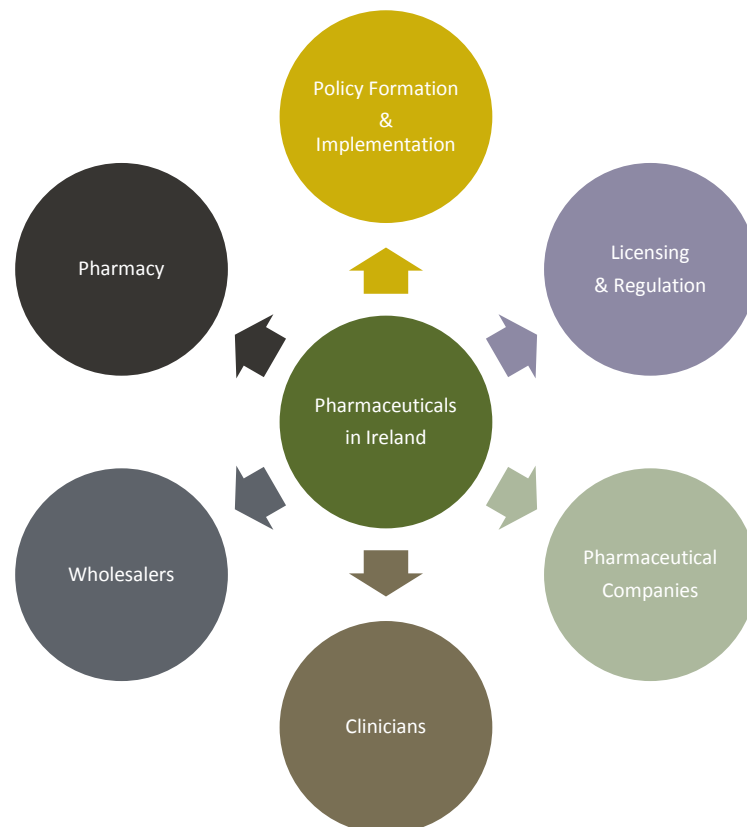
As with any set of recommendations, resource costs are an issue, particularly in a time of fiscal austerity. However, because the proposed changes are incremental and build on what has already gone before, the costs of implementation are likely to be minimal. The agreements between the State and the pharmaceutical firms are due to expire in 2012; the legislation to implement reference pricing and generic substitution is expected to be introduced in 2012. Many of the measures to liberalise pharmacy could be accommodated within the existing legislative framework. However, other policy changes may require legislation, but a considerable amount can be achieved by refining current policy.

While these recommendations and proposals are likely to improve the efficiency and effectiveness of the pharmaceutical market, they are not likely to be the last word. Apart from the fact that new problems may arise or that the report may have inadequately specified a problem, the participants in the pharmaceutical delivery system are likely to react to the proposals in ways that prevent the intended outcome of a particular recommendation. Hence the Health Service Executive and the Department of Health need to maintain constant vigilance of the system and, where appropriate, to take action to achieve publicly stated and agreed objectives.

The recommendations contained in this report are designed to ensure that taxpayers get better value for money from the €1.9 billion public pharmaceutical budget, but also that the cash paying patients benefits too. They are also designed to ensure that patients, irrespective of whether or not the State pays for the pharmaceutical, receive safe and effective pharmaceuticals without interruption to supply.

Chapter 1

Introduction



1.1 BACKGROUND

The Irish health care system, like many others, is under severe pressure. Demand is rising as the population increases and ages and expectations change, while new health technologies, treatments and procedures are constantly coming to market.¹ Yet, at the same time, the ability to pay for health care is constrained for households, firms and government by the recession, which puts a squeeze on household incomes, firm balance sheets and government budgets. Not surprisingly, the mismatch between demand and ability to pay leads to pressures for better value for money and greater efficiencies in the provision of health care. This applies to all aspects of health care from the overall structure of health care delivery to individual services such as cancer treatment or the location of accident and emergency centres.²

¹ For a discussion of the drivers of demand see, for example, Normand (2011), who argues that too much attention has been given to ageing as a driver.

² For details of the challenges see, for example, the annual reports of the Department of Health and the HSE (DoHC, 2010c; HSE, 2011a).

The demand-led, publicly-funded, General Medical Services (GMS, i.e. medical card) and Community Drug Schemes (CDS) are among the fastest growing components of publicly-funded health care in Ireland.³ Indeed, the growth rate has exceeded the overall rate of growth of public health care expenditure with the result that the share of public health care expenditure accounted for by expenditure on pharmaceuticals and payments to community pharmacists has increased from 10.1 per cent to 13.6 per cent between 2000 and 2009, respectively (Brick and Nolan, 2010).⁴ Furthermore, the indications are that on unchanged policies both the volume and value of the schemes will continue to grow – the number of prescriptions grew by a factor of between 1.39 to 1.85 from 2006 to 2020 (Bennett *et al.*, 2009, p. 97).

In view of both its importance and rapid growth rate the provision of pharmaceuticals under the GMS and CDS has been the subject of a series of reports and policies to reduce the cost of pharmaceuticals.⁵ These reports and policies have to a large extent concentrated on the supply side – lowering the ex-factory price, reducing wholesalers' and pharmacists' mark-ups - rather than the demand side – influencing prescribers' and patients' behaviour – in seeking to create cost savings and greater efficiencies. Building on this earlier research and policy change, this report not only looks at the supply side but also at the behaviour of prescribers.

We do not analyse the behaviour of patients in this report. While patient demand is to a large extent dependent on the decisions of the prescriber, a key determinant of their behaviour is also the current structure of entitlements to public health services, an issue that is outside the scope of this report. Previous reports have examined this issue in greater detail (e.g. Ruane, 2010), highlighting the many anomalies that characterise the current system.

This chapter is organised as follows. The mandate and scope of the report is outlined in Section 1.2. The research methodology is set out in Section 1.3, while Section 1.4 explains the terminology and other conventions used in the report. Finally, Section 1.5 outlines the structure of the report.

³ While Bennett *et al.* (2009) include the GMS in the CDS, we follow the practice adopted by the Department of Health of referring to the GMS and CDS separately (Brick *et al.*, 2010). Using this definition of the CDS the three main components of the CDS are the Drug Payment (DP), Long Term Illness (LTI) and High Tech Drugs (HTD) schemes. See Chapter 2 for further details.

⁴ Per capita expenditure on pharmaceuticals in Ireland exceeded the OECD average in 2009, and was exceeded only by the US, Canada and Greece. In addition, the annual rate of growth in per capita expenditure over the period 2000-2009 was approximately 9 per cent, second only to Greece (Borowitz *et al.*, 2011, p. 48). For further discussion on these trends see Chapter 2.

⁵ For details see Annexe A.

1.2 MANDATE AND SCOPE OF REPORT

The report was commissioned by the Health Service Executive (HSE), the terms of reference for which are reproduced in Annexe B. The overall objective of the report is to set out the roadmap for reforming the delivery of pharmaceuticals to the patient "...within a framework that guarantees security of supply and value for money." Furthermore the report will "provide guidance as to how the HSE can lead in fashioning the new institutional and market arrangements".

The discussion is concerned primarily with the State-funded GMS and CDS. These schemes account for the majority of pharmaceutical expenditure in the State and influence the pricing and other facets of pharmaceutical delivery in the hospital sector and the cash sector at the retail level. Thus it is important to take into account these sectors and the interaction with the public community sector.

In seeking better value for money, while at the same time ensuring security of supply, the approach used was to first gain a thorough understanding of the current model for the delivery of pharmaceuticals from the manufacturer through to the prescriber and the patient. Next the problems and shortcomings of the current system were identified. In many instances the earlier reports referred to above provide an excellent point of departure. Attention then turns to possible solutions and the development of a roadmap for reform.

In seeking to improve the current model of pharmaceutical delivery, so as to achieve better value for money while ensuring security of supply, it is likely to be necessary to consider changing the rules or parameters that currently govern the behaviour of the key existing and possible future participants in the current model.⁶ At one extreme the current model can be improved with minor tinkering, at the other, radical change. Thus the report will not provide one best purpose model, but rather a menu of different models or options. To some extent the issue revolves around the question of timing. Some of the minor changes may be introduced relatively quickly – quick wins – while others will take longer – new legislation may be needed, fresh procurement arrangements and so on.

The approach used here is to consider the current model employed in Ireland, and then gradually change more and more of the rules, except those desired for reasons of safety. Arguably, the more the rules of the current model are changed or varied the better the outcome. This reflects the fact that as more of the rules are changed

⁶ By rules we mean the current arrangements that govern the current model. Some of these rules are laws and regulations; in other instances they are agreements between the HSE and representative bodies involved in pharmacy and the supply of pharmaceuticals; and in others the reimbursement formula set by the HSE.

the opportunity set of choices increases and hence the probability of designing a better model. Revising more and more of the rules implies the possibility of a larger shift from the *status quo*. However, given the unprecedented austerity situation that Ireland finds itself in, it is difficult to think of a more powerful driver for moving to an improved pharmaceutical delivery model, even if it involves radical change.

1.3 RESEARCH METHODOLOGY

Three main research tools are used in this report. *First*, desk research which draws on the extensive literature on getting better value for money in pharmaceutical delivery was undertaken.⁷ Attention is paid to both the literature concerning Ireland and other jurisdictions. This reflects the fact that many of the same problems occur in the delivery of pharmaceuticals across a number of different jurisdictions. Thus there is an opportunity to learn from this experience in designing policy for Ireland.

Nevertheless, great care needs to be taken in applying the models of other jurisdictions to Ireland. These models reflect different histories, institutions, policy preferences, problems and other factors. It may not be possible to select and apply/adapt successfully one aspect of these models without, at the same time, also taking into account a series of related policy initiatives. Nevertheless, if cognisance of these differences is taken, valuable lessons can be learnt. Furthermore, to the extent that aspects of a model have been shown to work successfully in other jurisdictions, this makes it much more likely that it will work well in Ireland.

Second, we engaged with those responsible for the delivery of pharmaceuticals to the patient in both Ireland and elsewhere, including Northern Ireland, New Zealand and Ontario, the largest Canadian province. Attention is devoted to both existing participants – regulators, manufacturers, parallel importers, wholesalers, pharmacists, medical practitioners⁸, purchasers, patients – and future possible participants – supermarkets, other retail outlets and internet providers.⁹ Annexe C provides a listing of the various stakeholders (e.g. regulators, industry representative bodies and pharmaceutical reimbursement agencies) with whom discussions took place. Typically, we met with representatives of these institutions, although on occasion a conference call was the only practical method of communication (e.g. the Pharmaceutical Management Agency of New Zealand, or PHARMAC). In some instances formal written submissions were also made. The report has been immeasurably strengthened by these meetings and the engagement of those concerned. It has resulted in insights into the way in which the pharmaceutical

⁷ The list of references in the report provides an indication of the literature consulted.

⁸ Throughout this report, we use the term medical practitioners to refer to doctors (GPs, hospital consultants).

⁹ Of course the future and existing participants may overlap. For example, pharmacies may, if allowed, provide internet pharmacy services.

delivery model functions and also enabled the interviews to be used as a sounding board in the development of proposed changes to the current model.

Third, data provided by the HSE and others, including wholesalers, were analysed. The data can be used both to inform the description of the current model of pharmaceutical delivery and identify the magnitude of possible problems and resulting solutions. For example, it was often stated by market participants that parallel imports accounted for a large percentage of the sales of high volume single source in-patent pharmaceuticals. However, in the absence of reliable data it is difficult to gauge the extent and durability of parallel imports and hence whether it is worth considering policy reforms in this area. HSE data can determine whether parallel imports are an ice cube, accounting for a trivial market share, or an iceberg, accounting for a substantial market share.

1.4 TERMINOLOGY AND OTHER CONVENTIONS

There is a certain amount of discretion in the terminology used to characterise the pharmaceutical delivery system. Thus some decisions over terminology have to be made for the purposes of clarifying the exposition. We have adopted the following conventions. *First*, in general pharmaceuticals are used as opposed to the more general term drugs or medicines. By pharmaceuticals we in general refer to those products covered by the GMS and CDS which are by and large only available on prescription, although there are some over-the-counter (OTC) preparations.¹⁰ The term drug is used on occasion where it is specifically named by the HSE and others.

Second, an issue arises as to whether or not the term patient or consumer should be used. The use of the term consumer implies a well informed individual making decisions with respect to pharmaceutical necessity and choice, while the term patient implies a principle agent relationship between the prescriber and the individual based on asymmetric information.¹¹ Put in these terms it is clear that the term patient is a better characterisation of how the process of pharmaceutical choice is made. Nevertheless, this should not take away from the fact that patients

¹⁰ There is, of course, of the issue of the dividing line between prescription and OTC products. A prescription pharmaceutical is defined by the Irish Medicines Board (IMB) as those "...which require medical supervision and [are] available only with a doctor's or dentist's prescription and dispensed through pharmacies." In contrast, an OTC product is defined as those "...medicines [that] are available without a prescription and are usually for milder conditions and short-term use. While some of these products are available on general sale in retail outlets, others can only be purchased in pharmacies." It is beyond the scope of this report to comment on the implications of where the dividing line should be drawn. However, simply reclassifying products as OTC rather than prescription and hence excluding the product from reimbursement under either the GMS or CDS may not result in large savings if patients request medical practitioners to prescribe more expensive prescription-only products. The definitions are taken from the IMB's website: www.imb.ie (accessed 8 December 2011).

¹¹ Information asymmetry is discussed further in Chapter 2 in reference to the rationale for government intervention in the pharmaceutical market.

are becoming increasingly well informed in health matters with a whole range of resources available on which to rely, often easily accessed through the internet.

Third, pharmaceuticals on the market for the purposes of this report can be divided into two broad categories: single source in-patent products, and multiple source off-patent products (Table 1.1). Single source in-patent products are brand name pharmaceuticals (sometimes also referred to as proprietary pharmaceuticals) without a generic equivalent. These are new products with patent protection, often new chemical entities (NCEs), which are typically marketed by the large multinational firms that are responsible for the vast majority of research and development (R&D) in the pharmaceutical industry. Multiple source off-patent pharmaceuticals comprise brand name products that have a generic equivalent (i.e. which are no longer subject to patent protection). Generic pharmaceuticals refer to products that are the same active ingredient, strength and dosage form¹² as the proprietary product. Generic pharmaceuticals enter the market once the brand name product no longer has patent protection. Generic pharmaceuticals can be either branded or unbranded. Parallel imports are identical to the proprietary product except that they may be packaged differently and may not carry the original manufacturer's warranty. These parallel imports into Ireland are in-patent pharmaceuticals from another EU Member State. Such imports are undertaken without the authorisation of the patent owner, by specialist firms taking advantage of arbitrage opportunities due to price differences between Member States.¹³

TABLE 1.1 Classification of Pharmaceuticals

Single source in-patent	1. Brand name or proprietary pharmaceutical without a generic equivalent
Multiple source off-patent	2. Brand name or proprietary pharmaceutical with a generic equivalent
	3. Branded generics (i.e. generic pharmaceuticals that use a brand name)
	4. Unbranded generics use the international non-proprietary name (INN)

Note: Parallel imports are usually single source in-patent pharmaceuticals.

Fourth, instead of referring to European Union Member States, reference will be made to Member States. EU-15¹⁴ will refer to those Member States that formed the EU prior to enlargement in 2004 and 2007. Enlargement added 12 new Member States, constituting the present EU-27.¹⁵

¹² Dosage form refers to the method of administration of the pharmaceutical: capsule, tablet, liquid *etc.*

¹³ Off-patent pharmaceuticals may also be subject to parallel imports. However, in this report attention is focused on imports of the in-patent pharmaceuticals.

¹⁴ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom.

¹⁵ Malta, Cyprus, Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Slovenia and Hungary joined in 2004; Bulgaria and Romania in 2007.

Fifth, the term 'personal communication' refers to instances in which information (unpublished) was received from the various individuals/organisations that we met with during the preparation of this report.

Sixth, the report relates to events as of December 2011.

1.5 OUTLINE OF REPORT

The report is divided into eight Chapters. Chapters 2 and 3 set the scene. Chapter 2 provides an overview of the main trends in pharmaceutical consumption in Ireland and presents an overview of the pharmaceutical pricing, reimbursement and delivery system, while Chapter 3 explores in more depth the two objectives of the pharmaceutical delivery system that we are concerned with, securing value for money while ensuring security of supply. The remaining five chapters explore ways in which these objectives can be achieved.

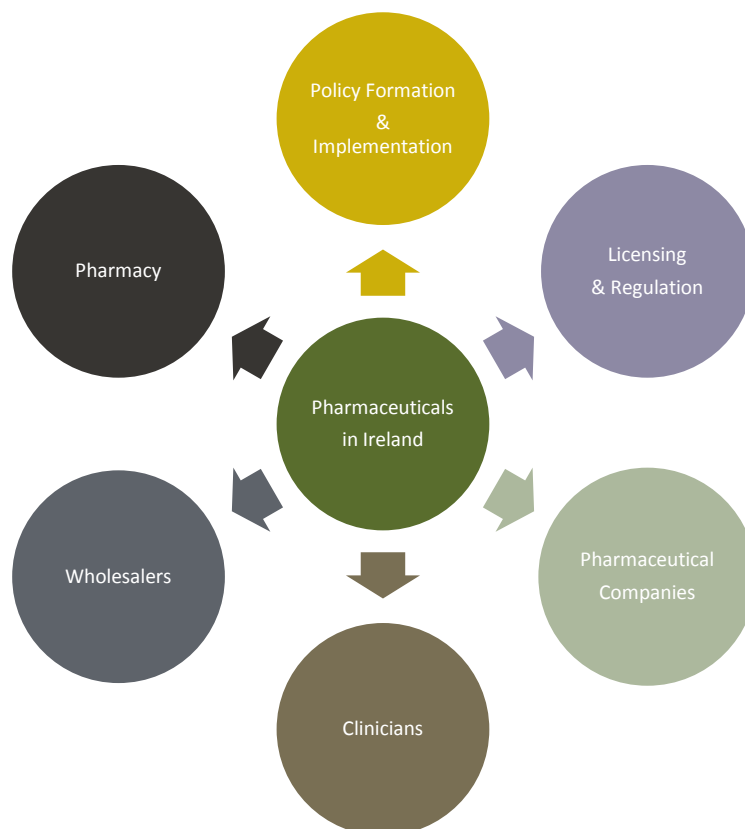
The setting of the ex-factory price of pharmaceuticals is the subject of Chapter 4. For this purpose pricing options are presented for three categories: single source in-patent pharmaceuticals; parallel imports; and multiple source off-patent pharmaceuticals. Next attention turns to the pricing of the services of the wholesaler in Chapter 5, before the issue of the role and pricing of the services of the pharmacist is addressed in Chapter 6. Demand for pharmaceuticals is mediated through the prescriber, the subject of Chapter 7. The roadmap for reform brings together all the various strands of the discussion in Chapter 8, together with the twenty-three recommendations made in the report. The roadmap provides the HSE and government with a set of options for policy which will inform the renewal of agreements with the proprietary and generic manufacturers in 2012.¹⁶

We have adopted a fairly conventional approach to considering alternative proposals for obtaining better value for money and security of supply from the pharmaceutical delivery system, from the ex-factory price through to the pricing of the pharmacy services, before attention turns to the prescriber. However, demand and supply measures are considered together and not, as appears from the outline, separately. For example, in considering generic pricing, issues such as generic substitution by the pharmacist and the use of tenders are considered, one of which is demand side, the other supply side (Kanavos *et al.*, 2011, Table 1, p. 35). In other words, the report concentrates on the best way of obtaining value for money and security of supply with respect to a particular issue, irrespective of whether the best policy approach is supply or demand side or a combination of the two.

¹⁶ See Chapter 4 for details.

Chapter 2

The Irish Pharmaceutical Market



2.1 INTRODUCTION

In 2010, total expenditure on pharmaceuticals in Ireland amounted to €2.2 billion.¹ By far the largest component of total expenditure on pharmaceuticals in Ireland is public expenditure on pharmaceuticals (administered by the Primary Care Reimbursement Service, PCRS), which amounted to €1.9 billion in 2010.² Public expenditure on pharmaceuticals was one of the fastest growing components of public health expenditure over the period 2000 to 2010. It increased by 158.5 per cent in real terms and accounted for 12.9 per cent of total public health expenditure in 2010 (up from 10.1 per cent in 2000).³ Per capita expenditure on pharmaceuticals in Ireland exceeded the OECD average in 2009, and was exceeded only by the US, Canada and Greece. In addition, the annual rate of growth in per capita expenditure

¹ In 2007, it was estimated that approximately 85 per cent of expenditure on pharmaceuticals in Ireland related to state expenditure on the General Medical Service (GMS) Scheme and Community Drugs Schemes (CDS) (Barry *et al.*, 2008). Applying the same split to 2010 expenditure on pharmaceuticals under the GMS and CDS results in a total spend of approximately €2.2 billion in 2010.

² HSE, personal communication, 1 September 2011.

³ Calculated from PCRS, *Statistical Analysis of Claims and Payments*, various issues; DoHC (2006a); DoH (2011).

over the period 2000-2009 was approximately 9 per cent, second only to Greece (Borowitz *et al.*, 2011).⁴ Numerous reports have highlighted concerns over the sustainability of pharmaceutical expenditure in Ireland, and have proposed a number of policy changes.⁵ In recent years, the government has introduced a number of reforms to the pricing and reimbursement regimes, and the decline in public pharmaceutical expenditure from 2009 to 2010 in part reflects these efforts.

In this context, ensuring value for money in pharmaceutical expenditure (both public and private) is a key policy concern, as is ensuring security of supply.⁶ Governments and international agencies intervene in a number of ways to achieve these objectives, from the provision of patent protection, the regulation of pharmaceutical licensing and marketing procedures, the regulation of the behaviour of the various actors in the market (manufacturers, wholesalers, prescribers, pharmacists and patients), and the control of pricing and reimbursement decisions. Here we are primarily concerned with policy in relation to the aspects of the Irish pharmaceutical market that are largely under the control of the Health Service Executive (HSE) and Department of Health (DoH); in particular, the decisions on pricing and reimbursement.

In this chapter, we examine the current arrangements in relation to the pricing and reimbursement of pharmaceuticals in Ireland, while also reviewing policy in relation to the behaviour of those active in the supply chain (manufacturers, wholesalers and pharmacists), prescribers and patients. Section 2.2 outlines the rationale for government intervention in the pharmaceutical sector, detailing the various forms of market failure that characterise the sector. Section 2.3 provides an overview of recent trends in pharmaceutical expenditure in Ireland, as well as the key role played by the State in the financing of pharmaceuticals in Ireland. Section 2.4 provides a brief overview of the pricing and reimbursement procedures in Ireland and the delivery structure (Chapters 4-7 discuss these issues in greater detail). Section 2.5 concludes this chapter.

⁴ Undertaking cross-country comparisons of pharmaceutical expenditure is difficult, due to differences in the types of pharmaceuticals consumed, the quantities of pharmaceuticals consumed and the different prices between countries. These factors are in turn influenced by the demographic composition of the population, lifestyles and behaviours of patients, prescription behaviour of medical practitioners, existence of public insurance, share of prescription and OTC pharmaceuticals, level of self-care, level of generic entry, level of parallel trade, government regulation, level of in-country pharmaceutical production, incidence rate of diseases (e.g. cancer), intensity of care and use of technology, etc. (ECORYS Research and Consulting, 2009).

⁵ For details see Annexe A.

⁶ See Chapter 3 for further discussion.

2.2 GOVERNMENT INTERVENTION IN THE PHARMACEUTICAL MARKET

2.2.1 Rationale for Government Intervention

Government intervention in the pharmaceutical market is motivated by the presence of a number of potential market failures, such as the absence of competition, the presence of externalities, information asymmetry and uncertainty. Governments also intervene for reasons of equity (i.e. to ensure that those on low incomes or in poor health are not denied access to appropriate health care due to cost). Government intervention in the pharmaceutical market can take numerous forms including the provision of information, regulation of conduct, financing and direct provision of services.

2.2.1.1 Absence of Competition

If pharmaceutical manufacturers were to sell products at the marginal cost of production and distribution, they would be unable to recoup the cost of R&D and would thus have no incentive to develop new innovative products that would potentially benefit public health.⁷ In the absence of patent protection legislation which allows firms to recoup the large fixed costs of R&D, output would be lower than the socially optimal level due to the possibility of free riding behaviour on the part of competitors. The provision of patent protection is the main form of government intervention to deal with this market failure. A common European patent system is still under development; currently, patents may be filed with national patent offices or with the European Patent Office (EPO). In the latter case, national validation in each country is still necessary (ECORYS Research and Consulting, 2009).

However, high initial investment in the form of R&D expenditure can also act as a barrier to entry for new firms and thus reduce competition.⁸ There are, therefore, concerns about potential abuse of market power by pharmaceutical firms. This has led to two responses. *First*, regulation of the pricing and reimbursement regime (e.g. setting the ex-factory price, promoting the use of generic products, restricting the list of publicly reimbursable items, etc.) is designed to stimulate competition and limit market power directly.⁹ However, it is important that in setting the regulatory framework security of supply is not put at risk, an issue discussed in Chapter 3.

⁷ The evidence suggests that patents are particularly important in the development of pharmaceuticals because of the necessity to address current and emerging health problems, and the long life cycle of products (including long development periods). The exclusivity periods granted through patent law provide incentives to originator companies to continue innovating. The pharmaceutical industry is one of the main users of the patent system (European Commission, 2009, p. 9).

⁸ A study of originator companies by the European Commission over the period 2000-2007 found that they spent on average 17 per cent of their turnover generated at global level on R&D for new or improved prescription pharmaceuticals (European Commission, 2009, p. 7).

⁹ Of course in designing these measures to encourage competition cognisance has to be taken of the fact that the patient does not always pay for the pharmaceutical and that the choice of pharmaceutical treatment is a decision of the medical practitioner rather than the patient.

Second, competition policy is enforced at the EU level through merger control and enforcement of Articles 101 and 102 of the Treaty of the Functioning of the European Union (TFEU).¹⁰ A sector inquiry into the pharmaceutical industry was published in 2009 (European Commission, 2009). The inquiry was concerned that generic entry was being delayed, inter alia, due to the practices of the brand name firms.¹¹ Subsequently, the European Commission instituted a number of antitrust proceedings in the pharmaceutical sector. The most recent case, in October 2011, concerned allegations that an agreement between two firms had hindered the introduction of a generic version of fentanyl in the Netherlands.¹²

2.2.1.2 Externalities

Pharmaceutical markets are also characterised by the presence of externalities, both positive and negative. Externalities imply that private costs or benefits are out of line with social costs or benefits. For example, for a positive externality, the private benefits of the activity are less than the social benefits (vaccinations for infectious diseases confer wider benefits on society in addition to the private benefit to the individual). The standard solution is to offer a subsidy in the case of products that produce positive externalities to encourage their consumption (Bennett *et al.*, 1997). Negative externalities can be addressed using a range of measures such as taxes that aim to offset the externality and legal measures that assign liability for harm caused by products.

2.2.1.3 Information Asymmetry

Information asymmetry is a feature not only of pharmaceutical markets, but also of the health sector more generally. In the pharmaceutical market, the asymmetry operates on a number of different levels. The patient often knows less than the prescriber or dispenser, and, in turn, prescribers and dispensers must depend (at least partially) on the manufacturer for information about the effects of the product. The former often gives rise to the phenomenon of supplier-induced demand, whereby the provider, acting as an agent for the patient, is able to stimulate demand. This is particularly relevant when the provider is paid on a fee-for-service basis (as opposed to capitation or salary). Similarly, manufacturers may exert undue influence on prescribers and dispensers via marketing and sales promotion activities. This may lead to the prescribing of recently-introduced brand name pharmaceuticals in place of generics or less expensive older pharmaceuticals that may be just as effective. The presence of asymmetric information justifies a role for government in improving patients' information, regulating the licensing and marketing of

¹⁰ Cases have been brought on, for example, attempts to restrict parallel trade (see O'Donoghue and Macnab, 2009 for a discussion).

¹¹ For a discussion of these issues in a US context see FTC (2010, 2011).

¹² The two firms were Johnson and Johnson and the generic branches of Novartis. For details see European Commission (2011).

pharmaceuticals and regulating the behaviour of prescribers and other medical practitioners.

2.2.1.4 Uncertainty

Healthcare markets are also characterised by uncertainty, i.e. lack of information about the future. Illhealth is inherently unpredictable, both in terms of financial costs and physical and emotional suffering. This necessitates a role for insurance in offering the patient protection against uncertainty. Moral hazard behaviour, where an individual's behaviour is affected by their insurance status, may arise in the form of excessive utilisation of pharmaceuticals on the part of the patient. User fees, which aim to make patients more aware of the resource implications of their decisions, are often used to temper the moral hazard effects of free or heavily subsidised health care. However, the degree to which user fees are effective in changing behaviour has been questioned, and there are well-documented adverse impacts on access. In particular, user fees have been observed to have a dissuasive impact on both necessary and unnecessary health-care utilisation and in terms of pharmaceuticals, are at risk of "...impairing access to needed medicines in addition to those that are less effective or unnecessary" (OECD, 2008, p. 139).¹³

However, user fees, as well as acting as a source of revenue when the costs of administration are low, can act as a useful policy tool where the objective is to discourage *all* use of a product. For example, where the government is seeking to discourage consumption of brand name pharmaceuticals when a generic is available, a user fee on the brand name product can be an effective policy tool.¹⁴

2.2.1.5 Equity

Apart from efficiency concerns, the desire to ensure that health care should be distributed equitably across the population motivates government intervention in health care. Many governments attempt to smooth out differences in health outcomes that are not related to need factors such as age, gender or health status, but rather to socioeconomic characteristics such as income, area of residence, level of education, etc. They do so primarily by intervening in the financing of healthcare services, offering free or subsidised services to those on low incomes or in particularly vulnerable situations (e.g. those with particular health conditions).

¹³ In addition in the US, Kaiser Permanente found that an increase in pharmaceutical cost-sharing led to patients skipping their blood pressure and other essential medications, an increase in hospital costs and a spike in mortality (Mongan, 2009).

¹⁴ This issue is discussed further in Chapter 4.

2.2.2 Scope of Government Intervention

In this report, we are concerned primarily with policy in relation to the pricing and reimbursement of pharmaceuticals, rather than patent protection, enforcement of competition and marketing authorisation policies (as they are often also influenced by the behaviour of international agencies). The regulation of both pricing and reimbursement is exercised through a wide variety of policy instruments that may affect either the supply side for pharmaceutical production or the demand side for consumption of pharmaceutical products, or both. Typical supply side measures include regulation of product price, control of expenditures, industry regulation, and product reimbursement. Demand side measures include policies aiming to influence behaviour by prescribers, pharmacists and patients (ECORYS Research and Consulting, 2009). Such intervention can be justified on grounds of absence of competition, externalities, information asymmetry, and uncertainty.

Finally, it is important to recognise that while government intervention to correct market failures is an accepted feature of modern economies, government failure may itself harm efficiency or equity. In particular, regulatory capture by vested interests may result in regulations that lead to an inefficient level of output and the creation of additional incomes for providers, e.g. the restrictions on pharmacy locations which existed prior to the revocation of the Health (Community Pharmacy Contractor Agreement) Regulations, 1996 (SI 152 of 1996) in 2002 (Gorecki, 2011).

2.3 THE IRISH PHARMACEUTICAL MARKET

2.3.1 Eligibility for Pharmaceutical Schemes

State assistance towards the cost of pharmaceuticals is available under a number of different schemes. The General Medical Services (GMS, or medical card) Scheme provides free public health care (including GP care and prescription pharmaceuticals) to those who satisfy an income means test. In April 2011, over 1.6 million individuals had a medical card, accounting for 36.2 per cent of the population. A further 2.6 per cent of the population are eligible for free GP services (but not prescription pharmaceuticals) under the GMS Scheme (and are known as GP Visit card holders) (CSO, 2011; HSE, 2011b).

Non-medical card holders can avail of State assistance towards the cost of prescribed pharmaceuticals under a number of Community Drugs Schemes (CDS). The three largest (in expenditure terms) are the Drugs Payment (DP), Long Term Illness (LTI) and High Tech Drug (HTD) schemes. All those ineligible for a medical card are eligible for the DP Scheme, whereby the State pays the full cost of prescription pharmaceuticals and certain appliances above a monthly threshold of €120 per family (increasing to €132 from January 2012). Individuals who suffer from one or

more of a schedule of long-term illnesses are entitled to obtain, without charge and irrespective of income, necessary pharmaceuticals and appliances under the LTI Scheme (Table 2.1). High tech drugs are generally only prescribed or initiated in hospitals and include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or growth hormones (PCRS, 2010). Table 2.1 outlines the main schemes under which individuals are entitled to receive free or subsidised prescription pharmaceuticals in Ireland.

TABLE 2.1 Primary Care Reimbursement Services Schemes, Eligibility for Free or Subsidised Pharmaceuticals, 2011

Scheme/Payment	Description
General Medical Services (GMS)	Persons who are unable without undue hardship to arrange general practitioner (GP) medical and surgical services for themselves and their dependants receive free General Medical Services. Drugs, medicines and appliances supplied under the Scheme are provided through retail pharmacies. In most cases the doctor gives a completed prescription form to a person, who takes it to any pharmacy that has an agreement with the HSE to dispense GMS prescription forms. In rural areas the GP may dispense for those persons who opt to have their medicines dispensed by him/her.
Drugs Payment (DP)	Under the Drugs Payment Scheme persons who are ordinarily resident in the State and who do not qualify for GMS can benefit if their spend on approved drugs, medicines and appliances for themselves or their family exceeds a monthly threshold (€120 per month from January 2010; rising to €132 per month from January 2012).
High Tech Drugs (HTD)	High Tech Drugs are generally prescribed or initiated in hospitals, and include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or growth hormones. The medicines are purchased by the HSE and supplied through community pharmacies for which pharmacists are paid a patient care fee. Patients receive these pharmaceuticals on the basis of their eligibility under the DP or GMS schemes, i.e. HTD are supplied without charge to GMS patients (HTD are not subject to the 50c prescription fee), and to DP patients above the monthly threshold.
Long Term Illness Scheme (LTI)^a	On approval by HSE, persons who suffer from one or more of a schedule of long-term illnesses are entitled to obtain, without charge and irrespective of income, necessary drugs, medicines and appliances under the LTI scheme.
Methadone Treatment Scheme (MT)	Methadone is prescribed and dispensed by doctors and pharmacists for approved clients under the Methadone Treatment Scheme. Capitation fees payable to participating doctors and community pharmacists and claims by pharmacies for the ingredient cost of the Methadone dispensed and the associated dispensing fees are processed and paid by the PCRS.
European Economic Area (EEA)	Residents from one of the other States of the European Economic Area, with established eligibility, who require emergency GP services while on a temporary visit to the State are entitled to receive from a GP a GMS prescription form for necessary medication and to have such medication dispensed in a pharmacy that has entered into an agreement with the HSE within the State. Students, posted workers and their dependants are entitled to full services on presentation of a valid form E128.
Health (Amendment) Act 1996 Scheme (HAA)	Under the Health (Amendment) Act 1996, certain health services are made available without charge to persons who have contracted Hepatitis C directly or indirectly from the use of Human Immunoglobulin – Anti D or the receipt within the State of another blood product or blood transfusion.
Dental Treatment Services Scheme (DTS)	Under the Dental Treatment Services Scheme, GMS eligible adults have access to a range of treatments and clinical procedures, comprised of Routine Treatments and Full Upper and Lower Dentures. Routine Treatments are now available for all eligible persons. Dentists may also prescribe a range of medicines to eligible persons.
Primary Childhood Immunisation Scheme	A National Primary Childhood Immunisation Scheme provides for immunisation of the total child population, with the aim of eliminating, as far as possible, such conditions as Diphtheria, Polio, Measles, Mumps, Rubella and Meningococcal C Meningitis.
Immunisations for certain GMS Eligible Persons	Agreement was reached between the Department of Health and Children and the Irish Medical Organisation on fee rates to be applied to certain immunisations for GMS eligible persons. The immunisations encompassed by the agreement are: – Pneumococcal, Influenza, Hepatitis B and the combined Pneumococcal/Influenza. The HSE facilitated claiming for any of these immunisations by extending the range of codes for 'Special Items of Service'.

Notes: a Acute Leukaemia, Mental Handicap, Cerebral Palsy, Mental Illness (in a person under 16), Cystic Fibrosis, Multiple Sclerosis, Diabetes Insipidus, Muscular Dystrophies, Diabetes Mellitus, Parkinsonism, Epilepsy, Phenylketonuria, Haemophilia, Spina Bifida, Hydrocephalus, Conditions arising from the use of Thalidomide.

Source: Adapted from PCRS (2010).

2.3.2 Total Expenditure

Individuals receive prescription pharmaceuticals from two main sources in Ireland: community pharmacies and hospitals.¹⁵ In 2010, total expenditure on pharmaceuticals in Ireland amounted to €2.2 billion.¹⁶ In 2007, it was estimated that 85 per cent of total pharmaceutical expenditure in Ireland was accounted for by public pharmaceutical expenditure by the PCRS (Barry *et al.*, 2008; Barry *et al.*, 2010). While the majority of pharmaceutical expenditure relates to expenditure in the community (Table 2.2), a significant proportion of this expenditure derives from prescriptions that are initiated in hospital.¹⁷ Therefore, prescribing practices in the hospital sector have potentially important impacts on the types of pharmaceuticals consumed in the community sector, and by extension, total pharmaceutical expenditure.

The State is the main source of pharmaceutical financing in Ireland, with the PCRS administering the various State schemes that provide assistance towards the cost of pharmaceuticals in the community, and the HSE largely funding the purchase of hospital pharmaceuticals and pharmaceutical products dispensed in the community that are not reimbursed by the PCRS. Figures on private expenditure on pharmaceuticals are harder and sometimes impossible to source, but comprise out-of-pocket or cash payments by individuals, as well as pharmaceutical expenditure in private hospitals (which is often reimbursed by private health insurance plans).¹⁸

¹⁵ In 2009, 117 GPs were permitted to dispense pharmaceuticals. In rural areas where a GP has a centre of practice 3 miles or more from the nearest community pharmacy the GP dispenses for persons served from that centre who opt to be dispensed to. The GP is paid a dispensing fee for each such person. The GP's pharmaceutical requirements are obtained on a 'stock order' from a community pharmacy, approved in advance by the HSE (PCRS, 2010).

¹⁶ For details see Section 2.1.

¹⁷ Feely *et al.* (1999) estimated that approximately 38 per cent of GMS prescriptions in the late 1990s were initiated by hospital doctors.

¹⁸ The provision of pharmaceuticals to private patients in public hospitals is financed by the public hospital (St James's Hospital, personal communication, 1 July 2011).

TABLE 2.2 Components of Total Expenditure on Prescription Pharmaceuticals (€m), Ireland, 2009^a

Public	
Community	€
PCRS	2,010.09
Other HSE expenditure on pharmaceuticals	284.80
Hospital	€
Public hospital expenditure (HSE, voluntary)	308.64
Private	
Community	€
Out-of-pocket payments by individuals below the DP threshold ^b	188.23
Other private ^c	not available
Hospital	€
Expenditure by private hospitals (not reimbursed by private health insurance)	not available
Expenditure by private hospitals (reimbursed by private health insurance)	not available

- Notes:*
- a 2009 is chosen for illustration as it is the latest year for which data on public hospital expenditure on pharmaceuticals is available.
 - b This refers to private out-of-pocket pharmaceutical expenditure below the DP threshold of €120 per month (for those who spend over €120 per month). The threshold will increase to €132 from January 2012.
 - c This refers to private out-of-pocket pharmaceutical expenditure below the DP threshold of €120 per month (for those who do *not* spend over €120 per month). Dorgan (2008) estimated this figure to be €140 million in 2007.

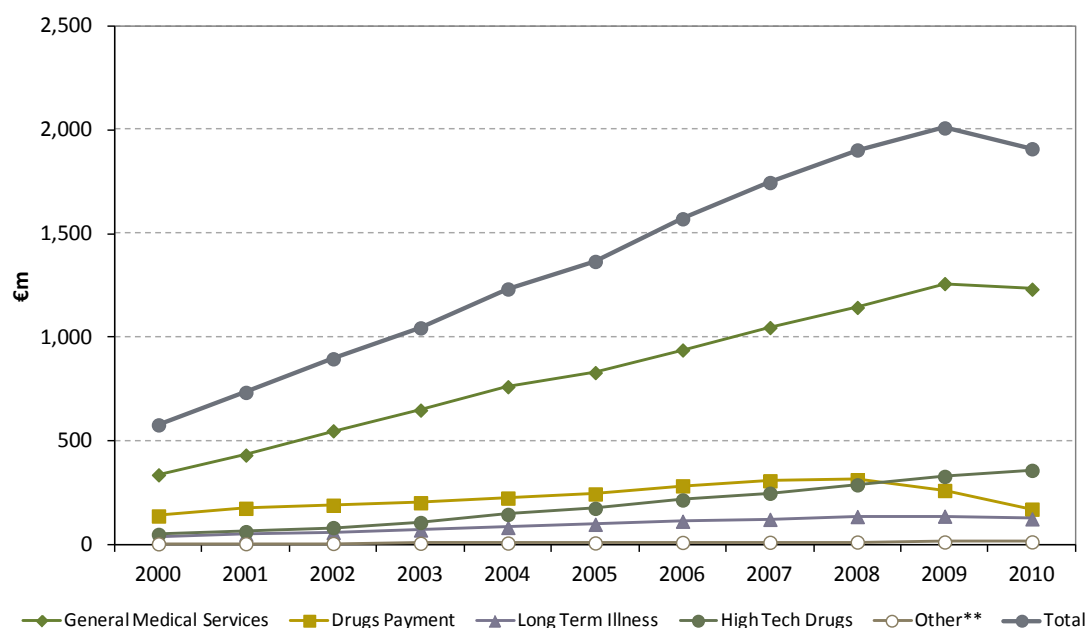
Sources: PCRS (2010); HSE (2010); HSE, personal communication, 30 June 2011.

2.3.3 PCRS Pharmaceutical Expenditure

The PCRS administers payments to community pharmacists for pharmaceuticals dispensed under the various State schemes. The PCRS is part of the Integrated Services Directorate (ISD) of the HSE and has an operational role in relation to making payments to primary care contractors (GPs, community pharmacists, dentists, optometrists/ophthalmologists) for services provided by them under the various State schemes.

In 2010, the PCRS spent €1.9 billion on pharmaceuticals and payments to community pharmacists, an increase of nearly 160 per cent in real terms since 2000. Expenditure on pharmaceuticals and payments to community pharmacists accounted for over 75 per cent of total PCRS expenditure in 2009.¹⁹ Over the period 2000-2010, pharmaceutical expenditure on the GMS (the largest scheme in expenditure terms) increased by 185.2 per cent in real terms, while expenditure on the LTI and HTD schemes increased by 138.3 per cent and 444.2 per cent in real terms respectively. In part as a result of a reduction in the retail mark-up in 2009 (described in Section 2.4), expenditure on the DP Scheme fell by just over 3 per cent in real terms over the entire period 2000-2010 (Figure 2.1).

¹⁹ Authors' calculations from PCRS (2010). While total PCRS pharmaceutical expenditure for 2010 is available, total PCRS expenditure (i.e. including payments to other medical practitioners such as GPs) for 2010 is not yet available (PCRS, personal communication, 1 September 2011).

FIGURE 2.1 Payments to Pharmacists under the GMS and CDS, 2000-2010 (real €m)*

Notes: * CPI Adjusted 2010=100

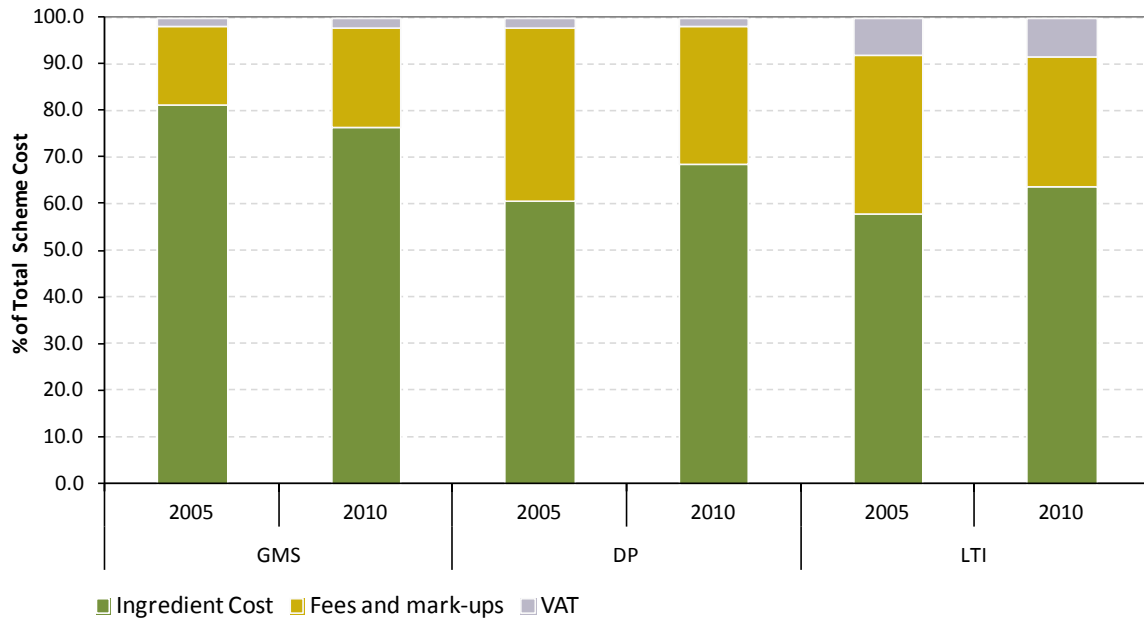
** Includes amongst others the Dental Treatment Services Scheme, the Methadone Treatment Scheme and training grants.

Sources: PCRS, *Statistical Analysis of Claims and Payments*, various years; PCRS, personal communication, 1 September 2011.

Pharmaceutical expenditure is a function of the price, volume and product mix of products dispensed. In terms of price, we can further disaggregate pharmaceutical expenditure under the three largest schemes (i.e. GMS, DP and LTI) into the ingredient cost, pharmacy fees/mark-ups and VAT. Figure 2.2 illustrates the trends in these components of the total payments for the GMS, DP and LTI schemes over the period 2005-2010.²⁰ In 2010, pharmacy fees and mark-ups comprised 21.4 per cent of total payments under the GMS Scheme, in contrast to 29.3 per cent and 27.8 per cent under the DP and LTI schemes respectively. The impact of the reduction in the wholesale and retail mark-ups on the DP and LTI schemes in 2009 (described in Section 2.4) is particularly apparent for the DP Scheme; pharmacy fees and mark-ups declined from nearly 40 per cent of the total payments under the DP Scheme in 2005 to just under 30 per cent in 2010.

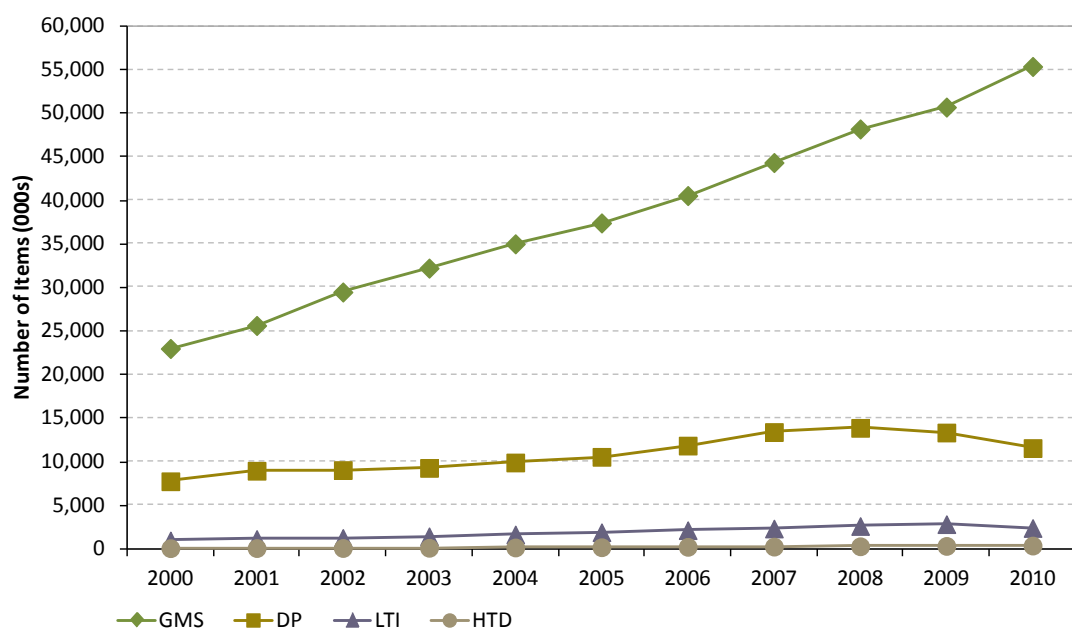
²⁰ Data on the ingredient cost, fees and mark-up and VAT components are only available from 2005 onwards (PCRS, personal communication, 30 June 2011).

FIGURE 2.2 Proportion of Payments to Pharmacists by PCRS Accounted for by Ingredient Cost, Mark-Ups, Fees and VAT; GMS, DP and LTI Schemes; 2005 and 2010



Notes: The ingredient cost refers to the ex-wholesale price (i.e. the ex-factory price plus the wholesale mark-up). See also Section 2.4.2.
Source: HSE, personal communication, 30 June 2011.

As discussed in Chapters 4, 5 and 6, there have been a number of significant policy developments in relation to the pricing of pharmaceuticals in Ireland in recent years. However, there have been fewer policy proposals in relation to volume and product mix. Over the period 2000-2010, the number of items dispensed increased by 140.6 per cent on the GMS Scheme, 49.0 per cent on the DP Scheme, 144.6 per cent on the LTI Scheme and 297.1 per cent on the HTD Scheme (Figure 2.3). With changing eligibility requirements, changing population composition, the introduction of new products, and changes in the DP threshold, it is difficult to isolate the precise reasons for the differential growth in the number of items dispensed across the various schemes over this period.

FIGURE 2.3 Number of Items Dispensed on the GMS, DPS, LTI and HTD, 2000-2010 (000s)

Sources: 2000-2009: PCRS, *Statistical Analysis of Claims and Payments*, various years.
2010: HSE, personal communication, 10 August 2011.

2.3.4 Non-PCRS Pharmaceutical Expenditure

As illustrated in Table 2.2, there is much less information available on the non-PCRS components of total pharmaceutical expenditure. In terms of community pharmaceutical expenditure, private out-of-pocket or cash payments by individuals below the monthly DP threshold comprise the remainder. For those individuals who exceed monthly DP threshold, the PCRS records the sub-threshold level of expenditure, and this amounted to €188.2 million in 2009. Pharmacists do not inform the PCRS of the remaining private out-of-pocket expenditure, i.e. sub-threshold expenditure by those who do not exceed the monthly DP threshold. Dorgan (2008) estimated this figure to be €140 million in 2007.

Expenditure in both public and private hospitals accounts for the remainder of total pharmaceutical expenditure. In 2009, total pharmaceutical expenditure in public hospitals amounted to €308.6 million, an increase of 19.8 per cent in real terms over 2006 levels.²¹ There are no publicly available figures on total prescription pharmaceutical expenditure in the private hospital sector.

²¹ Earlier data, and data for 2010, are not currently available (HSE, personal communication, 30 June 2011).

2.3.5 Provision of Data on Pharmaceutical Expenditure

An important ingredient of policy analysis and debate is high-quality reliable data with which to paint a picture of the composition and trends in expenditure on pharmaceuticals in Ireland. Although certain parts of this picture are clear, in several instances, especially in the hospital sector and out-of-pocket or cash payments in the community sector, the data is incomplete. Hence:

Recommendation 2.1: We recommend that the HSE should be responsible for the collection, preparation and publication of a comprehensive time-series of all components of pharmaceutical expenditure (public, private, community and hospital) on an annual basis.

The HSE is the appropriate body to collect this data as it is already responsible for compiling the data on the GMS and various CDS (published in the annual PCRS *Statistical Analysis of Claims and Payments* documents), and is thus best placed to co-ordinate data collection across the public and private community and hospital sectors.

One of the challenges for the HSE in putting together a complete picture of pharmaceutical expenditures in Ireland will be accessing data related to the private sector. One of the most important components of such expenditure is the out-of-pocket expenditure by individuals below the DP threshold of €120 per month (increased to €132 in Budget 2012). These data are already partially submitted to the HSE, but only for those patients who exceed the monthly threshold. However, in terms of minimising collection costs it would seem reasonable if the sub-threshold data were also submitted to the HSE so that it would be in a position to present a fuller picture of pharmaceutical expenditure, but without imposing an extra administrative burden on pharmacies. The collection of such data will also enhance the effectiveness of feedback and other mechanisms being developed by the HSE for prescribers (discussed in greater detail in Chapter 7) and also allows for the monitoring of disease incidence. It is not clear whether legislation would be required to allow the HSE to gather detailed disaggregated data on sub-threshold DP expenditure. Subject to clarification in relation to the legal requirements for such a move:

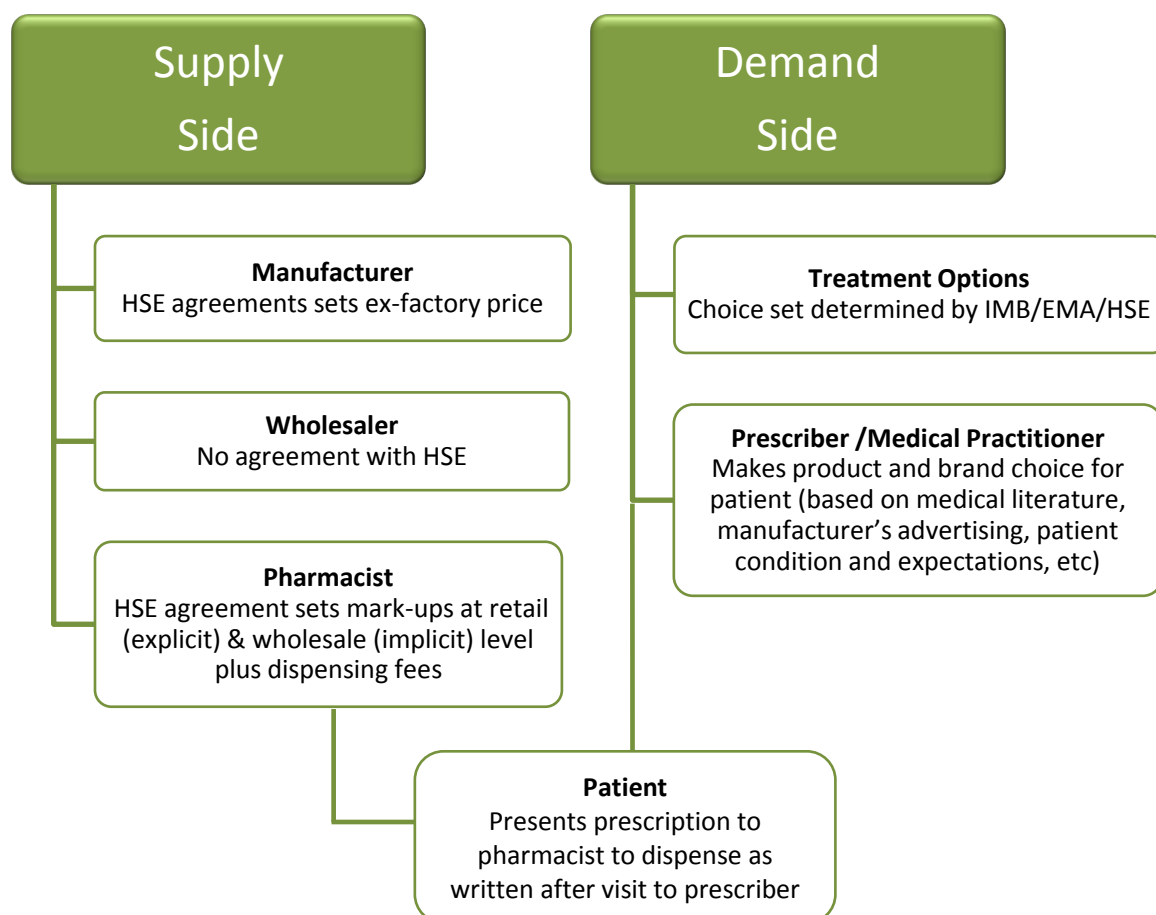
Recommendation 2.2: We recommend that pharmacists should be required to inform the PCRS of the out-of-pocket expenditure (i.e. sub-DP threshold expenditure), by those who do not exceed the DP threshold.

2.4 CURRENT ARRANGEMENTS FOR THE PRICING, REIMBURSEMENT AND DELIVERY OF PHARMACEUTICALS IN IRELAND

2.4.1 A Brief Characterisation of the Current Pharmaceutical Delivery Model

The current community pharmaceutical pricing, reimbursement and delivery model can be thought of as two quite distinct but related parts, which are illustrated in Figure 2.4. The first is the pharmaceutical delivery system from the manufacturer to the pharmacy to the patient. This is the supply side of the model. Second, is the demand side, the part that determines which, if any, pharmaceutical is chosen and which brand – assuming that there is more than one brand on the market – is selected when the patient visits a medical practitioner. The choice is the responsibility of the prescriber, in response to the symptoms presented by the patient. The supply and demand side connect when the patient presents the prescription to the pharmacist to be dispensed. In the following sections, the supply and demand side are briefly described, concentrating on the pricing and reimbursement arrangements in the community and hospital sectors (the supply-side), and the delivery of pharmaceuticals to patients (where demand and supply interact).

FIGURE 2.4 Pharmaceutical Pricing, Delivery and Choice, State Schemes, Community Sector, Ireland, 2011



2.4.2 Pricing and Reimbursement in the Community

The pricing of pharmaceuticals is strongly linked to reimbursement, i.e. pricing and reimbursement form part of the same procedure. This involves a number of different stages. We distinguish four main stages involved in setting the final reimbursable price:

- 1) the determination of the ex-factory price,
- 2) the application of a wholesale mark-up,
- 3) the application of a retail mark-up and dispensing fees,
- 4) the application of sales tax.

Table 2.3 summarises the various stages for the four largest schemes (i.e. GMS, DP, LTI and HTD). In many other jurisdictions in which the State provides assistance towards pharmaceutical costs, a similar approach is used to set the final reimbursement price.

TABLE 2.3 Community Pharmaceutical Pricing and Reimbursement Mechanism, Ireland, March 2008 – June 2011

Ex-Factory Price ^a	Regulated at the level of the manufacturer by way of agreements between the State and the manufacturers.			
		March 2008	July 2009 ^b	June 2011 ^c
Wholesale Mark-Up ^d	GMS:	17.66%	10%	8%
	DP/LTI:			
	HTD:			
Retail Mark-Up ^e	GMS:	n/a	n/a	n/a
	DP/LTI:	50%	20%	20%
	HTD:	n/a	n/a	n/a
Dispensing Fee	GMS:	€3.60 per item	Sliding fee structure (€5.00 to €4.50 to €3.50) depending on the number of items dispensed per month	Sliding fee structure (€5.00 to €4.50 to €3.50) depending on the number of items dispensed per month
	DP/LTI:	€3.16 per item		
	HTD:	n/a	n/a	n/a
Patient Care Fee	GMS:	n/a	n/a	n/a
	DP/LTI:	n/a	n/a	n/a
	HTD:	€60.52	€62.03	€62.03 (months product dispensed); €31.02 (months product not dispensed; max 3 months)
VAT	Oral:	0%	0%	0%
	Non-oral:	21%	21%	21%

- Notes:**
- a The HSE advises each manufacturer or importer of each quantity and value of his/her pharmaceuticals dispensed under the GMS and CDS each month and each manufacturer/importer rebates to the HSE an amount 4 per cent of the value (at price to wholesaler) of all pharmaceuticals dispensed in the schemes (except those subject to price reductions).
 - b As per the Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2009 – SI 246, except for the HTD patient care fee which was amended in line with ‘Towards 2016’ adjustments. The reduction in the HTD wholesale mark-up was an indirect effect post FEMPI (implemented March 2011). Prior to this there had been a 5 per cent discount historically applied to HTD products that were supplied to the pharmacist by the manufacturer or wholesaler.
 - c As per the Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2011 – SI 300. The reduction in the HTD wholesale mark-up was an indirect effect of FEMPI (implemented June 2011).
 - d In July 2009, the wholesale mark-up for controlled drugs and fridge items remained at 17.66 per cent, while it was reduced to 10 per cent for all other items. In June 2011, the mark-up for fridge items was reduced to 12 per cent, and for all other items (including controlled drugs) to 8 per cent.
 - e The retail mark-up applied to all items depends on which scheme they are supplied under. There is no retail mark-up for those supplied under the GMS scheme and a 20 per cent mark-up for those supplied under DP and LTI schemes.

Sources: PCRS (2008); Government of Ireland (2009, 2011); HSE, personal communication, 5 January 2012.

2.4.2.1 Ex-Factory Price

The price to the manufacturer (ex-factory price) is the basis for all prices in the market. The prices of pharmaceuticals supplied under the GMS and CDS at the level of the manufacturer are set by way of agreements between the State and the manufacturers. The price-setting mechanism follows the same procedure regardless of the type of pharmaceutical, except where the classification of a pharmaceutical changes between agreements.²² A single maximum price across hospital and community supply is also a feature of the agreements. It should be noted, however, that hospitals are free to negotiate prices directly with manufacturers.²³ The ex-factory price (manufacturer price) in Ireland is set with reference to the currency-adjusted average price to the wholesaler in nine nominated EU Member States (in which the pharmaceutical is available).²⁴ For products reimbursed prior to the commencement of the current agreements, a price freeze applies (Barry *et al.*, 2004).

2.4.2.2 Wholesale Mark-Up

The next stage in setting the final reimbursable price of pharmaceuticals is the application of a wholesale mark-up. As a result of concerns that the wholesale mark-up was excessive, the Minister reduced the existing wholesale mark-up from 17.66 per cent to 10 per cent with effect from 1 July 2009. A further reduction to 8 per cent for products dispensed under the GMS, DP and LTI schemes was announced in March 2011 effective July 2011.²⁵

2.4.2.3 Retail Mark-Up and Dispensing Fee

The next step in setting the final reimbursable price of pharmaceuticals is the application of a retail mark-up and retail dispensing fees. In Ireland there is no retail mark-up for products dispensed under the GMS Scheme, while there is a 20 per cent mark-up for products dispensed under the DP and LTI schemes (reduced from 50 per cent to 20 per cent from 1 July 2009).²⁶ All products dispensed under the GMS, DP and LTI schemes are subject to a dispensing fee, which is on a sliding scale which depends on the number of items dispensed per month/annum. For the Methadone

²² See Table 1.1 for the pharmaceutical classification used in this study.

²³ See Chapter 4 for further details.

²⁴ Chapter 4 discusses external price referencing in further detail.

²⁵ Chapter 5 discusses the wholesale function in greater detail. As shown in Table 2.3, the wholesale mark-up for controlled drugs and fridge items remained at 17.66 after the first round of wholesale mark-up reductions in 2009. In 2011, the wholesale mark-up for controlled drugs was reduced to 8 per cent (in line with other items), while the wholesale mark-up for fridge items was reduced to 12 per cent.

²⁶ It has been reported that pharmacists are still applying the 50 per cent retail mark-up to pharmaceuticals dispensed to patients below the monthly DP threshold. This means that, for the same drug, three retail prices may apply (Mitchell, 2010). For example, a parallel imported pack of 28 20mg Lipitor tablets by B&S Healthcare has a current ex-wholesale price of €30.52 (November 2011). Under these three scenarios, the pack would cost €34.02 for GMS patients (i.e. including a €3.50 dispensing fee), €40.12 for DP patients above the monthly threshold (i.e. including a 20 per cent mark-up and a €3.50 dispensing fee) and €49.28 for DP patients below the monthly threshold (i.e. including a 50 per cent mark-up and a €3.50 dispensing fee). Chapter 6 discusses this issue in greater detail.

and HTD schemes, pharmacists receive a monthly patient care fee. Pharmacists in Ireland must dispense the product written on the prescription.²⁷

2.4.2.4 Sales Tax

A value-added tax (VAT) is levied at 0 per cent on oral pharmaceuticals and at the standard rate (currently, 21 per cent) on other pharmaceuticals. The *National Recovery Plan 2011-2014* contains a commitment to re-examine the VAT system, including the goods taxed at 0 per cent (Department of Finance, 2010a). In December 2011, the government announced that the standard rate of VAT will increase to 23 per cent from January 2012 (Department of Finance, 2011). VAT is applied to the final reimbursable price for the GMS, DP and LTI schemes, but only to the ex-wholesale price for the HTD Scheme (NCPE, 2011).

2.4.3 Pricing and Reimbursement in the Hospital Sector

Under the terms of the IPHA and APMI agreements, a maximum ex-factory price applies to pharmaceuticals in both the hospital and community pharmacy sectors (HSE, 2006a; b). Hospitals may purchase pharmaceuticals direct from the manufacturer (at the ex-factory price or below) or via a wholesaler (at the ex-factory price plus the wholesale mark-up). However, hospitals are exempt from the wholesale mark-up if purchases from a single pharmaceutical company exceed €635 (Vogler *et al.*, 2010). Tendering procedures are increasingly used in hospitals' direct dealings with manufacturers; in such cases, the discounts on the ex-factory price can be considerable. Of the EU-27, Ireland is one of six Member States that places no restrictions on hospitals receiving cost-free pharmaceuticals, i.e. hospitals are allowed to receive pharmaceuticals directly from manufacturers without having to pay for them. The products are typically those which are of strategic relevance for the manufacturers. This practice is forbidden in many Member States (Vogler *et al.*, 2010).

2.4.4 Delivery

Demand and supply interact when the patient presents their prescription to the pharmacist. As discussed above, pharmaceuticals are dispensed by pharmacists operating in either a community or hospital setting.²⁸ The supply of prescription pharmaceuticals via the internet is illegal, and no online pharmacies are currently authorised to operate in Ireland (IMB, 2011). However, the supply of pharmaceuticals via alternative retail outlets such as supermarkets is legal, and Tesco opened the first of their in-store pharmacies in Ireland in November 2011.²⁹

²⁷ Chapter 6 focuses on the role of the pharmacist.

²⁸ As explained in Section 2.3.2, a small number of GPs are permitted to dispense pharmaceuticals.

²⁹ Tesco, personal communication, 24 June 2011; Hunter (2011a).

In most cases, community and hospital pharmacies purchase their pharmaceuticals from one of the three full-line wholesalers operating in the Irish market. In some cases, pharmacies may source their pharmaceuticals direct from the manufacturer (more common in the hospital sector),³⁰ or from parallel importers (rarely used in the hospital sector). In all cases, pharmacists negotiate discounts off the ex-wholesale price (or ex-factory price if applicable), with the size of the discounts substantially higher in the hospital sector. The use of tendering is limited; the HSE use tendering for the supply of blood products and certain vaccines, and some public hospitals tender for high-volume products. For pharmaceuticals dispensed under the HTD Scheme, the HSE purchase the pharmaceuticals direct from the wholesalers, who supply community pharmacists directly.

For GMS patients, a 50c per item co-payment applies (up to a maximum of €10 per family per month). This co-payment, which was introduced on 1 October 2010, was retained in Budget 2012 due to the very difficult budgetary situation. DP patients pay the first €120 per month in full (rising to €132 per month from January 2012).

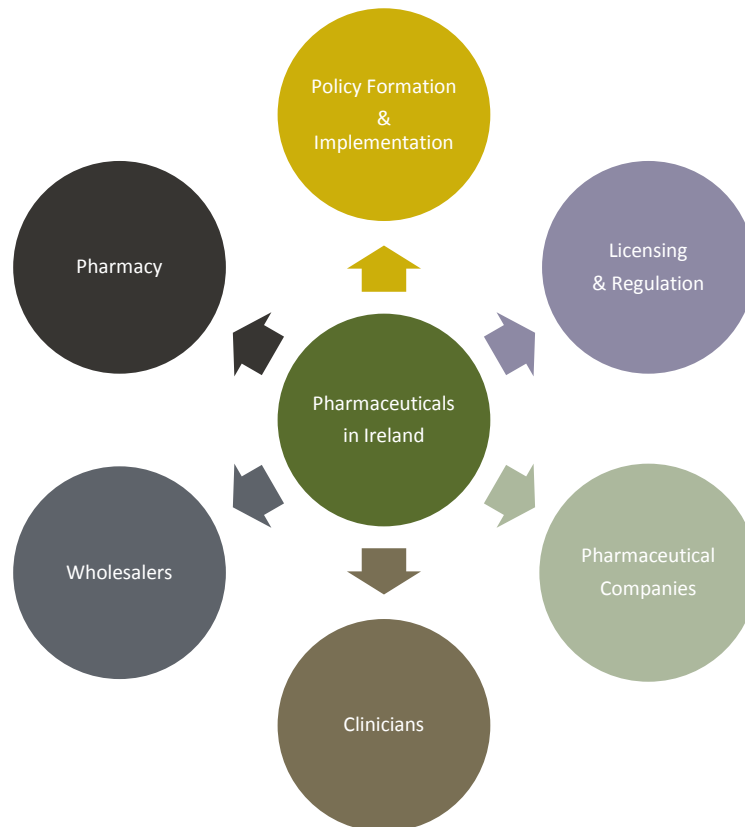
2.5 CONCLUSION

Public and private expenditure on pharmaceuticals is substantial, and public pharmaceutical expenditure accounted for an increasing share of public health expenditure over the period 2000-2010. In this context, ensuring value for money in pharmaceutical expenditure (both public and private) is a key policy concern, as is ensuring safety and security of supply. This chapter provides an overview of trends in total pharmaceutical expenditure in Ireland (primarily on the public side due to data availability), discusses the rationale for government intervention in the sector and briefly describes the current situation with regard to the pricing, reimbursement and delivery of pharmaceuticals in Ireland. The following chapters concentrate on aspects of the pricing, reimbursement and delivery structures in greater detail. It is beyond the scope of this report to consider the structure of the various State schemes that provide support for pharmaceutical expenses, and which influence patient behaviour with regard to the consumption of pharmaceuticals. However, the recent Expert Group on Resource Allocation and Financing in the Health Sector discusses in greater detail some of the inconsistencies in the schemes and make recommendations designed to remove these inconsistencies and ensure greater equity (Ruane, 2010).

³⁰ Ireland is among the countries where over 10 per cent of pharmacy sales originate directly from the manufacturer (Kanavos *et al.*, 2011). See Chapter 4 for further discussion.

Chapter 3

Objectives of the Pharmaceutical Delivery System



3.1 INTRODUCTION

The pharmaceutical delivery model has two main objectives: to provide value for money, both to the State and the patient; and to guarantee security of supply. These objectives are likely to attract widespread support and agreement. Hence models which are designed to meet them will therefore command commensurate acceptance. If there is disagreement then it will probably be over means rather than ends.

It is important to note what these two objectives omit. The purpose of the model is not to support earnings in the pharmaceutical sector or the status and/or income of the medical professions.¹ This does not mean, of course, that the expertise and advice of such groups should not be drawn upon and heeded. Indeed, meeting with such groups has proved invaluable in the preparation of this report. However, as has been noted in a number of instances, the non-traded sector of the economy is often

¹ Except, of course, that these service providers earn a sufficient rate of return to provide the services demanded.

quite uncompetitive and one of the key features of Ireland's EU-IMF bailout package is to increase competition in this sector.²

In this chapter we first discuss the two objectives in Sections 3.2 and 3.3. However, it could be argued that other objectives should also be taken into consideration. In other words, the specification of the objective function of the model is in some sense incomplete with the implication that the results and recommendations may not be fully relied upon. These issues are addressed in Section 3.4.

3.2 VALUE FOR MONEY

In any period, but particularly in one of sluggish growth, high unemployment, large budget deficits and cutbacks in public expenditure, it is hard to argue with the view that the pharmaceutical delivery model should provide value for money. Public and private resources are scarce and hence it is particularly important to ensure good value. However, what exactly is meant by the phrase 'value for money'? We adopt the definition of the UK's National Audit Office (NAO) which defines good value for money "...as the optimal use of resources to achieve the intended outcomes".³ Hence the definition links inputs – resources – with output – intended outcomes. This definition is also consistent with Department of Finance (2007) guidance in the area.

The inputs are the services provided by the key participants in the delivery of pharmaceuticals to patients, namely manufacturers, wholesalers, pharmacists, medical practitioners and, of course, the pharmaceutical itself. The output is the delivery of the pharmaceutical to the patient at the lowest possible cost. This is, in some sense, only an intermediate output, since the final intended outcome is that the patient receives the appropriate pharmaceutical for their condition and, as a result, their welfare is increased since they are cured or at least their symptoms alleviated. Considerable attention will be paid to the prescribing decision, particularly with respect to brand choice, but also other dimensions.

In considering the optimal use of resources at least two aspects are worth stressing. *First*, for any given model, we need to ask whether key input providers are receiving rents, defined as unnecessary factor payments; in common parlance overpayment or excessive returns or prices. The reforms of the pharmaceutical pricing and

² Indeed, there is specific reference to the reduction of the 50 per cent mark-up paid for pharmaceuticals under the DP. For details see EU/IMF (2010, p. 24). However, reference to this does not appear in the November 2011 update of the EU/IMF *Programme of Financial Support for Ireland*. (For details see www.finance.gov.ie).

³ For details see the NAO's website: http://www.nao.org.uk/what_we_do/value_for_money_audit.aspx. Accessed 19 April 2011.

reimbursement model in Ireland introduced from the mid-2000s have concentrated on this set of issues, for example by reducing wholesale and retail mark-ups. *Second*, we need to consider whether the inputs can be rearranged or reorganised so as to provide a better, more effective delivery system. Here attention is focused on alternative models to the current system such as, for example, greater use of tendering or preferential provider networks of pharmacists or distribution via the internet. These two aspects are, of course, related, although they are conceptually separate. For example, it has been argued that the existence of rents in the pharmacy sector led not only to, in some sense, 'excessive' entry of new pharmacies, but also attracted talent that might have been better employed in other sectors of the economy.⁴

Value for money applies both to the State and the cash paying patient. It is important that both are considered.⁵ The State acts on behalf of the taxpayer in organising the GMS and CDS described in Chapter 2. As such the State has a duty to taxpayers to ensure that it achieves value for money. However, there is always a danger in periods of austerity that increased value for money for the State may be, in part at least, shifting some or all of the cost of a scheme either to scheme recipients (e.g. the 50c co-payment per prescription item for GMS patients) and/or other cash paying users of the service (e.g. reducing the 50 per cent retail mark-up for DP payments above the monthly threshold, but not seeking a corresponding reduction in the 50 per cent retail mark-up for cash payments below the DP threshold).⁶ In other words, it is important to distinguish between policies that entail cost transference rather than cost containment. Such changes have the advantage that the State reduces its costs, but through, in part at least, shifting the cost to others either directly or indirectly. By including all patients in the definition of value for money the wider implications of cost transference are taken into consideration.

It should be noted that this is not to argue that the State should be precluded from shifting at least some of the cost of the GMS and/or CDS to the recipients. To restrict the State's freedom in this respect makes the assumption that the current exemptions, thresholds and copayments are optimal.⁷ This is not necessarily the case. A period of unparalleled fiscal austerity may mean what was appropriate in the period of high growth in the 1990s and early to mid-2000s may not be appropriate in

⁴ For further discussion, see, for example, Bacon (1999).

⁵ In the 2011 Programme for Government it is stated that reference pricing and greater use of generics will be introduced and that these measures "...will ... reduce the State's large drugs bill and the cost to individuals of their medications" (Department of the Taoiseach, 2011, p. 6). Hence both the taxpayer and the cash paying patient are considered.

⁶ In the case of local authority purchasing of long-term care places in residential homes in the UK, Hancock found that the authorities using their buying power were able to obtain prices below the market rate. In order to survive the homes raised prices to those residents who were self payers, who subsidised the local authority residents. For a brief summary and reference to Hancock's work see Haviid (2011).

⁷ See Ruane (2010) for a discussion of some of the inconsistencies inherent in the current system of public health entitlements.

today's climate. Rather what is being argued is that careful analysis should be undertaken of any proposed cost transference to ensure that the benefits are clearly shown to outweigh the costs.

3.3 SECURITY OF SUPPLY

The second key objective that any pharmaceutical delivery model must consider is security of supply. In other words, ensuring that when a patient goes to a pharmacy, or a pharmacy orders a pharmaceutical from a wholesaler, or a wholesaler orders a pharmaceutical from a manufacturer, that the pharmaceutical is supplied in a timely manner. Pharmaceuticals, like electricity or home heating fuels, are vital and the consequences of a lack of supply can be, potentially at least, life threatening. Hence, the requirement for security of supply.

However, security of supply is not exogenous to the model, but is to a considerable extent endogenous. In other words, it is determined by the actions of manufacturers, wholesalers and pharmacists, in part at least in response to economic incentives and policy changes. For example, in response to the reduction in retail pharmacy mark-ups, pharmacists withdrew support for methadone treatment⁸ and, on another occasion, forced those on the GMS and CDS to pay the pharmacist for their pharmaceutical treatment and then seek reimbursement from the State.⁹ There have also been reported shortages of pharmaceuticals in the US, especially those that are older and off patent, due to a combination of manufacturing problems, regulatory issues, pricing pressures and takeovers.¹⁰ Hence, in making regulatory and pricing decisions throughout the pharmaceutical chain from the manufacturer through to the wholesaler and pharmacy, cognisance needs to be taken by the State of its actions on security of supply.

The lesson to be drawn from past issues with security of supply is not that any input supplier can block reform and movement to a better model, but rather that the State needs to persuade those groups of the merits of the proposed changes and the legitimacy of the reforms. Of course, where the State fails to persuade particular groups of the merits of carefully considered and researched reform, it must go ahead with them in the broader public interest.

⁸ A number of pharmacies in 2007 stopped dispensing methadone in response to HSE moves to reduce fees paid to medical card holders. However, after the intervention of the Competition Authority and remarks by the Pharmaceutical Society of Ireland, methadone services were resumed.

⁹ In 2009, again on the foot of moves by the HSE to reduce fees paid to pharmacies, the latter began to terminate their contracts with the HSE. However, the fact that the HSE was able to organise contingency pharmacies and that the chain pharmacies such as Boots did not withdraw from HSE schemes, defeated the boycott.

¹⁰ For a discussion see Hunter (2011b) and Jack and Rappeport (2011a; b)

3.4 A COMPLETE SET OF OBJECTIVES?

While value for money and security of supply are the two main objectives for any pharmaceutical delivery model, there are also other objectives which, it might be argued, should also be included. We consider several of these. Although these may be legitimate objectives and we are aware of their importance, nevertheless, for reasons discussed below, they are not added to the two main objectives outlined above but rather addressed in other ways.

First, it could be argued, quite reasonably, that the pharmaceuticals consumed by the patient must be of the required quality, in terms, for example, of purity and consistency. However, this is primarily the responsibility of the Irish Medicines Board (IMB) and the various monitoring mechanisms that are in place to provide feedback from the use of pharmaceuticals. Furthermore, pharmaceutical manufacturers have a strong reputational motivation for ensuring that the quality is of the required standard. Nevertheless, to the extent that any of the proposals discussed below impact on the quality of pharmaceuticals, this will be taken into account.

Second, it could be argued that prescriber choice should be unconstrained. The prescriber is charged with taking care of the patient's health and is in the best position to identify the most appropriate course of treatment. The relationship between the prescriber and the patient is one built on trust and confidentiality. Damaging that relationship could thus undermine a vital element of the healthcare system. However, it is possible that certain types of limitations on the choices of prescribers are consistent with effective prescribing, do not compromise the healthy patient-prescriber relationship and would help to improve the value for money of the pharmaceutical purchasing system. We take the view that it would be inappropriate to rule out such measures per se by making unconstrained prescribing a precondition for the report.

The issue is thus not so much whether or not the prescriber's choice should be constrained, but rather in what way and under what conditions. Does, for example, providing increased information on pharmaceutical efficacy and prices so that the prescriber can make a better more well informed decision constrain choice? Equally, given the busy schedule of a prescriber, is it unreasonable to delegate the choice of brand, subject to some exceptions, for a particular pharmaceutical to an expert group of the prescriber's peers so as to ensure better value for money? These are issues that will be returned to below.

Third, it could be argued that patients should be provided with enhanced information and thus be in a position to make their own well informed choice.

However, this is not so much an objective or constraint on the model as it is a possible measure to be employed to improve outcomes and efficiency. What information should be provided and in relation to what decisions? When the prescriber makes the decision as to the appropriate course of action is the time when the prescriber and patient should discuss issues in relation to treatment choice, while the pharmacist can answer further questions when the pharmaceutical is being dispensed. Nevertheless, the availability of information on pharmaceutical costs may cause the patient to question both the prescription and dispensing decisions, which is likely to lead to a better more informed outcome for the patient.

Fourth, it could be argued, given the importance of innovative research-based pharmaceutical firms to the Irish economy, the pharmaceutical delivery model should play a supportive role for this sector. However, there are many other more important factors that determine the location of pharmaceutical firms in Ireland with low corporate taxation often identified as significant (Kanavos *et al.*, 2011, p. 29). Increased value for money measures would concentrate more on other parts of the pharmaceutical delivery system such as generic manufacturers, parallel importers, wholesalers, pharmacists and patients, rather than brand name firms. The HSE would have to balance supporting the latter group of firms against obtaining greater value for money. The recent banking crisis highlights the problems of such dual mandates. The regulator in that case had the responsibility of both promoting the financial sector and ensuring financial stability, which arguably contributed to the depth of the financial crisis in Ireland (Honohan, 2010).¹¹

Fifth, it could be argued that a key objective of the pharmaceutical delivery model should be to ensure equitable access to pharmaceuticals. For example, a patient's income should not prevent them from gaining the appropriate pharmaceutical to treat their condition. Access to pharmaceuticals should thus be based on need. However, providing equitable access to pharmaceuticals depends upon the eligibility conditions for the GMS and CDS. As noted in the Conclusion to Chapter 2, recent recommendations have been made to improve eligibility for free public health services in Ireland. In this report the focus of attention is on securing value for money and security of supply, given the current eligibility conditions for the GMS and CDS.

We have eschewed adding these additional conditions to the objectives that the fit for purpose model must satisfy for three sets of reasons. *First*, the quality/industrial policy issue is the responsibility of another part of the wider pharmaceutical

¹¹ Another example, highlighted in a *Financial Times* editorial, concerns the dual role with respect to the nuclear industry of the Japanese trade and industry ministry, "...which has been responsible for both promoting and regulating nuclear energy. This created a damaging conflict of interest and compromised safety" (*Financial Times*, 2011, p.8).

approval and monitoring system, not pricing and reimbursement. *Second*, some of the conditions would involve accepting the constraints of the current model and hence largely vitiate the purpose of this report. This does not mean, of course, that in making proposals for revising the rules that attention will not be paid to the wider implications of a proposal. *Third*, in considering any model or policy the greater the proliferation of goals and objectives the more difficult it is to achieve any of the goals. How does one estimate let alone trade-off one goal against another? The current exercise is no exception.

3.5 CONCLUSION

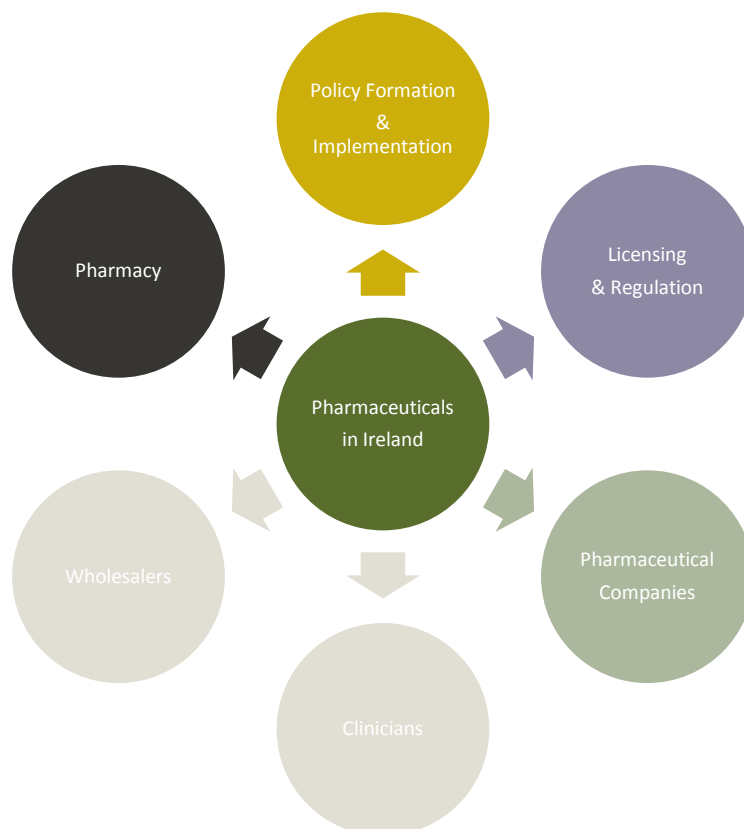
In this section we have considered the merits of alternative objectives for the pharmaceutical delivery system from value for money to supporting the innovative research-based pharmaceutical firms. However, after careful consideration;

Recommendation 3.1: We recommend that the two objectives of the pharmaceutical delivery system from the perspective of the HSE should be obtaining value for money and ensuring security of supply.

Other objectives are better achieved by other policy instruments and/or would lead to an unnecessary proliferation of objectives that would involve the HSE in making inherently difficult trade-offs for which it is not equipped.

Chapter 4

Setting the Ex-Factory Price of Pharmaceuticals



4.1 INTRODUCTION

This chapter addresses the issue of how the ex-factory prices of pharmaceuticals are currently determined before making proposals as to future pricing so as to secure better value for money while ensuring security of supply for the HSE and patients more widely. In analysing the ex-factory price, pharmaceuticals are divided into three categories: single source in-patent pharmaceuticals, parallel imports and multiple source off-patent pharmaceuticals.

First, are single source in-patent pharmaceuticals. These pharmaceuticals are still subject to patent protection. They are the newer products that often gather huge media interest when they are first launched or even before in the early stages of the research and development process.

Second, parallel imports of in-patent single source pharmaceuticals. Although single source in-patent pharmaceuticals are typically protected from competition due to patent protection, the EU single market imperative means that firms can import a single source in-patent pharmaceutical (i.e. parallel imports) from another Member State (e.g. the UK or Spain) for sale in Ireland without the permission of the patent owner. The parallel import thus competes with the single source in-patent pharmaceutical.

Third, multiple source off-patent pharmaceuticals. When the patent expires on a pharmaceutical then new suppliers may enter the market in order to compete with the incumbent. These are sometimes referred to as generic firms. Sometimes these firms brand their products (branded generic) while in others this is not the case (unbranded generics). Typically it is the higher volume pharmaceutical products that attract generic competition.

As we shall see there are further nuances concerning whether or not the pharmaceutical is new or existing.

The chapter is organised as follows. The current agreements between the State and pharmaceutical suppliers that set the framework within which ex-factory prices are set is briefly set out in Section 4.2. Next, Section 4.3 deals with price setting for single source in-patent pharmaceuticals, while Section 4.4 discusses price setting for parallel imports. Attention then turns to the pricing of off-patent pharmaceuticals with generic competition; in Section 4.5 for generic competitors with the same or similar chemical entity, dosage form and strength, in Section 4.6, for generic competitors in the same therapeutic category. The chapter concludes with Section 4.7.

4.2 SETTING THE FRAMEWORK: AGREEMENTS BETWEEN THE STATE AND PHARMACEUTICAL SUPPLIERS

The ex-factory pricing and supply of single source in-patent and multiple source off-patent pharmaceuticals is set out in the agreements between the HSE and the Irish Pharmaceutical Healthcare Association (IPHA),¹ representing the brand name manufacturers, and the Association of Pharmaceutical Manufacturers of Ireland

¹ The Irish Pharmaceutical Healthcare Association (IPHA) represents 53 research-based pharmaceutical companies, which includes both manufacturers of prescription and non-prescription pharmaceuticals (IPHA, undated). The mission of IPHA is "...to create a favourable economic, regulatory and political environment, which will enable the research-based pharmaceutical industry in Ireland to meet the growing healthcare needs and expectations of patients" (IPHA, 2011, p. 1). For further details of the IPHA see, <http://www.ipha.ie>.

(APMI),² representing the generic manufacturers.³ These agreements serve as the basis for all prices in the market, for the public and the private sector, in the hospital and the community.⁴ The present agreements commenced in 2006 and were due to expire in September 2010.⁵ However, in 2010 a number of amendments to the IPHA/HSE agreement (on two occasions, January and December) and APMI/HSE agreement (once, September) were announced, including a provision that the current agreements will be extended: in the case of the IPHA/HSE agreement to March 2012;⁶ and in the case of the APMI/HSE agreement until the commencement of a scheme of reference pricing and generic substitution, which is likely also to be in 2012.

The IPHA/HSE and APMI/HSE agreements apply to all pharmaceuticals that can be prescribed, reimbursed and supplied to the GMS Scheme and the Community Drug Schemes (CDS).⁷ These agreements also cover all pharmaceuticals supplied to the HSE, State-funded hospitals and to State Agencies whose functions normally include the provision of pharmaceuticals (HSE, 2006a, p. 1). Such pharmaceuticals are subject to marketing authorisation by the Irish Medicines Board (IMB) or European Commission.

The price-setting mechanism follows the same procedure regardless of the type of pharmaceutical, except where the classification of a pharmaceutical changes between agreements. A single maximum price across hospital and community supply is also a feature of the agreements. It should be noted, however, that hospitals are free to negotiate lower prices directly with manufacturers.

Pharmaceuticals under the 2006 IPHA/HSE and APMI/HSE agreements can be divided into existing (i.e. at the date of the commencement of the agreement) and new (i.e. subsequent to the date of the agreement). Existing pharmaceuticals were subject to a price freeze, subject to some exceptions (e.g. production becomes uneconomic, thus threatening security of supply). In considering single source in-

² The Association of Pharmaceutical Manufacturers of Ireland (APMI) represents nine generic manufacturers (eight of which are currently involved in manufacturing in Ireland), and two indigenous manufacturers of OTC products (APMI, personal communication, 6 July 2011). The APMI does not have a website.

³ Not all manufacturers supplying pharmaceuticals to the Irish market are covered by the IPHA and APMI agreements.

⁴ Although parallel import prices are not determined in the IPHA/HSE and APMI/HSE agreements, they are nevertheless set in relation to the prices that result from these agreements. The issue is discussed in greater detail in this chapter.

⁵ The first agreement between the State and manufacturers (then represented by the Pharmaceutical and Allied Industries Association) was dated July 1969. HSE, personal communication, 6 January 2012.

⁶ Details of these changes may be found in DoHC (2010a), while the revision to the HSE/IPHA appears as Annexe A to the 2006 IPHA/HSE agreement, which is available on the IPHA website: <http://www.ipha.ie/alist/ipha-hse-agreement.aspx>. Accessed 27 September 2011. The extension the agreement to 1 March 2012 was qualified in clause 3 which stated that "...the IPHA recognises and accepts that the Agreement may stand amended on the introduction of legislation to provide for reference pricing and/or generic substitution." Note that in some instances in 2010 the Minister of Health and Children was also party to the agreement.

⁷ See Chapter 2.

patent pharmaceuticals the report confines its attention to new pharmaceuticals. Multiple source off-patent pharmaceuticals can be either existing or new pharmaceuticals, although in most cases such pharmaceuticals will be existing.

The ex-factory price set in accordance with the IPHA/HSE and APMI/HSE agreements is a maximum price. In the case of new pharmaceuticals, for example, reference is made to the fact that the ex-factory price "...shall not... exceed the currency adjusted price to the wholesaler in the nominated EU member states" (HSE, 2006a, p. 3). However, for pharmaceuticals that "...may be high cost or have a significant budget impact" a pharmacoeconomic assessment can be undertaken (*ibid*, p. 2). This procedure, which is discussed in Section 4.3.3, may result in a lower ex-factory price than that set in accordance with the application of the external reference pricing or, in an extreme case, the HSE deciding not to pay for the pharmaceutical under the GMS or CDS.

Under the terms of the 2006 IPHA/HSE and APMI/HSE agreements, manufacturers are required to pay 3.53 per cent of the ex-factory price of all pharmaceuticals dispensed under the GMS Scheme to the PCRS (with the exception of patent-expired pharmaceuticals subject to the price reductions outlined in the agreements). From 1 January 2010, the rebate was increased to 4 per cent, and extended to the CDS.

The successive agreements between the HSE and the IPHA and the APMI have, it is argued, resulted in substantial savings.⁸ The 2006 IPHA/HSE agreement was expected to result in savings in the order of €300 million between 2006 and 2010, or €75 million per annum.⁹ There were further savings agreed between the IPHA and the HSE in early 2010 of €94 million in a full year. Later in 2010 the IPHA agreed to savings of an additional €200 million in 2011.¹⁰ The APMI/HSE in 2010 agreed to savings expected to yield €25 million in a full year. These savings are in relation to the State pharmaceutical expenditure in both the community and hospital sector, which in 2010 stood at approximately €1.9 billion as detailed in Chapter 2.

The proposals made in this chapter involve amending the IPHA/HSE agreement with respect to the determination of the price of single source in-patent pharmaceuticals and the replacement of the IPHA/HSE and APMI/HSE agreements with a different

⁸ These estimates are taken from DoHC (2006b; 2010a; 2011, p. 25) and HSE, personal communication, various dates 2011.

⁹ Since the 2006 IPHA/HSE agreement was amended and extended to 2012, these annual savings can be expected to continue to the latter date. The €300 million estimate appears to have been reduced to €250 million subsequently.

¹⁰ These savings are as follows: "... €155 million are expected under the GMS and community drug schemes through a combination of price reductions and increased rebates to the HSE, €35 million under the High Tech Scheme and €10 million on hospital medicines" (DoHC, 2011, p. 25). The combination of price reductions and increased rebates was at the discretion of individual IPHA members. The €155 million savings includes both a reduction in the ex-factory price and increased rebates (€140 million) and additional downstream savings (€15 million).

mechanism for the determination of multi-source off-patent pharmaceuticals. In both cases prices should be lower and market forces should be used to greater effect and extent to price pharmaceuticals than the current administrative pricing arrangements. However, the changes proposed are not revolutionary, but rather are consistent with the evolving trend in pharmaceutical pricing in Ireland as well as practice in other jurisdictions, in both the EU and beyond.

4.3 SETTING THE EX-FACTORY PRICE FOR SINGLE SOURCE IN-PATENT PHARMACEUTICALS

One of the important ways in which the HSE has achieved greater value for money is through reductions in the ex-factory price of single source pharmaceuticals still subject to patent protection. Where a firm is in a monopoly position and assuming that it is profit maximising, it will charge a monopoly price. Thus the HSE is seeking to reduce the monopoly rents that accrue to the firm. Ex-factory price setting consists of two mechanisms: international or external reference pricing; and, a pharmacoeconomic assessment. The first mechanism is intended to reduce monopoly rents, the second, in part, to influence the direction of pharmaceutical innovation and, in part, to ensure that the benefits that flow from the pharmaceutical exceed the costs, particularly compared with other pharmaceuticals on the market as well as alternative treatment options.

In considering how to achieve better value for money for single source in-patent pharmaceuticals, attention will first concentrate on the formula in the IPHA/HSE agreement for determining the ex-factory price of these pharmaceuticals and how that formula might be amended and administered. Attention then turns to the impact of parallel imports and how these might be used to assist in setting prices for single source in-patent pharmaceuticals.

4.3.1 External Price Referencing

External reference pricing consists of three essential elements: a choice of a basket of benchmark Member States,¹¹ a rule for using the ex-factory price from the basket Member States to set the ex-factory price or reference price, and, finally, a means of updating the ex-factory price as more pricing data becomes available. Each of these elements is described, with reference being made to the experience elsewhere in the EU, before some recommendations for revision are considered.

¹¹ As we shall see in some instances some Member States that employ external reference pricing use non-Member States such as Switzerland. However, our interest is confined to Member States only.

4.3.1.1 External Pricing: Current Arrangements in Ireland

External price referencing (also referred to as international price referencing) for a new pharmaceutical in Ireland involves, under the 2006 IPHA/HSE agreement, setting the price of the pharmaceutical by reference to the price charged for the pharmaceutical in a **basket of nine other Member States** by the firm seeking a listing. The lower priced Member States of Spain, Austria and Belgium were added as well as Finland in 2006 to the pre-existing basket of five Member States (i.e., Denmark, France, Germany, the Netherlands, and the UK). The current basket is drawn exclusively from Member States prior to EU enlargement in 2004 and 2007. Hence the basket is representative of the EU-15 not the EU-27. The firm provides the ex-factory price data to the HSE using a Price Application Form.¹²

External price referencing is currently the norm in the EU for setting the ex-factory price. Of 25 Member States for which information is readily available all but four use external reference pricing (Table 4.1). Typically, however, these Member States use a basket of more than nine countries; of the 20 other Member States (besides Ireland) that use external reference pricing, 13 use more than nine reference countries. In some cases as high a number as 28 countries is used, since non-Member States such as Norway and Switzerland are included on occasion. However, the main message from Table 4.1 is that there is no apparently agreed upon ideal number of benchmark countries, although some Member States, such as France, Germany, Italy, Spain and the UK, appear more frequently than others in the basket selected by Member States.

TABLE 4.1 Ex-Factory Price Setting Mechanisms in the European Union, 25 Member States,^a 2010

Price Setting Mechanism	Member States
Free Pricing	Denmark, Germany, Sweden, UK
External Reference Pricing	
Average Price	(Number of Member and Non-Member States used to Estimate Reference Price) Austria (24), Belgium (12), Ireland (9), Finland (17), ^b Lithuania (16), ^c Netherlands (4), Portugal (4).
Lowest Price	Bulgaria (12), Cyprus (10), ^d Czech Republic (26), Estonia (28), France (4), Greece (25), ^e Hungary (13), Italy (3), Latvia (28), Poland (8), Romania (13), ^f Slovak Republic (27), ^g Slovenia (3), Spain (9).

- Notes:
- a Excluding Malta and Luxembourg.
 - b Median rather than average.
 - c The average minus 5 per cent.
 - d The lowest four prices.
 - e Average of the 3 lowest EU-15 and 1 lowest from EU-10.
 - f The lowest three prices.
 - g The lowest six prices.

Source: Kanavos *et al.*, (2011, Appendix 1, pp. 80-81).

¹² The HSE can verify the accuracy of the price information by contacting the relevant authorities in other jurisdictions. The form may be found at: <http://www.ipha.ie/alist/ipha-hse-agreement.aspx?article=b7c7daed-94ac-45bf-b900-8b1e017dc77b>. Accessed 28 September 2011.

The next step in applying external price referencing is to choose a ***formula for setting the ex-factory price*** using the ex-factory prices of the basket of reference jurisdictions. Under the IPHA/HSE agreement the formula is the (unweighted) average of the basket of nine Member States. In 2010 the average or some variant was used by seven (including Ireland) of the 21 Member States that used external price referencing to set the ex-factory price (Table 4.1). There are, however, alternative formulae that could be introduced that would facilitate lower prices, ensure early adoption and yield the certainty required in order to ensure that planning, production and marketing can take place. Instead of using a simple average of ex-factory prices, the formula could attach a higher weight to the Member States in the basket with lower prices and a lower weight to those with higher prices. This should, other things being equal, lead to lower ex-factory prices. A special case of this approach is to apply a zero weight to all prices but the lowest; fourteen of the 21 Member States in Table 4.1 that employ external price referencing use the lowest price or some variant of the lowest price from the selected basket of Member States to determine the ex-factory price.

The final step in external price referencing is choosing ***the frequency with which ex-factory prices are re-assessed or updated***. Under the IPHA/HSE agreement the ex-factory price shall not exceed the average price by reference to nine Member States. However, if a new pharmaceutical is not available in all of the nine Member States at the date of initial notification to the HSE to be listed for reimbursement purposes, then the average price is set by reference to only those Member States out of the basket of nine where the new pharmaceutical is available at that date. As the pharmaceutical becomes available in the remaining Member States the average price is adjusted accordingly. However, this does not happen immediately. In the 2006 IPHA/HSE agreement there was a Price Monitoring and Review mechanism at two distinct time points (two and four years after the commencement of the agreement, in 2008 and 2010) to take into account currency adjustments and the availability of the pharmaceutical in the remaining Member States in the basket. However, there is no adjustment for a year after the date of reimbursement approval from the HSE. In other words, once a new pharmaceutical was approved for reimbursement its ex-factory price was reviewed between a year and three years later. Under the 2010 amendments to the 2006 IPHA/HSE agreement there is no further price monitoring and review.

The evidence suggests that typically Ireland is an early launch Member State for a new pharmaceutical.¹³ As a result the pharmaceutical is often available in only two or three of the basket of nine Member States when its price is set in Ireland. For example, in 2010, 14 out of 24 new chemical entities examined by the HSE for reimbursement used prices for two Member States for the purposes of setting the ex-factory price. In the majority of cases Denmark, Germany and/or the UK were selected. All three of these jurisdictions have free pricing, in contrast to the external price referencing system of most of the other Member States in Table 4.1. The evidence suggests that Germany and the UK had higher than average prices compared to other Member States.¹⁴ Prices in Denmark are similar to those in Germany and the UK.¹⁵ Given the one to three year delay before review of prices to reflect the availability of a pharmaceutical in other Member States in the basket, this means that the benefit of lower prices is deferred. In contrast to Ireland most Member States re-align the ex-factory price at least annually, and in the case of four Member States twice a year.¹⁶

There are certain advantages to the current system of pricing in-patent pharmaceuticals embodied in the IPHA/HSE agreement. It is administratively straightforward, once the basket of Member States is chosen. By selecting a basket of Member States that includes jurisdictions that typically have higher and lower prices, the result could be seen in some sense as representative of an EU price.¹⁷ Furthermore, external price referencing, when set out in an agreement such as that between the HSE and the IPHA, provides a stable and predictable environment within which planning, production, and marketing can take place. This facilitates security of supply. However, that does not mean that the current agreement cannot be improved upon nor that it does not suffer shortcomings (OECD, 2010, p. 164).

¹³ For details see European Commission (2009, Figure 36, p. 152). The sequence of Member States in which a pharmaceutical is launched reflects a number of factors (*ibid*, pp. 149-153). An important factor concerns the speed with which a pharmaceutical can be marketed. Member States such as Denmark, Germany, and the UK have free pricing and require no prior approval. Member States such as France, Italy, and the Netherlands allow submission of a "...pricing and reimbursement dossier before the marketing authorisation is officially granted." (*ibid*, p.151). These Member States are those when pharmaceuticals are first launched in the EU (*ibid*, Figure 36, p. 152).

¹⁴ Kanavos *et al.* (2011, Figure 6, p 23) for price comparisons across 150 products for 2008 show that of the nine Member States in the Irish basket, Germany ranked one followed by Belgium, the UK, Finland, the Netherlands, Austria, Spain and France. Data for the other Member States, including Denmark, in the Irish basket were not presented. The prices referred to the retail prices.

¹⁵ Based on the data supplied by the brand name firms to the HSE for setting the ex-factory price under the IPHA/HSE agreement. The mean of the Denmark/Germany price was slightly above 1.00 (at launch, 1.17, at the 2008 price review, 1.10, at the 2010 price review, 1.05); in contrast, the Denmark/UK price ratio was slightly below 1.00 (at launch 0.90, the 2008 price review 0.90, the 2010 review, 0.84).

¹⁶ For details see Kanavos *et al.* (2011, Appendix, pp. 80-81).

¹⁷ It is of course a negotiated compromise between the IPHA and the HSE. See DoHC (2006b) and Barry *et al.* (2004).

4.3.1.2 External Referencing Pricing: Some Proposals

In considering the method by which the ex-factory price is set, we do not advocate radical revision of the *status quo*, but rather consider each of the three elements of external reference pricing separately, suggesting reforms so as to achieve lower ex-factory prices but at the same time ensure security of supply.

In terms of the ***selection of the basket of Member States***:

Recommendation 4.1: We recommend that, initially at least, the basket of Member States used for the purposes of determining the maximum ex-factory price of in-patent pharmaceuticals should be confined to the nine Member States in the 2006 IPHA/HSE agreement.

These nine Member States are the higher income Member States drawn from the EU-15 and hence are more similar to Ireland than the new Member States that joined with the enlargement of the EU in 2004 and 2007. It could, of course, be argued that all Member States should be included since pharmaceutical prices tend to be positively related to per capita income, particularly for in-patent pharmaceuticals (Kanavos *et al.*, 2011, p. 33). However, there is danger, since Ireland is used in the basket of 10 other Member States that use external price referencing, that firms may delay listing new pharmaceuticals in Ireland since it may lead to price reductions in other Member States. Nevertheless, the discussion below concerning parallel trade suggests a mechanism by which other Member States not only in the EU-15 but also those which joined in 2004 and 2007 might be added to the basket. Furthermore, the ex-factory price is a maximum due to the necessity of conducting a pharmacoeconomic assessment that might result in a lower price or refusal to reimburse the pharmaceutical.

In terms of the ***pricing formula*** used to determine the ex-factory price, the issue revolves around how the ex-factory price for Ireland should be set based on the corresponding prices for each of the nine Member States in the basket. Table 4.1 suggests the choice is between the average and the lowest priced of the nine Member States, with the latter the most frequently used formula. Since we are interested in securing greater value for money:

Recommendation 4.2: We recommend that the maximum ex-factory price of in-patent pharmaceuticals should be the lowest price of the basket of nine Member States in the 2006 IPHA/HSE agreement.

The choice of the lowest priced basket Member State should lead to lower ex-factory prices which should benefit all purchasers of pharmaceuticals, whether in the public or private sector, community or hospital sectors.

There is, of course, a possibility that by using such an approach that there will be a move to parallel exports from Ireland. This may lead to shortages. However, this latter possibility should not be overstated. First, as noted above, ex-factory prices are likely to be more similar amongst the EU-15, than if some of the Member States added at enlargement were included in the basket. Thus the approach adopted in this report to setting the ex-factory price reduces the opportunity for parallel exports compared to a more expansive approach. Second, wholesalers in Ireland have to "...ensure appropriate and continued supplies [to pharmacists and other healthcare professionals] so that the needs of the patients in the State in respect of such medicinal products are covered."¹⁸ Parallel exports that result in shortages are thus inconsistent with this regulation.

In terms of the *frequency of the price alignments*, it is not clear why there is a need to delay the inclusion of the prices of other Member States in estimating the ex-factory price. The IPHA informed us that the differences in availability of pharmaceuticals across Member States reflected differences in the speed with which Member States processed manufacturer's requests for inclusion for reimbursement, rather than for strategic reasons. Hence if Ireland decided to update the ex-factory price on a new in-patent pharmaceutical with a greater frequency than one to three years this should, in principle, occasion no further repercussions such as on promptness of availability. Hence:

Recommendation 4.3: We recommend that the maximum ex-factory price for in-patent pharmaceuticals should be updated every six months , i.e. on 1 January and 1 July.

Since, as noted above, other Member States update¹⁹ with a similar frequency this should not prove too great an administrative burden, especially if it brings price reductions forward by up to three years compared with the 2006 IPHA/HSE agreement.

¹⁸ Schedule 2 paragraph 11 of S. I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

¹⁹ Such price reviews are clearly appropriate where the ex-factory price has been set solely with reference to the basket of nine Member States. Where, after a pharmacoeconomic assessment, the ex-factory price is negotiated below the maximum ex-factory price, such reviews are likely to have less relevance. Of course, eventually the maximum ex-factory price might be below the negotiated price, in which case the ex-factory price would equal the lower maximum price.

For the basket of nine Member States used to derive the ex-factory external reference price under the IPHA/HSE agreement, the HSE supplied in anonymised format all the prices submitted by the brand name firm at launch and at the 2008 and 2010 price reviews or realignment. Each different formulation and strength is a separate record. The pharmaceuticals were classified by category of scheme at launch (i.e. GMS, High Tech or HTD, hospital). The ratio of the average of the prices that were submitted (i.e. the ex-factory or external reference price agreed under the IPHA/HSE agreement) to the lowest of the prices that were submitted was calculated for each in-patent pharmaceutical for which information was provided. This ratio was calculated at launch and for each of the two price reviews (i.e. 2008, 2010). For example, if at launch, the prices were submitted for three Member States in the basket of nine were €4.00 per pack, €3.00, and €2.00, the ratio would be 3/2 or 1.50. If, at the first price review, a fourth Member State price was added, €1.50, then the ratio would be 2.625/1.50 or 1.75. Thus if the lowest price were used compared to the average, the reduction in the ex-factory price would be a third at launch and 43 per cent at the first price review under this example.

TABLE 4.2 The Ratio of the Basket of Nine Average Price^a to the Basket of Nine Minimum Price, by Scheme, at Year of Launch and Realignment, 2006-2010

		Scheme at Launch			Total	
		GMS	High Tech	Hospital		
Product Launch Year	2006	Launch	1.10	-	-	1.10
		2008 Realignment	1.30	-	-	1.30
		2010 Realignment	1.24	-	-	1.24
	2007	Launch	1.60	1.10	1.10	1.37
		2008 Realignment	1.23	1.21	1.23	1.23
		2010 Realignment	1.31	1.22	1.62	1.34
	2008	Launch	1.25	1.23	1.16	1.23
		2008 Realignment	n/a	n/a	n/a	n/a.
		2010 Realignment	1.39	1.25	1.26	1.34
	2009	Launch	1.26	1.23	1.30	1.27
		2008 Realignment	n/a	n/a	n/a	n/a.
		2010 Realignment	1.61	1.67	1.30	1.45
	2010	Launch	1.35	1.26	1.12	1.29
		2008 Realignment	n/a	n/a	n/a	n/a.
		2010 Realignment	n/a	n/a	n/a	n/a.
2011 ^a	Launch	1.17	1.19	1.18	1.17	
	2008 Realignment	n/a	n/a	n/a	n/a.	
	2010 Realignment	n/a	n/a	n/a	n/a.	
Total	Launch	1.32	1.21	1.18	1.27	
	2008 Realignment	1.26	1.21	1.23	1.25	
	2010 Realignment	1.35	1.25	1.39	1.33	

Notes: a Of those nine Member States for which data was available.
 For the purpose of reimbursement by the HSE, manufactures/parallel importers applies for reimbursement under the GMS, High Tech and/or hospital lists.
 Data are available on 525 products (not unique) launched between September 2006 and July 2011.
 Products for which data was missing were excluded from the analysis.
 Products launched on two schemes were excluded.
 Products for which a basket price was indicated but not available were excluded.
 Final analysis is based on 464 unique products.

Source: ESRI calculations from HSE personal communication, 11 August 2011.

The mean of the ratio of the average to the lowest price in the basket at launch, for the two price reviews, by scheme type,²⁰ is presented in Table 4.2. It shows, for example, that at launch in 2007 for HTD products on average the average or external reference price was 10 per cent above the lowest price. Overall, the data show – the bottom right hand corner of the table – that if the lowest price were used to set the ex-factory price rather than the average, the ex-factory price would fall by between 20 and 25 per cent depending on whether at launch, or either of the subsequent two price reviews is considered.

4.3.2 External Price Referencing and Parallel Imports

The EU Single Market allows firms, whether parallel importers, wholesalers, pharmacies and others, to purchase in-patent and other pharmaceuticals in Member States with lower prices and re-sell them in Member States where prices are higher, without the authorisation of the patent owner.²¹ A series of European Court of Justice rulings have underpinned its legitimacy. Parallel importation of pharmaceutical products from non-EU or non-EEA countries into the EU is not, however, permitted. Parallel imports are identical to the original manufacturer's products²² except that they may be packaged differently and may not carry the original manufacturer's warranty. Parallel imports into Ireland are thus, by definition, in-patent pharmaceuticals from another Member State.^{23,24}

Parallel imports are usually undertaken by specialist firms such as Autumn Healthcare Limited and B&S Healthcare, that must comply with certain regulatory requirements, concerning for example packaging and labelling.²⁵ The determination of the ex-factory price for parallel imports is not part of either the IPHA/HSE or APMI/HSE agreements. Instead, the HSE sets an ex-factory price for parallel imports which is at a small discount – at least 3 per cent in 2010, 7 per cent in 2011 – to the single source in-patent ex-factory price. In other words, if the single source in-patent pharmaceutical ex-factory price is €10.00 per unit and the discount is 3 (7) per cent, then the ex-factory price for the parallel import would be €9.7 (€9.3) per unit.

²⁰ Not all pharmaceuticals are available under all schemes. The manufacturer/parallel importer of the in-patent pharmaceutical decides for which schemes to request listing.

²¹ There is an extensive literature on various legal and economic aspects of parallel imports of pharmaceuticals. See, for example, Kyle (2009), Kanavos & Coatsworth (2005), Kanavos & Kowal (2008) and O'Donoghue & Macnab (2009).

²² Identical in that the "...parallel-distributed product must have the same active substance(s), the same pharmaceutical form and be identical to, or have no significant therapeutic difference from, the Irish-market product" (IMB, 2007, p. 4). The latter source contains the IMB's guidance on parallel import product authorisations.

²³ Manufacturers undertake various strategies to protect their interests from parallel trade, such as applying for marketing authorisation for different dosages and strengths and rationing supply to wholesalers believed to be engaged in parallel trade (e.g. Canada) (OECD, 2008).

²⁴ Off-patent pharmaceuticals may also be subject to parallel imports.

²⁵ For details see the IMB website, www.imb.ie.

Overall, in 2009 it was estimated that 9 per cent of Irish pharmaceutical sales were accounted for by parallel traded products; the comparable figure for the UK was 14 per cent, for Denmark 20 per cent.²⁶ The importance of parallel imports in the community pharmacy sector has risen dramatically in Ireland.²⁷ In nominal terms the increase was from €50 million in 2005 to a peak of €250 million in 2010 before an anticipated decline in 2011 to €220 million.²⁸ Table 4.3 provides details of the importance of parallel imports in respect of the ten leading individual high volume products, by value, for the GMS and one of the CDS, the DP Scheme.

The value and volume shares of parallel imports are quite similar reflecting the small price discount of parallel imports in relation to the brand name price. For virtually all the high volume in-patent pharmaceuticals in Table 4.3, there are at least some parallel imports, fentanyl is the only exception. The importance of parallel imports varies considerably across the leading ten in-patent pharmaceuticals for the GMS and DP Scheme. The highest penetration of parallel imports was lansoprazole at 25-26 per cent in 2010. If a 10 per cent share is taken as significant, then in 2010 parallel imports are significant in six of the 10 leading in-patent pharmaceuticals, for both the GMS and the DP Scheme.

²⁶ European Federation of Pharmaceutical Industries and Associations (2011, p. 3). It is not clear if value or volume is used to measure parallel import market share. However, in the case of Ireland this would make little difference due to the fact that whether measured by value or volume, the market share of parallel imports is very similar (Table 4.3), reflecting the fact that applications for reimbursement of parallel imports were only accepted if the price was at a least 3 per cent in 2010 and 7 per cent in 2011 below the brand name price. Since parallel imports are priced at a discount to the brand name in-patent product, the market share of parallel imports measured using volume should be greater than that using value. While this is typically the case in Table 4.3 it is not always the case. This may be due to the fact that some dosage forms and strengths – typically small volume – of a pharmaceutical there may be no parallel imported product either for some or all of the time period referred to in the table.

²⁷ Parallel imports play a very limited role in the hospital sector. Based on discussions with industry participants, we understand that such products are unattractive, inter alia, due to the fact that the source Member State can change, which often leads to a change in packaging.

²⁸ Based on IMS data supplied by the Pharmaceutical Distributors Federation (PDF), personal communication, 19 September 2011.

TABLE 4.3 Parallel Imports as a Proportion (Volume and Value) of the Top 10 Pharmaceuticals (Value) Without a Generic Equivalent by GMS and DP, 2010-2011^a

		GMS			
		2010		2011 ^b	
		Volume ^c	Value	Volume	Value
		%	%	%	%
1.	Atorvastatin	22.9	24.4	20.2	20.1
2.	Salmeterol and other drugs for obstructive airway diseases	7.8	8.1	7.1	7.3
3.	Pregabalin	13.5	13.1	15.7	15.3
4.	Olanzapine	14.4	13.6	7.2	7.2
5.	Tiotropium bromide	12.4	11.9	10.8	10.5
6.	Escitalopram	17.8	17.3	13.5	12.8
7.	Formoterol and other drugs for obstructive airway diseases	2.3	2.2	3.0	2.9
8.	Quetiapine	1.1	1.3	1.6	1.7
9.	Lansoprazole	23.1	25.5	20.4	20.3
10.	Fentanyl	0.0	0.0	0.0	0.0
		DP			
		2010		2011 ^b	
		Volume	Value	Volume	Value
		%	%	%	%
1.	Atorvastatin	21.5	22.9	19.5	19.5
2.	Salmeterol and other drugs for obstructive airway diseases	6.4	6.9	6.1	6.4
3.	Pregabalin	12.7	12.6	14.6	14.5
4.	Formoterol and other drugs for obstructive airway diseases	1.7	1.6	2.6	2.6
5.	Mesalazine	0.7	0.5	1.1	0.7
6.	Montelukast	3.3	3.2	6.7	6.6
7.	Escitalopram	16.6	16.2	13.6	13.0
8.	Tiotropium bromide	10.6	10.2	10.2	9.9
9.	Lansoprazole	24.5	25.9	22.7	22.7
10.	Olanzapine	13.6	13.0	7.6	7.4

Notes: a All dosage forms and strengths are included. For example, for atorvastatin, all available Lipitor tablets (10mg, 20mg, 40mg and 80mg) are included. In the case of Lipitor, all strengths are parallel imported by one or more importer. This may not be the case for all pharmaceuticals in the top 10, i.e. the parallel importer may only choose to import a selection of the dosage forms or strengths.

b Year to Date 30 June 2011.

c Volume refers to the number of dispensed items claimed for in a given year (e.g. 1 Lipitor 28 tablet package).

Source: HSE personal communication, 23 August 2011.

The presence of parallel imports suggests that ex-factory prices in other Member States are below those in Ireland. External price referencing, under the existing IPHA/HSE agreement, relies on price data for Member States in the basket supplied by the firm seeking reimbursement under the GMS and/or CDS and in public hospitals.²⁹ The IPHA/HSE agreement refers to the price charged to the wholesaler – the ex-factory price. However, this reported/listed ex-factory price may, for a variety of reasons, either be higher than the actual or effective price charged to the wholesaler or the actual or effective price paid by the reimbursement authorities in the other Member State. This may occur because the firm offers rebates and discounts, for a variety of reasons, off the listed ex-factory price. In the 2006 IPHA/HSE agreement, for example, there is a 3.53 per cent rebate for the HSE on in-patient pharmaceuticals, subsequently raised to 4 per cent in 2010. Such rebates are offered in other jurisdictions such as Germany (Paris and Docteur, 2008, pp. 23-24).

²⁹ It should be noted that in making an application a firm may request listing under the GMS, the CDS or for hospital use. See Tilson *et al.* (2010) for some examples.

According to the European Commission it is common for firms, in order to maintain prices for external price referencing purposes, to offer hidden discounts off the listed ex-factory price since that does not affect the reference price.³⁰ It is thus important that mechanisms are in place to detect these discounts so that the purchaser, the HSE, can address these issues with the firm supplying the in-patent pharmaceutical and seek a price adjustment. Here we distinguish between mechanisms to question the pricing information with respect to the nine Member States in the current basket and how such information might be used to expand the list of Member States that could be added to the basket itself.

The HSE could in principle track the Member State(s) from which parallel imports are supplied since this information is supplied to the IMB, although we understand that this is not currently coded on the PCRS database. The HSE will be aware, however, through the use of the PCRS database, of the market penetration of parallel imports for a particular in-patent pharmaceutical. All of the parallel importers into Ireland for a particular in-patent pharmaceutical will be priced at a discount to the ex-factory price of the in-patent pharmaceutical, typically the ex-factory price less a small percentage. Discounts to the pharmacist are used as a way for parallel imports to gain market. However, these discounts are not reflected in lower prices to the HSE or the cash paying customer. The higher the market share of an in-patent pharmaceutical accounted for by parallel imports and the larger the number of parallel import competitor pharmaceutical products, the greater is the likely discount off the price paid by the HSE.

Information on the ***penetration of parallel imports can be used in two ways with respect to external price referencing, where attention is confined to only those nine Member States in the basket.***

- *First*, if the parallel imports come from a Member State *above* the ex-factory price set in accordance with the IPHA/HSE agreement, it suggests that the price used for such Member State(s) in the Irish basket is higher than the actual or effective price in the other Member State. If, for example, the ex-factory price in Ireland is, using the basket of nine Member States, €0.20 per dose and extensive parallel imports come from a Member State in the basket where the listed ex-factory price supplied to the HSE was €0.50 per dose, then that would be grounds for questioning the appropriateness of the latter price. The difference may, of course, be due to delays in updating the basket of prices or exchange rate adjustments, rather than a lower ex-factory price in the basket Member State.

³⁰ This is discussed further in European Commission (2009, p. 151) and, for Germany, Paris & Docteur (2008, p. 19).

- *Second*, parallel imports may come from a Member State that has a list price *below* the ex-factory price set in Ireland based on the basket of nine Member States. This would not, of course, be unexpected since this difference gives rise to the arbitrage opportunity which motivates parallel importers to enter the market. However, if after adding to the listed ex-factory price supplied for the Member State an estimate of the transaction costs of bringing the parallel imported product to the Irish market, the price is above the ex-factory price set in accordance with the IPHA/HSE agreement, then this suggests that the listed ex-factory price used for the Member State is too high.³¹ For example, suppose that the ex-factory price is using the basket of nine Member States again €0.20 per dose, the listed ex-factory price in the other Member State supplied to the HSE is €0.16 per dose, and the transaction costs €0.10 per dose. As €0.26 is greater than €0.20, there are grounds for questioning the appropriateness of the listed ex-factory price of €0.16.

Of course, under the proposals set out earlier in the chapter the ex-factory price would be set with respect to the lowest priced Member State in the basket, not the average.

Parallel imports can also be used to assist in determining the basket of Member States that should be used for the purposes of setting the ex-factory price under the IPHA/HSE agreement. Where parallel imports are important across a range of in-patent pharmaceuticals from a particular Member State on a consistent and sustainable basis, then this is *prima facie* evidence that prices are lower in this Member State than the ex-factory price set under the IPHA/HSE agreement. Furthermore, the successful penetration of the Irish market suggests that the price differences are real and not just theoretical. Hence consideration could be given to adding this Member State to the basket from which the ex-factory price is set.

Hence, given this discussion of how parallel imports can inform ex-factory pricing in Ireland:

Recommendation 4.4: We recommend that the HSE monitor parallel imports in order to assist it to: (i) validate the pricing information provided to set the maximum ex-factory price for the current basket of nine Member States; and, (ii) determine whether additional Member States should be added to the basket of Member States.

³¹ These transaction costs include the licensing, relabeling, discounts, distribution costs and an allowance for risk. Parallel importers could be requested to provide an estimate. The purpose is not to be exact, but rather to give a reasonable estimate.

The issue is what filters or triggers should be in place for the HSE to investigate the veracity of the price supplied by the pharmaceutical firm or to add another Member State to the basket. Although this is to a considerable extent a matter of judgement, simple rules could be set up using the PCRS database that would result in the HSE raising questions about the appropriateness of the basket of prices supplied to estimate the ex-factory price under the IPHA/HSE agreement as well as suggesting new Member States that should be added to the basket. If, for example, parallel imports account for a large market share of an in-patent pharmaceutical (e.g. greater than 10 per cent), for a sufficiently long time (e.g. three to six months), and the pharmaceutical is important in terms of PCRS pharmaceutical expenditure (e.g. top 20 or top 50 in-patent pharmaceuticals) then this might be an appropriate trigger. No doubt some experimentation would be necessary in order to perfect the appropriate trigger.

4.3.3 Pharmacoeconomic Assessment

Establishing the maximum ex-factory price is the first step in a two-step procedure for reimbursement under the GMS and CDS. The second step is a pharmacoeconomic assessment. Under the 2006 IPHA/HSE agreement provision is made for pharmacoeconomic assessment prior to reimbursement of pharmaceuticals that "...may be high cost or have a significant budget impact on the Irish healthcare system" (HSE, 2006a, p. 2). This marked a major change, replacing an informal process.

The IPHA/HSE agreement's procedures are designed to ensure speedy access to market of new pharmaceuticals, with decisions to be made by the HSE within 90 days of receipt of the reimbursement application.³² According to the 2006 IPHA/HSE agreement the assessment will be conducted using the existing Health Technology Assessment Guidelines, with any new guidelines to be agreed between the IPHA and HSE.³³ At the present time new guidelines are being developed under the Health Information and Quality Authority (HIQA), which under the Health Act 2007 has a statutory remit for the development of such guidelines.³⁴

Since 2009 the National Centre for Pharmacoeconomics (NCPE) considers the cost-effectiveness of all new pharmaceuticals applying to the HSE for reimbursement

³² There are appeal procedures in the IPHA/HSE agreement. There has been one appeal between 2006 and 2009 when the National Centre for Pharmacoeconomics (NCPE) recommended refusal for reimbursement. The NCPE's decision was confirmed. See Tilson *et al.* (2010, p. 313) for details.

³³ These 2000 guidelines were developed by the IPHA and NCPE with input from the DoHC.

³⁴ For further discussion of HIQA role see <http://www.hiqa.ie/healthcare/health-technology-assessment/guidelines> (accessed 15 July 2011). In 2010 HIQA published on their website *Guidelines for Budget Impact Analysis of Health Technologies in Ireland* and *Guidelines for Economic Evaluation of Health Technologies in Ireland*. These guidelines were developed by HIQA with input from the NCPE and a Scientific Advisory Committee, which included representative of IPHA as well as experts in Health Technology Assessment (HTA) methodology from outside of Ireland.

under the GMS and CDS.³⁵ All such pharmaceuticals are first subject to a rapid review by the NCPE where considerations such as cost, budgetary impact and other factors are considered. The rapid review, which takes two weeks, either recommends that the pharmaceutical is approved for reimbursement or is subject to a HTA. Of the twelve pharmaceuticals subject to a HTA between September 2006 and February 2009, the average duration of the process was 2.7 months, less than the 90 day limit in the 2006 IPHA/HSE agreement.³⁶

There are certain important parameters that determine the result of the HTA. The discount rate used is 4 per cent, while the benefit is measured in terms of quality-adjusted life years (QALY) with initially a price used of €45,000 per QALY, more recently reduced to €20,000 per QALY. Thus fewer pharmaceuticals will be reimbursed using the HTA approach with the latter price per QALY. Summaries of the HTAs are posted on the NCPE website.

In an analysis of the 12 HTAs conducted between 2006 and 2009 referred to above, Tilson *et al.* (2010, Table II, p. 314) report that the NCPE recommended six being reimbursed (including one where the QALY was €57,280, well above the €45,000 threshold, on account of its innovative nature), two were recommended with restrictions and two were not recommended either because cost effectiveness was not demonstrated or insufficient clinical evidence for use was available. However, several in the latter two categories were reimbursed by the HSE after a price reduction by the firm submitting the application. Hence instead of being a zero/one decision, to reimburse or not to reimburse, the use of the HTA by the HSE seems to have developed into a more subtle instrument that is used to negotiate the reimbursement price with the firm applying to have its product listed when it does not fall below the threshold cost per QALY.

When a pharmaceutical is approved it will have a specific targeted use and population where its use is most appropriate. In some cases the new pharmaceutical product may be a marginal improvement over existing pharmaceuticals on the market which would confine its use to those patients particularly able to benefit from that improvement. However, since the new in-patent pharmaceutical will often be heavily marketed, its use may possibly extend also to patients that can be treated perfectly adequately with existing, but lower cost, pharmaceuticals. Thus the HSE's pharmaceutical expenditure is needlessly raised, with no obvious benefit to patients.

³⁵ The discussion relies on papers published by the NCPE. See, for example, Barry *et al.* (2009), Barry *et al.* (2010), Barry & Tilson (2010), Tilson and Barry (2010) and Tilson *et al.* (2010). In addition the NCPE website provides considerable additional material. For details see <http://www.ncpe.ie/>. The NCPE was set up in 1998 with funding from DoHC. Accessed 15 July 2011.

³⁶ This underestimates the speed of the process because it includes "...the time taken to make amendments to the original submission which is not included in the 90-day time limit" (Tilson *et al.*, 2010, p. 321).

Thus:

Recommendation 4.5: We recommend that the HSE negotiates risk sharing agreements with firms seeking eligibility for reimbursement under the GMS and Community Drug Schemes for new pharmaceuticals on introduction in terms of expected sales and market penetration.

Under such agreements the HSE and the firm concerned would agree not only the ex-factory price but also the expected sales of the new in-patent pharmaceutical based on its use and the size of the population likely to take advantage of the new in-patent pharmaceutical. Above the threshold of expected sales, the cost of the additional sales – measured as the difference between the cost using the closest alternative pharmaceutical and the new in-patent pharmaceutical – would be shared between the HSE and the firm. In other words, for those additional sales the firm would not receive the full ex-factory price but some amount less. For a completely new chemical entity with no close substitutes then the discount off the ex-factory price might be quite small; for a new in-patent pharmaceutical for which there are large number of existing close substitutes, the discount would be much larger.

These risk sharing agreements or variants thereof are currently employed in a number of OECD countries.³⁷ In surveying what it refers to as product-specific pricing agreements, the OECD (2010, p. 172) argues that they "...could well prove to be a useful new instrument in promoting patient access to innovative treatments while linking public funding to therapeutic value."...However, it notes that many of these agreements are recent and as yet "...there is insufficient evidence to be confident of their utility" (*ibid*, p. 172). This suggests that in taking forward the above recommendation that the HSE should select those instances where the benefits are most likely to outweigh any costs and carefully review the outcome so as to inform any future agreements.

³⁷ The HSE has already entered a small number of such agreements for hospital pharmaceuticals.

4.4 SETTING THE EX-FACTORY PRICE OF PARALLEL IMPORTS FOR IN-PATENT PHARMACEUTICALS

Parallel imports can pose a significant competitive challenge to the position of the brand in-patent firm.³⁸ On occasion, parallel imports account for 25 per cent by value of a particular in-patent pharmaceutical product (Table 4.3). Furthermore, the number of applications to the HSE by parallel importers for reimbursement has increased markedly in the recent past: from 242 applications in 2008 to 951 in 2010. Parallel imports represented 47 per cent of all applications to the HSE for reimbursement in 2008, rising to 70 per cent in 2010.³⁹ In order to gain market share or protect it against subsequent entrants, these parallel importers need to offer pharmacists reasons to dispense their products. Hence successive parallel importers offer improved terms and conditions in order to attract pharmacy business through, for example, discounts of one sort or another (e.g. buy one get three free and so on) off the HSE reimbursement price.

The IPHA/HSE agreement, together with the setting of the parallel import product ex-factory HSE reimbursement price, provides considerable incentives for parallel imports.⁴⁰ The IPHA/HSE agreement, for reasons set out above, tends to set a high initial price by EU standards for in-patent pharmaceuticals. This price is slow to adjust as the pharmaceutical is made available in other lower priced Member States within the basket of nine Member States used for external price referencing. At the same time the HSE ex-factory reimbursement price for a parallel import is set only somewhat below the corresponding in-patent brand name ex-factory price: at least 3 per cent in 2010 and at least 7 per cent in 2011. The price of parallel imports in the source Member State is likely to be substantially more than the discounted price, which is consistent with Table 4.2.⁴¹ This provides powerful arbitrage opportunities for parallel importers.⁴² However, for reasons set out above, a large portion of the price advantage goes to the pharmacist, not the HSE.⁴³ This conclusion is consistent with the available EU research which shows parallel imports have little effect on the brand name in-patent product price and that the benefits of arbitrage largely accrue to the distribution chain rather than the health insurer – the HSE in the case of

³⁸ Manufacturers undertake various strategies to prevent or restrict parallel imports such as applying for market authorisations for different dosages and strengths and rationing supply to wholesalers believed to be engaged in parallel trade. For details see European Commission (2009) and OECD (2008).

³⁹ Based on data supplied by the HSE Products Committee (HSE, personal communication, 30 June 2011). In 2010 the applications were made by 17 firms.

⁴⁰ There is also nothing to prevent pharmacists from dispensing the parallel imported product when the brand name in-patent pharmaceutical is prescribed. The pharmacist is not acting illegally in dispensing a parallel import.

⁴¹ It is also consistent with Kanavos et al (2011, Appendix 9, p. 86) which presents mark-up for parallel imports for selected Member States, but not Ireland.

⁴² Brand name manufacturers do not appear to lower prices to compete with the parallel imports as evidenced by the fact that wholesalers state that they cannot compete with such imports. See, for example, UniPhar (2009, p. 15).

⁴³ This is likely to vary by the number of parallel importers per pharmaceutical product. As more and more enter, the discount offered by the most recent entrant is likely to be the higher than existing discounts in order to gain market share.

Ireland.⁴⁴ At the same time parallel trade can cause shortages in the Member State from which the exports take place.⁴⁵ Nevertheless, given the single market imperative, parallel trade is a permanent part of the institutional and economic landscape.

The issue thus becomes how more of the benefits of the trade in parallel imports, currently most of which are captured in the distribution chain, can be reflected in lower ex-factory prices to the HSE, while at the same time continue to provide appropriate incentives for parallel imports. Hence:

Recommendation 4.6: We recommend that the HSE set an ex-factory price for parallel imports that shares the difference between the imported price of the parallel import and the brand name ex-factory price of the in-patent pharmaceutical between the parallel importer and the HSE.

If, for example, the ex-factory price set under the agreements with the pharmaceuticals industry was €2.00 per unit and the imported price, including any additional costs of bringing the product to market in Ireland, was €1.50 per unit, then the issue would be how to share the difference – €0.50 per unit in this example – between the HSE and the parallel importer.

When the parallel importer applies for HSE reimbursement disclosure could be made by the importer as to the price in the Member State(s) from which the parallel imported product is sourced. To this would need to be added an allowance for the parallel importer's costs of additional repacking and labelling, license requirements from the IMB, etc. The HSE could check the veracity of reported prices by contacting authorities in the relevant Member State.⁴⁶ The HSE would then have to make a commercial judgement of how much of the difference between the imported price of the parallel import and the brand name ex-factory price of the in-patent pharmaceutical to capture, in negotiation with the parallel importer. If all the difference were captured by the HSE then that would remove the incentive of parallel importers to supply into Ireland. If all of the difference were captured by the

⁴⁴ See, for example, Kanavos and Costa-Font (2005), and Kanavos and Kowal (2008, p. 25) who comment that "[E]vidence suggests that parallel distributor rents were between 2.5 and twenty times higher than savings to health insurance" and Kanavos and Vadoros (2011).

⁴⁵ However, see discussion in Section 4.3.1.2 with respect to the obligation of wholesalers in Ireland to supply the needs of patients in the State.

⁴⁶ It is recognised, of course, that gathering such data may not always be easy or straightforward. Other Member States may not have the relevant information, taking into account rebates and discounts. Furthermore, the parallel importer into Ireland may not import directly from another Member State but rather go through a series of intermediaries each of which charges a mark-up.

distribution chain then the HSE captures little of the price difference. What is thus required is that the HSE shares enough of the price difference but at the same time there is still enough remaining to motivate and incentivise the parallel importer to supply Ireland and so benefit the HSE.

A 50:50 split seems an appropriate starting point, although each case would have to be considered separately.⁴⁷ Furthermore, the first parallel importer is taking more risk than subsequent parallel importers and so might be expected to receive a larger portion of the rent. It would also incentivise early entry of parallel importers. The HSE could monitor the timing and extent of penetration of the parallel imported product through the PCRS database. Furthermore, market penetration of parallel importers under a 50:50 split could be compared with the record of the current regime where most of the rent is captured by the distribution chain to judge the effect the policy is having.

The Falsified Medicines Directive (Directive 2011/62/EU)⁴⁸ adopted in June 2011 will introduce a new requirement for the packaging of most pharmaceuticals to bear a "safety feature" or anti-counterfeiting device. This requirement is due to be introduced over the coming 3-5 years. Where a pharmaceutical is repackaged by a parallel importer, the importer will be required to place a safety feature on the pack which is "equivalent" to the device placed on the original pack by the originator firm. This requirement may potentially increase the cost and complexity of repackaging activities and consequently, it may be difficult to predict the future parallel trade market until the impact of safety features is better understood.

4.5 SETTING THE EX-FACTORY PRICE FOR HIGH VOLUME MULTIPLE SOURCE OFF-PATENT PHARMACEUTICALS

Up to now, our discussion of pharmaceutical pricing has focused on pharmaceuticals that are still in-patent. Off-patent pharmaceuticals where there is no generic competition are priced as though they were in-patent, as set out in the IPHA/HSE agreement and discussed above. These will tend to be the lower volume off-patent pharmaceuticals where the potential return to a generic supplier is insufficient to attract entry because the market size is small or where generic substitution is deemed inappropriate for medical reasons such as epilepsy products where medical practitioners might have bio-equivalence concerns. In this section attention turns to the pricing of off-patent pharmaceuticals where, for a specified dosage form and

⁴⁷ In other words, if the parallel imported price and the costs of bringing the product to market in Ireland was €3.00 per pack and the brand name ex-factory price in Ireland was €4.00 per pack, then the ex-factory price of the parallel import would be €3.50 per pack.

⁴⁸ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

strength, the identical pharmaceutical form has been approved by the IMB and is available for "...prescription in the Schemes and all pharmaceuticals supplied to the HSE, State funded hospitals to State agencies whose functions normally include the provision of pharmaceuticals" (HSE, 2006a, p. 4). These will be referred to as generic competitors to the brand name or originator. Taken together, for a given pharmaceutical product, these will be termed as interchangeable pharmaceutical products. Generic products will tend to be for the higher volume off-patent pharmaceuticals where the return is likely to be sufficient to attract generic entry.

It should be noted that the distinction between off-patent pharmaceuticals with generic competition and those without generic competition is not determined exogenously to the regulatory and pricing model, but rather is determined endogenously. In other words, the market conditions in large part determine the presence and success of generics. These market conditions refer to the regulatory (e.g. the fees charged by the IMB for registration, etc.), legal (e.g. whether pharmacists can select a different brand from that prescribed by a medical practitioner) and the reimbursement (e.g. the IPHA/HSE agreement that sees brand name prices falling with the onset of generic competition, the speed of price and reimbursement approval) framework. At the present time Ireland has short delays for price and reimbursement.⁴⁹ The introduction of reference pricing and generic substitution legislation in 2012 is likely to provide greater incentives for more generic competition.

In this section the current pricing arrangements in Ireland for off-patent pharmaceuticals with generic competition are first set out, before attention turns to current proposals for reference pricing and generic substitution. These proposals, while moving in the right direction, in terms of securing better value for money, do not address certain important issues relating to, for example, how the reference price is set, the treatment of 'no substitution' prescriptions and the issue of prescriptions using the International Non-proprietary Name (INN). Hence the report discusses two alternative mechanisms to set the reference price and provides some guidance on when they might be best employed. While the focus of the discussion relates to the HSE, the application of the proposals to the cash paying patient is also considered.

⁴⁹ European Generic Medicines Association (2009, pp. 19-20).

4.5.1 Current Pricing Rules & Mechanisms

Under the 2006 IPHA/HSE agreement, where a generic is available under the GMS and CDS then the ex-factory price of the brand falls in two stages:⁵⁰

- By an initial 20 per cent;
- Twenty-two months later an additional 15 per cent also measured relative to the brand name price prior to the entry of the generic.

Thus under the IPHA/HSE agreement the brand name pharmaceutical declines by 35 per cent over 22 months.

In early 2010 the 2006 IPHA/HSE agreement was extended from September 2010 to March 2012. Annex 1 was added to the 2006 IPHA/HSE agreement. Brand name pharmaceuticals which had commenced the 35 per cent reduction over 22 months by 1 February 2010 were reduced by an additional 40 per cent. This subset of products, in effect, has been reduced in price by 61 per cent from their original in-patent price. However, all off-patent reductions post 1 February 2010 reverted to 35 per cent over 22 months. In late 2010 the IPHA agreed to a further package of savings. However, it was left to individual IPHA members as to how they achieved the reductions. In some cases this resulted in further declines in the price of off-patent pharmaceuticals where there was generic competition, in others a rebate was given to the HSE.

Generic ex-factory prices are set by reference to the off-patent ex-factory price of the brand name pharmaceutical. A framework for setting maximum prices forms part of the agreement between the trade association representing the generic firms, the Association of Pharmaceutical Manufacturers of Ireland (APMI), and the HSE.⁵¹ Although the APMI/HSE agreement does not specify the generic ex-factory price relative to the brand name price, the HSE stated that the generic ex-factory price must be at least 5.6 per cent lower than the brand name ex-factory price, for all products launched after 1 February 2010.⁵² Thus if the brand name ex-factory price falls by 35 per cent 22 months after the generic first appears, the generic ex-factory price is 38.6 per cent lower than the brand name ex-factory price prior to the entry of generic competition.⁵³ Hence, like the pricing of parallel imports, it is the brand

⁵⁰ There are certain phasing in arrangements under the IPHA/HSE agreement. For details see (HSE, 2006a, p.5).

⁵¹ The APMI/HSE agreement, like the IPHA/HSE agreement, also ran from 2006 to 2010. The APMI/HSE agreement, like the IPHA/HSE agreement was extended in 2010 until 2012 (DoHC, 2010a). However, when the IPHA agreed to further reductions, the APMI did not follow suit immediately meaning that some generic ex-factory prices exceeded the brand name ex-factory price for a period in late 2010/early 2011. Typically the IPHA/HSE agreement is agreed first, then the APMI/HSE agreement (APMI, personal communication, 6 July 2011).

⁵² Based on information supplied by the HSE, personal communication, 30 June 2011.

⁵³ This is a modest decline compared with the fall in price of generics, compared to the brand name price prior to generic entry, recorded for other Member States. Kanavos *et al.* (2011, pp. 26-27) find that "[G]eneric prices average about 25% of the originator price, 12 and 24 months following patent expiry."

name price that drives the ex-factory price of the generic. However, in both cases the difference between the ex-factory brand name price is quite small compared with either that of the parallel import or generic – a few percentage points.

The HSE's room for policy discretion with respect to lowering off-patent pharmaceutical prices experiencing generic competition arguably was and is limited. Generic penetration in Ireland is low by EU standards – of the 16 Member States for which the European Commission had data for 2007, the share of the pharmaceutical market accounted for generics was the lowest in Ireland, when measured in value terms (12 per cent) and third lowest, when measured by volume (34 per cent) (European Commission, 2009, Figure 11, p. 62). Furthermore, the importance of generic prescription appears to have fallen over time in Ireland – not risen as one might have expected.⁵⁴ This low penetration reflects the limited ability of the pharmacist to dispense a generic when the brand name is prescribed, due to legal constraints and the low levels of generic prescribing by medical practitioners. Therefore, no financial incentives exist for pharmacists to dispense lower priced generics. For the DP and LTI Schemes, the pharmacist faces a disincentive to dispense a lower priced product due to the existence of a 20 per cent retail mark-up in addition to a dispensing fee per item. As a result the HSE could not rely on competition and market forces to bring about lower prices, particularly over a short period. Hence the HSE intervened through administrative pricing in the form of agreements with the pharmaceutical sector.

4.5.2 Reference Pricing and Generic Substitution

The Minister for Health and Children signalled in 2010 the introduction of generic substitution of interchangeable generic products and reference pricing⁵⁵ following proposals for such changes.⁵⁶ This was affirmed in the Programme for Government of the incoming administration in early 2011 (Department of the Taoiseach, 2011, p. 36). Generic substitution and reference pricing go hand in hand:

- Generic substitution gives the pharmacist the legal authority to dispense a different brand of the same chemical entity, dosage form and strength from that prescribed by the medical practitioner. Such a group of products are considered interchangeable, perfect substitutes. Interchangeability is usually certified by an

⁵⁴ In 2007, 19 per cent of prescriptions were dispensed generically. Generic prescribing accounted for 8 per cent of GMS expenditure in 2007. In 1997 the "...the percentage of items prescribed generically exceeded 22 per cent by volume and 12 per cent by expenditure" (Barry *et al.*, 2010, p. 243). See Chapter 7 for further discussion.

⁵⁵ Not to be confused with external price referencing discussed above. Reference pricing in this discussion refers to setting the ex-factory price of interchangeable pharmaceutical products.

⁵⁶ For details see DoHC (2010b) and Moran (2010). The importance of reference pricing and generic substitution is likely to increase with a number of high volume pharmaceuticals, such as Lipitor (atorvastatin), coming off patent. See Economist (2010) and Moran (2010, p. 12).

expert body such as the IMB or a separate Committee on Interchangeability Medicines;⁵⁷ while,

- Reference pricing sets a common price for a group of interchangeable pharmaceutical products.

Such pricing schemes are commonly employed in other Member States, Canada, New Zealand and elsewhere.⁵⁸

Typically under reference pricing the medical practitioner can write a 'no substitution' prescription for a particular brand to be dispensed for medical reasons. Such no-substitution prescriptions are typically for the higher priced brand name product. If the HSE is the payer then it pays the brand name price; if it is in the cash market the patient pays the brand name price. If the preference of the patient is for a particular interchangeable product, then the patient in a State scheme will pay for the difference between the reference price and the product selected; if the patient is a cash paying customer then they will pay the full price.⁵⁹

An illustration may clarify the operation of reference pricing. Suppose there are four different suppliers of pharmaceutical X, which have been deemed interchangeable. Each supplier is asked to submit a price to the HSE for a specific dosage form and strength. The following four prices are submitted, one by the brand name supplier (Brand 1), the remaining three by generic suppliers (Generic 1, 2, and 3):

Brand 1 €0.80

Generic 1 €0.10

Generic 2 €0.08

Generic 3 €0.07

Under this stylised example it is assumed that the brand name is not reduced in price with the entry of generic competition, while the generic suppliers price at a much lower level than the brand.⁶⁰ In effect, the generics compete and establish a price that reflects competition between the generics rather than related to the price of the brand as is the case under current pricing arrangements. A reference price is selected, typically the lowest; €0.07 in this example. However, if the patient was

⁵⁷ The latter body was recommended by Moran (2010, pp. 9-10).

⁵⁸ On the EU see Moran (2010, p. 8, and Annex B, p. 14).

⁵⁹ In the community sector, the State through the DP Scheme provides insurance for all residents subject to a monthly deductible of €120 (increasing to €132 from January 2012), as set out in Chapter 2.

⁶⁰ In the example, Generic 1 is assumed to have entered the market first and gained a degree of product differentiation so that it can charge a somewhat higher price than Generic 2 and so on.

under the GMS or one of the CDS and had a preference for Brand 1 then there would be a co-payment of €0.73 (i.e. €0.80-€0.07). On the other hand, if the prescriber, for medical reasons, felt that Brand 1 should be dispensed then the State would pay €0.80 not €0.07.

If reference pricing is to succeed in getting better value for money, there is a need to ensure that competition and competitive mechanisms set prices. The Working Group on Reference Pricing and Generic Substitution (Working Group) that examined reference pricing in Ireland was aware of the importance of the promotion of competitive markets (Moran, 2010, p. 1). The question thus becomes how should the reference price be set? If market mechanisms are to be used this implies a shift away from the current administrative pricing arrangements for off-patent pharmaceuticals outlined above in the IPHA/HSE and APMI/HSE agreements, which terminate in 2012. However, there is a clause in the Annexe to the IPHA/HSE agreement "may stand amended" on the introduction of reference pricing and/or generic substitution prior to the expiry of the agreement.

The Working Group acknowledges the importance of competitive markets, the importance of a sufficient number of competing pharmaceuticals and low barriers to entry as well as suggesting the reference price should be the lowest priced interchangeable supplier – €0.07 in the above example.⁶¹ However, it did not consider what alternative mechanisms can or should be used to determine the prices submitted by suppliers, beyond the statement that these prices be "...submitted by suppliers in line with national pricing arrangements" (Moran, 2010, p. 6). This is an important issue. There is a literature on these issues which can be used to inform the decision as to the most appropriate form of determining the reference price. It is to these and related issues that attention now turns.

4.5.3 Setting the Reference Price: Competition for the Market versus Competition in the Market?

Two methods of setting the reference price are considered: competition for the market and competition in the market. The former is sometimes referred to as competitive tendering, the latter as side-by-side competition. Each is considered separately, before attention turns to instances where it might be appropriate to employ each method. The discussion concludes by arguing that competition for the market should be used for the leading high volume off-patent pharmaceuticals with generic competition, while for low volume items competition in the market is likely

⁶¹ The Working Group stated that the reference price is "...usually the lowest unless there are concerns about continuity of supply" (Moran, 2010, p. 7).

to be more appropriate. However, the line between the two will become clearer as the HSE gains experience in implementing reference pricing.

Competition for the market through a tendering process. Suppliers submit tenders to supply the market for a specified period of time. The period would need to be long enough to cover any transaction costs of setting up the tender, but short enough so as not to discourage entry into the Irish market. The lowest priced tender wins the competition. This price becomes the reference price. The supplier winning the tender supplies *all* of the pharmaceutical for the period of the tender. There is no opportunity for unsuccessful bidders to supply at lower prices for the period of the tender. Those firms bidding for the tender would clearly have to have demonstrated that they would be able to supply this volume of the pharmaceutical.⁶² Tendering has been used by New Zealand since the mid-1990s and the province of Saskatchewan since the mid-1970s. Details on the former are presented in Box 4.1. More recently the Netherlands has introduced tendering (Kanavos *et al.*, 2009).

There are exceptions to the lowest priced brand being dispensed. Typically these exceptions will be for the brand name product, which will usually be priced above the reference price. First, the medical practitioner prescribes a particular brand, an issue discussed in Section 4.5.5. Second, the patient has a preference for a particular brand and requests the medical practitioner to prescribe that brand. The pricing arrangements in both instances were discussed in Section 4.5.2.

⁶² Given the importance of security of supply it is important that this requirement is credibly evaluated and that measures are put in place to ensure compliance, such as the successful bidder posting a bond to be forfeited in case of full or partial non-adherence to the contract.

BOX 4.1 The New Zealand Tendering Experience: 1996 – present

The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown agency that decides, on behalf of District Health Boards (DHBs), which medicines and related products are subsidised for use in the community and public hospitals.

One of the main roles of PHARMAC is the management of the medicines budget. This budget is set each year by the Minister of Health, on the advice of DHBs and PHARMAC. The Pharmaceutical Budget includes funding for medicines dispensed in the community, and for cancer medicines that are used in DHB hospitals. For community medicines, DHBs reimburse community pharmacists for dispensing prescribed medicines and PHARMAC works on their behalf to manage the spending. The list of subsidised medicines is published in The Pharmaceutical Schedule. One of the tools employed by PHARMAC for the supply of pharmaceuticals in New Zealand is tendering.

PHARMAC uses tendering for many off-patent pharmaceuticals, offering sole supply status to the successful supplier, which means that supplier's brand would be the only one subsidised for a particular formulation for a specified period of time (usually no more than 3 years). This involves issuing tender documents to pharmaceutical suppliers inviting their bids for a set list of pharmaceuticals, and evaluating bids taking account of product acceptability, relevant clinical issues, supply and distribution arrangements and price. Nearly one-third of the approximately 1,700 formulations listed on the Pharmaceutical Schedule are sourced through tendering arrangements.

PHARMAC has employed tendering as a way to reduce the cost of medicines since 1996-1997 when the first tender (for one product, paracetamol), led to a 44 per cent price reduction. By 2002-03, tenders for over 1,000 line items were issued, and this produced savings of about NZ\$23 million. By 2008, cumulative savings from tendering are estimated to exceed NZ\$300 million.

Source: PHARMAC, 2009; <http://www.pharmac.govt.nz>; personal communication, PHARMAC, 2 November 2011.

Competition in the market whereby suppliers submit prices. These prices might, for example, be list prices or the list price net of usual and customary discounts, that are not related to efficient buying (e.g. electronic ordering). The lowest price submitted becomes the reference price. The pharmacist is reimbursed the reference price, irrespective of the brand dispensed. The same patient and medical practitioner exceptions apply as with competition for the market. This approach is used in a number of jurisdictions including Ontario, details of which are presented in Box 4.2.

In both cases the objective of the exercise from the view point of the HSE, acting as purchaser, is to set as low a price as possible for interchangeable products, while at the same time ensuring security of supply.

BOX 4.2 Interchangeable Pharmaceutical Products and Reference Pricing: The Ontario Experience, 1970s – present.

Ontario has longstanding policies to promote generic competition and reference pricing dating back to the 1970s. The Committee to Evaluate Drugs (formerly the Drug Quality and Therapeutics Committee) recommends that a pharmaceutical product should be an interchangeable product with the brand name pharmaceutical. All interchangeable products for a given pharmaceutical by dosage form and strength are listed in the Ontario Drug Benefit Formulary. Under the original system in the 1970s, pharmaceutical suppliers submitted prices to the Ontario Drug Benefit (ODB) programme. The ODB would only reimburse up to the lowest priced interchangeable product, irrespective of which interchangeable pharmaceutical product was dispensed.

A persistent theme of inquiries and commissions into the ODB dating from the 1970s is that the prices submitted to the ODB were too high in the sense that the generic firms supplied interchangeable pharmaceutical products to pharmacies at lower prices. At first, the discrepancy reflected the fact that ODB asked for prices to be based on smaller order sizes such as 50s and 100s so as to ensure that smaller pharmacies were not disadvantaged. However, for high volume multiple source interchangeable drugs the vast majority of purchases were for larger quantities, with consequent lower average prices due to quantity discounts.

There has, however, been a more persistent concern that even after controlling for order size, that the price submitted to the ODB for a generic product is higher, often considerably above the price paid by the pharmacist. This was consistent with research conducted by the ODB in the mid-2000s showing generic prices were much higher in Ontario than in the US, New Zealand, France, Germany or the UK. Under the *Transparent Drug System for Patients Act, 2006*, the generic price was fixed at 50 per cent of the brand name equivalent. Rebates and discounts were prohibited. However, generic firms found ways around this prohibition. Since the ODB only covers a certain sector of the Ontario market, rebates and discounts could still be offered on pharmacy orders for the private sector. Similarly, some Ontario pharmacies are part of Canada-wide chains so that rebates and discounts can be routed to these chains in other parts of Canada. Finally, the 2006 Act permitted professional allowances for patient care, which also became a vehicle for offering rebates and discounts to pharmacies.

In 2010, Ontario announced radical changes. The price of generic products will fall from 50 per cent to a maximum of 25 per cent of the reference brand price by 1 April 2012; professional allowances were abolished for the ODB and phased out in the private sector by 1 April 2013. Whether these changes will succeed in removing the rebates and discounts from the system remains to be seen. In any event, the history of Ontario in using competition in the market shows how hard it is to prevent generic firms competing to gain market share by offering discounts and rebates.

Source: Gorecki (1992) and information supplied by Drug Program Services, Ontario Ministry of Health and Long-term Care.

In considering whether competition in the market or competition for the market is likely to lead to a lower price it is important to characterise the nature of the competition involved. In competition for the market, the supplier with the winning tender is guaranteed the market for a specified period of time. The tender process thus determines jointly both the supplier and the reference price. In making a bid the supplier will be aware of the size of the market, since the HSE will provide such information in the tender document. The supplier will not have to fight for market share or market the product once the tender is won. The supplier thus has an incentive to bid a low competitive price, which in turn becomes the reference price.

In contrast, in competition in the market the supplier plays a two stage competitive game.

- First*, each supplier submits a price to the HSE for the given pharmaceutical. The lowest price of those submitted is the reference price. It is likely that all the generic suppliers will submit similar prices, as in the example above. Indeed, the reference pricing system might be structured so as to allow suppliers that submit a price above the reference price to subsequently match the reference price.⁶³ However, it seems likely whether or not there is a formal mechanism for such price matching, that all generic suppliers will in fact accept reimbursement at the reference price. Since the State pays the reference price, irrespective of the interchangeable product dispensed, the firm that submits the lowest price has no guarantee that it will supply all of the market, in contrast to competition for the market.⁶⁴ Thus the incentive to quote the competitive price is lower than under the tendering process. Indeed, the incentive is to submit a very high price and compete for market share through discounts to the pharmacist.
- Second*, while the first stage determines the price, the second stage determines the market shares of the suppliers. The decision as to which interchangeable brand to dispense rests with the pharmacist, providing, of course, that the prescriber has not for medical reasons selected a specific product. Here the pharmacist is likely to have several different, usually generic suppliers, from which to select. On what basis, given that all products are certified as equally effective (i.e. interchangeable) and have the same reimbursement price, will the choice be made? It is suggested that the pharmacist will select the product that yields the greatest return, measured as the difference between the reference price and the effective price that the pharmacist pays, net of all discounts and other inducements that are offered by the generic supplier (e.g. buy one get one free, etc.). Thus firms will compete on discounts to the pharmacist for market share.
- It is thus inherent in the second stage that suppliers, particularly generics, will compete for business through discounts to the pharmacist. While discounts can provide incentives for suppliers to become more efficient and thus in a better position to offer discounts, the magnitude that discounts can reach suggests that it is not due to efficiency gains but rather strategically setting a high price to the HSE, which occurred in Ontario (Box 4.2). However, the difficulty is that discounts accrue to the pharmacist, not the purchasing agency, the HSE or the

⁶³ This price matching is suggested in Moran (2010, p. 7).

⁶⁴ Unless of course the price is at a predatory level. Hoffman La-Roche employed this tactic in the hospital market in Canada in 1970-1971 in face of generic competition for its brand of diazepam, Valium, and was successfully prosecuted for predatory pricing under competition law. (For details see Gorecki, 1986). More recently in the UK, Napp Pharmaceuticals was found to have charged predatory prices in the hospital market for sustained release morphine (for details see Whish, 2009, pp.741-742).

cash patient. Hence the HSE needs to maintain careful market monitoring to ensure that these discounts are not unreasonable.⁶⁵

Thus given the two stage nature of competition in the market generic suppliers will have an incentive to offer a low/high price to the HSE. The submitted price will be *low enough* to be well below the brand name and thus satisfy the purchaser's (i.e. HSE's) concerns over value for money. The generic suppliers' ex-factory price is likely to at least match what is available under the current IPHA/HSE agreement or else there is little advantage for the HSE moving to reference pricing. Since the generic suppliers are likely to prefer reference pricing over the current arrangements, they also have an incentive to meet or beat the current IPHA/HSE price reductions. Indeed, the IPHA/HSE agreement might establish a focal point around which prices converge. The submitted price will, at the same time, be *high enough* for discounting and other forms of sales promotion/competition at the pharmacy level.

Competition for the market does not suffer from the problems outlined with respect to competition in the market; the price submitted is more likely to be the competitive price. Furthermore, competition for the market also avoids the anticompetitive price enhancing effects of price matching, which appears to be inherent in competition in the market.⁶⁶

Competition for the market and competition in the market should not necessarily be considered as alternatives, but to a considerable degree as complements. The transaction costs involved in tendering may be higher than for competition in the market. These costs refer to not only the tender process itself, but also ensuring that the supplier bidding for the tender can supply for the tender period. However, these costs should not be overstated or exaggerated. Some hospitals in the State conduct regular tenders for pharmaceuticals, while the HSE purchases vaccine via tendering. In Canada, the province of Saskatchewan conducts tenders for selected pharmaceuticals for its community pharmaceutical programme and yet it has a population of only 1.054 million. New Zealand, which conducts extensive tendering for pharmaceuticals, has a population of 4.4 million. In the Netherlands the largest

⁶⁵ Of course, it could be argued that discounts could be abolished or prohibited. However, discounts take many forms and it is unclear how they could all be abolished. Furthermore, there is a competitive impetus underlying discounts inherent in competition in the market: much better to utilise that impetus than ignore it.

⁶⁶ For references concerning price matching see Competition Authority (2003, p. 18, footnote 30). Price matching is where one firm promises to match another firm's price. For example, retailers often advertise that if a customer can find anybody that charges a lower price they will match the price. There is also a possibility of collusion to agree on the reference price among generic suppliers. Thus careful attention would need to be paid by the purchasing agency to detect and, if possible, prevent such behaviour. Such an agreement would most likely be a breach of competition law. For a discussion of other aspects of competition law in pharmaceuticals see Section 2.2.1.1.

health insurer has a client base of about 2.6 million.⁶⁷ On the other hand, accepting bids by generic firms at face value, given the incentives described above for these prices to be above the competitive level, is also likely to lead to monitoring costs. The HSE will have to constantly examine the magnitude of discounts and then take action to reduce reimbursement prices. This has been an ongoing characteristic of the Ontario system since the 1970s (Box 4.2).

The evidence suggests that tendering leads to substantial savings. Manufacturers have strong incentives to provide the best possible price, given that providers who are not successful will not gain any market share. The US Veterans Administration estimates that it has saved over US\$1.5 billion through national contracting arrangements between 1996 and 2003 (OECD, 2008), while savings of over NZD\$300 million have been achieved in New Zealand over a 10-year period (PHARMAC, 2010).⁶⁸ In Saskatchewan, tendering saved CDN\$18.5 million in 2009/10 off the provinces pharmaceutical expenditure or 4 per cent (Saskatchewan Ministry of Health, 2010a, p. 6, 13). Typically in the Netherlands savings on ten pharmaceuticals varied between 76 and 93 per cent (Kanavos *et al*, 2009, Table 3, pp. 20-21).

It could be argued, however, that competition for the market might be more likely to result in a monopoly situation whereas this is less likely in the case of competition in the market. Hence, while tendering results in short-term gains these could be offset by subsequent price increases. Two possible mechanisms can be identified.

- *First*, generic competition could be eliminated through predatory pricing by the brand name firm. Such below cost selling is, of course, illegal under both Irish and EU competition law. There have been, as noted above, successful prosecutions of such behaviour in other jurisdictions. There is no reason to assume that the Irish Competition Authority will be any less successful.
- *Second*, competition requires firms that can compete or credibly threaten to compete for the market. Without such competition market power will result in prices above the competitive norm. It could be argued that under tendering if the losing supplier(s) is unable to supply the market for the period of the tender – say six months – then it might be forced to withdraw from the market. If there were significant sunk costs⁶⁹ associated with entering the Irish market (i.e. participating in subsequent tenders), tendering might have the effect of raising a

⁶⁷ The population of the Netherlands in 2011 was 16.6 million, while the market share of the largest health insurer was 15.7 per cent in terms of gross premium income in 2008. Assuming all persons in the Netherlands are insured and that the market shares in terms of gross premium income and population are the same, results in 2.6 million for the largest insurer. For details see Dutch Association of Health Insurers (2011, Table 1.1 p. 12; Table 9.3, p. 107). When tendering was first introduced health insurers acted as a group in organising tenders. However, this was deemed inconsistent with competition law. Hence insurers now conduct tenders individually rather than collectively. For details see Kanavos *et al*. (2009, p. 37).

⁶⁸ On the basis of 2009 figures, the savings amount to approximately 5 per cent of total PHARMAC expenditure in that year (PHARMAC, personal communication, 15 February 2010).

⁶⁹ Costs that cannot be recovered if the firm later exits the market.

barrier to entry. However, it is not clear that there are substantial sunk costs of entry in Ireland; indeed, opportunistic entry by parallel imports might suggest entry is low cost. Also, if tendering were restricted to high volume off-patent pharmaceuticals, then suppliers that are unsuccessful in a tender will have a strong incentive to remain in the market. Furthermore, if hospitals continue to tender for pharmaceuticals independently of the GMS and CDS then they will provide a substantial market (Table 2.1)

The New Zealand market, as noted above, is of a similar size to that of Ireland and New Zealand has successfully engaged in tendering for sole supply for many years. Indeed, there are now more generic suppliers in the New Zealand market and competition is strong. Where suppliers have left the market it has occurred only in terms of HQs relocating to Australia and in no instance has a supplier ceased to sell in New Zealand.⁷⁰

4.5.4 Competition for the Market and Competition in the Market: Some Estimates of the Cost Savings

In order to gain a sense of what the savings might be if a tendering procedure were adopted we compared the ex-factory price of the leading 20 pharmaceuticals by value on the GMS Scheme in 2010 (September 2011 ex-factory price) with the equivalent price in New Zealand (September 2011 ex-factory price). Within each Anatomical Therapeutic Chemical (ATC), we selected the most frequently dispensed product (dosage form and strength), calculated the unit ex-factory price and the equivalent unit ex-factory price for the corresponding product in New Zealand. The results are presented in Table 4.4. In some cases tendering was not used as indicated in the table. Nevertheless, the table indicates that to the extent that the results of New Zealand can be replicated in Ireland, substantially lower prices and consequent better value for money could be obtained by competition for the market for selected high volume off-patent products.

⁷⁰ However, there are some key differences between New Zealand and Ireland, in that New Zealand only has one or two domestic-based manufacturers and the vast majority of pharmaceuticals are and have always been imported. However, rather than leaving the New Zealand market, the most significant manufacturer in the New Zealand market has moved from an approach largely based around the domestic market to source 70-80 per cent of its revenue from export sales (PHARMAC, personal communication, 15 February 2010).

TABLE 4.4 A Comparison of Ex-Factory 2011 Prices, Ireland and New Zealand, Top 20 GMS Pharmaceuticals by Value, 2010

		Ireland (HSE-PCRS – GMS only)					New Zealand (PHARMAC)					Ratio of Price per Unit IRE: NZ		
		GMS Product	Dose	Pack Size	Ex-Factory Price (€) ^a	Price per Unit (€) ^b	PHARMAC Product	Dose	Pack Size	Ex-Factory Price (€) ^c	Price Per Unit (€) ^b		Sole Supply	
ATC Description	1	Atorvastatin ^d	Lipitor	10 mg	28	15.53	0.55	Lipitor	10 mg	30	10.3	0.34	No	1.62
	2	Salmeterol ^e	Seretide Evohaler ^f	125mg	1	43.31	43.31	Seretide	125mg	1	27.95	27.95	No	1.55
	3	Esomeprazole ^g	-	-	-	-	-	-	-	-	-	-	-	-
	4	Pregabalin ^g	-	-	-	-	-	-	-	-	-	-	-	-
	5	Lansoprazole	Zoton Fastab	30mg	28	21.77	0.78	Solox	30mg	28	2.62	0.09	No	8.31
	6	Omeprazole	Losec Mups	20mg	28	13.16	0.47	Omezol Relief ^h	20mg	90	2.13	0.02	No	19.86
	7	Olanzapine	Zyprexa	10mg	28	93.76	3.35	Dr Reddy's Olanzapine ⁱ	10mg	28	3.57	0.13	No	26.26
	8	Clopidogrel	Plavix	75mg	28	36.43	1.30	Apo-Clopidogrel	75mg	90	9.14	0.10	Yes	12.81
	9	Rosuvastatin ^g	-	-	-	-	-	-	-	-	-	-	-	-
	10	Tiotropium bromide	Spiriva	18mcg	1	40.35	1.35	Spirivaj ^j	18mcg	1	39.37	1.31	No	1.02
	11	Escitalopram	Lexapro	10mg	28	20.94	0.75	Loxalate	10mg	28	1.49	0.05	Yes	14.05
	12	Formoterol ^e	Symbicort Turbohaler	200/6mg	1	46.4	46.40	Vannair ^k	200/6mg	1	22.53	22.53	No	2.06
	13	Quetiapine	Seroquel	25mg	60	37.77	0.63	Dr Reddy's Quetiapine ^l	25mg	60	3.94	0.07	No	9.59
	14	Pravastatin	Lipostat	20mg	28	11.52	0.41	Cholvastin	20mg	30	3.06	0.10	No	4.03
	15	Fentanyl	Durogesic Dtrans Transdermal Patches	25mcg	5	35.7	7.14	Mylan Fentanyl Patch	25mcg	5	5.15	1.03	Yes	6.93
	16	Pantoprazole	Protium	40mg	28	13.02	0.47	Dr Reddy's Pantoprazole	40mg	28	0.87	0.03	Yes	14.97
	17	Perindopril	Coversyl Arginine ^f	5mg	30	9.6	0.32	Coversyl ^m	4mg	30	14.06	0.47	No	0.68
	18	Amlodipine	Istin	5mg	28	5.53	0.20	Apo-Amlodipine	5mg	100	1.49	0.01	No ⁿ	13.26
	19	Donepezil	Aricept	10mg	28	44.18	1.58	Donepezil-Rex	10mg	90	7.91	0.09	Yes	17.95
	20	Alendronic acid	Fosamax	70mg	4	12.79	3.20	Fosamax ^o	70mg	4	12.88	3.22	No	0.99

Notes: Where more than one product of a particular strength is reimbursed in New Zealand we have selected the more expensive one for comparison.

a September 2011 prices.

b Price per unit refers to price per tablet, capsule, tube, inhaler, etc.

c September 2011 prices – NZ dollar converted at the Central Bank average exchange rate for January-June 2011 €1=NZ\$1.78.

- d PHARMAC have announced that a new brand of Atorvastatin (Dr Reddy's Atorvastatin) will be available from 1 November 2011 (Tab 10mg pack size 30 - €1.63 per pack or 0.05 per tablet). This change would increase the price ratio from 1:1.62 to 1:1.1. <http://www.pharmac.govt.nz/2011/09/14/2011-09%20Dr%20Reddy%27s%20Atorvastatin%20notification.pdf>
- e And other drugs for obstructive airway diseases.
- f The highest volume product in Ireland does not have an equivalent in the PHARMAC listing so an alternative had to be selected.
- g There is no PHARMAC record for this ATC.
- h Omezol Relief is currently in the transition period of a sole supply arrangement, with sole supply being effective 1 January 2012.
- i Two brands of the same dose, pack size and price available, the other brand is Olanzine.
- j A *Special Authority for Subsidy* is required for Tiotropium bromide.
- k A *Special Authority for Subsidy* is required for combination inhalers in New Zealand. Additional subsidy by endorsement for Symbicort Turbuhaler is available for patients where the initial dispensing was before 1 July 2011 (Symbicort Turbuhaler 200/6mg is €33.71).
- l Two brands of the same dose, pack size and price available, the other brand is Seroquel.
- m The highest volume product in Ireland (5mg Coversyl) does not have an equivalent in the PHARMAC listing so 4mg has been used as an illustration. It should be noted that this ACE inhibitor is hardly used in New Zealand. It is only used for patients who were on this product before June 1998 and requires a written endorsement from a physician to be fully subsidised in New Zealand. Most of the New Zealand ACE inhibitor market is shared between Quinapril, Enalapril, and Cilazapril. These products are all on sole supply arrangements and are significantly cheaper than Perindopril (all less than €0.06 per tablet vs. €0.30-0.50 for Perindopril). In the last financial year PHARMAC subsidised approximately 1m prescriptions (up to 3 months supply for a patient) for Cilazapril and these three products combined compared to just 3,000 for Perindopril (PHARMAC, Personal Communication 05 October 2011).
- n There will be sole supply from this manufacturer from 1 November 2011.
- o A *Special Authority for Subsidy* is required for Fosamax.

Sources:

ESRI Calculations.

Ireland: HSE personal communication, 30 September 2011.

New Zealand: PHARMAC (2011a, b); PHMAC, personal communication 5 October 2011.

In order to provide a benchmark against which to compare the savings from reference pricing where the firms submit prices to the HSE for reimbursement purposes, we estimated, for the 20 most frequently prescribed pharmaceuticals with a generic equivalent under the GMS (by value), the savings if they were priced at the lowest rather than the actual ex-factory price. For example, if there were two suppliers of a given interchangeable pharmaceutical with ex-factory prices of €0.50 (i.e. the brand name) and €0.25 (i.e. the generic) per unit and each supplier claimed for 50 units, then the total cost would be €37.5, the revised cost, if the lowest priced generic were used, €25, with savings of 33.3 per cent.⁷¹ For the 20 most frequently prescribed pharmaceuticals with a generic equivalent, these savings, as shown in Table 4.5, vary from approximately 30 per cent for lansoprazole to close to zero for diclofenac.

TABLE 4.5 Potential Cost Savings of Using Lowest Priced Generic Equivalent Compared to Ex-Factory Price, Top 20 (by Value) Most Frequently Dispensed Pharmaceuticals on the GMS Scheme, 2010

			A	B	C	D
			Number of Items	Total Cost	Revised Total Cost	% Difference Between B and C
ATC Description	1	Bisoprolol	962,746	2,652,161	2,546,703	-4.0
	2	Amlodipine	815,923	5,302,884	5,192,348	-2.1
	3	Ramipril	765,250	3,475,696	3,353,670	-3.5
	4	Esomeprazole	753,774	18,526,091	17,942,902	-3.1
	5	Lansoprazole	683,422	13,609,651	9,564,659	-29.7
	6	Omeprazole	650,866	8,152,730	6,890,147	-15.5
	7	Rosuvastatin	581,934	11,285,873	9,951,577	-11.8
	8	Diclofenac	562,854	4,528,215	4,502,146	-0.6
	9	Pantoprazole	503,557	5,611,118	5,194,413	-7.4
	10	Pravastatin	489,338	5,362,750	5,135,220	-4.2
	11	Clopidogrel	342,349	12,310,381	9,729,518	-21.0
	12	Venlafaxine	320,377	4,321,574	4,125,736	-4.5
	13	Alendronic acid	319,919	4,215,288	4,107,088	-2.6
	14	Doxazosin	289,922	5,466,280	4,676,268	-14.5
	15	Tamsulosin	217,806	4,318,392	3,298,912	-23.6
	16	Olanzapine	196,858	13,489,462	12,938,893	-4.1
	17	Risedronic acid	161,902	3,208,429	3,045,827	-5.1
	18	Risperidone	131,714	3,418,850	2,811,089	-17.8
	19	Lamotrigine	124,943	6,713,496	-	-
	20	Donepezil	119,312	4,725,006	4,478,048	-5.2
Total			8,994,766	140,694,327	123,437,779	-12.3

Notes: For 16 of the 678 products listed no ex-factory price was provided. For these products 8 per cent was subtracted from the reimbursable price (i.e., ex-wholesale) provided by the HSE.

A: Number of items in this ATC claimed in 2010.

B: Number of items dispensed in 2010 multiplied by the ex-factory price (1 September 2011) for each listed pharmaceutical

C: Number of items dispensed in 2010 multiplied by the minimum ex-factory price (1 September 2011) summed over dose and pack size within the ATC.

D: Percentage difference between B and C.

For lamotrigine, which is used to treat epilepsy, there are concerns about equivalence and so a price comparison is not reported in the table. However, if it were considered interchangeable, the reduction would be 41 per cent.

Source: ESRI Calculation from HSE personal communication, 30 September 2011.

⁷¹ As noted in Table 4.5, the estimates control for dose and pack size. The HSE conducted a similar exercise to that in Table 4.5 for the top 100 pharmaceutical products by expenditure with a generic for 2009 (accounting for 80 per cent of expenditure on GMS and CDS) and estimated potential savings, using the lowest cost generic, of €55.4 million under the GMS and €22.3 million under the DP Scheme (Moran, 2010, pp. 11-12).

Given these differences between competition for the market and competition in the market:

Recommendation 4.7: We recommend that the reference price for high volume off-patent interchangeable pharmaceutical products should be set through competitive tendering.

At first the HSE might wish to limit tendering to a small number of such pharmaceuticals and as experience is gained a judgement can be made as to where the line can be drawn. In designing the tenders the experience of the HSE itself in tendering for vaccines and blood products, as well as those hospitals that already tender and the international examples mentioned above can be drawn upon.

4.5.5 No Substitution Prescriptions: What Rules?

It is common as part and parcel of reference pricing systems, irrespective of whether the price setting mechanism is competition for the market or competition in the market, that medical practitioners can insist on a particular interchangeable product being dispensed. Typically this product is the long-standing brand name that until generic entry accounted for 100 per cent of the market.⁷² There is a budgetary implication of these no substitution prescriptions, since the brand name price is usually much higher than the generic. The exception of no substitution prescriptions is allowed on medical or clinical grounds. The issue thus becomes how no substitution prescriptions should be accommodated within reference pricing. Two options are considered; the very permissive option suggested by the Working Group; and a much more rigorous policy exemplified by the rules in Ontario and Saskatchewan.

It should perhaps be noted that the dispensing of generics, while in some instances accounting for in excess of 50 per cent of a particular pharmaceutical product, in other instances generics account for less than 5 per cent of prescriptions (Table 4.6). This suggests considerable prescribing by brand name. Whether this translates into no substitution prescriptions is, as yet, unclear.

⁷² In this context parallel imports are included with the brand name.

TABLE 4.6 Generics (Branded and Unbranded) as a Proportion of the Top 10 Pharmaceuticals with a Generic Equivalent, by Value, GMS and DP, 2010 and 2011

	GMS			
	2010		2011	
	Volume	Value	Volume	Value
	%	%	%	%
	esomeprazole	5.7	4.4	24.5
Rosuvastatin	2.5	1.8	21.6	19.6
Clopidogrel	16.0	12.6	28.3	27.2
Pantoprazole	30.8	33.2	41.7	40.4
Omeprazole	52.2	54.6	58.1	59.8
Acetylsalicylic Acid-Aspirin (Antithrombotic)	22.2	16.2	17.5	12.9
Venlafaxine	19.5	23.0	24.4	25.8
Lamotrigine	5.3	4.2	5.9	4.5
Budesonide	41.1	48.1	5.7	6.9
Tamsulosin	22.7	17.9	27.6	25.6
	DP			
	2010		2011	
	Volume	Value	Volume	Value
	%	%	%	%
	esomeprazole	3.2	2.4	15.4
Rosuvastatin	1.5	1.0	15.2	13.6
Clopidogrel	10.3	7.9	19.3	18.1
Omeprazole	33.2	35.6	38.9	41.2
Pantoprazole	19.7	21.2	29.2	27.6
Venlafaxine	12.9	15.2	17.1	17.6
Acetylsalicylic Acid-Aspirin (Antithrombotic)	10.1	7.0	8.5	6.0
Gabapentin	10.5	7.7	14.2	9.0
Anastrozole	0.0	0.0	3.0	2.4
Amlodipine	28.2	33.8	33.1	31.9

Notes: ^a Year to Date June 2011

For lamotrigine and gabapentin, which are used to treat epilepsy, there might be concerns about equivalence.

Source: ESRI calculations from HSE personal communication, 23 September 2011.

The Working Group view on the procedures for dealing with no substitution prescriptions are set out as follows:

Some patients will require a particular brand of pharmaceutical for clinical reasons. In these instances prescribers may object to substitution by including a specified code on the prescription. This will enable the HSE to monitor the usage of exemptions by prescribers (Moran, 2010, p. 5)

A footnote in Moran (2010, p. 5) refers to Sweden where prescribers objected to substitution in 2.5 per cent of cases, by simply ticking the appropriate box on the prescription form.⁷³ The 2.5 per cent appears a low figure. However, no substitution

⁷³ In Sweden in 2006 generics accounted for 44 per cent of the market measured by volume and 14 per cent by value, while no substitution pharmaceuticals accounted for 2.5 per cent by volume. These percentages imply that non-generic pharmaceuticals were 4.8 times more the price of generic pharmaceuticals. If the no substitution prescriptions were priced at the same price as generic then expenditure on off-patent pharmaceuticals experiencing generic competition would increase by 5.4 per cent (100 to 105.4); if, on the other hand, these no substitution drugs were priced at the brand level then expenditure on off-patent pharmaceuticals would increase by 26 per cent from 100 to 126. Thus expenditure on off-patent pharmaceuticals with generic competition is raised by 19 per cent because of no substitution prescriptions (i.e. 1 – 126/105.4). This calculation relies on a number of obvious simplifying assumptions and hence should be regarded as indicative rather than definitive. The data is drawn from Redman and Hoggard (2007, pp. 51-52).

prescriptions account for 5.4 per cent of prescriptions where substitution was possible (i.e. off-patent pharmaceuticals with generic competition) and it increased expenditure on off-patent pharmaceuticals where generic competition existed by close to 20 per cent in Sweden.

If all that is required for a no substitution prescription is a specified code on the prescription, then this approach has a number of difficulties. *First*, it may create incentives for either the patient or the pharmacist to add the code, if the process used does not prevent them from doing so.⁷⁴ It would be much better to require the prescriber to complete the specified code and, in his/her own hand, write the words 'no substitution' across the prescription.⁷⁵ *Second*, there is limited feedback to the HSE and/or the body responsible for certifying interchangeability as to why it is clinically necessary not to permit substitution. This is important since if there are problems with the process then this should be determined sooner rather than later. *Third*, casual empiricism suggests that Irish consumers are brand conscious and hence may request prescribers to use no substitution prescriptions in view of the low proposed bar to their use.⁷⁶ Furthermore, as noted above the incidence of generic prescribing in Ireland is low by international standards and appears to have declined in the last decade, suggesting that medical practitioners are also brand loyal. *Fourth*, as pointed out by Bloom and Van Reenen (1998), the HSE (i.e. the principal) would like medical practitioners (i.e. the agent) to prescribe in a cost-effective manner by carefully evaluating all prescriptions on the basis of budgetary cost versus therapeutic benefit trade-off.⁷⁷ However, medical practitioners are "...far more likely to be concerned with patient welfare than with ensuring value-conscious prescribing" (*ibid*, p. 323). This will tend to result in too many no substitution prescriptions when the bar is set as low as the Working Group's proposals.

In Saskatchewan the policy towards no substitution prescriptions is set out as follows:

It is recognized that extremely rare cases may exist in which a person is not able to use a particular brand of product. In such cases, the prescriber may request exemption from full payment of incremental cost when a specific brand of pharmaceutical in an interchangeable or

⁷⁴ The patient would thus escape paying the co-payment (the difference between the reference price and the brand dispensed) while the pharmacist could claim for the brand but dispense a generic or dispense the brand if it has a higher absolute mark-up than the generic. Such action would probably be in breach of the rules governing reference pricing and generic substitution and if enforced appropriately unlikely to occur. But such enforcement nevertheless consumes resources which might be better employed elsewhere.

⁷⁵ Prescriptions with no substitution printed across the script would be ineligible.

⁷⁶ For example, brand name milk and private label milk often exist side by side, despite a substantial difference in price although they would clearly be considered interchangeable products.

⁷⁷ The text paraphrases Bloom and Van Reenen (1998, p.323) which refers to the National Health System in the UK, but the argument applies equally to the HSE.

maximum allowable cost category is found to be essential for a particular patient. There is no provision for "blanket" exemptions. Each request must be patient and product specific.

The request may be submitted in writing or by telephone ... and must provide sufficient details to permit thorough, objective assessment. (Saskatchewan Ministry of Health, 2010b, p. 276.)

In Ontario similar procedures are in place, including completion of a Canada Vigilance Reporting Form designed to detect adverse reactions to pharmaceuticals marketed in Canada.⁷⁸ In Ireland, the corresponding form is the IMB's Adverse Reaction Report Form.⁷⁹

The two Canadian provinces set a much higher bar than the Working Group for the use of no substitution prescriptions. It reflects the view that interchangeable products are manufactured to the same standards and are considered bioequivalent, the same as in the EU. However, at the same time the Saskatchewan and Ontario approach meets all of the four criticisms set out above of the permissive approach to no substitution prescribing proposed by the Working Group. There is little chance of abuse; the HSE and the body certifying interchangeability gets feedback as to the reasons for no substitution; the medical practitioner is in a much better position to resist requests from patients for the brand to be written as a no substitution prescription; and, the trade-off takes much greater account of budgetary considerations. Hence:

Recommendation 4.8: We recommend that for the HSE to reimburse an interchangeable pharmaceutical product at a price higher than the reference price, the medical practitioner must complete an IMB Adverse Reaction Report Form and write, in his/her own handwriting, 'no substitution' across the prescription form.

The form may have to be modified slightly since there may be instances where no-substitution is warranted but this may not be due to an adverse reaction to the pharmaceutical. For example, it may be a swallowing difficulty that requires a dispersible tablet or a known hypersensitivity to an excipient, which is likely to be very rare.⁸⁰

⁷⁸ For details see Ontario, Ministry of Health (2008, p 1.9).

⁷⁹ For details see: http://www.imb.ie/images/uploaded/documents/Adverse%20Reaction%20Form_HM_May%202011.pdf. Accessed 1 November 2011.

⁸⁰ The experience of New Zealand, discussed in Section 7.3.3, might also be drawn upon.

An example can be used to illustrate the impact of no substitution prescriptions (Table 4.7). If the brand price is 60 per cent higher than the reference price and no substitution prescriptions account for 10 per cent of the market, the HSE expenditure would rise by 6 per cent, but if the brand name price was twice the reference price, the increase in HSE expenditure would be 10 per cent.

TABLE 4.7 Illustrative Example of the Impact of No Substitution Prescriptions on Pharmaceutical Costs

Share of No. Substitution Prescriptions (%)	Total Expenditure (€)	
	Brand/Reference Price = 1.60	Brand/Reference Price = 2.0
0	100	100
10	106	110
20	112	130
50	130	150

Source: See text.

4.5.6 International Non-Proprietary Name Prescriptions

At the present time if a medical practitioner writes a prescription using the INN,⁸¹ then the pharmacist decides which pharmaceutical product to dispense to the patient. If there is one or more generics available then the pharmacist can either dispense one of those or the higher priced brand name. Of course, under the current IPHA/HSE agreement and the pricing rules that flow from it there is not a large price difference between the ex-factory price of the brand and the generic. That, however, is likely to change with the introduction of reference pricing, where it seems unlikely that the brand name will lower its price to compete with the generics, especially if the rather permissive conditions for no substitution prescriptions set out by the Working Group are implemented. Hence it is vital that reference pricing also applies to prescriptions written in INN. In other words, only the reference price will be paid. While it is implicit in the Working Group's proposals it should nevertheless be made explicit.

Hence:

Recommendation 4.9: We recommend that if a prescription is written using the international non-proprietary name then the pharmacist is reimbursed at the reference price.

⁸¹ INN prescribing is discussed further in Section 7.2.2. INN prescribing means that the active ingredient name is used (e.g. atorvastatin) rather than the brand or proprietary name (e.g. Lipitor).

4.5.7 Patient Adherence to Pharmaceutical Regime

Pharmaceuticals appear in different sizes, shapes and colours. Pharmaceuticals considered interchangeable products may not always be identical in terms of these characteristics. Hence an issue arises when generic substitution and reference pricing are introduced that the patient's mix of size, colour and shape of pharmaceuticals may change solely because a different interchangeable product is dispensed. This may be a problem for patients on multi-pharmaceuticals.⁸² Problems may occur with ensuring patient adherence with their pharmaceutical regimen. However, the answer is not to abandon generic substitution and reference pricing, but rather ensure that some of the savings generated are used to address this problem by the prescriber and the dispenser, where it should be seen as part of a wider problem of ensuring patient adherence rather than as a problem in its own right.

There are a number of solutions to this potential problem. Generic firms have an obvious incentive to make their pharmaceuticals the same colour and shape as the brand to gain market share. Indeed, a leading generic supplier informed us that to the extent possible that their pharmaceuticals are the same shape and colour as the brand name or originator product. In some cases, however the shape may be a registered trademark (e.g. Viagra) or the brand name firm may change the shape, size or colour of a pharmaceutical as its patent nears expiry (e.g. Lipitor, which will shortly become off-patent, is changing the size and shape of its tablets in Ireland).⁸³ One of the factors considered in awarding a tender could be the degree and seriousness of any confusion due to differences in size and colour. Furthermore, for persons on multiple pharmaceuticals monitored dosage systems exist in which the pharmaceuticals can be pre-sorted by the time they are supposed to be taken in order to encourage compliance.⁸⁴

The issue of patient adherence to a pharmaceutical regime is part of the wider issue of ensuring that when reference pricing and generic substitution are introduced that patients, medical practitioners and pharmacists are aware of the proposed changes and the fact that those products which are considered interchangeable can be substituted for each other and have the same therapeutic impact. The success of an information campaign is essential, especially with respect to patients in that success will mean that medical practitioners and pharmacists will need to devote less time to explaining generic substitution to patients. The Working Group in its report set out

⁸² The Irish Longitudinal Study on Ageing (TILDA) found that one in five adults over the age of 50 years in Ireland take five or more medications, with one in two of all over 75s on five or more medications (Barrett *et al.*, 2011; Table 5.A45).

⁸³ Based on an undated letter from Pfizer Healthcare Ireland to pharmacists titled "Smaller Lipitor Tablets". It is believed that the letter was circulated in October 2011.

⁸⁴ See, for example, the MyMed system offered by Unicare in Ireland.

For details see http://www.unicarepharmacy.ie/Care_at_Home/Default.668.html. Accessed 8 November 2011.

the basis of a communication strategy that serves as a useful point of departure (Moran, 2010, p. 19).⁸⁵

4.5.8 A Matter of Definition: Same or Similar

An issue arises as what is meant by an interchangeable product. Traditionally, this has been taken to mean that all products with the same active ingredient and the same dosage form and strength are considered interchangeable. However, an issue arises with respect to where the brand name firm changes the presentation – (e.g. from a capsule to a tablet as occurred with respect to Losec (i.e. omeprazole) in Ontario, or a tablet that is slightly different size and shape as in the Lipitor illustration above) or formulation (e.g. the use of a different salt in Coversyl).⁸⁶ Should the different presentations/formulations be considered interchangeable? In answering this question it should be remembered that what is of interest is that the different presentations/formulations of the same active ingredient should be considered equivalent or interchangeable in terms of treating the patient. If an unduly narrow interpretation of interchangeability is taken then this is likely to create an incentive for the brand name firm to change the presentation and/or formulation prior to entry of the generic in order to impede competition. While such conduct might be challenged under competition law, it would be preferable to act to prevent such conduct from occurring in the first place by not having a narrow definition of interchangeability.

Hence:

Recommendation 4.10: We recommend that the definition of interchangeability should be broad enough to accommodate minor changes in formulation (e.g. use of different salts) and presentation (e.g. different shaped solid dose forms).

In Ontario, for example, interchangeability is defined as follows:

In order for one drug product to be designated as interchangeable with another, both drug products must contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product. "Similar active ingredients" means

⁸⁵ Another potential problem that occurred in Ontario when generic substitution was first being introduced was the issue of legal liability if generic substitution takes place and the patient suffers an adverse reaction. In the case of Ontario the liability was assumed by the province. However, this issue has not to date been raised in the discussion on generic substitution in Ireland. If a similar concern does arise, however, the same solution as used in Ontario would seem appropriate.

⁸⁶ See Kubler (2006) and Health Canada (2006).

different salts, esters, complexes or solvates of the same therapeutic moiety.⁸⁷

As noted above decisions concerning interchangeability could be made by a Committee on Interchangeable Medicines, as recommended by the Working Group,⁸⁸ or by the Irish Medicines Board.

4.5.9 Interaction Public/Private

At the present time the IPHA/HSE and APMI/HSE agreements determine the ex-factory price of pharmaceuticals that are off-patent and which experience generic competition. These agreements set the ex-factory price irrespective of whether or not the pharmaceutical is paid for by the HSE under the GMS or one of the CDS or whether the patient pays for the pharmaceutical because, for example, it is under the monthly DP threshold. The proposals in this section concerned with reference pricing and generic substitution suggest an alternative mechanism for setting the ex-factory price for off-patent pharmaceuticals subject to generic competition. There should no difficulty in such an arrangement. The prescription written by a medical practitioner for a pharmaceutical does not vary by who pays for the pharmaceutical. One difference will be payment for no substitution prescriptions: for the GMS and CDS, the State pays the difference between the reference price and the brand name price, while in the cash sector the patient pays the full price for the brand name (once they are below the monthly threshold for the DP Scheme or do not participate in any State scheme).

4.6 REFERENCE PRICING FOR DIFFERENT PHARMACEUTICALS: THERAPEUTIC SUBSTITUTION

The discussion of reference pricing and generic substitution has concentrated on interchangeability of pharmaceuticals with the same active ingredient.⁸⁹ However, it has been argued that substitution should take place at other levels where different pharmaceuticals are grouped together to treat the same condition. Frequently, the different pharmaceuticals employ a similar mechanism to treat the condition. Irrespective of the mechanism the end result is very similar. Sometimes in the literature these are referred to as me-too pharmaceuticals, minor improvements over existing pharmaceuticals. Thus these pharmaceuticals are close substitutes for each other, but at the same time there may be substantial differences in price. Hence there may be grounds for applying reference pricing and generic substitution to such instances. The two instances most frequently mentioned are statins and proton pump inhibitors (PPI). Saskatchewan, for example, will only pay up to a

⁸⁷ The definition is set out on the website of the Ontario Ministry of Health and Long-Term Care. For details see: <http://www.health.gov.on.ca/english/public/pub/drugs/generic.html>. Accessed 14 December 2011.

⁸⁸ Moran (2010, pp. 9-10).

⁸⁹ This is sometimes referred to as ATC Level 5. For details see http://www.whocc.no/atc_ddd_index. Accessed 3 November 2011.

certain amount per tablet for a group of six proton pump inhibitors (PPIs), details of which are provided in Box 4.3. The practice dates back to 2004.⁹⁰ In contrast to reference pricing and generic substitution discussed in Section 4.5, if such measures are extended to therapeutic substitution then this could, in theory, involve setting the price for in-patent pharmaceuticals.

BOX 4.3 Saskatchewan's Approach to Reimbursement of Proton Pump Inhibitors – Maximum Allowable Cost (MAC)

For many common medical conditions, drug manufacturers market a wide variety of prescription drugs that often vary in price but achieve the same medical effect. Under the MAC policy, the Drug Plan obtains expert advice on which prescription drug products within a group of similar medications are safe and beneficial, and the most cost-effective. The price of the most cost-effective drugs are used as a guide to set the maximum allowable cost the Drug Plan will cover for other similar drugs used to treat the same condition. The price is not necessarily set at the lowest cost drug.

Patients have two options if they are prescribed a drug whose price is above the MAC for the group; (1) they can either continue to take the higher priced drug and pay the difference in cost over the MAC or, (2) they can talk to their physician about switching to a drug that is within the MAC. If the patient wishes to switch medications they will need a new prescription from their physician.

If the patient chooses to remain on a higher priced drug, then only the maximum allowable cost will go towards their deductible and/or calculation of their co-payment.

The expert drug review committees assess the need for exemptions (and any exemption criteria) as they review each possible MAC group. Exemption criteria (where applicable) are noted in the chart below for each group. Exemption requests are considered on a case-by-case basis. Prescribers or pharmacists may make exemption requests, with supporting detailed information, to the Drug Plan via the Exception Drug Status process.

The MAC policy applies equally to all Saskatchewan residents eligible for benefits under the Drug Plan and Extended Benefits Branch.

Maximum Allowable Cost Group(s)

Proton Pump Inhibitors (PPIs)

Group includes:	esomeprazole, lansoprazole, omeprazole, pantoprazole magnesium, pantoprazole sodium, rabeprazole.
Maximum Allowable Cost:	CDN\$1.51 per tablet or capsule (subject to the patient's usual co-payment and deductible).
Exemption Criteria:	Patients who are intolerant or refractory to at least two drugs priced within the MAC policy. Patients requiring administration of a PPI by nasogastric tube.
Notes:	These drugs are available under the Exception Drug Status (EDS) program. Patients must meet EDS criteria to qualify for coverage. See Appendix A for information on EDS criteria for specific PPIs. HP-PAC prescriptions are not affected by this policy. Please refer to formulary/website for actual prices.

Source: Saskatchewan Ministry of Health (2011, p. 275).

Once the HSE has the generic substitution and reference pricing in place for pharmaceuticals that are the same chemical entity then attention should be paid to broader therapeutic substitution where there may also be substantial savings. However, as the example in Box 4.3 makes clear careful attention will need to be

⁹⁰ Consideration might also be given to the STEPS system used in Northern Ireland for cost-effective pharmaceutical management. See, for example, Scott *et al.* (2007).

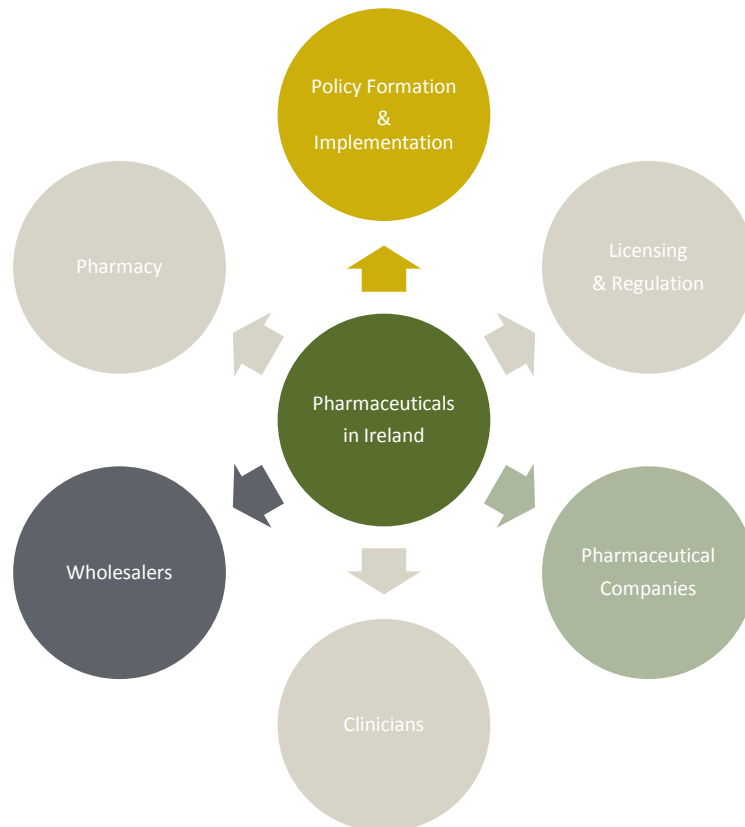
given to the criteria for exception such that it commands widespread support amongst medical practitioners and pharmacists. This suggests that the legislation introducing reference pricing and generic substitution should be framed so that it can accommodate therapeutic substitution.

4.7 CONCLUSION

This chapter has set out proposals for the ex-factory pricing and reimbursement of single source in-patent and off-patent pharmaceuticals with generic competition which will, we believe, lead to lower prices and better value for money, while at the same time ensuring security of supply. In the case of the former, the changes reflect the retention of the current administrative pricing arrangements, but important changes in price determination. In contrast, for multisource off-patent pharmaceuticals a new approach is proposed: reference pricing and generic substitution, with an important role for tendering for high volume interchangeable pharmaceutical products. While new to Ireland, this is the norm elsewhere in the developed world. In considering all these changes every attempt has been made to use market mechanisms and information to set prices. The reforms attempt to harness market forces to get better value for money, rather than attempting to subvert or ignore them.

Chapter 5

The Middle Man: The Wholesale Function



5.1 INTRODUCTION

The wholesale function is an important component in the pharmaceutical delivery system, helping to ensure safe and efficient delivery of pharmaceuticals. The wholesaler acts as a middle man between the manufacturer and the pharmacy, whether the latter is located in a hospital or in the community. In this chapter, we first set out the role of the wholesaler (Section 5.2), before attention turns to the recent HSE moves to reduce the wholesale mark-up (Section 5.3). An issue that has arisen, in part because of these changes, is whether the current wholesale business model, which relies on a mark-up over the ex-factory price of a pharmaceutical, is sustainable and what alternatives might be more appropriate, issues considered in Sections 5.4 and 5.5, respectively. Section 5.6 concludes the chapter.

5.2 THE WHOLESALER'S FUNCTION AND ROLE¹

The wholesale function in Ireland is largely the responsibility of full-line wholesalers, who are authorised and regulated by the Irish Medicines Board (IMB).² These firms carry an extensive range of pharmaceuticals: approximately 12,500 individual items or stock keeping units (SKUs).³ The wholesalers deliver pharmaceuticals twice daily to pharmacies from a small number of distribution depots (i.e. 3 or 4). Pharmacies order electronically from wholesalers. There is a short lead time for ordering.⁴ The three leading full-line wholesalers, Cahill May Roberts Group Limited (CMR);⁵ Uniphar Group plc (Uniphar);⁶ and, United Drug plc (United Drug),⁷ offer nation-wide distribution. In 2008, the three wholesalers accounted for 90 per cent of the wholesale market, with United Drug the market leader, accounting for 44 per cent.⁸ The present structure of the wholesaling function emerged after a period of intense competition in the mid-1990s.⁹

Individual pharmacies, whether in the hospital or the community, are unable to stock the variety of pharmaceuticals that a wholesaler carries. Storage space constraints are frequently a consideration. Wastage is also likely to be a factor since the pharmacy may not be able to predict demand with great accuracy. The wholesaler, by acting for a large number of pharmacies, is better able to manage variations in demand. Furthermore, by responding rapidly to pharmacy orders, wholesalers reduce the need of pharmacies to carry a large inventory.

Each of the main full-line wholesalers also acts as an agent for individual brand name manufacturers of pharmaceuticals and so distribute these firms' products to other wholesalers. This is referred to as pre-wholesaling. There is a limited degree of forward linkage, with CMR owning the Dr Morris/Unicare chain of around 70 retail

¹ This discussion is based on Competition Authority (2002), Indecon (2007), the websites of the three leading full-line wholesalers and meetings with industry participants.

² There are about 150-160 authorised wholesalers, which includes brand name pharmaceutical manufacturers, short-line wholesalers, pharmacies and the HSE. In some instances the same organisation has more than one authorisation. For example, the HSE has two, the Medicinal Products Division and Shared Services. For details see the IMB website: <http://www.imb.ie/EN/Medicines/Wholesale-Distribution/Licensing-.aspx>. Accessed 19 September 2011.

³ A SKU is number or code used to identify each unique product or item for sale. A different SKU will be used for each pharmaceutical, by supplier, strength, dosage form and so on.

⁴ This frequency of deliveries and the use of electronic ordering is not unusual by EU norms. For details see Indecon (2007, Table 4.3, p. 38).

⁵ Cahill May Roberts is owned by Celesio which has operations in a number of EU Member States, in retail and mail-order pharmacy as well as pharmaceutical wholesale operations. For details see Celesio (2010; 2011).

⁶ Uniphar also distributes other items besides pharmaceuticals and in 2008 purchased a firm in the UK distributing medical and surgical devices to hospitals. Uniphar also purchased Boileau and Boyd Ltd., which operated mainly in the Dublin area. Uniphar, through its Independent Pharmacy Ownership Scheme (IPOS), has interests in retail pharmacy in Ireland. For details see Uniphar (2009).

⁷ United Drug has interests in a wide array of health-care and pharmaceutical activities. In 2010, 60 per cent of its profits were generated outside Ireland. For details see United Drug (2011).

⁸ The 90 per cent figure is from Dorgan (2008, p. 12), while Macarthur (2007, p. 57) also cites the 90 per cent figure as well as individual market shares: Uniphar, 30 per cent and CMR, 20 per cent.

⁹ Based on two High Court judgments discussed later in the chapter.

pharmacies and Uniphar assisting young pharmacists purchase pharmacies through its Independent Pharmacy Ownership Scheme (IPOS).¹⁰ We understand that United Drug has no involvement in the ownership of pharmacies.

Pharmacies typically use two full-line wholesalers: a primary wholesaler that supplies most of the pharmacy's needs and a second wholesaler if there are supply problems with the primary wholesaler. Wholesalers thus compete to be the primary wholesaler for the pharmacist's business. Competition takes place on both quality and price dimensions. First, wholesalers compete on the quality of service, in terms of the range of pharmaceuticals stocked, the frequency of delivery and response time, where it appears that the wholesalers are quite similar. Second, they may offer competitive discounts and rebates.¹¹ Some of these rebates are related to cost-savings, e.g. in return for ordering electronically or paying bills within a certain period time. In other instances, the rebates are essentially price cutting to secure and retain business from the pharmacy.

If there is vigorous competition between the wholesalers for the business of pharmacies, which are able to play one wholesaler off against the other, then the wholesalers should earn normal rates of return and any rents that might exist in the distribution chain would accrue to the pharmacist.¹² Of course, it is perfectly possible that although the rents accrue to the pharmacist that this does not necessarily result in high returns to community pharmacy, since without controls on entry, additional pharmacies will be attracted into the market by the high returns.¹³ It is an issue we will return to in Chapter 6.

5.2.1 Alternative Wholesaling Models

Although the discussion has centred on full-line wholesalers, the traditional pharmaceutical distribution model, mention also needs to be made of short-line wholesalers. Instead of carrying an inventory of 12,500 SKUs the short-line wholesaler's inventory is much lower, perhaps in the 100s, normally with much less frequency of delivery than the full-line wholesalers. In a number of instances short-

¹⁰ In 2004, Uniphar estimated that between 0 and 20 per cent of its sales were to IPOS-linked pharmacies, which were under no contractual obligation to source with Uniphar (Competition Authority, 2004, para. 1.9). For details of the IPOS scheme see *ibid*, para. 1.6 and 1.7. The IPOS scheme has recently caused considerable financial difficulties for Uniphar. For details see discussion in Section 5.4.1.

¹¹ The terms rebate and discount are used interchangeably to indicate a reduction in price conditional on meeting some requirement, such as a minimum level of sales.

¹² A rent is a payment for a good or service greater than is necessary to pay for the factors of production (e.g. land, labour and capital) required to supply and sustain the good or service. For example, a famous football player might be paid €100,000 a week, but would be prepared to supply his services for €20,000 a week (his next best alternative), the difference, €80,000, is rent.

¹³ To the extent that entry lowers the returns, pharmacies will be observed earning a normal rate of return. However, at the same time entry will have been excessive compared to a situation where such high returns did not exist.

line wholesalers supply parallel imports and thus are in a position to undercut the full-line wholesalers who are more likely to source from the brand name manufacturer, particularly in view of their pre-wholesaling agreements. However, this situation has changed. In 2011 the three full-line wholesalers either distribute parallel imports or anticipate doing so in the near future.¹⁴

Another model of wholesale distribution that has gained a limited foothold is Direct to Pharmacy (DTP).¹⁵ Under this model the brand name manufacturer uses a Logistics Service Provider (LSP), which may be a full-line wholesaler, to distribute its products.¹⁶ The LSP does not take title to the pharmaceuticals since the brand name manufacturer deals directly with the pharmacist. The manufacturer sets the price and other terms of supply (e.g. frequency of delivery) to the pharmacist and pays the LSP a fee for distribution to standards set by the manufacturer. Instead of wholesalers competing for pharmacy business, under the traditional full-line distribution model, wholesalers have to compete, with other LSPs, for the business of the brand name manufacturer. Until the summer of 2011, DTP was used to only a limited degree, often for only selected pharmaceutical products of a supplier. However, subsequently Novartis Ireland, Janssen Pharmaceuticals and Acetelion have moved to DTP for products under the High Tech Drug Scheme.¹⁷

5.3 REDUCING THE WHOLESALE MARGIN FOR GMS AND COMMUNITY DRUG SCHEMES

Since wholesalers are remunerated indirectly, via pharmacy payments, there is no direct pricing agreement between the HSE and wholesalers, either individually or through the full-line wholesaler's trade association, the Pharmaceutical Distributors Federation (PDF).¹⁸ This contrasts with the HSE agreements with manufacturers and pharmacists, discussed in Chapters 4 and 6, respectively. The absence of a separate PDF/HSE agreement in part reflected the fact that there was a 17.66 per cent wholesale mark-up built into the reimbursement price paid to the pharmacy by the HSE under the GMS and CDS;¹⁹ and, in part, by the fact that when the HSE decided to consider the issue of the wholesale margin in 2005-2006, legal advice suggested that negotiations with the PDF were inconsistent with the Competition Act 2002.²⁰

¹⁴ This is not unusual for wholesalers in other Member States. See Macarthur (2007, p. 127) for details.

¹⁵ This model is described in greater detail in Office of Fair Trading (2007) and Macarthur (2007). The ex-factory price is the same irrespective of the distribution model. It is that set in accordance with the IPHA/HSE and APMI/HSE agreements discussed in Chapter 4. Equally the price that the pharmacist is reimbursed is the same irrespective of the distribution method.

¹⁶ The brand name manufacturer could decide to perform the wholesaling function itself or contract to a logistic firm such as DHL or UPS.

¹⁷ Based on discussion with market participants.

¹⁸ The three full-line wholesalers are the only members of the PDF.

¹⁹ This mark-up has been expressed in a couple of ways. It is 17.66 per cent of the ex-factory price or 15 per cent of the ex-wholesale price. Thus if the ex-factory price is €85.00, the 17.66 per cent wholesale margin results in an ex-wholesale price of €100. Thus the wholesale margin is €15 or 15 per cent of the ex-wholesale price.

²⁰ For further discussion on the latter issue see HSE (2007).

In order to establish an appropriate benchmark mark-up for wholesalers, the HSE commissioned research to assist in setting "...a fair price for the service provided" (Indecon, 2007, p.i). The research established that the wholesaler's mark-up in Ireland was twice that of selected European countries (Indecon, 2007, Table 4.1, p. 35). Bar one country, the UK, none had a wholesale mark-up above 10 per cent. The research concluded that the wholesale mark-up was in fact divided 50:50 between the wholesaler and the pharmacist (HSE, 2007).²¹ The mechanism that facilitated the division was the common practice of wholesalers offering rebates and discounts off the wholesale price to the pharmacy.²² It is, in effect, price competition. It reflects the fact that there is competition between the wholesalers for pharmacy business. Without such competition – if there was, for example, only one wholesaler and entry barriers into wholesaling were high – then there would be no rebates and discounts – apart from those related to efficiencies in purchasing – and the wholesale mark-up would accrue almost entirely to the wholesaler and not be shared with the pharmacy.

The HSE decided to reduce the wholesale mark-up; in other words, squeeze the rents out of the distribution system. On 17 September 2007, after a consultation period and drawing on Indecon (2007), the HSE decided to unilaterally reduce the wholesale mark-up.²³ It was announced that the GMS and CDS wholesale mark-up would be reduced from 17.66 per cent of the ex-factory price to 8 per cent from 1 December 2007 and to 7 per cent from 1 December 2008.²⁴ Thus the wholesale mark-up was reduced by lowering the reimbursement price paid to pharmacies by the HSE; the reduction was thus captured by the HSE. However, there is many a slip between the cup and the lip, as implementing the policy demonstrated.

Although the first stage of the reduction was to come into effect from 1 December 2007, the HSE delayed its implementation until 1 March 2008. A case was taken by Hickey Pharmacies, a chain of 26 pharmacies, against the HSE claiming the HSE were in breach of its pharmacy contract by unilaterally reducing the wholesale mark-up, without consultation. The High Court ruled in favour of Hickey Pharmacies and the wholesale mark-up of 17.66 per cent was reinstated by the HSE in October 2008.²⁵

²¹ The division is redacted from the published Indecon (2007, p. ii) report, but appears in the HSE (2007) press release.

²² Discounting appears to have started in the late 1970s, having become relatively widespread in the 1980s and well established and quite significant by the early 1990s. In the case of the Hickey Pharmacy Group, consisting of 26 pharmacies, the discount from its primary wholesaler was 11-12 per cent. For details see *Hickey & Ors trading as Hickeys Pharmacy v The Health Service Executive* [2008] IEHC 290. This High Court judgment will be referred to as *Hickey v Health Service Executive*.

²³ This process is described in some detail in *Hickey v Health Service Executive*.

²⁴ This was announced in a letter to pharmacies from the HSE dated 17 September 2007. The letter is reproduced in *Hickey v Health Service Executive*.

²⁵ *Hickey v Health Service Executive*.

The ruling by the High Court on 11 September 2008 centred on clause 12(1) of the Community Pharmacy Contractor Agreement for the Provision of Community Pharmacy Services under the Health Act 1970 (the 1996 CPC Agreement), which in turn was based on a 1971 Memorandum of Agreement between the Minister for Health and Children and the Irish Pharmaceutical Union (IPU).²⁶ The judgment said that under clause 12(1) the pharmacists were contractually entitled to receive payments at a rate, or rates, unilaterally determined by the Minister (not the HSE) by approval or direction, following consultation. However, there had not been the required consultation. The judgment pointed out that it was not concerned with the merits of the case, only whether the 1996 CPC Agreement had been adhered to by the Minister for Health and Children.

The Minister did, however, subsequently reduce the wholesale mark-up: from 1 July 2009 from 17.66 per cent to 10 per cent;²⁷ with a further reduction to 8 per cent in June 2011.²⁸ The reductions took place under the provisions of the Financial Emergency Measures in the Public Interest Act 2009 (FEMPI). The legislation reflected severe economic crisis and the need to take a range of measures. These included, under Section 9 (1), the power to the Minister for Health and Children, after consultation, and with the consent of the Minister for Finance, to "...by regulation, reduce ... the amount of payment to be made to health professionals... ." As with the earlier attempt to reduce the wholesale margin there was a High Court challenge by pharmacists, but this time it was unsuccessful.²⁹ It was argued, on behalf of the pharmacists, that under FEMPI, and the consequent statutory instruments, the consultation was not meaningful, the swingeing reductions were never intended under the legislation, and, that the reductions amounted to an interference with the pharmacists' property rights and were arbitrary and/or capricious. The High Court judgment vindicated the legislation and the statutory instruments containing the reductions.³⁰

In sum, the Minister and the HSE have reduced the wholesale mark-up and thus squeezed, albeit not easily, rents out of the distribution chain and obtained better value for money, without compromising security of supply.

²⁶ The IPU and the Department of Health and Children negotiated the CPC Agreement and its predecessors. Using this template, individual pharmacies then entered into contractual agreements with the Health Boards and their successor, the HSE. See also Chapter 6. Note that the IPU subsequently changed its name to the Irish Pharmacy Union.

²⁷ The wholesale mark-up remained at 17.66 per cent for controlled drugs and fridge items. The change was effected through a S. I. No. 246 of 2009, Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2009. See Table 2.3.

²⁸ The wholesale mark-up for controlled drugs was reduced from 17.66 to 8 per cent, while it fell to 12 per cent for fridge items. This change was effected through S. I. No. 300 of 2011, Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2011. See Table 2.3.

²⁹ In contrast to the earlier unsuccessful attempt to reduce wholesale margins, there were some offsetting policy changes such as adjusting the dispensing fee. These are discussed further in Chapter 6.

³⁰ See *J & J Haire & Company Ltd & Ors v Minister for Health and Children & Ors* [2009] IEHC 562. This will be referred to as *Haire v MfH&C*. The language in the previous sentence in the text closely follows the wording of the judgment.

5.4 IS THE CURRENT WHOLESALE BUSINESS MODEL BROKEN?

Business models can change for a variety of reasons. The underlying economic and technological conditions can change rendering the old model redundant. The internet, for example, revolutionised the way in which airline reservations are made and boarding passes are issued. Equally, irrespective of changing technology, an entrepreneur may come up with a better model, such as just in time production for assembling automobiles which avoids the necessity of holding large stocks of spare parts and to a lesser extent to be vertically integrated. In the case of pharmaceutical wholesaling, it could be argued that recent and prospective changes in economic conditions result in the need to reconsider the current model. Independently, new models are emerging elsewhere. In some instances such as DTP these are the result of market forces, while in others, such as Public Service Obligation, the result of government intervention.³¹

In this section we first examine recent changes that have affected the economics of the full-line wholesale business. These include the various moves by the HSE to reduce pharmaceutical prices and mark-ups that have already been discussed earlier, the growth in demand for pharmaceuticals, bad debt provision and cherry picking by parallel importers and brand name manufacturers. In order to address the impact of some of these changes in more detail we undertook a survey of the three full-line wholesalers, and this is the subject of the second part of the section.

5.4.1 Economic Conditions, Government Policy, Bad Debt and Cherry Picking

The current wholesale business model relies on a percentage mark-up over the ex-factory price in order to generate enough revenue for wholesalers to cover their costs and make at least a normal rate of return. There seems to be an acceptance that the wholesalers compete vigorously with each other (e.g. Competition Authority, 2004; Indecon, 2007), so that costs are unlikely to be excessive because of lack of competition. However, there are a number of policy and other changes that may have an impact on the viability of the model.

First, the IPHA/HSE agreements resulted in a series of *ex-factory price reductions* dating from 2006 for single source in-patent pharmaceuticals and multiple source off-patent pharmaceuticals, while reference pricing and generic substitution will be introduced in 2012. These reductions in price will mean that the ex-factory price, on which the wholesale mark-up is based, will fall, reducing, other things being equal, the income of wholesalers. However, while it is the case that the ex-factory price is

³¹ In the UK, for example, there has been a move to Direct to Pharmacy models by manufacturers. See Office of Fair Trading (2007) for a discussion. The representative body for the full-line wholesalers, the PDF, has argued for the introduction of a Public Service Obligation (PSO) under which all wholesalers would be required to carry the full range of pharmaceuticals (Unipharm, 2010, p. 6). The IPU (2011b) also favours a PSO. This is discussed further later in the chapter.

lower than it otherwise would be on these pharmaceuticals, it may nevertheless be the case that the overall value of pharmaceutical expenditures increases. Hence, while the absolute amount earned on an individual item may have been lower than it otherwise would be, this may be more than offset by the growing volume of pharmaceuticals. Hence, if the mark-up is based on overall sales, then wholesaler revenue may well increase, albeit at a slower rate than if prices remained unchanged.

The overall growth in demand, measured in volume and value, for pharmaceuticals in Ireland was considerable between 2000-2010, as shown in Chapter 2. The growth in pharmaceutical demand in Ireland, measured on a per capita basis, was also high by EU³² and OECD³³ standards in the 2000s. Overall pharmaceutical expenditure in Ireland still increased after 2006, although there has been some moderation in growth in expenditure and even a small decline in 2009/2010.³⁴ In terms of future growth, Bennett *et al.* (2009, p. 97) forecast for the GMS and CDS that the number of prescriptions will, other things being equal, increase from 54 million in 2006 to approximately 75-100 million in 2020, with the estimated total pharmaceutical cost increasing 1.4 to 2 fold – from €1.1 billion in 2006 to €1.5-2.3 billion by 2020.³⁵

The projections of Bennett *et al.* (2009) do not take into account the impact of the recession on the demand for pharmaceuticals, the price reductions under the IPHA/HSE agreement, or the possible impact of generic substitution and reference pricing (the latter two were discussed in Chapter 4). As noted above, despite the IPHA/HSE agreement overall pharmaceutical expenditure continued to increase post 2006 no doubt reflecting the key drivers of population growth and ageing, as well as rising expectations, although there has been a moderation in expenditure growth. Some of the recent moderation in pharmaceutical expenditure growth is undoubtedly due to the measures taken by the State and some by the decline in demand due to the recession. Looking ahead the economy will eventually recover from the current recession. However, there will likely continue to be downward pressure on pharmaceutical prices, especially if the recommendations in this report are implemented.

³² Kanavos *et al.* (2011, Figure 1, p. 11) measured over the period 2000-2008.

³³ Borowitz, *et al.* (2011, Figure 15, p. 48) measured over the period 2000-2009.

³⁴ However, the volume of pharmaceuticals continued to rise in 2009 and 2010. This picture is consistent with the record of growth of the full-line wholesalers as presented in Section 5.4.2, while Figure 2.1 details the annual growth on the GMS and CDS.

³⁵ In 2010, PCRS expenditure on pharmaceuticals and payments to community pharmacists had reached €1.9 billion (Chapter 2).

Nevertheless, the overall trends outlined above may not be replicated with respect to full-line wholesalers.³⁶ Under certain assumptions – two-thirds of products on the High Tech Drugs Scheme move to a DTP model, that within twelve months of an in-patent pharmaceutical coming off-patent a generic competitor(s) enters the market and prices drop by 60 per cent and that overall volume grows by 3 per cent per year – the PDF estimate that the sales of full-line wholesalers will decline, perhaps substantially. However, before these forecasts are accepted the accuracy and veracity of these important assumptions would need to be established.

Second, under the GMS and CDS, the price paid to the pharmacy contained an implicit wholesale mark-up. This *mark-up was reduced by the HSE* on the grounds that it was much higher than in other EU Member States and that much of it accrued to pharmacists through wholesalers discounting to attract and retain pharmacy business. In other words, the rents – measured by the reduction in the wholesale mark-up - were captured by the pharmacist not the wholesaler, as evidenced by the widespread protests by pharmacists when the mark-up was reduced. Hence this change should have had little or no net effect on the full-line wholesale model.

Third, it is likely that wholesalers are adversely affected by *bad debt* from the pharmacy sector. This reflects two separate but related issues. *First*, the various supply side measures taken by the HSE in the recent past aimed at reducing the wholesale mark-up are likely to have placed at least some pharmacy businesses under financial stress, especially if they had purchased pharmacy premises at inflated prices.³⁷ This, combined with the severity of the recession, may have knock-on effects on their ability to pay wholesalers. *Second*, to the extent that wholesalers are involved in pharmacy operations either directly through ownership or via assisting pharmacists purchasing pharmacies, then it is likely that wholesalers will be experiencing financial difficulties. Uniphar, with its IPOS scheme for assisting young pharmacists to purchase pharmacies, has had to take significant impairment charges: in 2008 these amounted to €97 million (Uniphar, 2009, p. 5). Celesio, the owner of CMR and the Unicare/DocMorris pharmacy chain, recorded a fall in revenue from its Irish pharmacy business of 6.3 per cent in 2010 compared to 2009 (Celesio, 2011, p. 70). United Drug has no direct ownership interest in retail pharmacy.³⁸

The impact of bad debt due to the recession and HSE policy changes has varied by wholesaler. Nevertheless, these difficulties reflect business decisions taken by these wholesalers and it is not at all clear that it has any implications for the wholesalers'

³⁶ This paragraph is based on unpublished estimates by the PDF.

³⁷ However, as we shall see in Chapter 6, community pharmacy numbers increased through the recession, albeit at a declining rate, while the exit rate has remained more or less constant.

³⁸ However, United Drug has provided "...significant guarantees ... to retail pharmacists to assist in start-up costs" (HSE, 2007).

business model, as opposed to individual wholesalers. Furthermore, to a considerable extent these bad debts reflect cyclical factors such as the property bubble bursting and weakness in retail demand and thus do not provide a sound justification for revising the current business model.³⁹ Finally, businesses in many sectors of the economy are contending with high levels of bad debts at the current time, so it is difficult to justify why pharmaceutical wholesalers should be singled out for special treatment.

Fourth, there may be cherry picking by short-line wholesalers that distribute parallel imports, with which the full-line wholesalers have difficulty competing. The parallel importer is able to import the in-patent single source pharmaceutical from another Member State and offer discounts and rebates that the full-line wholesaler cannot meet unless the brand name manufacturer drops its price to the wholesaler. These parallel imports are likely to compete with the more recently introduced higher priced pharmaceuticals where the wholesalers' percentage mark-up provides a valuable source of revenue. The wholesalers identify parallel imports as a source of competition and revenue loss (United Drug, 2011, p. 6; Uniphar, 2009, p. 15; 2010, p. 12; 2011, p. 12). Although full-line wholesalers have traditionally not distributed parallel imports, no doubt reflecting their pre-wholesaling agreements with the brand name manufacturers, in 2011 the three full-line wholesalers started or expected to start the distribution of parallel imports.

Fifth, there may be cherry picking by brand name manufacturers through DTP. Such a model is applied in the UK and since many of the same brand name manufacturers operate in both jurisdictions then the model may become more widely used in Ireland.⁴⁰ However, one of the reasons it is used in the UK – apart from claims of increased efficiency – is the desire by the brand name manufacturers to capture the discounts received by pharmacists from wholesalers.⁴¹ Given the recent reduction in the wholesale margin by the HSE, this is much less likely to be the case in Ireland. Nevertheless, if the DTP model became widespread then there may be a danger that this could lead to a fall in the quality of service standards to pharmacies (e.g. less frequent deliveries) which might affect the standard of patient care provided by the pharmacist.⁴² However, the penetration of the DTP model has been very limited to date in Ireland and we do not have any evidence that it has led to a decline in service quality.

³⁹ In the case of the bursting of the property bubble there is also likely to be a structural element as well.

⁴⁰ For a discussion of the DTP model in the UK see Office of Fair Trading (2007) and more generally Macarthur (2007).

⁴¹ As noted above in the sample of countries used by Indecon (2007) the only country with a wholesale mark-up over 10 per cent, apart from Ireland, was the UK.

⁴² This is argued in an Office of Fair Trading (2007) report on wholesale pharmaceutical distribution in the UK.

In sum, it is not clear that the reduction in the wholesale mark-up or possible reduction in pharmaceutical expenditure has any implications for the viability of the full-line wholesaler model. In the latter case, for example, this may result in a decline in the number of full-line wholesalers, rather than an abandonment of the model. Although competition would not be as strong with two full-line wholesalers as three, pharmacists would still be able to play one off against the other. Impairment changes may threaten some wholesalers more than others, but it is not at all clear that it threatens the full-line wholesaler model as such. However, this is not the case with respect to cherry picking implied by parallel imports or DTP. On the first issue, full-line wholesalers are either selling or expect to sell parallel imports, while DTP is in its infancy. Nevertheless, we will return to the latter issue in the conclusions to the chapter.

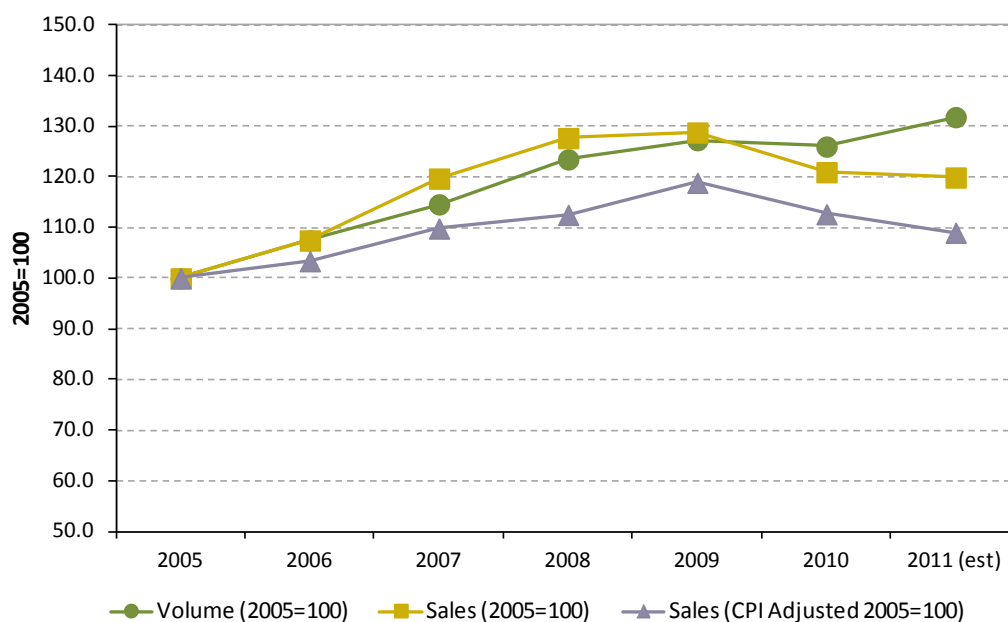
5.4.2 Full-Line Wholesaler Survey

In order to gain a better understanding of the position of the three full-line wholesalers, we undertook a survey in relation to sales, measured both in value and volume, as well as a measure of the major costs of the three full-line wholesalers.⁴³ The survey was confined to the prescription pharmaceutical business and operations in Ireland and covered the period 2005 to 2010 with a forecast for 2011. Details for hospital and community pharmacy operations were broken out separately for some purposes. Since the wholesaling market is competitive, it was of course necessary for each wholesaler to respond to the survey separately. In presenting the survey results the data are aggregated in such a way that individual wholesalers cannot be identified.

All three full-line wholesalers stock a large number of pharmaceuticals, when measured by the number of SKUs – around the 12,500 figure referred to above. The volume of sales of the three full-line wholesalers, taken together, measured in terms of SKUs, increased year on year, over the period 2005 to 2011 (Figure 5.1). The only exception was a decline in 2010 with a strong recovery in 2011 to exceed the 2009 sales volume. A similar pattern up to 2010 is repeated for sales measured in value, whether measured in real or nominal terms (Figure 5.1), but the sales do not recover their previous highs.

⁴³ Annex D contains a copy of the covering letter and the survey itself.

FIGURE 5.1 Full-Line Wholesalers, Total Sales, Volume and Value, Ireland, 2005-2011



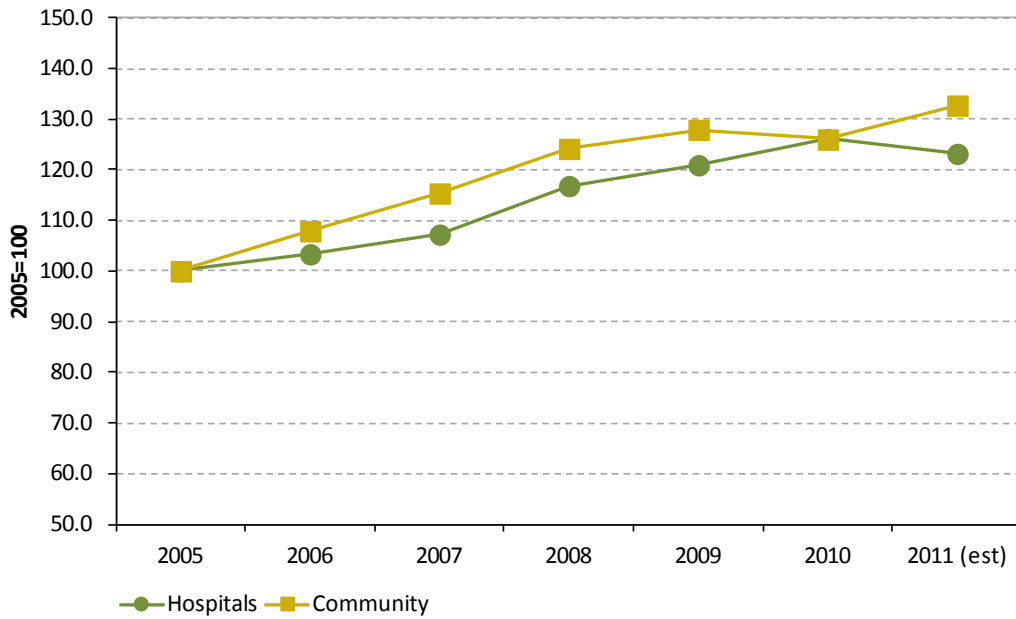
Notes: Volume measured by number of SKUs.
Total sales includes both hospital and community sales.

Source: Full-line Wholesaler Survey.

The pattern of sales by value and volume reflects a number of factors. *First*, the volume and value decline reflect the market penetration of parallel imports which took market share from the full-line wholesalers. One way of testing for this is the pattern of sales in the hospital and community pharmacy sector, since parallel imports are more likely to penetrate the community than the hospital sector.⁴⁴ The data in Figure 5.2, which presents trends in the volume of SKUs by each sector, is consistent with this view. There is no decline in the volume of sales in the hospital market for 2010 except for a small decline forecast for 2011, but there is in the community sector, although recovery in community sales is forecast for 2011. In part the change in 2011 might be that the hospital sector is shifting some of the GMS and CDS expenditure to the community sector. In other words, but for this change hospital sales of the full-line wholesalers would continue to have risen while community sales levelled off.

⁴⁴ Based on interviews with parallel importers and hospital pharmacists. See also Chapter 4.

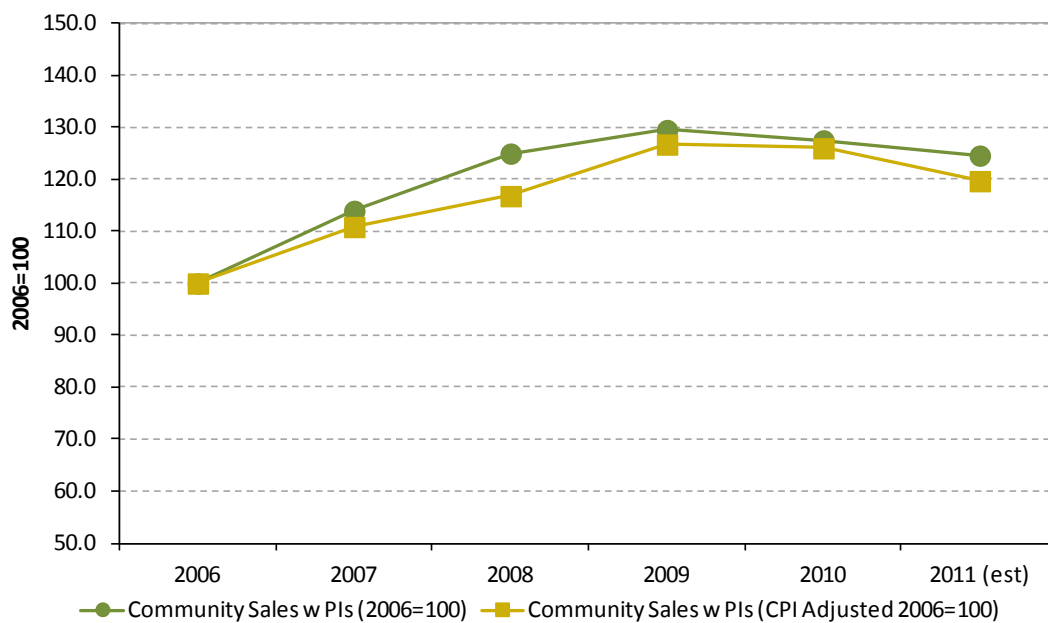
FIGURE 5.2 Full-Line Wholesalers, Community and Hospital Sales, Volume, Ireland, 2005-2011



Note: Volume measured by number of SKUs
 Source: Full-Line Wholesaler Survey

A *second* way of determining the influence of parallel imports is to add parallel imports to the sales of full-line wholesalers. The data is available for 2006 to 2011 but for community sales only. Parallel imports rose from €50 million in 2006 to peak at €250 million in 2010, before being expected to decline in 2011 to €220 million.⁴⁵ The results are presented in Figure 5.3. This shows sales levelling off in nominal and real terms in 2010, and falling into 2011.

⁴⁵ These data on parallel imports were provided by the PDF based on IMS.

FIGURE 5.3 Community Pharmaceutical Sales, Full-Line Wholesalers and Parallel Imports, Ireland, 2006-2011

Source: Full-line Wholesaler Survey and information provided by the PDF.

The full-line wholesaler survey also asked questions on the structure of the wholesaling distribution function. While aggregating volume and value of sales across the three full-line wholesalers is comparing like with like, the same does not necessarily apply to the breakdown of costs, since not all of the three full-line wholesalers used comparable breakdown of costs of wholesaling and distribution. Nevertheless, for all three full-line wholesalers wages and salaries formed by far the largest component of costs.

As noted above, cherry picking by parallel imports and DTP sales may have raised questions concerning the viability of the full-line wholesaler model. However, whether revenue covers costs reflects other factors such as the recession, the efficiency of the wholesalers, and prescribing practices of medical practitioners. Isolating the impact of any one influence is likely to be a difficult exercise. Hence these caveats need to be borne in mind in interpreting cost and revenue data.

In order to see whether the full-line wholesalers are covering their costs, we took the net revenue, or income earned, by the full-line wholesalers, and then subtracted from it the costs of distribution. It is assumed that wholesalers make a mark-up of 8 per cent on community sales and zero on hospital sales. The assumption concerning the wholesale margin reflects the discussion above on the reduction of the wholesale mark-up, while the full-line wholesalers argued that there was no mark-up

on hospital sales.⁴⁶ All costs are totalled, except bad debts.⁴⁷ For the purposes of this illustration, the costs have been accepted at face value and we have not audited them. The difference between income and cost is the return to the wholesaler. In each year between 2005 and 2011, wholesalers, as a group, cover their costs. If income is expressed as a percentage of total sales (i.e. community and hospital), the data show the resulting price-cost margin increased steadily from 2005 to 2007, before declining subsequently. Hence like other sectors of the Irish economy pharmaceutical wholesalers have experienced falling returns, but as a group, continue to cover their costs.

5.5 ALTERNATIVE MODELS

It is not at all clear that the current full-line wholesale or traditional model is broken. Nevertheless, apart from general macroeconomic conditions which are affecting all business sectors, there are threats to the model, the largest of which appears to be cherry picking either due parallel imports or, perhaps in the future, DTP. Alternative models have been proposed to address these concerns:

- Public Service Obligation model under which all wholesalers, irrespective of whether they are full or short-line, would be required to adhere to the same standards of service, including distributing all 12,500 SKUs. Brand name manufacturers would still be able to use the DTP model, but would be required to supply their entire range of SKUs to wholesalers; and/or
- Instead of a mark-up over the ex-factory price, wholesalers would be reimbursed for their wholesaling service provision through a fee per SKU or a deregressive mark-up (i.e. the mark-up varies inversely with the ex-factory price). There has been a trend towards such pricing models in the EU.⁴⁸

5.5.1 Cherry Picking: Why a Problem?

Cherry picking can only pose a threat to the stability of the current model if cross-subsidies from high profitability products to low profitability ones are essential to sustain full-line supply. In other words, the threat must involve a loss of sales of high profitability items so great that profits from the sales of the remaining items become negative. Whether this is so depends upon two factors: the relative importance of revenues from items vulnerable to competition; and, the relative costs of supplying these classes of items. If it is a material threat, regulatory responses may address the

⁴⁶ If the total sales of the three full-line wholesalers to community pharmacies are TPHS, then wholesaler revenue is: $(TPHS \times 0.85) \times (0.08)$. TPHS includes the 17.66 per cent wholesaler mark-up, since the reduction in wholesale margins discussed in Section 5.3 affected the reimbursement price paid to pharmacies, not the wholesale price to the pharmacy.

⁴⁷ The costs of wholesaling distribution are those listed in the full-line wholesaler survey in Appendix D.

⁴⁸ At the present time six Member States use the wholesale mark up model (including Ireland), 11 employ a deregressive mark up, two use a mixture of a fixed fee and a mark-up and seven use a fee for service model. Based on a personal communication, European Association of Pharmaceutical Full-Line Wholesalers, 3 October 2011.

revenue or cost sides of the market. However, as discussed above it is not at all clear that recent economic, institutional and other changes have made the current model untenable.

5.5.2 Revenue-Side Solutions: A PSO

One revenue-side response might be to impose a Public Service Obligation (PSO) on all wholesalers whereby they would all be required to carry the full 12,500 items that the full-line wholesalers carry. However, the introduction of the PSO would likely have adverse effects on competition and the development of new models of distribution.

A PSO would dampen competition between the full-line and short-line wholesalers. The latter would be required to invest in facilities similar to full-line wholesalers, which given the uncertainty surrounding parallel imports price advantage on a medium to longer term basis and the fact that there are already three full-line wholesalers, is likely to mean that parallel importers would exit the market.⁴⁹ While full-line wholesalers are beginning to respond to the threat of parallel imports by distributing these pharmaceuticals, given their pre-wholesaling agreements combined with the PSO, they may discontinue distribution of parallel imports. This is likely to eliminate the possibility of the HSE taking advantage of parallel imports to secure better value for money, but also adversely affect trade between Member States and thus may breach EU law on free movement of goods.

A PSO that compelled brand name manufacturers to supply all their products to full-line wholesalers is likely to reduce the attractiveness of the DTP model. If the DTP model is designed to give the brand name manufacturer greater control over the distribution of their product portfolio and realise efficiencies through selecting one or more LSPs, then having to supply all wholesalers removes the rationale for DTP. Hence a PSO requirement is likely to reduce the attractiveness of the DTP model as well as stifle the development of alternative distribution models.

Even if a PSO-type mechanism were considered desirable, regulators in others sectors such as air transport and electronic communications have recently developed PSO models that are more efficient than a blanket requirement on all suppliers. The option used to ensure that broadband connections are available in rural areas (the National Broadband Scheme) and (until recently) to provide for regional air connections is to tender for the minimum subsidy required for a single firm to provide the unprofitable element of coverage. After all, the logic of a PSO is

⁴⁹ This point is reinforced by the observation of excess capacity in the full-line wholesalers distribution depots (Competition Authority, 2004, pp. 20-21).

that *someone* should provide universal coverage, not necessarily that *everyone* should do so.

A variant of the PSO is a duty on all pharmaceutical firms to supply, subject to usual and customary conditions, the full range of products to full-line wholesalers. However, this seems to be similar to the PSO, although not exactly the same. The duty to supply would remove the advantage of the DTP model for the pharmaceutical manufacturer. However, the duty to supply would not have the other unattractive features discussed above. Nevertheless, it would interfere with the choice of distribution models that pharmaceutical manufacturers could select.

In sum, the evidence does not suggest that introducing a PSO requirement that requires all wholesalers to replicate the product offering of the full-line wholesalers is merited as a way of preventing cherry picking. Full-line wholesalers are currently distributing, or expect to market, parallel imports to pharmacies, while the DTP has limited market penetration. A PSO which would restrict competition and discourage new forms of wholesale distribution is a disproportionate response. The duty to supply, while not so onerous would, nevertheless limit the options of the pharmaceutical manufacturer.

5.5.3 Cost Side Solutions: Fee Per Pack

A possible *cost side response* would be a *fee per SKU method of pricing*, so as to gear the compensation for carrying each type of item more closely to the cost of doing so, thereby removing the need for cross-subsidies. However, the case for doing this rests more on what is economically efficient than on the unsustainability of the overall model. A fixed fee reflects the fact that the cost of distributing one SKU differs little from another, apart from obvious differences such as whether or not cold storage is used. Agency distribution models, such as DTP, often charge a fixed fee per item distributed. Furthermore, in the mark-up model there is a danger that for certain low cost items that the mark-up may be insufficient to cover the cost of distribution. Hence there is a danger that efficiency and security of supply may be undermined.

However, it could be argued that it is inappropriate to consider each item on its own. The wholesaler provides a full service to the pharmacist and considers the overall revenue situation. It is vital from a competitive point of view for a full-line wholesaler to be able to provide such a service. Furthermore, it is important to make the distinction between the average and marginal cost. While the mark-up on some low cost items may not be sufficient to cover the average wholesale cost, it may nevertheless be the case that the marginal costs are covered. In other words, the

full-line wholesaler obtains a large portion of its revenue from a small number of SKUs – the high selling in-patent pharmaceuticals – which more than cover the costs and there is a tail of lower cost SKUs which given the fixed costs already incurred for the high volume, have a low marginal cost of distribution. Thus, it is not at all clear that a wholesale model which relies on an average fee per SKU is superior to the current mark-up model.

In sum, it does not appear that there is a compelling case that recent events have provided sufficient grounds for revising the business model of wholesalers. Furthermore, at least some of the wholesalers' statements suggest that they can cope with the current situation. For example, United Drug (2011, p. 6) state that "[W]hilst it is likely that austerity measures will continue in the current economic climate, United Drug has proven that it is in a strong position competitively to deal with these measures and can continue to grow revenue and market share." Celesio (2011, p. 76) continues to invest in CMR.

Nevertheless, it could be argued that there is an inconsistency between the recommendation in Chapter 6 for a fixed dispensing fee and the rejection of a fixed distribution fee for the wholesaling function. However, that view would be mistaken for two reasons. *First*, abolition of the current percentage mark-up for the pharmacist removes the incentive for the dispensing of higher priced pharmaceuticals. The wholesaler, in contrast, is not able to influence the pharmaceuticals purchased by the pharmacist or prescribed by the medical practitioner. *Second*, there is limited competition in community pharmacy for patient business whereas there is competition amongst wholesalers for the business of pharmacies. By switching the compensation of pharmacists to a fixed dispensing fee, this can be advertised by pharmacists to attract patients and thus encourage community pharmacy competition.

5.6 CONCLUSION

The wholesale function is an important bridge between the manufacturer and the pharmacist. The evidence suggests that there is vigorous competition between the three full-line wholesalers. The market appears to work well. Government intervention has consisted primarily of clawing back rents through a reduction in the wholesale margin in the distribution chain that were largely accruing to the pharmacist not the wholesaler. While it is the case that the current recession and policy moves have placed wholesalers under financial pressure, this is insufficient reason to change the wholesalers' current business model. Many other sectors are experiencing falling profits and demand. Government policy needs to create the conditions for the overall growth of the economy, not come to the assistance of every sector that may be in difficulty with tailor made interventions.

However, there are some issues that might raise concerns over the DTP model. Under this model the brand name manufacturer sets the quality standards. A recent Office of Fair Trading (2007, p. 9) study on pharmaceutical distribution, although it reached no view on the merits of DTP as compared to the traditional wholesale distribution model, concluded that, "DTP schemes have the potential to impact on the service levels provided to pharmacies and the service levels that they can in turn offer to patients." Since DTP has limited penetration in Ireland these potential concerns are not likely to be realised in Ireland. Furthermore, under the relevant regulation, in Ireland wholesalers, irrespective of whether they are full-line or DTP, have to "...ensure appropriate and continued supplies [to pharmacists and other healthcare professionals] so that the needs of the patients in the State in respect of such medicinal products are covered."⁵⁰ Nevertheless:

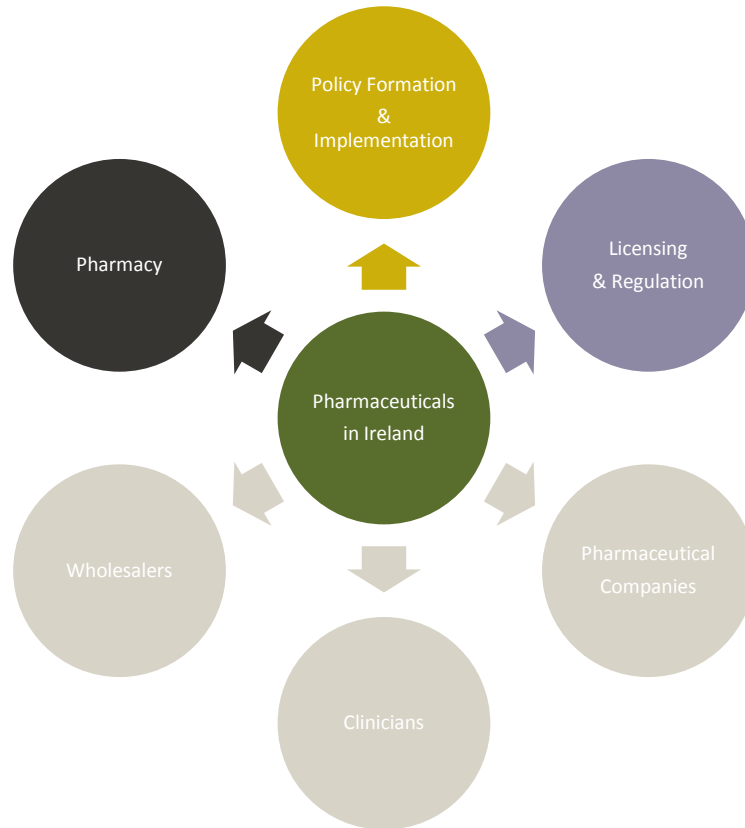
Recommendation 5.1: We recommend that the HSE actively monitor the importance and service levels offered by DTP brand name manufacturers. If the service levels fall below levels considered acceptable to the HSE, then it should negotiate minimum quality standards with brand name manufacturers using the DTP model.

This we feel is a proportionate response to recent developments in the wholesale pharmaceutical sector.

⁵⁰ Schedule 2 paragraph 11 of S. I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

Chapter 6

Pharmacy Services: The Dispensing Function



6.1 INTRODUCTION

The dispensing role of the pharmacist brings together the supply and demand sides of the pharmaceutical chain. On the supply side the pharmacist is the last stage in the distribution chain from the supplier or manufacturer and the wholesaler to the patient; on the demand side, the patient presents the prescription written by the prescriber who has assessed the patient's condition and decided that a pharmaceutical is the appropriate course of treatment. The role of the pharmacist is to dispense the pharmaceutical deemed appropriate by the prescriber, together with associated services. There may, of course, be interaction between the pharmacist and the prescriber, if the former has concerns over the pharmaceutical prescribed (e.g. the quantity).

In this chapter the function and role of the pharmacist is first set out (Section 6.2), before attention turns towards HSE policy towards the reimbursement of the dispensing function under the GMS and CDS (Section 6.3). The section also considers

how the move to the new model of pharmacy reimbursement, with its greater emphasis on the dispensing fee component, can be advanced. Next attention turns in Section 6.4 to the inter-relationship between pharmacy costs and restrictions on advertising and the provision of information to patients. Alternative models of delivery of the dispensing function are the subject of Section 6.5. Section 6.6 concludes.

There are certain issues which have already been dealt with concerning the dispensing role in previous chapters and hence do not need to be rehearsed here. In particular reference pricing and generic substitution (Chapter 4) and the reduction in the wholesale mark-up implicit in the reimbursement price paid to pharmacies by the State (Chapter 5) are not discussed in this chapter.

6.2 THE DISPENSING ROLE AND FUNCTION

The pharmacist is responsible, on receipt of a valid prescription, for dispensing the pharmaceutical(s) stated on the prescription to the patient.¹ The pharmacist may also provide the patient with advice on when (e.g. after a meal), how (e.g. with water) to take the pharmaceutical, where to store the pharmaceutical (e.g. in the fridge) as well as inform the patient on the possible side-effects of the pharmaceutical. In addition, where the patient is taking several pharmaceuticals the pharmacist may provide information on possible adverse reactions. For a patient that may have difficulty complying with the pharmaceutical regimen, the pharmacist may furnish the patient with a dose administration aid which makes compliance easier (e.g. monitored dosage systems whereby all pharmaceuticals to be taken at breakfast, lunch and dinner are grouped separately by time of consumption). Recently, the role of the pharmacist has been extended to include the provision of the seasonal influenza vaccine² and the dispensing of emergency hormonal contraception (which was switched from a prescription-only to an OTC basis in February 2011 (Donnellan, 2011)).

6.2.1 Growth in Pharmacy Businesses

Pharmacy services are provided through pharmacies. Apart from the fact that for each pharmacy business there has to be a supervising pharmacist with at least three years experience and various other regulatory requirements concerning record keeping and a patient consultation area,³ there is no limitation on the overall

¹ The Code of Conduct (PSI, 2009a) sets out what is expected of the pharmacist. More detail in relation to dispensing is found in Section 9 of S. I. No. 488 of 2008 Regulation of Retail Pharmacy Businesses Regulations 2008 and Clause 9 of the 1996 CPC Agreement.

² For details see: http://www.thepsi.ie/gns/pharmacy-practice/current-developments/Seasonal_Influenza_Vaccination.aspx. Accessed 16 December 2011.

³ These are set out in S. I. No. 488 of 2008 Regulation of Retail Pharmacy Businesses Regulations 2008.

number of pharmacy businesses nor on how many can be owned by a chain pharmacy.⁴ Furthermore, pharmacies can be owned by non-pharmacists. Internet sales of pharmaceuticals are prohibited, but not OTC products.⁵

In 2011, there were 1,734 pharmacy businesses registered with the Pharmaceutical Society of Ireland (PSI).⁶ A separate business is registered for each pharmacy outlet, irrespective of whether or not it is part of a pharmacy chain. The vast majority of pharmacy businesses are community or retail, with the remainder classified as hospital pharmacy businesses (Table 6.1). In 2011, for example, 95.7 per cent of pharmacy businesses were community outlets. The number of pharmacy businesses has gradually increased, year-on-year, from 1,372 in 2004 to 1,734 in 2011 or by 26 per cent.⁷ The rate of openings has dropped from a peak of 9.3 per cent in 2005, to 1.9 per cent in 2011. Closings have generally remained at 1.6 per cent or less since 2006. Hence despite the deep recession that started in 2008 and the reductions in wholesale and retail margins under the State pharmaceutical schemes, the number of pharmacy businesses has continued to increase.⁸

TABLE 6.1 Pharmacy Businesses, Community and Hospital, Openings and Closings, Ireland, 2004-2011

	Community	Hospital	Total	Openings		Closings	
	N	N	N	N	N/Total	N	N/Total
2004	1,323	49	1,372	55	4.0	n.a.	
2005	1,419	49	1,468	137	9.3	41	2.8
2006	1,510	50	1,560	95	6.1	7	0.4
2007	1,567	61	1,628	68	4.2	0	0.0
2008	1,608	72	1,680	66	3.9	14	0.8
2009	1,628	76	1,704	51	3.0	27	1.6
2010	1,652	76	1,728	43	2.5	19	1.1
2011	1,659	75	1,734	34	1.9	22	1.3

Notes: Openings are defined as new openings and exclude relocations and transfer of ownership; closings are defined as closure of existing businesses and exclude relocations and transfers of ownership. The data for 2011 refer to events as of 1 July 2011. However, in order to estimate the number of openings and closings for 2011 it was assumed that the same number of openings and closings occurred in the second half as occurred in the first.

Source: Pharmaceutical Society of Ireland, *Annual Report*, various years, and PSI, personal communication, 15 September 2011.

6.2.2 The Importance of Pharmacy Chains

Pharmacy chains, under which two or more pharmacy businesses are under common ownership, are of limited importance. In 2007, for example, the largest pharmacy

⁴ It should be noted that between 1996 and 2002 there were regulations that limited the entry of new pharmacy businesses. For details and discussion see Gorecki (2011). The PSI (2009b) in a recent submission argued unsuccessfully for reintroduction of such restrictions on entry.

⁵ As noted in Chapter 1, the terms pharmaceutical as used in the report refers to prescription pharmaceuticals.

⁶ The PSI is "...an independent statutory body, established under the Pharmacy Act 2007. ... charged with ... the effective regulation of pharmacy services in Ireland." The quote is taken from the PSI's website: <http://www.thepsi.ie/gns/about-psi/overview.aspx>. Accessed 13 September 2011. The PSI is governed by a 21 member board, with a non-pharmacist majority appointed by the Minister for Health.

⁷ This increase applied to both community or retail and hospital pharmacy businesses.

⁸ This seems inconsistent with the views of the IPU (2009) as to the impact of margin reductions and other changes made under FEMPI.

chain had 58 outlets accounting for 3.7 per cent of all community pharmacy businesses (Table 6.2). The seven chains with 16 or more outlets accounted for only 13.3 per cent of all community pharmacy businesses. Single outlet pharmacies accounted for 55 per cent of all community pharmacies in 2006 (PwC, 2007, Table 1). Non-pharmacist ownership accounted for only 12 per cent of outlets (*ibid*, Table 2).

It appears that since 2007 there has been a gradual increase in the importance of the leading pharmacy chains, but the share of community pharmacies accounted for such chains is still modest (Table 6.2). As noted in Chapter 5, Unicare/Doc Morris currently has around 70 pharmacies or 4.2 per cent of community pharmacies in 2011, while Boots has 63 pharmacies⁹ or 3.8 per cent of community pharmacies in 2011. In contrast, the McSweeney pharmacy chain has 18 outlets in 2011, down from 28 pharmacy businesses in 2007.¹⁰ Nevertheless, the majority of pharmacies – 52 per cent – were still single outlet in 2011.¹¹ Non-pharmacist ownership accounted for 15 per cent of all community pharmacies in 2011; such ownership was especially important with respect to chain pharmacies.¹² In terms of new entry, in November 2011 Tesco Ireland, the largest grocery supermarket chain, announced the opening of three in-store pharmacies with up to 10 more planned over the next two to three years.¹³

TABLE 6.2 Community Pharmacy Businesses, Leading Pharmacy Chains, Ireland, 2007 and 2011

Pharmacy Chain	Number of Outlets		Share of All Community Pharmacies	
	2007	2011	2007	2011
	N	N	%	%
Unicare/Doc Morris	58	70	3.7	4.2
Boots	41	63	2.6	3.8
McSweeney	28	18	1.8	1.1
Hickeys	26	20	1.6	1.2
Sam McCauley	22	25	1.4	1.5
McCabes	17	21	1.1	1.3
Bradleys	16	16	1.0	1.0
Others	1,359	1,426	86.7	85.9
Total	1,567	1,659	100	100

Note: The identity of the leading pharmacy chains was taken from Macarthur (2007) for 2007, with the number of outlets of stores for 2011 was taken from the websites of the individual chains.

Source: Macarthur (2007, Table 3.3, p. 58), the websites of the leading pharmacy chains, and Table 6.1.

⁹ For details see <http://www.boots.ie>. Accessed 14 September 2011.

¹⁰ For details see <http://www.mcsweeneygroup.ie/>. Accessed 13 September 2011.

¹¹ For details see IPU (2011a, p. 13). The estimate is based on the IPU membership.

¹² *Ibid*, p 13. Non-pharmacists owned 28 per cent of chain pharmacies, but only 9 per cent of non-chain pharmacies. A chain pharmacist owned two or more community pharmacies.

¹³ Tesco personnel communication, 24 June 2011 and media reports 3-4 November 2011. Note that prior to November 2011 four pharmacies operated in Tesco stores on a franchise basis.

6.2.3 Pharmacies, Pharmacists and the Population Served

Ireland has a low average number of pharmacists to pharmacies and a low ratio of population per pharmacy (Table 6.3). Low in this instance is measured relative to five other jurisdictions – Great Britain, Northern Ireland, New South Wales (Australia), British Columbia (Canada) and New Zealand - that were selected by the PSI in conducting a study of the level of registration fees that the PSI should charge. These data suggest that for this sample of jurisdictions that Ireland has relatively small scale pharmacy outlets measured in terms of the population served and the number of pharmacists per pharmacy.

TABLE 6.3 Pharmacy, Pharmacies, and Population, Comparative Data for Six Jurisdictions, 2006

Jurisdiction	Average Number of Pharmacists per Pharmacy	Population per Pharmacy (N)
Great Britain	3.03	4,571
Northern Ireland	3.54	3,428
New South Wales	4.50	3,902
British Columbia	4.02	4,333
New Zealand	3.11	4,602
Ireland	2.68	2,771

Source: PSI (2008a, Figure 3, p. 13).

6.2.4 Composition of Pharmacy Sales: Prescription, OTC and Other Products

Community pharmacy businesses typically not only dispense pharmaceuticals, but also sell a variety of other products, such as beauty products, and over-the-counter pharmaceuticals (OTC) products. In 2005, for example, pharmaceuticals accounted for 67 per cent of community pharmacy turnover, OTC, 14 per cent and other sales 19 per cent (PwC, 2007, Figure 3). This is a similar distribution to a 2001/02 survey, where the corresponding percentages were 61, 20 and 19, respectively (Indecon, 2002, Table 6.5, p. 43).¹⁴ The majority of pharmaceutical sales of community pharmacies are funded by the GMS and CDS – 72 per cent in 2001/02 (*ibid*, Table 6.3, p. 42) and 81 per cent in 2005 (PwC, 2007, Figure 3).¹⁵ Nevertheless, a substantial proportion of pharmaceutical expenditure is accounted for by out of pocket or cash payments, which is likely to increase with the raising of the DP Scheme threshold to €132 in 2012.

¹⁴ Differences between the two data sources may be due to different survey methodologies and the fact that PwC (2007) excludes VAT from turnover while Indecon (2002) appears to include VAT in its turnover measures.

¹⁵ These data refer to payments made under the GMS and CDS. Hence expenditure below the DP Scheme threshold is not included as funded by the State.

6.2.5 Provision of Information to Patients

In providing pharmacy services to the patient pharmacists are required, according to the PSI Code of Conduct:

Provide honest, relevant, accurate, current and appropriate information to patients regarding the nature, cost, value and benefit of medicines, health-related products and services provided by them. (PSI, 2009a, n.p.)

Such information might, for example, explain not only matters in relation to how the patient should take the pharmaceutical but also how the pharmacy set the price for dispensing a prescription. Typically, this consists of a dispensing fee, mark-up (in some cases) and the ingredient or pharmaceutical cost. If the patient is a cash paying customer then the retail price includes a mark-up of between 20 and 50 per cent.¹⁶ The pharmacist has to dispense the prescription as written. The dispensing fee is fixed. However, it is not clear how often such information is imparted to patients, if at all. In terms of the cost information readily available in the pharmacy there is typically no posting of pricing information, such as the dispensing fee, while the information contained in the receipt issued when purchasing a pharmaceutical is limited.¹⁷

In 2009 the PSI clarified the meaning of the Code of Conduct with respect to advertising and promotion of medical products on the basis of price or quantity discounts in *Practice Notice No. 5*,

... the position is that neither the regulatory provisions, nor the professional codes in place, permit or support the advertising or promotion of medicinal products to the public on the basis of price or quantity discounts (PSI, 2009c).

The PSI's position on advertising and promotion of pharmaceuticals was subsequently restated and elaborated in October 2011 in *PSI Guidance to pharmacists in relation to the advertising, promotion and sale of medicinal products, and related matters* (PSI, 2011b). This replaced *Practice Notice No. 5*. Not only were discounts deemed inappropriate advertising and promotion, but also the use of sales

¹⁶ While there is no maximum mark-up for the cash paying customer, 50 per cent has been the traditional pharmacy mark-up. For details see Fair Trade Commission (1957).

¹⁷ The Prescription Claim Form receipt issued to a DP patient, for example, only has the total price as does the till/credit card receipt. Attempts to ascertain how the price was calculated and the magnitude of the mark-up resulted in answers such as "it's all in the machine." (Based on the experience of one of the authors in presenting a prescription to a Dublin pharmacy on 29 August 2011 which was below the €120 threshold). Patients can access information on the ingredient cost (i.e., ex-wholesale price) of the pharmaceutical from a website linked from the main PCRS website (www.sspcrs.ie/druglist/search.jsp). However, the patient must know the levels of fees and mark-ups in order to calculate the final cost themselves.

targets, incentives or similar measures. The use of percentage discounts "...can be regarded as a commodification of medicinal products and may have the effect of distracting patients from making an objective evaluation of their normative needs" (*ibid*, p. 2). Furthermore, as we shall see in Section 6.3, the rules of the GMS and CDS strengthen these restrictions on offering patients information on pricing and/or discounts.

6.2.6 Characterising Regulation and Competition in Community Pharmacy

The delivery of the dispensing function of the pharmacist is heavily regulated, notwithstanding the lack of restrictions on entry and ownership, primarily by the PSI. Although the rules concerning ownership and the overall number of pharmacies is largely deregulated, the provision of information to patients on discounts and prices is severely constrained. The importance of pharmacy chains is limited, while on average pharmacies serve small catchment areas, measured in terms of population and are staffed by a small number of pharmacists. In contrast to other jurisdictions, such as the US and some Member States such as the Netherlands (Macarthur, 2007, p.146) there are no internet pharmacies for the sale of pharmaceuticals, while other retail formats such as supermarkets do not have in-store pharmacies, although this is beginning to change with the November 2011 opening of in-store pharmacies by one supermarket chain.¹⁸ In sum, the retail format of pharmacy in Ireland is a traditional model, albeit with some signs of change.

6.3 REVISING THE PHARMACY REIMBURSEMENT BUSINESS MODEL: INGREDIENT COST AND DISPENSING FEE

In this section we consider the changes that have taken place in the way in which pharmacists are reimbursed, before moving to some suggestions as to how that can be improved, in both the public and private community sector.

6.3.1 The 2011 Reforms: Government Mandated Dispensing Fee Structure

Participation in the GMS and CDS is essential for the survival of community pharmacy businesses (e.g. Purcell, 2004). The vast majority of pharmacy turnover from prescribed pharmaceuticals is accounted for by these programmes.¹⁹ Over the period 2002 to 2007, only 2.1 per cent of pharmacies were without a GMS contract.²⁰ The contractual relations between the HSE and the community pharmacy thus affect the dispensing function for a substantial share of the market and likely influence practice for the cash paying patient.

¹⁸ See discussion in Section 6.2.2.

¹⁹ See discussion in Section 6.2.4.

²⁰ Gorecki (2011, Table 2, p. 525).

Prior to 1970 pharmaceuticals were provided free to certain groups of people through public dispensaries.²¹ However, the Department of Health and Children (DoHC) decided to use an alternative distribution method: the existing network of independent community pharmacies. In order to deliver the service an agreement was needed between the DoHC and individual pharmacists. As a result a template was developed between the DoHC and the representative body for pharmacists, the Irish Pharmaceutical Union (IPU).²² Individual pharmacies then entered into contractual agreements with the local Health Board, all of which subsequently become subsumed under the HSE. The first DoHC/IPU agreement was entered into in 1971, which was revised, with some amendments, in 1996.

The 1996 Community Pharmacy Contractor Agreement for the Provision of Services under the Health Acts (the 1996 CPC agreement)²³ set out the terms and conditions under which the pharmacist supplies pharmaceuticals to eligible persons under the GMS and CDS. It has clauses referring to the dispensing and pharmacy service to be provided by the pharmacist, a prohibition on inducements to persons to select a particular pharmacy, inspection of the pharmacy by the HSE, termination of the agreement, and an optional review of the agreement after five years. Several of the clauses concerning the delivery of pharmacy services were subsequently included in the Pharmacy Act 2007.²⁴

Pharmacies were, and are, reimbursed on a different basis under the GMS and CDS for providing the same dispensing service (Table 2.3). For example, under the GMS the pharmacist received only a fixed dispensing fee, while under the DP the pharmacist received both a dispensing fee and a percentage mark-up over the wholesale invoice cost of the pharmaceutical. These differences no doubt reflected the different circumstances under which the schemes arose. The HSE wanted to reform the reimbursement mechanisms across the various schemes to achieve greater uniformity and to change the basis on which pharmacists were compensated for the dispensing function – towards a model based on a dispensing fee and an ingredient cost where the latter contained no pharmacy mark-up over the wholesale invoice cost. In other words, "...the professional fees paid to [pharmacy] contractors should be decoupled from the ingredient price of medicines dispensed ..." (Dorgan, 2008, para. 4.4).

²¹ The paragraph is based on section 1 of *Haire v MfH&C*.

²² Full details of the IPU may be found on: www.ipu.ie. Note that the IPU subsequently changed its name to the Irish Pharmacy Union.

²³ All references are to the updated 2010 version of the 1996 CPC agreement (HSE, 2010), which includes, for example, references to the HSE rather than the Health Boards and the Pharmacy Act 2007, rather than earlier pharmacy legislation.

²⁴ The Pharmacy Act 2007 marked major changes and reforms to the regulation of pharmacy. For details see: <http://www.thepsi.ie/gns/about-psi/pharmacy-act-2007.aspx>. Accessed 5 October 2011.

After the HSE made an unsuccessful offer of an interim dispensing fee of €5.00 to community pharmacists, pending the completing of a new pharmacy contract, the Minister for Health and Children in early 2008 appointed the Independent Body on Pharmacy Contract Pricing (the Independent Body) to address the issue of the appropriate dispensing fee. The terms of reference stated, in part, that the dispensing fee should "...represent a fair and reasonable price to be paid for the pharmaceutical service currently being provided by community pharmacists to the HSE under the GMS and [C]ommunity [D]rug [S]chemes" (Dorgan, 2008, para. 1.3). The Independent Body took the view that fair and reasonable meant, "...as the rate that might reasonably pertain under competitive conditions" (*ibid*, para. 5.1).

The Independent Body also took the view that given the heterogeneity of costs that a single fixed dispensing fee would be inappropriate and thus recommended a tiered structure depending on the volume of prescriptions dispensed by the pharmacy (Table 6.4). This structure reflected the "...professional costs of the pharmacist, as the prime resource in pharmacy, to which are added other staff and overhead (including financial) costs" (Dorgan, 2008, para. 6.10). Since no agreement was reached between the IPU and the DoHC/HSE as to the fee level and structure, in 2009 the government mandated a fee structure after consultation (Table 6.4). Although the mandated fees are below the recommended fees of the Independent Body, to some extent apples and oranges are being compared. Under the mandated fees regime the DP Scheme retained a mark-up, albeit 20 per cent not 50 per cent. Nevertheless, the mandated fee structure combined with the reduced mark-up was a significant move towards decoupling the professional fee of the pharmacist from the pharmaceutical cost.

TABLE 6.4 Pharmacy Dispensing Fee: Independent Body Recommendation and Government Mandated Fee, 2008 and 2009^a

Number of Items Dispensed Per Annum	Independent Body Recommended Fee (2008)	Government Mandated Fee (2009)
Less than or equal to 20,000	€7.00	€5.00
20,001 to 30,000	€6.50	€4.50
Over 30,000	€6.00	€3.50

Notes: a Dispensing fee excluding any mark-ups.

Sources: Dorgan (2008, Table 5.1, p. 27) and S. I. No. 246 of 2009, *Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2009*, Table 1.

6.3.2 Taking the Reforms Forward: Strengthening the Importance of the Dispensing Fee

There are good arguments that the appropriate method of reimbursement for the pharmacist is a dispensing fee rather than a combination of a mark-up and a dispensing fee. As the HSE observed it decouples the compensation paid to the pharmacist from the cost of the pharmaceutical. The pharmacist has no incentive to dispense higher priced products since there is no mark-up. If anything the pharmacist has an incentive to stock and dispense lower priced products since that will reduced inventory costs. Furthermore, as the IPHA argue a dispensing fee reflects that what is being supplied is a professional service by the pharmacist in performing the dispensing service.²⁵ In other words, the pharmacist is not seen as a retailer selling a product to a patient where the usual method of charging is a mark-up, but rather as supplying a professional service. As such it fits with the widening number of professional services provided by pharmacists, including the administration of seasonal influenza vaccine and the dispensing of emergency hormonal contraception. Hence:

Recommendation 6.1: We recommend that pharmacists are compensated for dispensing a prescription on the basis of a professional dispensing fee only. This should apply to both prescriptions dispensed under the GMS and Community Drug Schemes as well as for the cash paying patient.

The ingredient or pharmaceutical cost will be priced as set out in Chapter 4. It would still be permissible for pharmacists to receive discounts from wholesalers where orders reflect efficiency gains such as electronic ordering and prompt payment. Furthermore, we accept that pharmacists are likely to receive and seek additional discounts from dispensing parallel imports and generic products. However, rather than seeking to ban such discounts, the HSE should monitor the incidence of such discounts, as suggested in Chapter 4, and adjust reimbursement prices accordingly.

In terms of implementation for the GMS and CDS, the FEMPI regulations move very much in this direction with a reduction in the mark-up – where it applies – to 20 per cent from 50 per cent (Table 2.5).²⁶ However, for the cash paying customer there is no automatic read across from changes in the public to the private sector. The 50 per cent mark-up is longstanding within retail pharmacy (Fair Trade Commission, 1957). The evidence, albeit anecdotal, is that for the cash paying customer below the

²⁵ As reported in Dorgan (2008, paragraph 4.18).

²⁶ While FEMPI allows the Minister to reduce the rates of payments to community pharmacists contractors, it does not provide for the abolition of payments or the reduction of rates to zero. Switching to a reimbursement system based on a dispensing fee only may be considered as part of the development of the new pharmacy contract.

monthly DP threshold the 50 per cent mark-up has been retained, although the extent is not clear.²⁷ However, this may change with the entry of Tesco into retail pharmacy in November 2011 with its publicly announced policy of a mark-up of 20 per cent and a dispensing fee of €3.50, regardless of whether the individual is above or below the monthly DP threshold.

At one level it is not clear why a different rule should apply to the public and private sector. The HSE has been successful, as a large and powerful buyer of pharmacy services, in changing the basis on which dispensing services are provided under the GMS and CDS. Surely these benefits should also accrue to patients more generally. Such a position is consistent with the discussion in Chapter 3 ensuring that the benefits of better value for money should apply to both the public and private patient. However, limitations on advertising may mean that the pharmacy market is less competitive than it could (or should) be. The answer here is to consider reforming the restrictions on advertising, an issue to which we now turn, rather than relying on direct price controls.

6.4 PHARMACY COSTS, RESTRICTIONS ON ADVERTISING AND THE PROVISION OF INFORMATION

The dispensing fees recommended by the Independent Body and that are mandated under FEMPI are based on the existing structure of pharmacy in terms of the level of costs and in terms of the number and size of pharmacies. The Independent Body stated explicitly that the competitive level of costs and returns are the appropriate benchmark for determining what is fair and reasonable. We agree. However, there are good reasons for concluding that the current level of costs and pharmacy structure are not reflective of the competitive norm. However, it is beyond the scope of this report to adjudicate on the appropriate level of the dispensing fee.

6.4.1 Why Pharmacy Costs Might Be Too High?

At first sight such a conclusion may seem counterintuitive, since entry and exit from the community pharmacy is easy both in theory and practice (Table 6.1), while rules on ownership are relatively liberal. However, there are three sets of reasons for suggesting that despite this pharmacy costs are too high in Ireland. *First*, there are barriers to pharmacy businesses being able to successfully differentiate themselves so as to attract patients. Differentiation takes many forms such as location, service quality (e.g. home delivery, waiting times, opening hours, medicine use reviews and so on) and price (e.g. lower dispensing fee, reduced mark-up). In order to attract patients pharmacies convey, via media, websites and other methods, information in

²⁷ Based on a series of press reports in the *Irish Independent* and the pricing policy of Tesco on entry into the pharmacy market in November 2011. See also Section 2.4.2.3.

order to attract patients. To a considerable extent pharmacies already do this for OTC products and non-pharmaceutical items. The pharmacy businesses that are best able to attract patients grow and prosper.

In community pharmacy in Ireland there are significant barriers to the pharmacy businesses competing for patients through the provision of information to the patient. PSI rules prevent advertising with respect to price or discounts. The PSI restrictions are reinforced by the HSE's interpretation of the 1996 CPC agreement. Under that agreement, clause 4(4) states that:

The pharmacy contractor shall not give, promise or offer to any person any gift or reward (whether by way of a share of, or dividend on, the profits of the practice or by way of discount or rebate or otherwise) as an inducement to or in consideration of his/her presenting, or directing the placing of, an order for medicines.

This clause has been used, for example, to prevent one pharmacy chain that offered to defer the implementation of the €100 co-payment from patients due under the DP until April 2009. In other words, the pharmacy chain undertook to absorb some of the increase in patient co-payment for a limited period.²⁸ Finally, there is no posting of information in relation to the price of a pharmaceutical nor the dispensing fee in a pharmacy or on the receipt.

These rules have the effect of reducing competition between pharmacies. Pharmacies that want to develop a better service may require, for example, a minimum number of patients. Making patients aware of the service through media as well as the price to be charged is one way of generating the required footfall. Equally a pharmacy might through a new way of organising the dispensary be able to offer lower prices.

Second, *pharmacy costs may reflect economic rents* – the wholesale margin, discounts off reimbursement prices for generic pharmaceuticals and parallel imports – which would, in a competitive market be competed away resulting in lower prices. However, in the pharmacy market these rents become, at least in part, capitalised in higher costs – employee compensation and the purchase price of premises. As discussed in Chapters 4 and 5 there are good reasons to assume that there are rents in the pharmaceutical distribution chain that accrue to pharmacies. Admittedly, the recent policy moves of the State, such as lowering the wholesale margin, are likely to

²⁸ Based on the contents of a letter from the HSE to the pharmacy chain chief pharmacist (HSE, personal communication, 30 August 2011).

have reduced these rents; nevertheless, it seems that they have not been eliminated.²⁹

Third, *the size distribution of pharmacies means scale economies are not realised.* The pharmacy dispensing fee structure – either as proposed by the Independent Body or as mandated under FEMPI – suggests that there are economies of scale. In other words, a pharmacy dispensing a higher volume of prescriptions experiences lower dispensing costs per prescription. However, the evidence in Table 6.3 is consistent with the suggestion that pharmacies in Ireland are relatively small in comparison with other jurisdictions. More competition might be expected to result in a change in the number and size of pharmacies, so that the larger more efficient pharmacies increase.

It should be noted that there is nothing inconsistent with pharmacy costs being too high and many pharmacies only making a normal rate of return. As more and more pharmacies enter in response to the rents that can be captured, to some degree that takes patients away from existing pharmacies, whose returns fall. The policy changes designed to reduce wholesale and retail margins, combined with the financial crisis and the bursting of the property bubble, has put further pressure on pharmacies.

6.4.2 Can the Restrictions on Advertising and the Provision of Information be Justified?

This discussion naturally raises the issue of whether or not there are good and valid grounds for the current prohibitions by the PSI on advertising and the provision of information and the restriction contained in the 1996 CPC agreement. We consider each in turn.

The PSI is quite naturally concerned about patient safety and the quality of care. Since advertising and providing information to consumers is usually undertaken, in part at least, to increase demand, the PSI might be concerned that advertising by pharmacies might lead to increased consumption of pharmaceuticals which might lead, in turn, to adverse effects on patient health.³⁰ In the PSI's 2009 *Practice Notice 5* on the issue of advertising referred to above it is stated that:

²⁹ The presence of rents is also consistent with the observations of Dorgan (2008, paragraphs 3.16 – 3.18) concerning the profitability of community pharmacies and the continuing creation of new pharmacies presented in Table 6.1.

³⁰ No doubt this concern is reflected in the ban on advertising of prescription-only medicinal products under S. I. No. 541 of 2007, Medicinal Products (Control of Advertising) Regulations 2007. However, this does not mean that information concerning dispensing fees, mark-ups, prices and pharmacy services cannot be communicated to patients. Such information is *not* concerned with advertising product claims or characteristics. The difference is that information concerning dispensing fees, mark-ups, prices and pharmacy services is more likely to determine which pharmacy the patient uses to dispense a prescription, while advertising product claims is more likely to increase overall demand. Nevertheless, great care needs to be taken to ensure that the presentation of information on dispensing fees etc., does not take away from the rational use of

Pharmacists must discharge their professional obligations to patients seeking advice, guidance and assistance in respect of their pharmaceutical care and treatment. *Self-selection of medicinal products without the provision of appropriate supervision, professional support, advice and information by the pharmacist is not appropriate.* Supervising and superintendent pharmacists are reminded of their particular responsibilities to ensure that policies and procedures in place comply with these requirements. (PSI, 2009c, emphasis added).

However, the pharmaceuticals that are the subject of this report are not self selected by the patient. Rather, the patient first needs to visit a medical practitioner, which involves costs for the patient in terms of time and the GP fee, if they are not in possession of medical or GP Visit card. Would a rational patient go to a medical practitioner with the intention of obtaining a prescription for (say) Lipitor because a pharmacist put an advert in a local paper or posted a notice in the pharmacy, saying '10 per cent off all pharmaceuticals this week?' Thus it is not clear that the rationale put forward by the PSI applies to such pharmaceuticals.

In October 2011 the PSI replaced *Practice Notice No. 5* with somewhat longer guidance on advertising and promotion.³¹ However, the tenor did not change. While the updated PSI (2011) guidance stated that pharmacists are required to provide honest and relevant information regarding the "...nature, cost, value and benefit" of a pharmaceutical product, there were clear limitations to the extent to which this information could be imparted to the public and the patient as set out above. This reflects the PSI (2011) view that "Inappropriate advertising or promotion of medicines based on cost impacts on the essential understanding of the medical needs of the patient" (p. 1). Advertising can lead to the "commodification" of pharmaceuticals which may have "...the effect of distracting patients from making an objective evaluation of their normative needs." However, as pointed out above with respect to *Practice Notice No. 5* it is not clear to what extent these concerns apply to pharmaceuticals that require a prescription from a medical practitioner, which are the subject of this report.

pharmaceuticals. Hence, for example, if the pharmacist proposes to charge differential mark-ups this might – although it seems extremely unlikely – lead the patient to request the medical practitioner to prescribe the product with the lower mark-up. However, it is not clear that this will lead to an irrational use of pharmaceuticals. The alternative might be, for example, that the patient who is (say) under the DP Scheme threshold and is working poor, goes without the pharmaceutical. Hence the rational use of pharmaceuticals, which at times seems to assume away any budget constraint that the patient may face in times of austerity, needs to take into account these considerations when coming to a judgement as to what is the rational use of pharmaceuticals.

³¹ The decision was made in October and circulated in November 2011.

Turning to the evidence on the impact of advertising, it suggests across a number of professions and services (such as opticians, optometrists, pharmaceuticals and legal) that allowing advertising results in lower prices and unchanged quality (Gorecki, 2011, p. 526). As the former head of the US Federal Trade Commission, Muris (2003, p.37) argued, "[R]estrictions on truthful and nondeceptive advertising harm competition, because they make it more difficult for consumers to discover information about price and quality of goods and services, thereby reducing competitors' incentives to compete with each other with respect to such features."

Furthermore, in Ireland the Medical Council in 2009 removed restrictions on registered medical practitioners advertising prices and services (Competition Authority, 2010, p. v). Equally the Dental Council of Ireland requires that dental fees are displayed and in a standard format.³² Websites can and are used to provide this information to the consumer.³³ The PSI does not place a similar obligation on pharmacies. The PSI have informed us that it is acceptable that pharmacists post their dispensing fee.³⁴ However, as yet this does not appear to be mentioned in the PSI *Code of Conduct*, nor is there any guidance on the PSI website as to how this information might be imparted so as to facilitate providing the information in a patient friendly manner.

It could argued, however, that this reflects the PSI view on the type of model on which a pharmacy business should be based. In its submission to the Expert Group on Resource Allocation and Financing in the Health Sector, the PSI argued that,

The role of a pharmacist ... should be reflected in any new incentivised, contractual or direct employment system. Any system of funding must facilitate pharmacists in having an active and meaningful direct impact on clinical care and treatment of patients and the public. A model based on the 'free market' should be discouraged and instead the normative need of patients and population should be the driving force behind a new generation of pharmacy services. Restrictions on new pharmacy openings should be considered and a methodology that optimises fair access for patients and ensures pharmacies are located where need is identified, should be developed (PSI, 2009b, p. 2)

³² This was approved in 2011. For details see: [http://dentalcouncil.ie/files/Display%20of%20Private%20Fees%20-%20Code%20of%20Practice%20\(Feb%202011\)%20-%2020110330.pdf](http://dentalcouncil.ie/files/Display%20of%20Private%20Fees%20-%20Code%20of%20Practice%20(Feb%202011)%20-%2020110330.pdf). Accessed 5 October 2011.

³³ See for example. <http://crowndental.ie/treatments?gclid=CJH0yLD6q6wCFcFw4AodM1Kv2g#crowns-and-bridges>. Accessed 10 November 2011.

³⁴ Personal communication, 4 October 2011. Furthermore it should be noted that the Pharmacy Review Group (2003, p. 32) recommended that "[T]here should be increased pricing transparency at point of sale, including advising of prescription prices in advance of supply and the price of all dispensing items on labels."

However, it is not clear why a somewhat more liberalised advertising regime with respect to the provision of information on prices, mark-ups, dispensing fees, and services for pharmacy is inconsistent with the provision of a new generation of services such as those outlined in the PSI's Pharmacy Ireland 2020 report (Pharmacy Ireland 2020 Working Group, 2008).³⁵ To the extent such services are purchased by the HSE on behalf of patients then this will involve a careful evaluation of the costs and the benefits by the HSE before deciding on the fee. To the extent that it is the patient that makes the choice then providing information on the price of the service and the benefits enables the patient to make a more informed decision.

Turning to the 1996 CPC agreement, this was, of course, negotiated between the representative body of pharmacy, the IPU, and the DoHC. The restriction on offering inducements, was consistent with the accompanying restrictions on opening of new pharmacies referred to above. It is not clear, however, why pharmacists should not be able to offer inducements such as that outlined above in order to attract DP patients. The patient benefits, particularly if they are working poor and not eligible for a medical card, while the HSE pays the same whether or not the inducement takes place. In Ontario, for example, where there is \$2.00 co-payment for poorer senior citizens, many pharmacies in urban areas waive this fee.³⁶ Why should analogous conduct be prohibited in Ireland? Why should the HSE be a party to an agreement that restricts competition between pharmacies for no obvious reason?

In sum, there are no compelling arguments for the present PSI and 1996 CPC Agreement restrictions on pharmacies providing information in relation to prices, discounts, and new services so that patients can make better and more well informed decisions. Not only will the removal of such restrictions benefit patients directly, but also indirectly, since increased competition is likely to result in the more efficient pharmacies expanding and those that are not able to offer good quality service at the right price declining in importance.

6.4.3 Removing the Restrictions on Advertising and Providing Information to Patients

In order to ensure that the provision of information is structured in such a way that leads to patients being well informed and providing incentives for pharmacists to provide information to patients:

³⁵ And referred to by the IPU (2011b, p. 42).

³⁶ Details of the co-payment may be found on the Ontario Drug Benefit (ODB) website: http://www.health.gov.on.ca/en/public/programs/drugs/programs/odb/opdp_after65.aspx. Accessed 30 September 2011. Information on the waving of the fee was provided by officials of the ODB.

Recommendation 6.2: We recommend that all pharmacies be required to post, in a manner clearly accessible to patients, a notice setting out their usual and customary dispensing fee and mark-up together with what services are included for the dispensing fee. A standard template should be used.

The provision of such information in an easily accessible format will enable patients to make sensible choices concerning which pharmacy to select. A standard template makes comparisons much easier, as has been developed by the Dental Council of Ireland. It is mandatory for dentists to display their fees for certain treatments from 1 June 2011.³⁷ One possible template is that used in Ontario pharmacies for a number of years, which is presented in Figure 6.1. Finally, of course, this usual and customary dispensing fee refers to the dispensing fee charged to the cash customer (i.e., under the DP Scheme threshold and those patients not covered by any State scheme). The template is issued by the Ontario College of Pharmacists, the corresponding body to the PSI. It is not clear whether the PSI could compel pharmacists to display such a notice as part of the Code of Conduct or whether the Minister for Jobs, Enterprise and Innovation could issue a Retail Display Order³⁸ or whether separate legislation would be required.

FIGURE 6.1 Dispensing Fee Information Posted in Ontario Pharmacies.

Prior to dispensing, and at your request we will provide the price of your prescription without obligation.

OUR USUAL AND CUSTOMARY FEE FOR PROFESSIONAL SERVICES WHEN DISPENSING A DRUG PRODUCT IS

\$ _____

Certain prescriptions may warrant a different fee.

The services included in our fees, in addition to professional dispensing, are checked below

Patient medication profiles

Professional consultation


Health care service information

After hours emergency prescription services

Delivery service

Other _____

Some of the services listed above may be available at an extra charge.

 ONTARIO COLLEGE OF PHARMACISTS

Source: Ontario College of Pharmacists.

³⁷ For details see the Dental Council's website: <http://dentalcouncil.ie/files/Display%20of%20Private%20Fees%20-%20Code%20of%20Practice%20%28Feb%202011%29%20-%2020110330.pdf>. (Accessed 8 November 2011).

³⁸ For information on such orders see: http://www.citizensinformation.ie/en/consumer_affairs/consumer_protection/pricing/price_display_of_goods_and_services.html. Accessed 12 December 2011,

However, while the provision of information under R 6.2 would be mandatory there is also a need to relax the current restrictions imposed by the PSI and those contained in the 1996 CPC Agreement that impose unnecessary restrictions on the ability of pharmacies to advertise. Hence:

Recommendation 6.3: We recommend that PSI permit pharmacists to advertise dispensing fees, services provided and price discounts and rebates with respect to prescription pharmaceuticals.

As noted above it appears on one reading of *Practice Notice No. 5* and the November 2011 PSI guidance that the current restrictions on advertising do not appear to cover pharmaceuticals that are prescribed. However, it would be useful if explicit guidance were given in such cases. Even if the November 2011 PSI guidance did apply to prescription pharmaceuticals, the discussion above suggests that the restrictions are a disproportionate response to the concerns stated. This does not, of course, mean that some restrictions may be necessary, but the case needs to be made carefully to ensure that they are not disproportionate.³⁹

Finally, in terms of the ability of pharmacists to attract patients on public schemes:

Recommendation 6.4: We recommend that pharmacists are able to offer and to advertise that they will pay, in part or whole, any patient co-payment that is part of the GMS and Community Drug Schemes.

We understand that this would probably require an amendment to primary legislation.

These recommendations to increase transparency and competition in the provision of pharmacy services are likely to encounter some resistance from pharmacies. There is a danger of collective action as has occurred in the past. This needs to be firmly resisted. Collective action to restrict advertising or to co-ordinate the dispensing fee, whether on a local or a national level, is a breach of competition law. The Competition Authority (2009) has issued guidance in this area so as to remove any doubt on this issue. In order to assist in the monitoring of the implementation of the above recommendations as well as gather information relevant to setting dispensing fees for public schemes:

³⁹ And of course, consistent with existing regulations. See the discussion in footnote 30 above.

Recommendation 6.5: We recommend that the HSE should carefully monitor the pharmacy market, conducting regular surveys of dispensing fees and offers made by pharmacies.

If prima facie evidence of a breach of competition law were discovered that should be referred to the Competition Authority. Of course, the HSE need not necessarily conduct the surveys itself, but do so in partnership with, for example, the National Consumer Agency which has experience of conducting consumer surveys in a retail setting.

6.5 ALTERNATIVE WAYS OF DELIVERING PHARMACY SERVICES

The internet, combined with delivery by mail or other means, is widely used today to supply goods and services. It has revolutionised, for example, the business of selling airline tickets, with the rapid decline of bricks and mortar travel agent retail outlets to be replaced by online booking. Books, CDs and groceries are also, in varying degrees, marketed through the internet and delivered through the mail. In some jurisdictions such as the US pharmaceuticals are sold extensively through the internet/mail order,⁴⁰ with some US state pharmaceutical reimbursement programmes also using the internet/mail order to distribute pharmaceuticals.⁴¹ In August 2011 the Dr Thom website offered advice in Ireland for patients suffering from asthma, erectile dysfunction or wanting a contraceptive pill. Prescriptions are sent to the patient through the post.⁴² The distribution of OTC products is permitted in Ireland over the internet. However, the distribution of pharmaceuticals through the internet and mail order is prohibited. It is not clear that this is a proportionate response. While internet/mail order pharmacies pose well known problems,⁴³ a complete prohibition may not be the answer. Such pharmacies would, of course, be subject to PSI regulation as to, for example, supervision by suitably qualified personnel. Indeed, internet/mail order pharmacies could be an extension of existing community pharmacies. If internet pharmacies can offer lower cost distribution in a safe manner for certain selected pharmaceuticals such as maintenance products for

⁴⁰ In terms of sales mail order accounted for 22.8 per cent of retail sales in the US in 2009. For details see: <http://nacds.org/user-assets/pdfs/2010/publications/2009Results.pdf>. Accessed 10 November 2011. In some US States laws have been passed under which it is prohibited to offer "...more favourable cost-sharing arrangements for use of a mail-order pharmacy than for the use of retail pharmacy." (Maryland Health Care Commission and Maryland Insurance Administration (2005, p. 1). This retards the growth of internet/mail order distribution of pharmaceuticals.

⁴¹ For a discussion see Maryland Health Care Commission and Maryland Insurance Administration (2005) and US General Accounting Office (2003).

⁴² For details see: <https://www.drthom.ie/> (Accessed 8 November 2011). Note that Dr Thom is a registered medical practice with the Medical Council of Ireland.

⁴³ See, for example, the 2004 Statement on 'Internet Drug Sales' by William Hubbard of the US Federal Drug Administration (<http://www.fda.gov/NewsEvents/Testimony/ucm114792.htm>. Accessed 11 November 2011) and the notice of the IMB concerning the importation of body building products. (<http://www.imb.ie/EN/Safety--Quality/Advisory-Warning--Recall-Notices/Human-Medicines/STATEMENT-ON-BODY-BUILDING-PRODUCTS.aspx?page=1¬icetypeid=-1&year=2007>. Accessed 11 November 2011).

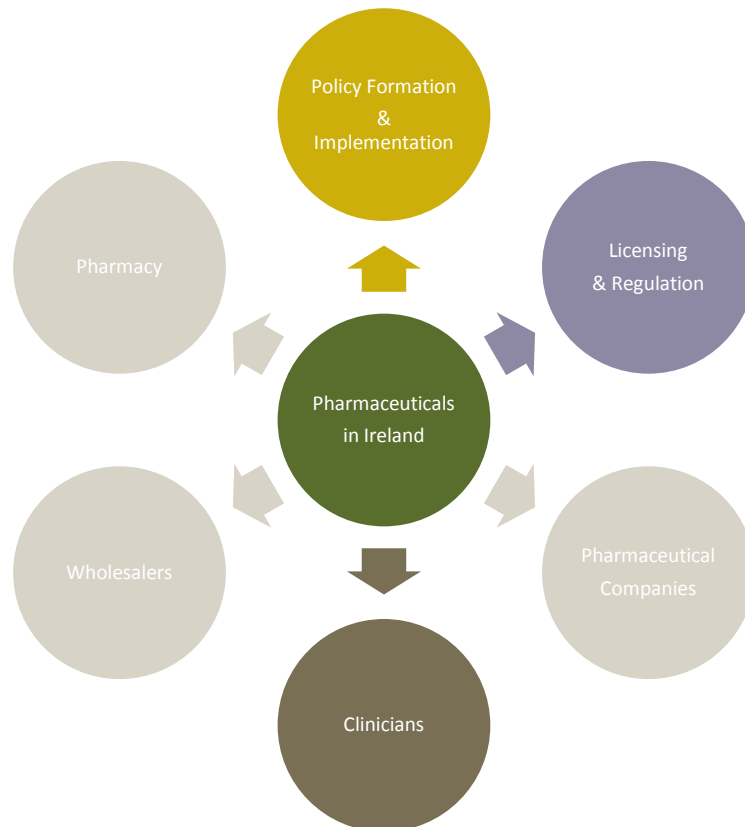
high blood pressure, high cholesterol and diabetes where the patient is likely to be familiar with their medical requirements, then the HSE should consider the viability of their use on a trial basis, perhaps initially using the services of one internet/mail order pharmacy awarded on the basis of competitive tender. This would, of course, necessitate legislative change.

6.6 CONCLUSION

Pharmacists provide a vital service to the community in dispensing pharmaceuticals and providing the associated services. This chapter has addressed the issue of how that service should be provided by decoupling the pharmacists' payment for dispensing services rendered from the cost of the pharmaceutical. The dispensing fee would form the sole way in which the pharmacist would be compensated. However, there is some evidence and good *a priori* reasoning for concluding that pharmacy costs are above the competitive norm – accepted as a reasonable benchmark for setting the dispensing fee. At the same time, patients are poorly served by the current restrictions on the provision of information concerning prices, discounts, and services by pharmacists. These restrictions also have the effect of dampening competition between pharmacies. Sensible regulatory reform of these restrictions should not only make patients better off, but also lead to a more competitive market place and hence lead to a better basis on which to set dispensing fees.

Chapter 7

The Prescriber



7.1 INTRODUCTION

For pharmaceuticals, an important feature of the market is that the consumer (i.e., the patient) is not the main decision-maker. Patients rely on their medical practitioner to prescribe appropriate pharmaceuticals. In many cases, patients do not bear the full cost of the prescribed pharmaceuticals due to the existence of public insurance (thus creating a moral hazard problem).¹ In addition, moral hazard effects can be exacerbated by expectations on the part of patients regarding prescriptions.² Medical practitioners' prescribing decisions are the result of input from the patient, commercial sources, professional colleagues, academic publications and the State (via regulation, licensing, etc.) (Soumerai *et al.*, 1989). These features may result in resources being used inefficiently (for example, more expensive pharmaceuticals may be prescribed when a cheaper generic is available)

¹ Moral hazard is discussed in greater detail in Chapter 2.

² Evidence suggests that over 87 per cent of visits to a medical practitioner in Spain, Italy and France result in a prescription, while this figure is lower than 75 per cent in the UK, Sweden and the Netherlands (Kanavos *et al.*, 2011, p. 45). A recent analysis of UK GPs estimated that approximately two-thirds of their consultations result in a prescription (Duerden *et al.*, 2011). Comparable figures for Ireland are not available.

(Kanavos *et al.*, 2011). The key role of the prescriber in driving expenditure on pharmaceuticals is highlighted in a recent paper on the Greek experience over the period 1996-2005 (Lambrelli and O'Donnell, 2011).

The preceding chapters have dealt with strategies focusing on the pricing and reimbursement of pharmaceuticals. Policies targeting the behaviour of pharmacists were discussed in Chapter 6. In this chapter, we consider the role of the prescriber. We describe the current role of prescribers in Ireland and previous attempts to influence the prescribing behaviour of Irish GPs (via the now-suspended Indicative Drug Targeting Scheme) in Section 7.2. Internationally, policies which target prescribers may be grouped under three broad headings: prescribing by International Non-Proprietary Name (INN), financial incentives and prescription guidelines, feedback and monitoring. Experience with these alternative strategies in other countries is used to inform the policy proposals that are outlined in Section 7.3. Section 7.4 summarises and concludes.

7.2 THE CURRENT ROLE OF THE PRESCRIBER IN IRELAND

7.2.1 Context

In Ireland up to 2007, only registered medical practitioners and registered dentists were permitted to prescribe pharmaceuticals. In 2007, the legislation was amended to allow nurses and midwives to prescribe pharmaceuticals, with some restrictions (An Bord Altranais, 2010).^{3,4} As described in Chapter 2, a small number of medical practitioners are permitted to dispense pharmaceuticals but in general, medical practitioners concentrate on the prescribing decision. The Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* lays out the requirements for prescribing on the part of medical practitioners (Medical Council, 2009, section 59). Currently, medical practitioners have considerable influence over the volume and product mix of pharmaceuticals that are dispensed due to the 'dispense as written' provisions stipulated by the PSI in their guidance to pharmacists.⁵ Prescribers are thus a key player in the pharmaceutical market, and their decisions have important consequences for pharmaceutical expenditure.

³ The primary legislation is the Irish Medicines Board (Miscellaneous Provisions) Act, 2006 (An Bord Altranais, 2010).

⁴ In 2010, 238 nurses (or 0.3 per cent of registered active nurses) were permitted to prescribe (authors' calculations from An Bord Altranais, 2011).

⁵ The guidance explicitly states that "...where a prescriber specifies a particular branded product on the prescription, the pharmacist is required to dispense the product specified. The pharmacist cannot supply a different equivalent brand without consulting the prescriber concerned, except where such supply is covered by a brand substitution agreement entered into in advance by both the pharmacist and prescriber concerned" (PSI, 2008b, p. 23).

Medical practitioners face few, if any, restrictions on the volume and type of products they may prescribe (other than limits on the length of a prescription).⁶ Medical practitioners are not obliged to write prescriptions generically and there are no financial incentives for them to do so. In addition, with the exception of certain hospitals, medical practitioners are not provided with formal prescription guidelines. Despite the existence of a comprehensive data-set on community dispensing,⁷ and with the exception of two specific areas (benzodiazepine and controlled drugs), prescribing by medical practitioners in the community currently is not audited nor do medical practitioners receive standardised feedback on their prescribing behaviour.

Figure 2.3 in Chapter 2 illustrated the strong upward trend in the number of items dispensed across the various PCRS schemes over the period 2000-2010. While increases in eligibility (particularly on the GMS Scheme in recent years) are an obvious driver of volume increases, changing demographics and increasing rates of chronic disease have an important influence on prescribing. In particular, as a result of deteriorating health, older individuals are both more likely to be on medication, and also to be on multiple medications.⁸ Analysing the growth in the number of items by age groups shows strong growth in the number of items per claimant over the period 2005-2010 for the GMS, DP and LTI schemes, particularly in the older age groups. For example, over the period 2005-2010, the number of items per claimant per annum aged over 75 on the GMS Scheme increased from 61 to 80 (Figure 7.1).⁹ While one possible contributory factor to the increased volume of pharmaceuticals dispensed is an increase in potentially inappropriate prescribing, in the absence of formal audits of medical practitioners, it is difficult to obtain information on the appropriateness of prescribing in Ireland, although recent attempts to quantify the extent of the problem suggests that it is not absent in Ireland.¹⁰ In the context of population ageing and increasing co-morbidity, and the economic and clinical

⁶ In Ireland, the maximum duration of a repeat prescription is six months (IMO, personal communication, 7 July 2011).

⁷ The PCRS maintains a record of every claim for reimbursement under the various State pharmaceutical schemes. Information recorded includes the manufacturer name, pharmaceutical name, ATC 5 code, dosage form and strength, route of administration, patient details and GMS number (where appropriate), GP (or other prescriber) details and dispensing pharmacist details.

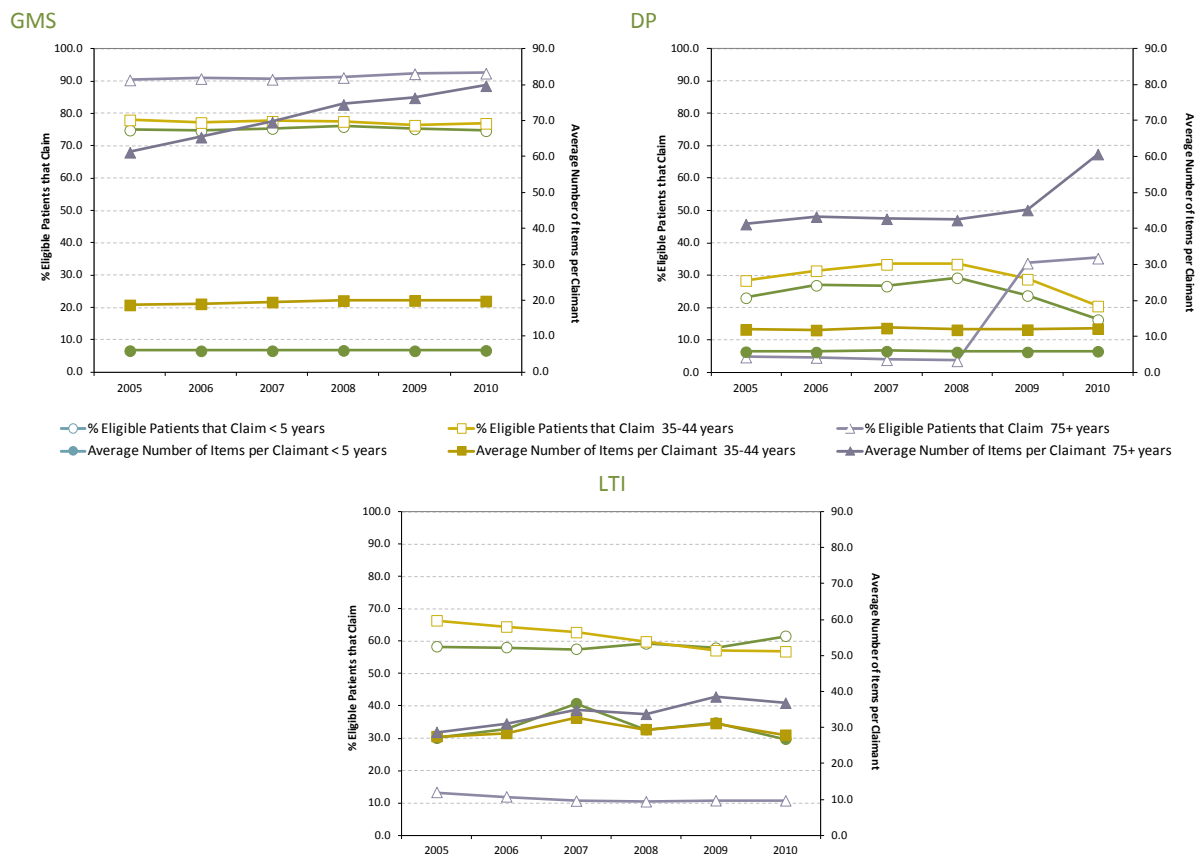
⁸ In Ireland, information from *The Irish Longitudinal Study of Ageing* shows that the percentage of those on 5 or more medications increases from 12 per cent for those aged 50-64 years to 29 per cent for those aged 65-74 years and to 41 per cent for those aged 75+ years (Barrett *et al.*, 2011; Table 5.A45). Information from the US Medicare programme suggests that Medicare beneficiaries with five or more chronic conditions see an average of 13 physicians and fill an average of 50 prescriptions per year (Medicare Payment Advisory Commission, 2009).

⁹ The DP Scheme was introduced in 1999 with a monthly deductible of £43 (Barry *et al.*, 2010). The monthly deductible for the DP Scheme increased from €85 in January 2005 to €90 in January 2008 to €100 in January 2009 to €120 in January 2010 (PCRS, personal communication, 30 August 2011; www.citizensinformation.ie).

¹⁰ Barry *et al.* (2008) cite evidence in relation to inappropriate prescribing of proton pump inhibitors (PPIs) on the GMS Scheme in 2005. In addition, a recent review suggests that rates of potentially inappropriate prescribing among the older population in Ireland range from 21 per cent in primary care to 35 per cent in a hospital setting to 60 per cent in a nursing home setting (O'Mahony *et al.*, 2010). Using data from the PCRS database, Cahir *et al.* (2010) estimate that over one-third of the Irish population aged 70+ were prescribed at least one potentially inappropriate product in 2007, accounting for approximately 9 per cent of total expenditure on pharmaceuticals for this group. Polypharmacy (evaluated in this study as the number of different repeat pharmaceutical classes per claimant) was significantly associated with potentially inappropriate prescribing.

implications of steadily increasing levels of prescribing, ensuring that prescribing is safe and cost-effective is even more pressing.

FIGURE 7.1 Percentage of Claimants and Number of Items Dispensed per Claimant by Selected Age Groups on the GMS, DP and LTI Schemes, 2005-2010



Notes: See Annexe E for complete data tables.

Source: ESRI calculations from HSE, personal communication, 30 June 2011.

7.2.2 Prescribing of Generics

Apart from the potential for any cost savings, generic prescribing is a recognised quality prescribing indicator. Prescribing by international non-proprietary name (INN), whereby prescribers use the active ingredient name (e.g. atorvastatin) rather than the brand name (e.g. Lipitor), reduces the potential for confusion and error on the part of the prescriber, pharmacist and patient (Barry *et al.*, 2009; National Medicines Information Centre, 2009).

In an international comparison of generic market shares across 16 Member States in 2007, the share of the pharmaceutical market accounted for generics was the lowest in Ireland, when measured in value terms (12 per cent) and third lowest, when

measured by volume (34 per cent) (European Commission, 2009, Figure 11, p. 62).¹¹ The importance of generic prescriptions appears to have fallen over time in Ireland.¹² The comparison with the UK is particularly striking. It is estimated that 83 per cent of prescriptions under the UK NHS were issued generically in 2007 (with 64 per cent dispensed generically) (Barry *et al.*, 2008).¹³ In 2010 in England, 67.4 per cent of all prescription items were dispensed generically, representing 29.6 per cent of the total cost. In 2009 these figures were 66.1 per cent and 28.3 per cent respectively and in 2000 they were 51.8 per cent and 21.6 per cent respectively (NHS Information Centre, 2011b). In 2010 in Lithuania, 47 per cent of all items dispensed were generics (in comparison with 42 per cent in 2008) (Garuoline *et al.*, 2011).

In 2011, just over 18 per cent of items dispensed¹⁴ on the GMS Scheme were generics (16.2 per cent branded and 2.1 per cent unbranded). Brand name products without a generic equivalent accounted for 50.2 per cent of total items dispensed on the GMS Scheme in that year, with brand name products with a generic equivalent accounting for 26.8 per cent of all items dispensed on the GMS Scheme in 2011.¹⁵

Rates of generic dispensing are lower still on the DP and LTI schemes, and rates of dispensing for brand name products with a generic equivalent are correspondingly higher (30.2 per cent on the DP Scheme and 41.2 per cent on the LTI Scheme in 2011). Data for 2010 indicate that the share of generics has increased across all schemes over the last year (particularly for unbranded generics, albeit from a low base). On the HTD Scheme, over 85 per cent of products in both years were proprietary products without a generic equivalent (Figure 7.2).¹⁶

NCPE (2009) report that in 2008, 25 per cent of items on the GMS Scheme and 27 per cent of items on the DP/LTI schemes¹⁷ were dispensed as brand name products when a generic equivalent was available. Rates of generic dispensing on the GMS and DP/LTI schemes in 2008 were 18.3 per cent and 10.9 per cent respectively.

¹¹ See also European Generic Medicines Association (2009).

¹² In 2007 19 per cent of prescriptions were dispensed generically. Generic prescribing accounted for 8 per cent of GMS expenditure in 2007. In 1997 the "...the percentage of items prescribed generically exceeded 22 per cent by volume and 12 per cent by expenditure" (Barry *et al.*, 2010, p. 243).

¹³ The discrepancy arises because some pharmaceuticals prescribed generically are only available as a brand product (they are still 'in-patent') and a small number cannot be supplied as a generic product because the pharmacist (or dispensing medical practitioner) does not have the generic version in stock (Duerden *et al.*, 2011).

¹⁴ As explained in Chapter 2, the main source of data on pharmaceutical consumption in Ireland is pharmaceutical dispensing information from the PCRS, which administers the payments to pharmacies under the various State schemes. Assuming that all prescriptions are brought to a pharmacy, and dispensed correctly, data on dispensed pharmaceuticals should be equivalent to data on prescribed pharmaceuticals.

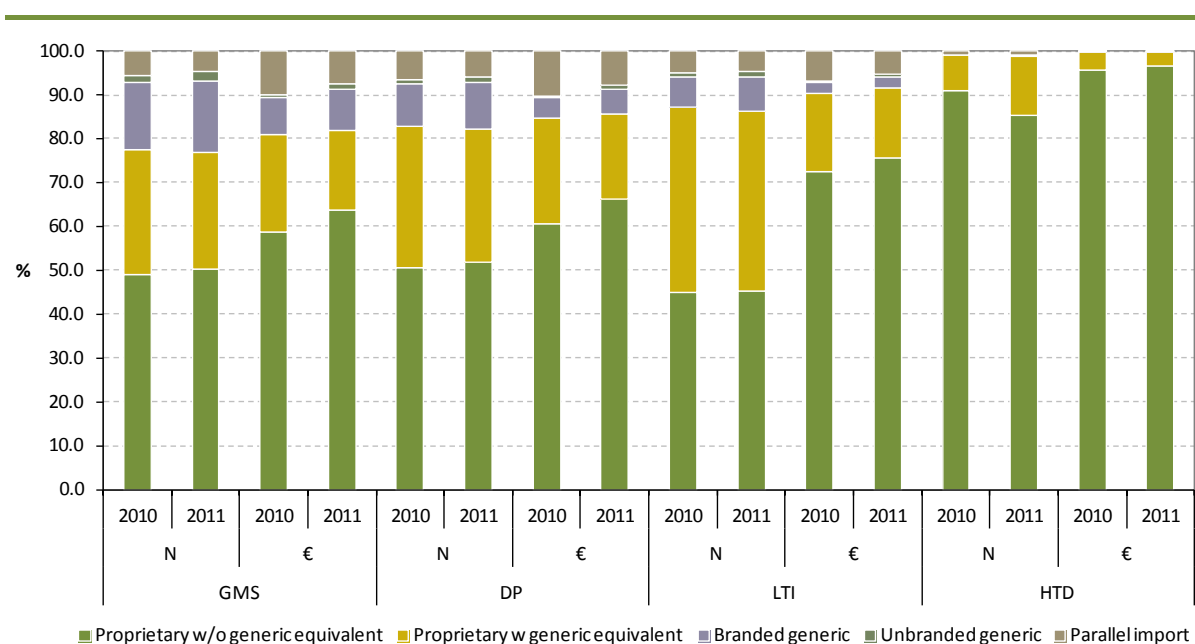
¹⁵ The remaining 4.7 per cent of items dispensed on the GMS Scheme in 2011 were parallel imported products.

¹⁶ Across all schemes, the share of parallel imported products has declined into 2011 (Chapter 4 discusses parallel imports in greater detail).

¹⁷ NCPE (2009) does not distinguish between the DP and LTI schemes.

However, the pre-2010 data are not directly comparable with the data from 2010 onwards presented in Figure 7.2 as the earlier research did not separately identify parallel imported products (Barry *et al.*, 2009; NCPE, 2009). However, recent trends do suggest that the proportion of brand name products dispensed when there is a generic equivalent is increasing (Table 7.1). In England in 2008 in contrast, just 5 per cent of prescription items were prescribed by brand when a generic was available (Department of Health, 2010).

FIGURE 7.2 Market Share (Volume and Value) by Pharmaceutical Type, GMS, DP, LTI and HTD Schemes, 2010 and 2011^a



Notes: a Year to Date June 2011.

Source: ESRI calculations from HSE, personal communication, 23 September 2011.

For the top ten brand name products with a generic equivalent by value, variation across the different products is illustrated in Table 7.1 for the GMS and DP schemes. On the GMS Scheme in 2011, the proportion of generics dispensed ranges from 5.7 per cent for budesonide to 58.1 per cent for omeprazole. Similarly, the range is broad on the DP Scheme in 2011; from 3.0 per cent for anastrozole to 38.1 per cent for omeprazole. In comparison with 2010, the share of generics (in both volume and value terms) is increasing in most cases for both schemes.

It is not clear why the proportion of generic products dispensed varies so much across the GMS and DP schemes; for the seven products that are common to the two schemes, the divergence between rates of generic dispensing on the GMS and DP schemes ranges from approximately six percentage points for rosuvastatin to over 19 percentage points for omeprazole. However, a study examining the

influence of socio-economic status on quality of prescribing in the over 70s population in Ireland in the early 2000s found that those on lower incomes (i.e., existing medical card holders or GMS patients) were significantly more likely to be prescribed generics than more affluent patients (i.e., those newly eligible for the GMS Scheme after the extension of medical card eligibility to all over 70s in July 2001) (Odubanjo *et al.*, 2004). French research (further discussed in Section 7.3.1) finds that GPs consider the financial situation of their patients in making prescribing decisions. However, GMS patients are eligible for free pharmaceuticals (subject to a 50c charge per item, i.e., unrelated to the value of the item), so it is difficult to argue that a concern for the financial situation of GMS patients explains the divergent patterns observed in Table 7.1.

Table 7.1 Generics (Branded and Unbranded) as a Proportion of the Top 10 Pharmaceuticals *With a Generic Equivalent* by Value, GMS and DPS, 2010 and 2011

	GMS			
	2010		2011	
	Volume	Value	Volume	Value
	%	%	%	%
Esomeprazole	5.7	4.4	24.5	25.7
Rosuvastatin	2.5	1.8	21.6	19.6
Clopidogrel	16.0	12.6	28.3	27.2
Pantoprazole	30.8	33.2	41.7	40.4
Omeprazole	52.2	54.6	58.1	59.8
Acetylsalicylic Acid-Aspirin (Antithrombotic)	22.2	16.2	17.5	12.9
Venlafaxine	19.5	23.0	24.4	25.8
Lamotrigine	5.3	4.2	5.9	4.5
Budesonide	41.1	48.1	5.7	6.9
Tamsulosin	22.7	17.9	27.6	25.6
	DP			
	2010		2011	
	Volume	Value	Volume	Value
	%	%	%	%
Esomeprazole	3.2	2.4	15.4	16.2
Rosuvastatin	1.5	1.0	15.2	13.6
Clopidogrel	10.3	7.9	19.3	18.1
Omeprazole	33.2	35.6	38.9	41.2
Pantoprazole	19.7	21.2	29.2	27.6
Venlafaxine	12.9	15.2	17.1	17.6
Acetylsalicylic Acid-Aspirin (Antithrombotic)	10.1	7.0	8.5	6.0
Gabapentin	10.5	7.7	14.2	9.0
Anastrozole	0.0	0.0	3.0	2.4
Amlodipine	28.2	33.8	33.1	31.9

Notes: a Year to Date June 2011.

Source: ESRI calculations from HSE, personal communication, 23 September 2011.

The low rate of generic prescribing in the community in Ireland by international standards is also a feature of the hospital sector. Notwithstanding the existence of hospital pharmaceutical prescription guidelines/formularies in many Irish hospitals, a comparison of prescribing practices in a HSE hospital and an NHS hospital in 2009 found significantly higher rates of generic prescribing in the NHS hospital (79.7 per cent versus 52.5 per cent in the HSE hospital). Analysing hospital-only products (to

overcome the potential influence of pre-existing prescriptions from the community), the difference in generic prescribing rates was still significantly different between the two hospitals (80.4 per cent in the NHS hospital versus 53.5 per cent in the HSE hospital). Reviews of prescribing behaviour by the clinical pharmacist were also significantly less common in the HSE hospital. While limited in its scope, the study also highlights the emphasis placed on prescribing education in the NHS (Murphy and McWilliams, 2010).¹⁸

A 1997 survey of Irish GPs found that the main deterrent to generic prescribing was a concern over the reliability and quality of generic products. GPs were also concerned that pharmacists may legally dispense more expensive branded products for private prescriptions written generically. Contrasting the situation in Ireland with that in England and Northern Ireland (where rates of generic prescribing and dispensing were much higher), Feely *et al.* (1997) stressed the role of the authorities in reassuring medical practitioners (and the public) about the effectiveness and safety of generic products.

In summary, despite the fact that prescribing by INN is a feature of medical education in Ireland (Section 7.3.1), that the IMO recommends generic prescribing and that the IMB is involved in reassuring medical practitioners (and the public) about the safety and efficacy of generic pharmaceuticals,¹⁹ rates of generic prescribing in Ireland are low and considerably out of line with those in other countries.

7.2.3 Indicative Drug Targeting Scheme

In January 1993, an agreement was implemented between the DoHC and the IMO which included provision for the allocation of an indicative individual monthly drug target for each GP to enable him/her to better pursue the objective of "responsible and cost effective prescribing" (Murphy, 1997, p.17). The scheme, known as the Indicative Drug Targeting Scheme (IDTS), was suspended in early 2006. Savings were used to further develop general practice by allocating 50 per cent to the individual GP to investment in specific practice development and 50 per cent to the Health Board for overall development of general practice (Murphy, 1997). Prescribing targets were adjusted for panel size and demographics, as well as 'high cost' patients.²⁰ The scheme was voluntary and there were no sanctions on those who failed to meet their target.

¹⁸ See also Section 7.3.3.

¹⁹ See also Section 7.3.1.

²⁰ The budget was set by a combination of the GP's previous prescribing costs and the national average (Walley *et al.*, 2000). A General Practice Unit (GP Unit) was established in each Health Board. Each month, the General Medical Services Payments Board (the precursor to the PCRS) returned statistics on prescribing for each participating GP to the GP Unit for analysis. From 1995 onwards, adjustments to targets were made on a monthly basis (Comptroller and Auditor General, 1997). The budget was set by a combination of the GP's previous prescribing costs and the national average (Walley *et al.*, 2000).

It was estimated that IR£13.5 million was saved in the first year of the scheme and a trend towards increased generic prescribing was reported, with no discernible negative effects on quality of prescribing (Murphy, 1997). Analysis by the Comptroller and Auditor General revealed savings of £18 million over the first four years of the scheme. Of the 1,395 GPs who participated in the IDTS continuously for the first four years, only 5 per cent achieved savings in each of the four years while 27 per cent did not achieve savings in any year. However, the proportion of GPs coming in under their prescribing target or within 10 per cent of their target increased from 65 to 73 per cent over the first four years of the scheme. The rate of increase in pharmaceutical expenditure on the GMS Scheme over the period 1993-1996 decreased to a little over half its rate over the previous four years, with the proportion of substitutable pharmaceuticals prescribed at their lowest cost increasing over the period (Comptroller and Auditor General, 1997). By 2005 however, less than 3 per cent of participating GPs were achieving savings, and total savings in that year amounted to just €0.7 million, down from €3.6 million in 2000 (Comptroller and Auditor General, 1997).

Walley *et al.* (2000) also found that savings were short lived. They carried out an analysis of prescribing behaviour by 233 GPs in the Eastern Health Board (EHB) area over the period 1990-1995.²¹ They divided GPs into three groups based on their spending per GMS patient relative to their indicative budget for 1994 (labelled 'savers', 'modest overspenders' and 'large overspenders'). They found that while cost increases in the year before the introduction of the IDTS were similar and not significantly different for the three groups, in the year after the scheme was introduced, there was a significant difference between the groups (with mean increases in costs of -7.9 per cent, 1.2 per cent and 7.3 per cent for savers, modest overspenders and large overspenders respectively). However, by the final year of the study, the cost increases were similar and not significantly different for the three groups.

A review of the IDTS completed by the Health Boards and the DoHC in April 2005 recommended that the existing IDTS should be comprehensively reviewed with all stakeholders and replaced by an enhanced scheme at the earliest possible date. Subsequently, the DoHC/HSE agreed terms of reference with the IMO for a review of the IDTS, to be overseen by a joint Department/HSE and IMO team, with appropriate analysis by an agreed expert (Deloitte and Touche, 2003). No further details are available on the team or any publications arising from its work. However, the IDTS was suspended in early 2006 (Dail Eireann, 2008). We return to the issue of financial incentives in Section 7.3.2.

²¹ At the time, the EHB was the largest in the country, representing 360,000 GMS (medical card) patients and 528 GPs (out of a total of 1,666). It included Dublin, and had a very small proportion of rural practices (Walley *et al.*, 2000).

7.2.4 Prescription Guidelines, Feedback and Monitoring

The HSE advice to GPs states that "medical practitioners have been asked for their co-operation in securing whatever economies are possible without reducing the effectiveness of the service or affecting the best interests of patients. They have been asked to consider, when prescribing, whether there is an equally effective but less expensive medicinal product available" (PCRS, 2006, pp. 77-78).

More recently the Irish Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* states that medical practitioners "...have a duty to assist in the efficient and effective use of health care resources ... [and] should be aware of the wider need to use limited health care resources efficiently and responsibly" (Medical Council, 2009, paragraph 49.2). In particular, the Council encourages medical practitioners to prescribe bio-equivalent generic medicines where they are safe and effective (*ibid.*, paragraph 49.2). Medical practitioners are asked not to "...rely solely or excessively on promotional literature distributed by pharmaceutical companies for information about particular drugs. You should seek independent evidence-based sources of information on the benefits and risks associated with medicines before prescribing" (*ibid.*, paragraph 59.8). The sources of the independent evidence-based information are not specified.

Despite the existence of a comprehensive data-set on pharmaceutical dispensing in the community,²² there is currently no standardised feedback mechanism for GPs. GPs who submit claims electronically are able to access monthly reports on the dispensing of benzodiazepine and controlled drugs under the GMS Scheme. The reports detail the number of prescriptions by age and sex, and allow the GP to compare their rate with the national average for all GMS GPs. A similar analysis of the prescription of oral nutritional supplements is currently planned (PCRS, 2011). However, it is not clear what proportion of GPs access these reports, how frequently they do so, and what impact the information has on their prescribing decisions (Section 7.3.3 discusses the issue of prescription guidelines, feedback and monitoring in greater detail).

As part of an exercise by the PCRS to make GPs more aware of the cost implications of their prescribing behaviour, an electronic monitoring tool is now being developed which will allow GPs to review the cost of pharmaceuticals dispensed for their GMS patients, and to calculate the cost savings that are possible with generic substitution. The analysis is available for brand name pharmaceuticals with generic equivalents. Tabulations of potential cost savings will be available for each GP, and for each

²² However, the PCRS do not at present have full information on pharmaceutical dispensing to patients below the DP threshold of €132 per month. This issue is discussed in greater detail in Chapter 2.

patient on a GP's list (PCRS, personal communication, 30 August 2011). In combination with the GPs' own records, the tool will also allow GPs to monitor their patients' consumption of pharmaceuticals by identifying where a prescription has not been filled, or where an alternative product was dispensed. As with the existing benzodiazepine and controlled drugs reports, the success of the tool will very much depend on the extent to which GPs engage with this process.

In the hospitals sector, nearly all hospitals have their own hospital pharmaceutical prescribing guidelines or formulary (Vogler *et al.*, 2010), in addition to/separate from the reimbursable lists for the various PCRS schemes.²³ The National Medicines Information Centre (NMIC) at St James's Hospital produces regular bulletins with treatment guidelines in relation to numerous conditions; in 2011 the bulletins covered the management of stroke, the use of antidepressants in adults and the management of dementia (National Medicines Information Centre, 2011a, b; c). Where pharmaceuticals are listed, the INN name, as well as the relevant brand name pharmaceutical, is listed. In 2009, the NMIC devoted a bulletin to the issue of generic prescribing (National Medicines Information Centre, 2009).

The extent to which Irish medical practitioners are aware of the costs of the pharmaceuticals they are prescribing is limited. While MIMS Ireland (or Monthly Index of Medical Specialities Ireland) is an independently edited publication designed as a prescribing guide for medical practitioners, it includes the ex-factory price only (i.e., it does not include pharmacy mark-ups, if applicable, and dispensing fees) (McGuire *et al.*, 2009). The Irish Medicines Formulary, a biannual publication which is provided free to all registered, practising GPs in Ireland by the ICGP, contains similar information on products and ex-factory prices. A study of over 100 consultants and non-consultant hospital doctors in two university teaching hospitals in Ireland found that medical practitioners' estimates of the cost of ten commonly used products were accurate in only 12 per cent of cases, too low for 50 per cent and too high for 38 per cent. In many cases, the MIMS was not available on the wards (McGuire *et al.*, 2009). In any case, it is our understanding that the British National Formulary (BNF) is the most usual source of information for Irish medical practitioners in a hospital setting, which does not contain Irish ex-factory prices.²⁴

²³ While the current IPHA and APMI agreements allow the HSE to carry out pharmacoeconomic assessment of new as well as existing products that may be high cost or have a significant budget impact on the Irish healthcare system, to date no products have been delisted from the GMS or DP scheme reimbursable lists. However, a review of glucosamine was undertaken to determine whether the product should continue to be reimbursed (Tilson *et al.*, 2010), with the resulting high incremental cost-effectiveness ratio leading the NCPE to recommend that "...the pricing and reimbursement of these products under the Community Drugs Schemes should be reconsidered" (NCPE, 2010, p.1).

²⁴ HSE, personal communication, 15 November 2011. See <http://bnf.org/bnf/index.htm> for information on the BNF (accessed 21 November 2011).

7.3 PROPOSALS FOR REFORM

Prescribing behaviour is influenced by numerous factors including the characteristics of the patient and medical practitioner, industry marketing and advertising, financial incentives (including those generated by method of payment) and non-financial incentives (such as medical ethics, information provision, guidelines, etc.). Here, we focus on three strategies that are frequently employed on the supply side with regard to prescriber behaviour.

7.3.1 Prescribing by INN

A key driver of the high rate of generic prescribing in the UK has been the acceptance by UK practitioners of writing prescriptions by generic name without specifying the brand or manufacturer, i.e. open prescribing (Barry *et al.*, 2009). In the UK, INN prescribing is strongly encouraged by the NHS and widely practised (Vogler and Schmickl, 2010). In addition to the potential cost savings, prescribing by INN is safer as it reduces the potential for confusion when prescribing a pharmaceutical or when seeking to identify a pharmaceutical that the patient has been taking (National Medicines Information Centre, 2009).

A study of French GPs' willingness to prescribe²⁵ by INN highlighted the key roles played by GPs' information about pharmaceuticals and the sources they receive this information from, by GPs' volume of cases and to a lesser extent by the socio-economic characteristics of their patients (Paraponaris *et al.*, 2004). The role of information was particularly important. GPs who consulted French prescription practice guidelines, who read several medical journals and who used a computer were significantly more likely to prescribe by INN. GPs who met with more than 10 pharmaceutical sales representatives a week were also significantly less likely to prescribe by INN.²⁶ Windmeijer *et al.* (2006) also found that Dutch GPs' pharmaceutical price sensitivity was adversely affected by promotional activity by pharmaceutical companies. A recent Irish study focused on the role of GP and practice characteristics as well as the characteristics of the product in motivating GPs' prescribing decisions concerning new pharmaceuticals (Bourke and Roper, 2011).

There is some international evidence that GPs consider the financial situation of their patients; GPs in areas with higher than average rates of public housing were

²⁵ Note that the study examined GPs' *willingness* to prescribe by INN, rather than their actual prescribing behaviour. It was also carried out before two significant reforms of the French system; from 2002, French GPs are required to prescribe by INN in exchange for fee increases, and in October 2003, reference pricing and generic substitution was introduced (Paraponaris *et al.*, 2004).

²⁶ In comparison to originator or brand name manufactures, manufacturers of generic pharmaceuticals devote fewer resources to marketing of their products (Paraponaris *et al.*, 2004).

significantly more likely to prescribe by INN in the French study discussed above (Paraponaris *et al.*, 2004). Lundin (2000), in an analysis of Swedish medical practitioners, also finds that medical practitioners are less likely to prescribe trade-name pharmaceuticals to patients that have to pay large sums out of pocket (see also Mott and Cline (2002) for US evidence). Dalen *et al.* (2011) note the international evidence on habit persistence in medical practitioners' prescribing behaviour, but in their analysis of Norwegian data find that as the price difference between generics and brand name products increase, medical practitioners become more inclined to prescribe a generic version. Medical practitioner (i.e., age, sex, GP or hospital medical practitioner) and patient characteristics (i.e., age, sex, extent of co-payment) were also found to be important.

The extent to which Irish GPs are still sceptical about the reliability and quality of generic products is questionable; the IMO recently issued a policy brief advocating the use of mandatory generic prescribing (IMO, 2010). Evidence from Sweden after the introduction of generic substitution by pharmacists in October 2002 suggests that resistance to generic substitution was more frequent among patients than prescribers, with prescribers rarely restricting substitution of generics (Andersson *et al.*, 2005).

Prescribing by INN is a strategy which is strengthened by complementary policies in relation to generic substitution on the part of pharmacists (Kanavos, 2008), and by complementary policies in relation to patient co-payments (Godman *et al.*, 2011). In addition, patients need to be reassured that generic products are equivalent and safe to consume; the IMB publishes information leaflets for the public which provide reassurance on the bioequivalence of generics (IMB, 2010). Currently, legislation to give effect to a system of reference pricing and generic substitution by pharmacists is being drafted. Clearly the body charged with certifying interchangeability will have a key role in assuring medical practitioners and patients on issues such as quality and safety.

A commonly cited reason for the significantly higher rates of generic prescribing in the UK is the role of medical education; however, we understand that medical practitioners are taught the INN in medical school²⁷ and, therefore, this should not be a barrier to INN prescribing on the part of Irish medical practitioners. A number of countries have a policy of mandatory prescribing by INN (including Estonia, Lithuania, Portugal and Romania) (Vogler and Schmickl, 2010). For single source in-patent pharmaceuticals and multiple source off-patent pharmaceuticals that will be deemed interchangeable with the introduction of reference pricing and generic

²⁷ PSI, personal communication, 17 June 2011.

substitution next year in Ireland, mandatory INN prescribing would be a safe and cost-effective policy change. Exceptions to mandatory INN prescribing would be allowed for legitimate 'no substitution' prescriptions (see Chapter 4) and for cases in which products are not deemed to be interchangeable.

Recommendation 7.1: We recommend that, taking into account forthcoming legislation on reference pricing and generic substitution, including interchangeability and no substitution prescriptions, mandatory prescription by INN should be introduced for all medical practitioners to encourage safe and cost-effective prescribing.

7.3.2 Financial Incentives

Financial incentives include performance payments to prescriber for achieving prescription targets and remaining within (acceptable) prescription limits. Financial penalties may be levied for missing targets or exceeding limits. Financial incentives may also take the form of budgets. Budgets are funds that are allocated by payers (e.g. the State, private health insurers) to individual medical practitioners or groups of medical practitioners, thereby giving them financial responsibility for the management of their own budget. As medical practitioners are financially responsible for any overspends, budgets provide incentives to prescribers to prescribe fewer and less expensive pharmaceuticals (such as generics) (Sturm *et al.*, 2011). A number of countries have experimented with performance-related payments and pharmaceutical budgets, and provide valuable lessons.

In Germany in 1993, it was agreed that if a regional pharmaceutical budget exceeded a maximum threshold, the medical practitioners would be responsible for the difference. In the first year (1993), medical practitioners' liability was limited to 1 per cent of their total fees, but after the first year, medical practitioners became fully responsible for any excess spending. There were no positive incentives; medical practitioners were not allowed to keep the difference if they underspent (Delnoij and Brenner, 2000). While the number of prescriptions initially declined following the introduction of the sanctions, the number began to rise again in 1995, and the scheme was eventually discontinued in 2001. Prescription levels returned to their previous levels mainly due to ineffective policy implementation and enforcement. A particular problem was that it was difficult to identify which medical practitioners were responsible for the overspend; some medical practitioners challenged the legality of the sickness funds' demands (Delnoij and Brenner, 2000). It has also been suggested that medical practitioners responded by referring more patients to

hospital; thus, estimates of cost savings may be overestimated (Kanavos *et al.*, 2011). There was also evidence of gaming; in anticipation of the pharmaceutical budget, the cost and volume of prescriptions showed a significant increase in the final quarter of 1992, just before the budget came into effect (Delnoij and Brenner, 2000).

Between 1991 and 1999, the UK GP Fundholding scheme made GPs responsible for prescribing costs (Delnoij and Brenner, 2000). GPs' fundholding budgets covered elective surgery, outpatient care, diagnostic testing, community nursing and prescribing, and budgets were based on historical trend. In terms of prescribing costs, Gosden *et al.* (1999) found that the prescribing costs of fundholding practices increased at a lower rate than non-fundholding practices. The reason for the reduction was that fundholders switched to cheaper, generic pharmaceuticals, rather than a reduction in the number of items prescribed. However, there is evidence that the differences between fundholding and non-fundholding practices declined over time (Delnoij and Brenner, 2000). In addition, it is difficult to establish a direct causal link between participation in GP fundholding and lower prescribing costs; it is possible that those practices which embraced fundholding may have delivered the same service improvements, or a significant part of them, in the absence of the scheme (Department of Health and Social Services, 1999). Problems associated with fundholding included the budget formula (as it was based on historical trend, past inefficiency was rewarded and the potential for gaming in the year before the scheme was introduced was increased), administrative costs and selection (Croxon *et al.*, 2001; Dusheiko *et al.*, 2003). The successor to GP fundholding, Practice Based Commissioning (PBC) has encountered many of the same problems (Curry *et al.*, 2008).

A recent cross-country analysis of pharmaceutical consumption among the over 50s found that pharmaceutical consumption among the over 50s was significantly lower in countries with budgets for prescribers (Lambrelli and O'Donnell, 2009). However, a comprehensive review of studies evaluating the impact of budgets on pharmaceutical spending found that while budgets for medical practitioners can limit pharmaceutical expenditure by limiting the volume of prescribed pharmaceuticals, increasing the use of generic pharmaceuticals or both, the majority of studies included were found to have serious methodological limitations. Thus clear recommendations on budgets could not be inferred (Sturm *et al.*, 2011).

Many countries now include prescribing targets as indicators and as part of a more general pay-for-performance elements of medical practitioner remuneration. For example, three of the 134 indicators in the UK Quality and Outcomes Framework

(QOF) relate to 'medicines management' (NHS Information Centre, 2010).²⁸ In 2009/2010, achievement on these three indicators was 92.0 per cent, 97.7 per cent and 96.1 per cent respectively.²⁹ In New Zealand, the Performance Management Programme (whereby Primary Health Organisations (PHO)³⁰ are eligible for extra performance-related payments) includes an indicator that tracks PHO pharmaceutical expenditure relative to a benchmark. In Australia, the Quality Prescribing Incentive of the Practice Incentives Program (PIP) aims to encourage practices to keep up to date with information on the quality use of pharmaceuticals by rewarding participation by practices in a range of activities recognised or provided by the National Prescribing Service (NPS) (Section 7.3.3). To qualify for a payment, practices are required to participate in three activities per annum.³¹ As most pay-for-performance initiatives are relatively recent phenomena, there are few evaluations of the various pay-for-performance schemes. While a number of studies of the QOF have found that the QOF has an impact on prescribing (see for example, MacBride-Stewart *et al.*, 2008), the extent to which the specific indicators in relation to 'medicines management' have been effective in reducing overall pharmaceutical costs has not been studied.

In summary, the evidence on the effectiveness of incentive schemes for medical practitioners in limiting pharmaceutical (and other healthcare) expenditure is weak (Bloor and Freemantle, 1996; Gosden *et al.*, 1999; Sturm *et al.*, 2011). What we do know is that most incentive schemes are only temporarily effective, by removing a degree of unnecessary expenditure from the system. This was also seen with the IDTS where the rise in prescribing costs for all three groups was similar in later years (Walley *et al.*, 2000). In addition, while they may reduce pharmaceutical expenditure, the extent to which costs are simply transferred to other parts of the health-care system is unclear. Such schemes also require significant investment in terms of data management and monitoring (Smith *et al.*, 2004). Hence:

²⁸ Medicines 10: The practice meets the prescribing adviser at least annually, has agreed up to three actions related to prescribing and subsequently provided evidence of change. Medicines 11: A medication review is recorded in the notes in the preceding 15 months for all patients being prescribed four or more repeat medicines. Medicines 12: A medication review is recorded in the notes in the preceding 15 months for all patients being prescribed repeat medicines (NHS Information Centre, 2010).

²⁹ Available from: http://www.ic.nhs.uk/webfiles/QOF/2009-10/National%20tables/QOF0910_National_Organisational.xls (accessed 16 August 2011).

³⁰ PHOs are not-for-profit entities that provide services either directly by employing staff or by contracting with independent providers. Although primary health care practitioners, such as GPs and allied health professionals, are encouraged to join PHOs, membership is voluntary. In 2009, there were 82 PHOs around the country (Cumming and Mays, 2011).

³¹ (i) A clinical audit of prescribing for specific pharmaceutical groups, using materials approved or produced by the NPS. (ii) Case studies using problem-based distance learning provided by the NPS. The case studies present a clinical scenario accompanied by a set of questions designed to help participants refine their clinical decision-making skills. The NPS presents each case study in two formats, a printed version inserted with NPS News and an online version. (iii) Practice visit(s) by an independent pharmaceutical detailer working from a number of Divisions of General Practice. These 'academic detailing' visits will act as a resource for GPs and promote the quality of prescribing (Medicare Australia, 2011).

Recommendation 7.2: We recommend that, on the basis of existing evidence, financial incentives to reduce pharmaceutical expenditure should not be introduced for medical practitioners in Ireland.

7.3.3 Prescription Guidelines, Feedback and Monitoring

Influencing medical practitioner prescribing decision involves numerous strategies, including dissemination of printed education materials, feedback on prescribing patterns, prompts and reminders at the time of prescribing and one-to-one education (Soumerai *et al.*, 1989). Most countries attempt to influence pharmaceutical prescribing to some extent, but there is variation in the level, frequency and intensity of the efforts (Kanavos, 2008, p. 2).

In some countries, an independent agency is responsible for collating information on prescription guidelines and presenting this information to medical practitioners. For example, in Australia, the National Prescribing Service (NPS) assists GPs to achieve more effective, quality prescribing through a range of education, support and prescribing information. The NPS is a professional organisation, run independently of the Australian Government with broad GP representation and leadership.³² As part of the PIP (described in Section 7.3.2), GP practices may receive additional payments for performance in relation to participation in quality prescribing activities, including clinical audits of prescribing for specific pharmaceutical groups and practice visits by independent pharmaceutical detailers providing advice in relation to quality prescribing. In New Zealand, the New Zealand Guidelines Group is an independent, not-for-profit organisation that promotes the use of evidence in the delivery of health and disability services.³³

In the UK, the NHS Prescribing Support Unit aims to support policy initiatives concerned with primary care by producing regular reporting on prescribing activity and by providing informed advice on prescription-related issues.³⁴ It maintains two important databases, the Prescribing Cost Analysis (PCA) database³⁵ and the Quality and Outcomes Framework Achievement and Exception Reporting database. Analysis of the PCA database results in two annual publications that present national-level trends and comparisons (NHS Information Centre, 2011b; a). Individual GP practices and Primary Care Trusts may also access real time on-line analysis of prescribing data

³² See www.nps.org.au for further details (accessed 5 October 2011).

³³ See www.nzgg.org.nz for further details (accessed 5 October 2011).

³⁴ See www.ic.nhs.uk/psu for further details (accessed 16 August 2011).

³⁵ PCA data refer only to prescriptions dispensed in England (although the prescription could be written in England, the Isle of Man, Northern Ireland, Scotland or Wales).

over the previous 60 months (termed the 'Prescribing Toolkit'). Data is updated on a monthly basis (six weeks after the dispensing month) and includes: budgets and expenditure forecasts; costs and volumes of prescribing; prescribing totals by prescribers at all British National Formulary (BNF) levels. Practice prescribing can be analysed comparatively across a variety of domains such as: patient; prescribing unit; ASTRO prescribing unit - age, sex and temporary resident prescribing unit; STAR prescribing unit – specific therapeutic age-sex related prescribing units.³⁶

In many countries, the existence of positive or negative reimbursement lists acts as an indirect control on prescribing behaviour (OECD, 2008; Lambrelli and O'Donnell, 2009). In New Zealand, prescribing behaviour is further regulated indirectly by PHARMAC, the State agency responsible for the pricing and reimbursement of pharmaceuticals in New Zealand, via additional requirements for reimbursement of certain products. In order for certain types of products to be subsidised by the State,³⁷ medical practitioners must fill out detailed 'special authority' or 'controlled drug' forms (for example, the 'special authority' form for the reimbursement of risperidone is reproduced in Figure 7.3).³⁸

FIGURE 7.3 Special Authority Form for Reimbursement of Risperidone by PHARMAC New Zealand

Ministry of Health Phone 0800 243 666	APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY	Page 1 Form SA0927 October 2011
APPLICANT (stamp or slicker acceptable)	PATIENT NH:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....	Address:
Fax Number:	Fax Number:
Risperidone orally disintegrating tablets		
INITIAL APPLICATION - Acute situations Applications from any relevant practitioner. Approvals valid for 6 weeks.		
Prerequisites (tick boxes where appropriate)		
<input type="checkbox"/> For a non-adherent patient on oral therapy with standard risperidone tablets or risperidone oral liquid		
and		
<input type="checkbox"/> The patient is under direct supervision for administration of medicine		
INITIAL APPLICATION - Chronic situations Applications from any relevant practitioner. Approvals valid for 1 year.		
Prerequisites (tick boxes where appropriate)		
<input type="checkbox"/> The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid		
and		
<input type="checkbox"/> The patient is under direct supervision for administration of medicine		
RENEWAL Current approval Number (if known):		
Applications from any relevant practitioner. Approvals valid for 1 year.		
Prerequisites (tick boxes where appropriate)		
<input type="checkbox"/> The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid		
and		
<input type="checkbox"/> The patient is under direct supervision for administration of medicine		
Note: Risperdal Quicklets cost significantly more than risperidone tablets and should only be used where necessary.		
I confirm the above details are correct and that in signing this form I understand I may be audited.		
Signed: Date:		
Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131		

³⁶ See www.nhsbsa.nhs.uk/ for further details (accessed 5 October 2011).

³⁷ Special authorisations are required where a medical practitioner is applying for access to subsidy or increased subsidy on behalf of a patient, or applying for the waiver of certain restrictions otherwise present on the Community Pharmaceutical Schedule (see www.moh.govt.nz/moh.nsf/indexmh/sectorservices-claims-specialauthority#what; accessed 7 November 2011).

³⁸ The issue is similar to that which arises in the case of 'no substitution' regulations for generic substitution (discussed in Chapter 4).

Kanavos (2008) concluded that it is unclear what effect non-financial incentives and measures have in practice, but it is thought that unless they are vigorously implemented and monitored, their effectiveness is likely to be poor. In particular, a comprehensive review of over 44 papers on prescribing in primary care found that there was no evidence that one of the most ubiquitous forms of prescribing education, i.e., distribution of printed education materials, had any influence on prescribing behaviour (when used in isolation) (Soumerai *et al.*, 1989).³⁹ A recent review of the effectiveness of various strategies to control the inappropriate prescription of antibiotics similarly highlights that the use of printed educational materials or audit and feedback alone results in no or only small changes in prescribing (Arnold and Straus, 2011). Feedback may be more effective when accompanied by explicit information on suggestions for alternative treatment (Soumerai *et al.*, 1989). There is also some evidence that one-to-one counselling or education outreach (by 'academic detailers') can be effective in changing prescribing behaviour, and also some evidence that such interventions can be cost effective, i.e., achieve net savings (Soumerai *et al.*, 1989; Figuerias *et al.*, 2001; Jamtvedt *et al.*, 2010). Given the international evidence on the efficacy of feedback to prescribers:

Recommendation 7.3: We recommend: (i) the PCRS should coordinate the provision of periodic benchmarking information to GPs; and (ii) the HSE should undertake a similar exercise for hospital medical practitioners practising in public hospitals. Both the PCRS and the HSE should be pro-active in following up with individual medical practitioners who demonstrate prescribing behaviour that is at variance with clinical guidelines. Protocols should be developed with the Medical Council that specify the procedures to be followed for cases referred to the Medical Council for inappropriate prescribing.

Feedback on prescribing behaviour requires information on the most appropriate course of treatment for particular conditions. Cognisant of the work of the HSE Directorate of Clinical Strategy and Programmes:

Recommendation 7.4: We recommend that consideration should be given to centralising and standardising the provision of prescription guidelines to both GPs and hospital medical practitioners.

³⁹ Even in situations involving significant risks to patients (i.e. the prescription of hazardous products), the evidence on the effectiveness of the distribution of printed warnings to prescribers was limited (Soumerai *et al.*, 1989).

7.4 CONCLUSION

In facilitating safer and more cost-effective prescribing, it is important to recognise the contribution of complementary demand- and supply-side measures (e.g. facilitating early entry by generic companies; reference pricing; reimbursement of pharmacists via flat fees and/or regressive mark-ups; generic substitution, etc.) (Kanavos, 2008). It is also important to recognise the extent to which prescribing behaviour in the community is influenced by prescribing decisions that are made by hospital prescribers. Notwithstanding these caveats, there are a number of strategies that have been suggested as mechanisms to encourage safer and more cost-effective prescribing, and the international evidence offers some directions for current policy. The key is to ensure that medical practitioners are provided with effective information and support to enable them to make the most appropriate clinical decisions for their patients.

Chapter 8

A Roadmap for Reform

In the face of the financial crisis, recession and the consequent budgetary pressures, many OECD governments introduced pharmaceutical price reductions (OECD, 2010). Ireland was no exception. However, such policy measures can only ever be short-term fixes. In this report we have sought to go beyond these short-term measures, by designing an appropriate framework for the delivery of pharmaceuticals that will improve value for money, while at the same time ensuring security of supply. In designing the policy framework we have drawn extensively on the experience of what works elsewhere, while at the same time paying careful attention to the different institutional, economic and social contexts that may limit the applicability of a lesson from (say) New Zealand to Ireland. However, we have also been fortunate that we have been able to draw on an extensive set of earlier reports undertaken for the Health Service Executive and/or the Department of Health. Our proposals for policy are, therefore, evolutionary rather than revolutionary. They build upon what has gone before. In part, this has been driven by evidence that variation *within* given health care systems is much greater than *between* them (Borowitz *et al.*, 2011, pp. 33-37), and that no one system fulfils all objectives. Thus by revising rather than redesigning the current model of pharmaceutical delivery better value for money can be realised, while at the same time the costs and unintended consequences of large changes in the pharmaceutical delivery system can be prevented.

Designing recommendations to a considerable extent involves creating the right set of incentives. Irrespective of the pharmaceutical delivery system, incentives exist upon which pharmaceutical suppliers, wholesalers, pharmacists, medical practitioners and patients act. It is therefore important to get these incentives right. The objectives of the pharmaceutical delivery system need to be clearly specified in terms of value for money and security of supply. The system is to serve the interests of patients and taxpayers, not the stakeholders that deliver the service. The system becomes ill-focused and difficult to manage if it has too many objectives to attain. Furthermore, to the maximum extent possible we have designed the various recommendations in order that they work with the grain of the market rather than against it. Several examples in the past, such as the quantitative restrictions on new pharmacies, show the problems created by not taking market forces into account. This, it seems to us, is part of a wider trend in the professions in Ireland, such as dentistry and medicine, of providing more information for patients while at the same

safeguarding patient interests through appropriate professional regulation of standards and conduct.

Nevertheless, it would be foolish to suggest that, even if all the recommendations in this report were implemented immediately, no further reform would be necessary. Apart from the fact that new problems arise or that we may have specified the problem/solution inadequately, the pharmaceutical delivery system consists of stakeholders at every stage in the pharmaceutical delivery system that are likely to react to the recommendations in ways in which we have not foreseen. In some instances the reaction may result in the desired policy objective of the recommendation not being reached. A number of examples were given in Chapter 4 with respect to reference pricing and generic substitution where stakeholder response meant that the policy did not achieve its objectives. This means that constant vigilance is needed by the Health Service Executive and policy makers in the Department of Health to ensure that appropriate action can be taken when this occurs. In a number of instances we have attempted to anticipate such reactions and specify appropriate responses. In this context, it is imperative that the Health Service Executive and Department of Health have at their disposal the most up-to-date and comprehensive data available, and a number of recommendations are made in this regard.

The recommendations in the report are presented in Table 8.1. The recommendations are grouped together by the particular issue to which they are addressed from data collection issues, to the ex-factory pricing of in-patent single source pharmaceuticals, to whether or not prescribers should be incentivised to reduce pharmaceutical expenditure. Often in implementing recommendations sequencing is important. Before a particular recommendation can be implemented, certain prior recommendations or policies should be introduced. In the case of the set of recommendations in Table 8.1, legislation is clearly needed to give effect to the introduction of reference pricing and generic substitution, which is expected to be introduced in the Dáil in 2012. It is not clear beyond this that any additional legislation is required, although some of the measures recommended concerning pharmacy may require legislation. In terms of sequencing, it is clear that the current arrangements concerning the pricing of off-patent multi-source pharmaceuticals can only be replaced once the legislation concerning reference pricing and generic substitution has been passed and implemented.

The recommendations contained in this report are designed to ensure that taxpayers get better value for money from the €1.9 billion pharmaceutical budget covering the GMS and Community Drug Schemes. They are also designed to ensure that patients, irrespective of whether or not the State pays for the pharmaceutical, are prescribed

the appropriate pharmaceutical for their condition and achieve an improved health status.

TABLE 8.1 Recommendations

Data Collection	
Recommendation 2.1	We recommend that the HSE should be responsible for the collection, preparation and publication of a comprehensive time-series of all components of pharmaceutical expenditure (public, private, community and hospital) on an annual basis.
Recommendation 2.2	We recommend that pharmacists should be required to inform the PCRS of the out-of-pocket expenditure, i.e., sub-threshold expenditure, by those who do not exceed the DP threshold.
Objectives	
Recommendation 3.1	We recommend that the two objectives of the pharmaceutical delivery system from the perspective of the HSE should be obtaining value for money and ensuring security of supply.
Ex-Factory Pricing of In-Patent Single Source Pharmaceuticals	
Recommendation 4.1	We recommend that, initially at least, the basket of Member States used for the purposes of determining the maximum ex-factory price of in-patent pharmaceuticals should be confined to the nine Member States in the 2006 IPHA/HSE agreement.
Recommendation 4.2	We recommend that the maximum ex-factory price of in-patent pharmaceuticals should be the lowest price of the basket of nine Member States in the 2006 IPHA/HSE agreement.
Recommendation 4.3	We recommend that the maximum ex-factory price for in-patent pharmaceuticals should be updated every six months, i.e., on 1 January and 1 July.
Recommendation 4.4	We recommend that the HSE monitor parallel imports in order to assist it to: (i) validate the pricing information provided to set the maximum ex-factory price for the current basket of nine Member States; and, (ii) determine whether additional Member States should be added to the basket of Member States.
Recommendation 4.5	We recommend that the HSE negotiates risk sharing agreements with firms seeking eligibility for reimbursement under the GMS and Community Drug Schemes for new pharmaceuticals on introduction in terms of expected sales and market penetration.
Ex-Factory Pricing of In-Patent Multi-Source Pharmaceuticals	
Recommendation 4.6	We recommend that the HSE set an ex-factory price for parallel imports that shares the difference between the imported price of the parallel import and the brand name ex-factory price of the in-patent pharmaceutical between the parallel importer and the HSE.
Recommendation 4.7	We recommend that the reference price for high volume off patent interchangeable pharmaceutical products should be set through competitive tendering.
Recommendation 4.8	We recommend that for the HSE to reimburse an interchangeable pharmaceutical product at a price higher than the reference price, the medical practitioner must complete an IMB Adverse Reaction Report Form and write, in his/her own handwriting, 'no substitution' across the prescription form.
Recommendation 4.9	We recommend that if a prescription is written using the international non-proprietary name then the pharmacist is reimbursed at the reference price.
Recommendation 4.10	We recommend that the definition of interchangeability should be broad enough to accommodate minor changes in formulation (e.g., use of different salts) and presentation (e.g., different shaped solid dose forms).

Monitoring Wholesale Developments

Recommendation 5.1	We recommend that the HSE actively monitor the importance and service levels offered by DTP brand name manufacturers. If the service levels fall below levels considered acceptable to the HSE, then it should negotiate minimum quality standards with brand name manufacturers using the DTP model.
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Providing More Information to Patients

Recommendation 6.1	We recommend that pharmacists are compensated for dispensing a prescription on the basis of a professional dispensing fee only. This should apply to both prescriptions dispensed under the GMS and Community Drug Schemes as well as for the cash paying patient.
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Recommendation 6.2	We recommend that all pharmacies be required to post, in a manner clearly accessible to patients, a notice setting out their usual and customary dispensing fee and mark-up together with what services are included for the dispensing fee. A standard template should be used.
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Recommendation 6.3	We recommend that PSI permit pharmacists to advertise dispensing fees, services provided and price discounts and rebates with respect to prescription pharmaceuticals.
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Recommendation 6.4	We recommend that pharmacists are able to offer and to advertise that they will pay, in part or whole, any patient co-payment that is part of the GMS and Community Drug Schemes.
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Recommendation 6.5	We recommend that the HSE should carefully monitor the pharmacy market, conducting regular surveys of dispensing fees and offers made by pharmacies.
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The Prescriber

Recommendation 7.1	We recommend that, taking into account forthcoming legislation on reference pricing and generic substitution, including interchangeability and no substitution prescriptions, mandatory prescription by INN should be introduced for all medical practitioners to encourage safe and cost-effective prescribing.
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Recommendation 7.2	We recommend that, on the basis of existing evidence, financial incentives to reduce pharmaceutical expenditure should not be introduced for medical practitioners in Ireland.
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Recommendation 7.3	We recommend (i) the PCRS should coordinate the provision of periodic benchmarking information to GPs; and (ii) the HSE should undertake a similar exercise for hospital consultants practising in public hospitals. Both the PCRS and the HSE should be pro-active in following up with individual medical practitioners who demonstrate prescribing behaviour that is at variance with clinical guidelines. Protocols should be developed with the Medical Council that specify the procedures to be followed for cases referred to the Medical Council for inappropriate prescribing.
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Recommendation 7.4	We recommend that consideration should be given to centralising and standardising the provision of prescription guidelines to both GPs and hospital medical practitioners.
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Annexe A

Reports on Pharmacy Services in Ireland, 2003-2011^a

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication
Report of the Pharmacy Review Group (2003) <i>Mortell, Michael (Chair)</i>	Minister for Health and Children	<p>'In the context of regulatory reform in Ireland and the vital role played by pharmacies in the health service, to review the Pharmacy Regulations with a view to:</p> <ol style="list-style-type: none"> 1. facilitating the provision, maintenance and development of a high quality pharmacy service to service recipients; 2. maximising the potential to increase competition within the sector with a view to ensuring lower prices and improved services to the consumer as envisaged in the <i>OECD Report on Regulatory Reform in Ireland</i>; 3. assessing and responding to the recommendations in the <i>OECD Report</i> on restrictions on the location of pharmacies while ensuring, in so far as is possible, a reasonable spread of pharmacies so that the service is convenient to the consumer; 4. assessing and responding to the recommendations in the <i>OECD Report</i> on the current restrictions on pharmacists educated in other EU countries with a view to enabling this country to discontinue the derogation incorporated in Article 2.2 of Council Directive 85/433/EEC on the free movement of pharmacists; 5. ensuring a high quality pharmacy service in remote and deprived areas (to include an assessment of the dispensing doctor scheme); 6. ensuring that the opening hours of pharmacies facilitate consumers and meet all reasonable health needs of the population in its area; 7. assessing the extent to which the 1996 Regulations (together with the Community Pharmacy Contract) have achieved their objectives in regard to taking full account of pharmacy regulation in other jurisdictions; 8. taking full account of the wider regulatory framework in which pharmacy operates; 9. considering how a universal service and public service obligation can be identified and met and assessing any funding consequences which may arise; 10. In conducting the review the Group is to consult widely with all interests involved and, in particular, consumer interests.' 	<ol style="list-style-type: none"> (i) A supervising pharmacist should have at least 3 years community or other relevant pharmacy experience, including at least 6 months post-registration community pharmacy experience. (ii) Contracts should be subject to and on the basis of, regulations currently in force. (iii) Contracts should be non-transferable i.e. not tradable and specific to that contractor and address. (iv) A contractor should undergo a review/performance assessment, by or on behalf of the health board, at least every 5 years. Compliance with contract conditions should be enforced by the health board, with a range of appropriate sanctions. (v) Pharmacies should prominently display a quality service charter, including Clause 9 of the pharmacy contract and other contractual quality service requirements, opening hours and out of hours arrangements. (vi) There should be increased pricing transparency at point of sale, including advising of prescription prices in advance of supply and the price of all dispensed items on labels. (vii) Health boards should identify, through a needs assessment, any areas with a significant pharmacy need (including areas served by dispensing doctors) which the market has not filled and is unlikely to do so. (viii) Where a needs assessment identifies such an area and where an unincentivised contract has been offered but not taken up, the health board may offer an incentivised contract for that area, on a full-time, continuous service basis. Contracts should be awarded by competitive tender, on the basis of service level and standards. (ix) Where a full-time incentivised contract is not feasible (i.e. no incentivised contract is taken up within a reasonable period), an auxiliary pharmacy contract, incentivised if necessary, may be made available to fulfil the area's needs. Auxiliary contracts should be awarded by competitive tendering, on the basis of service level and standards. An auxiliary contractor will provide pharmacy services by a qualified supervising pharmacist from a designated fixed premises, in accordance with the usual regulatory and contractual requirements, at defined times only. Health boards should review the quality of the pharmacy services delivered from auxiliary contracts on a regular basis, but at least every 2 years. Quality reviews should be carried out with reference to the Pharmaceutical Society of Ireland and its statutory role in the assurance of professional practice standards. (x) Health boards should review auxiliary pharmacy contracts on a regular basis (at least every five years) to determine if they can be replaced with a full-time, continuous and permanent pharmacy service. Where the health board receives an application to provide a full-time, continuous and permanent pharmacy service to replace the auxiliary service, it should conduct the review at that time. (xi) Health boards should review all incentivised pharmacy contracts on a regular basis (at least every five years) to determine if incentives are still required. (xii) Incentive options might include: differential remuneration scheme (budget neutral) such as weighted fees for marginal pharmacies or a universal sliding fee scale; exclusive contract for a finite period not exceeding 5 years and subject to review; tax concessions; establishment or other grants. (xiii) Contractors must provide a full pharmaceutical service under their contract, as defined in the new pharmacy act, subject to the conditions of an auxiliary contract. (xiv) There should be no beneficial ownership or business interest of any kind between dispensing and prescribing. (xv) Group practices and pharmacies: contracted pharmacies and general practices should occupy discrete premises, with separate entrances. (xvi) Any pharmacy can hold a contract, subject to quality and service standards and with a restriction on the number of community pharmacy contracts that can be held by a single entity in any one health board area. (xvii) A single entity may hold up to 8 per cent of the total number of community pharmacy 	

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication
			<p>contracts in each health board area and any contracts above this must be matched by the operation of contracts in CEO-designated areas with a significant unmet pharmacy need, without incentives.</p> <p>(xviii) The Minister for Health and Children should take interim measures immediately to implement the 8 per cent limit on the number of contracts that may be held in a health board area.</p> <p>(xix) The use of the EU derogation should continue until a pharmacy act, to include the provisions set out below, is in place and then be discontinued. The pharmacy act should be in place within 18 months of the date of this report.</p> <p>(xx) This model should be reviewed in 5 years.</p>	
<p>Commission on Financial Management and Control Systems in the Health Service (2003)</p> <p><i>Brennan, Niamh (Chair)</i></p>	<p>Minister for Health and Children</p>	<p>(i) Examine the various financial management systems and control procedures currently operated in the Department of Health and Children and by the key budget holders in the health boards and in the main spending and service areas of the health sector.</p> <p>(ii) Assess the various reporting procedures in these services.</p> <p>(iii) Assess the capacity of the systems and procedures to provide relevant, timely and reliable information, in relation to:</p> <ul style="list-style-type: none"> - current expenditure, - capital expenditure with particular reference to the measurement of resource use against outcomes and, - management of resources within budgets. <p>(iv) Evaluate the capacity of these systems to develop cost consciousness among resource managers and to provide incentives to manage cost effectively.</p> <p>(v) Examine international best practice in regard to health service financial management systems, cost control and reporting arrangements.</p> <p>(vi) Examine how the estimates in the health area are compiled and allocations finalised and monitored.</p> <p>(vii) Consider how the presentation of financial data can be enhanced so as to provide better information on how service delivery is proceeding.</p> <p>(viii) Make recommendations in accordance with its findings, with a view to enhancing the timeliness and quality of financial management information throughout the health services and provided to Departments.</p>	<p>1. Current arrangements for reimbursing pharmacists under the medical card scheme – i.e. reimbursement on a cost of ingredients basis (without mark-up) plus a flat-rate prescription fee – should be extended to the Drugs Payment (DP) Scheme.</p> <p>2. The operation of the DP Scheme should be reviewed immediately by the Department of Health and Children, in consultation with the Department of Finance, the GMS (Payments) Board and the health boards. The review should actively examine:</p> <p>(i) Introducing a system whereby health boards would actively monitor and evaluate prescribing patterns by individual GPs, Consultants or Dentists and reimbursement patterns by individual pharmacists, having regard to relevant demographic and epidemiological factors;</p> <p>(ii) Introducing incentive schemes for reducing levels of prescribing and drugs costs;</p> <p>(iii) In recognition of the influence of hospital generated prescribing on community drugs budgets, each health board/hospital CEO should immediately establish Drugs and Therapeutics Committees, comprising Consultants, GPs from the hospital catchment area, supported by pharmacy and financial management expertise, to agree clinically cost-effective common drug formulary; and</p> <p>(iv) Relevant international experience and the lessons from this in containing drug costs and the rate of growth;</p> <p>3. 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.</p> <p>4. The Irish Medicines Board should have its remit extended to not just examine new drugs for their efficacy and effectiveness, but also to:</p> <p>(i) Assess their cost effectiveness; and</p> <p>(ii) Approve the drug product for reimbursement under the community drugs schemes (including specifying the conditions under which it may be made available, for example restricted to named patients or in respect of defined clinical treatment regimes).</p> <p>5. The Irish Medicines Board should also be charged with the responsibility to monitor the continuing effectiveness of existing drugs and to delist those which are no longer considered appropriate or clinically cost-effective.</p> <p>6. Where the Irish Medicines Board determines that a cheaper, but equally effective, alternative exists, only the cost of the cheaper drug should be reimbursed by the GMS (Payments) Board. Where a GP prescribes the more expensive branded drug, the cost difference arising should be regarded as entirely private prescribing.</p>	<p>The retail mark-up on the DP Scheme was reduced from 50 per cent to 20 per cent in July 2009.</p> <p>Now carried out by the National Centre for Pharmacoeconomics (NCPE).</p> <p>NCPE carries out HTA reviews on behalf of the HSE.</p> <p>Reference pricing legislation due to go before the Dáil in 2012.</p>
<p>Review of Governance and Accountability Mechanisms in the General Medical</p>	<p>Department of Health and Children</p>	<p>The scope of our work is as set out as follows:</p> <p>(i) To analyse the governance and accountability mechanisms in the General Medical Services (GMS) Schemes and payments made by the GMS (Payments) Board on behalf of Health Boards,</p>	<p>(i) The requirement to assess whether the LTI should be merged into the GMS.</p> <p>(ii) The need to cap annual payments under the IDTS, at an agreed budget amount.</p> <p>(iii) The need to urgently amend or indeed cease the Advance Drawdown of Monies under the IDTS to limit financial exposures in this area.</p> <p>(iv) The need to evaluate the cost/benefits of the extension of the GMS to all over 70s,</p>	<p>IDTS suspended in 2006.</p> <p>Automatic entitlement to GMS for those</p>

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication								
<p>Services Schemes (2003)</p> <p><i>Deloitte and Touche</i></p>		<p>(ii) To examine the roles and responsibilities of the Department of Health and Children, the Eastern Regional Health Authority/Health Boards and the GMS (Payments) Board in this context,</p> <p>(iii) To examine the underlying reasons for increasing cost trends in the GMS Scheme,</p> <p>(iv) To validate the estimated outturn for 2002 and assess its implications going forward</p> <p>(v) To make recommendations for the immediate resolution of any identified weaknesses and inadequacies.</p>	<p>particularly in light of the significant current and prospective costs associated with this extension.</p> <p>(v) The requirement to amend the basis of remunerating pharmacists under the DPS and LTI to a fee for service basis and not a mark up on ingredient costs.</p> <p>(vi) The requirement to establish protocols for drugs prescribing and to monitor prescription data at GP level to ensure appropriate and effective prescribing patterns.</p> <p>(vii) The requirement for medical technology appraisal on an ongoing basis.</p> <p>(viii) GPs and other primary care contractors should be required to take on an appropriate form of budget holding responsibilities and be accountable for their actions relative to the budget.</p>	<p>over 70 years discontinued from 01 January 2009.</p>								
<p>Review of Pharmacy Wholesale Margins (2007)</p> <p><i>Indecon</i></p>	<p>Health Service Executive</p>	<p>Assist the HSE Negotiation Team in identifying a realistic cost for the provision of pharmaceutical wholesale distribution services. This would lead to the establishment of a new fee or rate.</p>	<p>This report outlined a number of options for setting a wholesale margin</p> <ul style="list-style-type: none"> - continue with current rate and practice, - no price regulation of wholesale or retail margins, - price regulation of retail margins only, - introduce flat rate related to current market conditions, - introduce a sliding fee related to the value of products. 	<p>The wholesale mark-up was to be reduced from 17.66 per cent to 8 per cent from 01 January 2008 and to 7 per cent of the ex-factory price from 01 January 2009. However, legal issues arose and this change was suspended in September 2008. From 01 July 2009, the wholesale mark-up was reduced to 10 per cent.</p>								
<p>Report of the Independent Body on Pharmacy Contract Pricing (2008)</p> <p><i>Dorgan, Sean (Chair)</i></p>	<p>Minister for Health and Children</p>	<p>To advise the Minister on an appropriate level of dispensing fee to be paid to community pharmacists for existing services under the GMS and community drugs schemes. The €5 per item fee offered in the Interim Community Pharmacy Contract was to be given consideration. ^b</p>	<p>Rather than a single flat dispensing fee a sliding dispensing fee structure was recommended for the reimbursement of pharmacists on the community drugs schemes</p> <table border="1" data-bbox="1005 724 1370 823"> <thead> <tr> <th data-bbox="1005 724 1370 745">Number of items dispensed per annum</th> <th data-bbox="1382 724 1742 745">Fee per item</th> </tr> </thead> <tbody> <tr> <td data-bbox="1005 750 1370 770">Up to 20,000 items</td> <td data-bbox="1382 750 1742 770">€7.00</td> </tr> <tr> <td data-bbox="1005 775 1370 796">20,001 to 30,000 items</td> <td data-bbox="1382 775 1742 796">€6.50</td> </tr> <tr> <td data-bbox="1005 801 1370 821">Over 30,000 items</td> <td data-bbox="1382 801 1742 821">€6.00</td> </tr> </tbody> </table>	Number of items dispensed per annum	Fee per item	Up to 20,000 items	€7.00	20,001 to 30,000 items	€6.50	Over 30,000 items	€6.00	<p>A sliding fee structure was introduced in July 2009 at lower rates than those proposed. The retail mark-up on the DP, LTI, EEA and HAA schemes remained in place but was reduced from 50 per cent to 20 per cent.</p>
Number of items dispensed per annum	Fee per item											
Up to 20,000 items	€7.00											
20,001 to 30,000 items	€6.50											
Over 30,000 items	€6.00											
<p>Economies in Drug Usage in the Irish Healthcare Setting (2009)</p> <p><i>Barry, Michael (Chair)</i></p>	<p>Minister for Health and Children</p>	<ol style="list-style-type: none"> 1. To recommend efficiencies and savings in drug costs under the GMS and CDS whether through more rational and cost-effective prescribing at GP level or otherwise. 2. To advise on the information and educational or training initiatives, or standards and protocols, that might be put in place to support more efficient and cost effective prescribing. 3. To identify areas where over use or inappropriate use of certain drugs could be reduced or eliminated. 4. To consider the capacity for increased generic prescribing by GPs. 	<ol style="list-style-type: none"> 1. The IPHA/HSE agreement should be monitored on an ongoing basis and the development of analytical capacity for this purpose should be a priority. 2. A cost-effectiveness analysis should be conducted for products reimbursed under the community drugs schemes where available evidence queries the value for money associated with such products and reimbursement should be reconsidered following assessment. In view of the current IPHA/HSE agreement initial savings in the region of €5m may be achieved with another €5 million over the coming years. 3. The reimbursement status of products such as clinical nutritional products, glucosamine and therapies under the DP Scheme should be considered, mindful of the IPHA agreement [€10 million per annum]. Consideration should be given to separate reimbursement lists for the GMS and DP schemes. 4. Patients should be better informed in relation to the pricing of medicines and the information that accompanies medications so that they may play a role in optimising value for money and reducing wastage. 5. The ex-factory price for generic preparations should be reviewed with consideration given to the introduction of a price considerably below the price of the relevant proprietary product [at 20 per cent to 30 per cent below current price, €15 million to €20 million per annum]. 6. Generic prescribing by general practitioners should be encouraged and facilitated by prescription software systems, prescription data analysis and professional prescribing advice and support [at current generic pricing, €10 million per annum]. 7. There should be feedback to GPs in relation to quality prescribing indicators. Further development and expansion of the new prescribing analysis reporting system will facilitate same [€15 million per annum]. Incentivising GPs to enhance quality and cost-effective prescribing using quality prescribing indicators should be considered. 	<p>Recommendation 10 was addressed in the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2009 – SI 246.</p> <p>See Chapter 7 for description of current initiative regarding GP feedback on prescribing patterns.</p>								

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication
			<p>8. Medicines use reviews should be considered in an attempt to improve compliance and health outcomes as well as reducing wastage associated with prescription drugs.</p> <p>9. In view of the influence of hospital prescribing on drug expenditure in the community the HSE should develop continuity across hospital and community prescribing.</p> <p>10. The HSE should continue its consideration of wholesaler margins and payments to pharmacies with a view to achieving value for money from the community drugs schemes.</p> <p>11. Audit and inspection procedures should be reviewed to ensure that they are robust and comprehensive enough to validate any state expenditure on any part of the medicines supply chain.</p>	
<p>Report of the Special Group on Public Service Numbers and Expenditure Programmes (2009)</p> <p><i>McCarthy, Colm (Chair)</i></p>	<p>Minister for Finance</p>	<ol style="list-style-type: none"> Review the scope for reducing or discontinuing Expenditure Programmes with a view to eliminating the current budget deficit by 2011. Analyse and make recommendations on reducing the numbers employed in each area of the Public Service Make recommendations on reallocation of staffing or expenditure resources between public service organisations as appropriate to deliver the objectives set out in the Programme for Government. Examine and make recommendations for further rationalisation of state agencies beyond the rationalisation proposals and principles set out in Budget 2009. 	<p><i>Primary Care</i></p> <p>In the area of Primary Care the group identified savings of €577 million in a full year. It is recommended that:</p> <ul style="list-style-type: none"> the income guidelines for the medical card be revised to the basic rate of social welfare (Jobseekers Allowance) and that all existing non-medical allowances and HSE discretion be removed and replaced with a set of clearly defined factors based on medical needs. the existing entitlement of a person who has been unemployed for a minimum of 12 months to retain their medical card for 3 years after commencing employment (irrespective of means or medical need) be reduced to 1 year. the HSE intensifies and maintains its recent efforts to improve the accuracy of its GMS medical card database register in order to avoid any overpayment of GP capitation fees and to improve its overall control processes governing the accuracy and probity of payments made to GPs, community pharmacists and other independent contractors. The potential outsourcing of this work should also be examined actively along with the potential to link the database to the Death Register database [€100.0m]. the threshold for the DP Scheme be increased to €125 [€37.0 million]. a co-payment of €5 for each prescription under the GMS and LTI be introduced [€70.0 million]. tenders by open competition to provide services under the GMS be introduced [€370.0 million]. <p><i>Generic prescribing in hospitals</i></p> <p>The group recommends the HSE introduce mandatory protocols requiring publicly funded hospitals and clinicians to prescribe generic medicines, off-patent drugs which also take into account the knock-on impact on prescribing of drugs by GPs, who are generally reluctant to change hospital consultant prescriptions. The Group considers that these actions in conjunction with a combination of centralised procurement and better management of stock, its use and wastage, should yield savings of €30m a year.</p>	<p>Increased to €120 in Budget 2010. Increased to €132 in Budget 2012. A co-payment of 50c per prescription item up to a monthly ceiling of €10 per family is currently in place (Department of Finance, 2010b).</p>
<p>'Proposed Model for Reference Pricing and Generic Substitution' – Working Group (2010)</p> <p><i>Moran, Mark (Chair)</i></p>	<p>Minister for Health and Children</p>	<p>The working group was asked to examine options and develop a reference pricing system suitable for Ireland, taking into account best international practice.</p>	<p><i>Interchangeability</i></p> <ul style="list-style-type: none"> The Minister for Health and Children should be responsible for policy matters relating to the interchangeability of medicines. The HSE should be responsible for implementing and operating the systems relating to interchangeability of medicines; A Committee on Interchangeable Medicines should be established. The criteria for interchangeability should be developed having regard to: <ul style="list-style-type: none"> the overall health needs of the population; the availability and suitability of existing medicines to be interchanged; the clinical benefits and risks of the pharmaceuticals which are proposed to be interchangeable; the cost to the State and patients; and international best practice. 	<p>Legislation due to go before the Dáil in 2012.</p>

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication
			<ul style="list-style-type: none"> - The list of interchangeable medicines, as approved by the CEO of the HSE, should be updated and published no more than four times per annum. - The list of interchangeable medicines should apply to medicines dispensed in hospitals, medicines provided under the GMS and community drugs schemes and medicines provided to private patients. - Only interchangeable medicines on this list can be substituted. - If a pharmacist is substituting an interchangeable medicine, he or she must inform the patient. - When an interchangeable medicine has been prescribed and a less expensive interchangeable medicine is available, the pharmacist must inform the patient of the availability of the less expensive interchangeable medicine. - The patient should decide whether or not to opt for a less expensive interchangeable medicine. - Some patients will require a particular brand of medicine for clinical reasons. In these instances prescribers may object to substitution by including a specified exemption code on the prescription. This will enable the HSE to monitor the usage of exemptions by prescribers. <p><i>Reference Pricing System</i></p> <p>The key features of the recommended reference pricing system are:</p> <ul style="list-style-type: none"> - The HSE may select interchangeable medicines for reference groups and determine reference prices for those groups in accordance with specified criteria, taking into consideration matters including the number of competitors, market size, the public interest, value for money and continuity of supply. - Some supplier prices may be higher than the reference price. - The HSE should pay a common reference price for all medicines within a reference group, unless a prescriber has objected to substitution on medical grounds and the product prescribed is priced higher than the reference price. - If a prescriber has objected to substitution on specified medical grounds, and the product prescribed is priced higher than the reference price, the HSE should reimburse the agreed price of the product for eligible patients (based on prices submitted by suppliers in line with national pricing arrangements). - The HSE should conduct a market review of all reference groups at least once a year and at most every three months. This will provide flexibility for the HSE to respond to changes in the market, e.g. new entrants, and will not impose an unnecessary administrative burden on the HSE or the pharmaceutical industry. - When a patient has been prescribed a specific reference medicine and the actual price is higher than the reference price, the patient can opt for a less expensive medicine within that reference group or can pay the difference between the reference price and the actual price (co-payment). - The HSE should monitor and report on the savings obtained from reference pricing. 	
<p>Expert Group on Resource Allocation and Financing in the Health Sector (2010)</p> <p><i>Ruane, Frances (Chair)</i></p>	<p>Minister for Health and Children</p>	<ol style="list-style-type: none"> 1. to analyse the strengths and weaknesses of the current resource allocation arrangements for health and personal social services 2. to recommend appropriate changes in these arrangements which would support and incentivise the achievement of the core objectives of the health reform programme 3. in the light of its work, to take a view on the most appropriate financing mechanism for the Irish health service 4. to base its examination and recommendations on the existing quantum of public funding for health 	<p><i>Recommendation 30</i></p> <p>The Group recommended that an evaluation be undertaken of all high-cost, high-use drugs on the current GMS/DP lists, based on Irish costs and international experience of their outcomes, and that the HSE and DoHC engage immediately in the development of official guidelines and clinical protocols on the use of new technologies.</p> <p><i>Recommendation 31</i></p> <p>The Group recommended that the DoHC/HSE create immediate plans to</p> <ol style="list-style-type: none"> (i) develop further the recently announced reference pricing system; (ii) review critically the comparator countries currently used for setting ex-factory price of pharmaceuticals with a view to adjusting these as soon as possible, and no later than March 2012; (iii) extend tendering for sole supply contracts for additional pharmaceutical products; 	<p>Reference pricing legislation due to go before the Dáil in 2012.</p>

Title (Year)/ Author/Chair	Commissioned by	Terms of Reference	Main Recommendations ^b	Policy Changes since Publication
			<ul style="list-style-type: none"> (iv) establish treatment and prescribing protocols that promote the use of generics; (v) introduce regulations to mandate that all prescriptions for public and private patients must contain the generic name of the drug prescribed; (vi) introduce regulations to mandate all pharmacists to dispense the lowest cost version of the drug unless the patient specifically requests a particular brand (in which case the patient is responsible for the additional cost); (vii) extend information on generics more widely among doctors, pharmacists and patients. 	

- Notes:**
- a The recommendations outlined here are those arising from the various publications that relate directly to the issues discussed in the report.
 - b An Interim Community Pharmacy Contract was offered by the HSE to pharmacists in 2008 pending the finalisation of a new pharmacy contract in response to their concern at the reduction of wholesale margins in 2008. It offered a flat dispensing fee of €5 per item for the GMS, DP, LTI, EEA and HAA schemes and removed the retail mark-up available on items under the DP, LTI, EEA and HAA schemes. The contract offer was voluntary and there was no uptake.

Sources: Barry *et. al.*, (2009), Brennan (2003), Deloitte & Touche (2003), Dorgan (2008), Indecon (2007), McCarthy (2009), Moran (2010), Pharmacy Review Group (2003), Ruane (2010).

Annexe B

Terms of Reference

This project will produce a report setting out the roadmap for reforming the delivery of drugs to 'patients/consumers' within a framework that guarantees security of supply and value for money. It will provide guidance as to how the HSE can lead in fashioning the new institutional and market arrangements.

The report will consist of three inter-related building blocks.

First, the point of departure: a description and analysis of the current model for the delivery of drugs. The key participants (i.e. medical/pharmaceutical professions, wholesalers, manufacturers, the IMB and HSE) and institutional characteristics (e.g. State drug schemes) will be detailed, together with determinants of demand (e.g. prescribers acting as agents for consumers, co-payment mechanisms) and supply (i.e. supply chain from manufacturer to retail pharmacist).

Second, the point of arrival, the destination: the fit-for-purpose model for delivering drugs to consumers. Such a model must pass two tests: provide value for money (both to the State and the patient/consumer) and guarantee both continuity and security of supply. In part the model will be informed by the problems of the current system (e.g. low penetration of generic drugs) and in part by considering (i) Reference pricing (ii) Approved Protocol Treatments and (iii) Direct to Patient models for certain specialist drugs. The model will, of course, build on the lessons from the recent successful HSE/DoHC reforms which have lowered the cost of delivering drugs to patients/consumers but remain cognisant of the challenges of delivering continuity of supply within a small market. The HSE is commissioning this work to (a) prepare for 2012/2013 but also (b) to address/consider the issues arising from the cross subsidisation of community wholesale (and its discounting arrangements) to Hospital wholesaling.

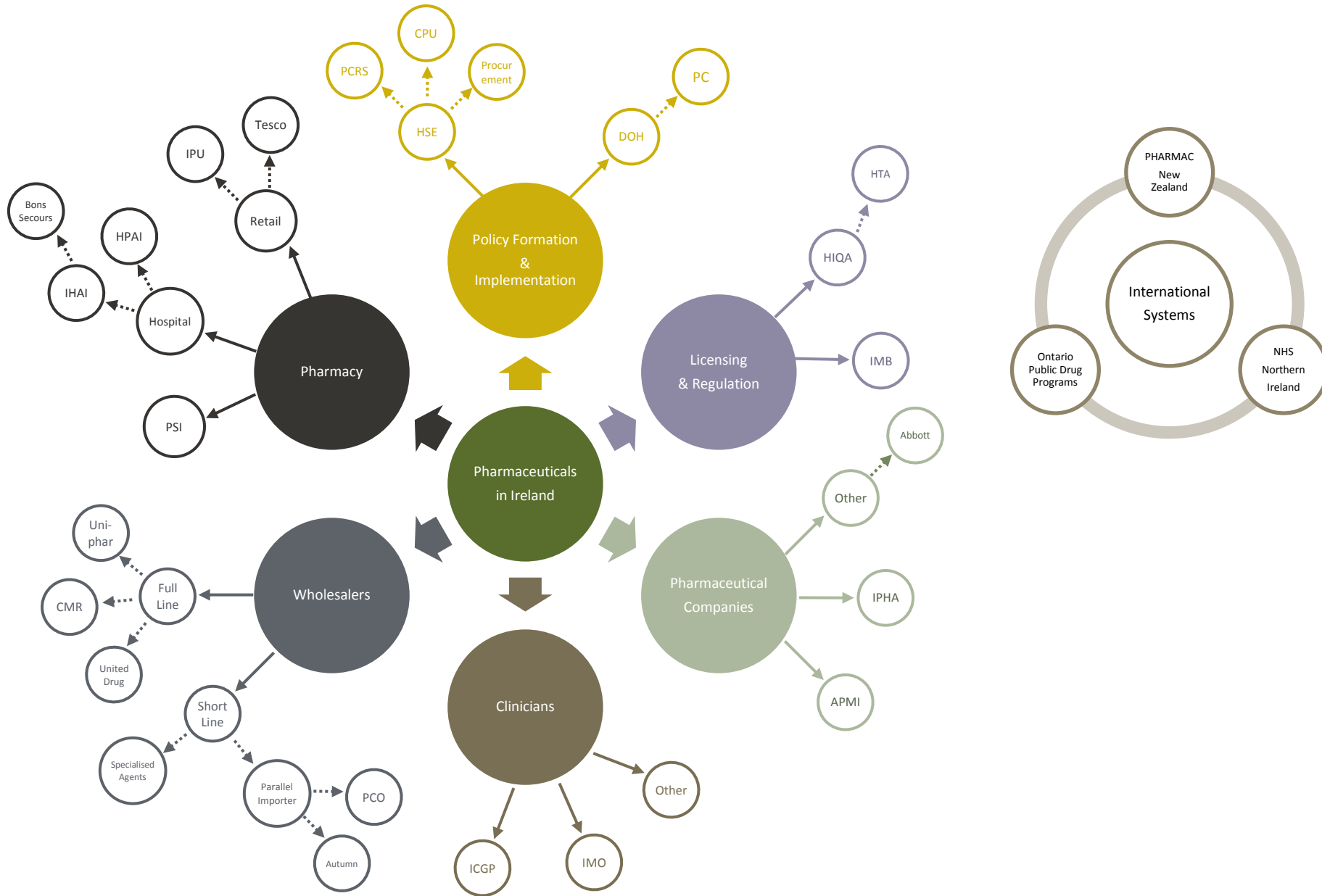
Third, the roadmap that sets out the path from the current model to the fit-for-purpose model. In some instances the choice and the timing will be clear; in others there may be several choices and further study will be necessary to select the optimum choice. Nevertheless, there will be a need to present the roadmap as a coherent whole which sets out the sequence of changes. The right time path can contribute vitally to outcome as a number of radical reforms have demonstrated in fields as diverse as the deregulation of the New Zealand economy and the 'Big Bang' of the UK financial sector. In designing the fit-for-purpose model the incentives of the key participants in the drug delivery system will be taken into account. It is only by understanding and building on such incentives that a mutually consistent and self-reinforcing system can be achieved.

Annexe C

Stakeholder Meetings

Stakeholders	Communication Type
Policy Formation and Implementation	
Corporate Pharmacy Unit, HSE	In-person
Portfolio & Category Management, HSE	In-person
Primary Care – DoH	In-person
Licensing and Regulation	
HIQA	In-person
Irish Medicines Board	In-person
Pharmaceutical Companies	
Abbott Laboratories Ireland Ltd	In-person
APMI	In-person
IPHA	In-person
Wholesalers	
Cahill May Roberts	In-person
Uniphar	In-person
United Drug	In-person
Parallel Importers	
Autumn Healthcare Ltd	Conference call
PCO Manufacturing Ltd	In-person
Clinicians	
IMO	In writing
Irish College of General Practitioners	In-person
Pharmacy	
Pharmacy Regulation	
Pharmaceutical Society of Ireland	In-person
Hospital Pharmacy	
Hospital Pharmacists Association Ireland	In-person
St James's Hospital	In-person
Bons Secours	In-person
Retail Pharmacy	
Irish Pharmacy Union	In-person
Tesco	Conference call
Other	
Competition Authority	In-person
International	
NHS Northern Ireland	In-person
Ontario Public Drug Programs	In-person
PHARMAC	Conference call

FIGURE C1: Stakeholders and the Pharmaceutical Delivery System



Annexe D

Wholesaler Survey



ESRI,
Whitaker Sq.,
Sir John Rogerson's Quay,
Dublin 2.

Dear X,

Re: ESRI Survey on Drug Delivery Systems: the Wholesaler's Role

As you know the ESRI has been commissioned by the Health Service Executive to consider systems for the delivery of pharmaceuticals to patients within a framework that guarantees security of supply and value for money. The wholesale function is a vitally important link in the pharmaceutical delivery system.

Following our meeting on 28 June 2011 we are keen to explore further the alternative business model that the Pharmaceutical Distributors Federation (PDF) recommends for compensating wholesalers for the distribution of pharmaceuticals. We are contacting United Drug, Uniphar and Cahill May Roberts, separately, given the possible commercially sensitive nature of the information request we are making, details of which are presented in the following table.

As you see in the table, information is sought concerning stock keeping units (SKUs), since it is our understanding that the PDF proposals centre on a fee per SKU.

We will not publish any information that could be used to identify an individual wholesaler. Our only interest is in gaining an overview of the wholesaling function. All information will be for all three wholesalers taken together. The information will form part of our report to the HSE, which may at some stage be released publicly.

Please complete and return the questionnaire attached by 5 August 2011.

If you require any clarification please do not hesitate to contact my colleague **Anne Nolan at (01) 863 2022**.

Best regards,

Paul

Professor Paul Gorecki
Email: paul.gorecki@esri.ie
Phone: 01 863 2039

Please complete the following table

Information Requested ^a	Units	2005	2006	2007	2008	2009	2010	2011 (Estimate)
Number of separate SKUs^b stocked	000s							
Total number of SKUs distributed								
- Hospitals	000s							
- Community	000s							
- Total	000s							
Total value of SKUs sold								
- Hospitals	€million							
- Community	€million							
- Total	€million							
Cost of Wholesaling/Distribution Operations in Ireland^c								
a) Interest & Other Capital ^d	€000/%							
b) Wages & salaries	€000/%							
c) Rents	€000/%							
d) Energy	€000/%							
e) Materials	€000/%							
f) Transport & Distribution	€000/%							
g) Other 1 (please specify) ^e	€000/%							
h) Other 2 (please specify)	€000/%							
i) Other 3 (please specify)	€000/%							
j) Total	€000/%							
Bad debt provision	€000							

- Notes:
- a Please specify the accounting period if different from the calendar year.
 - b Skus= stock keeping units.
 - ^c Please provide either cost of each function, or proportion of total costs accounted for by each function.
 - d Please specify how estimated
 - e Please detail major components of 'other' costs.

Please return to Aoife Brick at aoife.brick@esri.ie

Annexe E

Additional Tables

TABLE E1 Percentage of Eligible Persons that Claim by Scheme and Age Group, 2005-10

	% Eligible that Claim										
	< 5	5-11	12-15	16-24	25-34	35-44	45-54	55-64	65-69	70-74	75+
2005											
GMS	74.9	58.5	53.9	71.0	78.3	78.1	81.3	85.5	88.3	88.7	90.5
DPS	23.1	18.0	18.8	22.7	20.6	28.5	39.2	52.8	55.6	18.1	4.8
LTI	58.3	58.0	60.3	56.8	46.8	66.3	77.4	51.7	46.4	32.1	13.3
2006											
GMS	74.7	59.4	55.2	70.0	77.2	77.3	81.2	85.9	88.8	89.4	90.9
DPS	27.0	21.1	21.7	24.4	22.3	31.5	42.1	55.5	58.0	17.9	4.7
LTI	58.0	57.8	59.6	55.5	46.0	64.4	76.9	52.1	46.9	31.2	11.9
2007											
GMS	75.4	59.6	54.9	69.9	76.6	77.7	81.6	86.4	89.1	89.9	90.7
DPS	26.7	22.5	24.2	24.2	23.4	33.5	44.4	57.0	58.0	10.9	4.0
LTI	57.5	55.4	58.1	54.0	44.7	62.7	75.3	50.8	45.3	26.3	10.6
2008											
GMS	76.0	61.1	56.5	70.6	76.4	77.6	81.8	87.1	90.0	90.4	91.2
DPS	29.3	22.1	21.6	25.5	23.4	33.5	43.5	57.0	58.0	14.2	3.7
LTI	59.2	54.3	56.3	53.4	44.8	59.8	74.2	52.7	47.9	28.4	10.4
2009											
GMS	75.3	61.5	57.1	70.8	74.9	76.4	81.0	87.4	89.8	91.2	92.4
DPS	23.8	18.2	18.9	24.0	19.5	28.9	39.3	54.1	57.7	27.8	33.8
LTI	57.9	54.2	56.3	52.1	43.3	57.1	72.3	52.8	48.9	29.2	10.7
2010											
GMS	74.7	59.1	55.1	70.6	75.4	77.0	81.3	87.8	90.2	91.5	92.5
DPS	16.4	11.6	12.8	18.4	12.6	20.6	29.5	44.8	50.1	30.1	35.4
LTI	61.5	55.7	56.5	55.1	54.3	56.7	70.8	73.2	65.0	36.6	10.7

Source: HSE, personal communication, 30 June 2011.

TABLE E2 Average Number of Items per Claimant by Scheme and Age Group, 2005-2010

	Number of Items per Claimant										
	< 5	5-11	12-15	16-24	25-34	35-44	45-54	55-64	65-69	70-74	75+
2005											
GMS	6.08	5.09	5.37	9.42	14.03	18.80	28.79	41.27	46.19	47.74	61.29
DPS	5.83	5.21	5.66	8.04	10.38	12.02	19.80	30.24	34.74	19.16	41.32
LTI	27.02	29.71	28.63	23.97	23.92	27.48	36.17	41.52	41.86	29.90	28.66
HTD	4.25	7.47	8.05	7.04	7.36	6.95	7.97	7.60	6.59	6.22	6.30
2006											
GMS	6.03	5.15	5.51	9.45	14.22	19.11	30.05	43.39	48.56	50.48	65.49
DPS	5.74	5.15	5.53	7.93	10.23	11.86	19.74	30.77	35.40	19.02	43.38
LTI	29.51	29.75	29.72	25.37	24.70	28.35	38.75	44.56	44.31	31.60	31.02
HTD	4.38	7.04	7.76	6.56	6.85	6.75	7.58	7.51	6.45	6.00	5.99
2007											
GMS	6.05	5.27	5.62	9.49	14.53	19.60	31.32	45.60	51.45	53.19	69.65
DPS	6.00	5.31	6.01	8.07	10.68	12.41	20.82	32.51	38.35	24.23	42.81
LTI	36.66	33.19	34.44	28.21	27.61	32.63	44.31	50.29	51.98	37.18	34.83
HTD	5.22	8.09	8.82	7.05	7.62	7.53	8.37	8.03	6.85	6.39	6.41
2008											
GMS	6.15	5.44	5.74	9.63	14.72	20.03	32.59	48.08	54.50	55.73	74.59
DPS	5.76	5.19	5.43	7.75	10.05	11.92	19.69	30.85	34.80	17.98	42.44
LTI	29.43	28.68	26.61	25.77	24.92	29.41	38.82	45.80	44.53	33.33	33.68
HTD	4.51	7.89	7.59	7.14	7.28	7.13	7.99	7.68	6.72	6.54	6.57
2009											
GMS	6.04	5.42	5.84	9.71	14.42	20.04	32.75	49.02	55.54	57.37	76.44
DPS	5.76	5.54	5.67	7.83	10.22	11.96	20.07	31.87	37.42	28.36	45.24
LTI	31.25	30.76	29.93	28.20	26.84	31.11	42.83	50.70	50.94	39.91	38.50
HTD	4.62	8.77	9.23	7.68	7.11	7.08	8.56	8.33	7.29	7.06	7.06
2010											
GMS	6.15	5.49	6.00	9.80	14.31	19.89	32.77	49.39	55.86	59.66	79.80
DPS	5.96	5.99	6.08	8.15	11.00	12.25	20.55	32.04	37.78	35.35	60.79
LTI	26.75	29.58	26.95	24.97	21.88	27.87	39.83	44.84	46.11	35.55	36.76
HTD	4.23	9.19	9.26	8.35	7.61	7.56	8.85	8.63	7.70	7.49	7.82

Source: HSE, personal communication, 30 June 2011.

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The Economic & Social Research Institute
Whitaker Square
Sir John Rogerson's Quay
Dublin 2, Ireland
+ 353 1 863 2000 www.esri.ie
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