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Pharmaceutical Pricing and Reimbursement Information

IRELAND

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Pharma Profile

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Executive Summary

Background

Although Ireland's population is ageing, in comparative terms it remains relatively young. In 2002, the proportion of Ireland's population aged 65 years and over was 11.1%.

Life expectancy at birth has improved, rising from 73.0 to 75.1 years for males and from 78.5 to 80.3 years for females between 1996 and 2002 (CSO 2006). Nevertheless, life expectancy at age 65 still compares unfavorably with our EU partners.

The population of Ireland increased by 318,000 persons between 2002 and 2006, representing an 8.1% increase over a 4-year period. The highest rate of increase occurred in the counties with the youngest age profiles and the lowest in counties with the oldest age profiles. From a 10-year perspective, Ireland's population increased at an annual average rate of 1.6% between 1996 and 2006. This is the largest population growth in the EU.

In Ireland, there has been a period of unprecedented economic growth over the last decade, which is reflected in the increase in GDP per capita which has more than doubled over this period. In 2004, Ireland recorded the third highest GDP per capita in the world.

Ireland is a parliamentary democracy. The Irish Constitution is the fundamental legal document that sets down how Ireland should be governed. It was enacted in 1937. The two houses of the Oireachtas (Parliament) are Dáil Éireann (House of Deputies) and Seanad Éireann (the Senate). The Government is chosen by and is collectively responsible to the Dáil.

There are three main organizations within the health service:

The *Department of Health and Children* (DoH&C): The DoH&C has a dual role within the new structure which includes focusing on strategic and policy issues and having ultimate responsibility for holding the service delivery system to account for its performance.

Health Service Executive (HSE): The HSE functions as a single national agency that delivers services, specified by the DoH&C, within budget. There are two main bodies within the HSE:

- The National Hospitals Office (NHO) which is responsible for the management and co-ordination of the acute hospital sector nationally;
- The Primary, Community and Continuing Care (PCCC) Directorate, which is responsible for the management and delivery of non-hospital services.

The Primary Care Reimbursement Service (PCRS) is responsible for making payments to health professional contractors of PCCC.

Health Information and Quality Authority (HIQA): The HIQA was established to ensure that high quality information is available to the health care system and thus, to facilitate delivery of the key policy aim of the National Health Strategy.

Health care funding is mainly derived from taxation (75%) with private funding via insurance agents accounting for 11% and patient co-payment the remainder. In recent years, coincident with increased economic prosperity, public expenditure on healthcare in Ireland has increased considerably from €3.7 billion in 1997 to an estimated €11 billion in 2005.

There are two categories of entitlement to healthcare in Ireland (DOH&C 2006):

Category I: below an income threshold all inpatient and outpatient services including pharmaceutical therapy are free under the General Medical Services (GMS) Scheme. The GMS Scheme is also known as the medical card scheme and covers approximately 30% of the Irish population.

Category II: the rest of the population receives free inpatient treatment with a levy but they are not entitled to free GP services or prescribed medicines. Pharmaceutical expenditure is reimbursed above a threshold of €85 under the Drugs Payment Scheme (DPS). There is now a subcategory of persons who hold a GP Visit Card. Such persons are entitled to GP consultations without charge although they are still liable to the €85 co-payment for prescribed medication.

Pharmaceutical System

Chapter 2 describes the respective roles of the Department of Health and Children and the other main actors in the Irish pharmaceutical system.

Pharmaceuticals are classified In Ireland according to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 SI No. 540 of 2003 and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 SI No. 510 of 2005, which are to be construed as one piece of legislation.

Patent protection is harmonized under the European Patent Convention and ensures original pharmaceuticals market protection for 20 years. Under EU legislation, there is a possible extension of patent protection for a period not exceeding 5 years under a Supplementary Protection Certificate (SPC), which may only be obtained at national level, as the European Patents Office (EPO) does not issue SPCs.

In 2006, there were 3389 reimbursable pharmaceuticals of which 728 were generics. According to the Irish Medicines Board, there were 376 parallel traded pharmaceuticals on the Irish market in that same year.

Purchasing of pharmaceuticals via mail order or Internet is not allowed under Regulation 19 (Prohibition of mail order supply of medicinal products) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003.

Dispensing doctors are a feature of the GMS Scheme only. In the GMS Scheme, rural dispensing is at the patient's election.

Hospital pharmacies serve the institution's own pharmaceutical requirements. Except for psychiatric treatment, dental, ophthalmic or aural services, there is no outpatient dispensing.

Patient choice is supported in Ireland, with the objective of enhancing the ability of patients to have a greater say in the prescribing process with a view to choosing, in consultation with the prescriber, the medicine that best meets their needs and delivers best value for money.

In Ireland, pharmaceutical expenditure is diffuse in nature. For example, statistics for occupationally based reimbursement schemes are not published and some expenditure below the DPS co-payment threshold may not be captured at all. Accordingly, it is possible to quantify Total Pharmaceutical Expenditure (TPE) only from public sources, though not possible to state with precision the proportions of TPE comprised by the various sources of funds (public and private).

The main funding sources of public pharmaceutical expenditure are national taxation and Pay Related Social Insurance (PRSI) contributions. Most employed people over 16 years of age contribute to Social Insurance. The amount paid is based on earnings and the type of work done (Social Insurance Class).

The National Centre for Pharmacoeconomics (NCPE) reviews the cost-effectiveness and budget impact of individual pharmaceuticals in the Irish healthcare setting in response to requests from the Department of Health & Children. Evaluations of budget impact analyses have been informed by pharmaceutical utilisation data extracted from the GMS and the Community Drugs Schemes databases, as appropriate. Evaluations of cost-effectiveness models have been enhanced by the inclusion of Irish cost data as available.

Pricing

The framework in Ireland for pricing of pharmaceuticals consists of the Agreements between the HSE on the one part and the representative associations of the pharmaceutical industry (IPHA or APMI) on the other part. Statutory pricing is not applicable to Ireland. The pricing criteria have been determined as part of those agreements.

The IPHA and APMI Agreements apply, at the wholesale price level, to all medicines granted a marketing authorization by the Irish Medicines Board or European Commission, that can be prescribed and reimbursed in, and supplied to the GMS Scheme and the Community Drug Schemes, including the Drugs Payment Scheme, the Long Term Illness Scheme, the High Tech Scheme and the European Economic Area Scheme (the Schemes) and all medicines supplied to the HSE, State-funded hospitals and to State Agencies whose functions normally include the provision of medicines.

Pricing decisions are made at the ex factory (wholesale) price level. There is currently a price freeze applied in Ireland, which has a history of such price standstills by agreement, rather than by statutory regulation.

Effectively, free pricing exists for OTC pharmaceuticals alone. Over many years, the price level of OTC pharmaceuticals has been influenced by market forces in that segment of the pharmaceuticals marketplace in Ireland.

New features of the IPHA and APMI Agreements, compared with their predecessors, are that they provide for reductions in the price of existing pharmaceuticals and those coming off patent, and for a wider basket of countries for pricing new pharmaceuticals coming on the market. Also,

for the first time, reimbursement of new pharmaceuticals coming onto the Irish market can now be informed by pharmacoeconomic assessment, in line with other EU member States.

External price referencing is applied to POM (including generic) pharmaceuticals, at the wholesale price level. OTC pharmaceuticals are not generally covered by the Agreements. While there are no laws or decrees for external price referencing, the IPHA and APMI Agreements contain the formal rules to be applied.

For inclusion in the basket for external price referencing, the nominated EU States are Belgium, Denmark, France, Germany, the Netherlands, Spain, the UK, Finland and Austria. These countries were chosen in the discussions between the parties that negotiated the IPHA and APMI Agreements.

The IPHA and APMI Agreements cover hospital pharmaceuticals. Under Special Supply Arrangements, the HSE reserves the right to negotiate special arrangements for supply to the HSE, State funded hospitals and State agencies whose functions normally include the supply of medicines, with individual manufacturers or agents, designed to secure more favorable terms.

Price reductions will apply to specific dosage forms of patent expired medicines, under the IPHA and APMI Agreements where the identical pharmaceutical form of that medicine, approved by the Irish Medicines Board or EU Commission, is available for prescription.

In Ireland, originator pharmaceuticals and generics are reimbursable on substantially the same basis: the IPHA and APMI Agreements contain provisions that make this the position.

The system for the pricing of parallel traded pharmaceuticals does not differ from other pricing procedures for medicinal products. Parallel imports that comply with the criteria are separately identified from the originator product and reimbursed on the GMS Scheme.

Rural dispensing doctors receive a capitation fee in respect of persons on their GMS panel for whom they have a liability to dispense pharmaceuticals.

Hospital pharmacies in Ireland do not generally perform remunerable services to which a margin or fee payment would apply.

Reimbursement

The reimbursement framework is contained in the IPHA and APMI Agreements. There is no parliamentary or delegated legislation applicable to reimbursement policy.

The General Medical Services (GMS) Scheme was established to provide, free of charge, both a general practitioner (GP) service and medication dispensed by a community pharmacy, to persons who cannot afford such services from their own resources without undue hardship. All persons aged 70 years and over receive a free general medical service. Based on the CSO official population estimate of 4,130,700 (April 2005), 29.50% of Ireland's population was eligible for GMS services at December 2005 (PCRS Statistical Analysis of Claims and Payments 2005).

Under the Drugs Payment Scheme (DPS) persons who are ordinarily resident in the State and who do not have a current medical card can benefit - an individual or family has now to pay no

more than €85 in a calendar month for approved drugs, medicines and appliances for themselves or their families. In order to benefit under this Scheme a person must register themselves and their dependants with their HSE Local Health Office.

Persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the Long Term Illness (LTI) Scheme.

The High Tech Medicinal Products (HTMP) Scheme provides for the supply and dispensing of high-tech medicines through Community Pharmacies. The medicines are purchased by the HSE and supplied through Community Pharmacies for which pharmacies are paid a patient care fee by the PCRS each month. Examples of high-tech drugs are: anti-rejection drugs for transplant patients, chemotherapy and growth hormones. The patient's primary eligibility (GMS or other Scheme) determines whether there is a charge.

Through the IPHA Agreement, Clause 4.3 (Pharmacoeconomic Assessment prior to Reimbursement), the HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be high cost or have a significant budget impact on the Irish healthcare system.

For the GMS Scheme, there is a positive as opposed to a negative list, indicating reimbursable pharmaceuticals. The GMS List is updated on a monthly basis. Other Schemes (HTM and DTSS) are updated less frequently, since there may be no change in the pharmaceuticals covered in any given month.

Council Directive of 12 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC).

Three health insurance companies currently operate a number of reimbursement systems for members' claims arising from an in-patient setting.

The concept of reimbursement generally exists in the outpatient sector only. In the inpatient sector, patients in a publicly funded hospital will not be required to pay for the cost of their medication: pharmaceuticals for inpatient care are fully resourced by the hospital authorities. Patients in a private hospital may be billed for their medication: no information on the extent of such a practice is available.

Rational Use of Pharmaceuticals

In the GMS Scheme, where a GP prescribes a pharmaceutical without specifying a manufacturer's name or brand and the pharmacist receives such prescriptions with reasonable frequency the pharmacist will be expected to dispense one of the less expensive, if not the least expensive, of those reimbursable pharmaceuticals.

Doctors receive an evaluation of their prescribing habits through PCRS prescribing reports. In the recent past, savings have been encouraged through the form of incentives, although the methodology is currently under review.

Hospitals may operate formularies. Consultants wishing to introduce a new pharmaceutical may be required to seek approval from a 'new product committee', which is convened for the purpose of reviewing such novel entities.

The National Medicines Information Centre (NMIC) is based at the St. James's Hospital complex in Dublin. As part of its role in disseminating information to health professionals, NMIC bulletins are published every two months and the newsletter Therapeutics Today is published monthly.

There is no mandatory national treatment guideline system in Ireland, which is a country in the relatively fortunate position of not necessarily having to develop specific national treatment guidelines when relevant international guidelines, from countries with similar health challenges, are available in the English language. Direct advertising of OTC pharmaceuticals to patients is allowed, provided that the pharmaceuticals are not reimbursable, with the exception of pharmaceuticals for smoking cessation.

The HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be of high cost or have a significant budget impact on the Irish healthcare system.

Legal restrictions on the use of generics in Ireland tend not to be codified or consolidated in one statute. Rather, the major considerations are contractual. While on one level it may appear that generics are mainly a cost-containment tool, it is the case in Ireland that originators and generics are reimbursable on substantially the same basis. There is no *aut idem* rule, i.e. mandatory generic substitution unless the GP specifies the originator product (brand) in writing on the prescription. There is no current official campaign to promote the use of generic pharmaceuticals directly to patients, although there is a good degree of public awareness on the topic.

Consumption of pharmaceuticals is monitored inter alia by The National Centre for Pharmacoeconomics (NCPE). The aim of the centre is to promote expertise in Ireland for the advancement of the discipline of pharmacoeconomics through practice, research and education.The Health Protection Surveillance Centre (HPSC) is involved in measuring antibiotic consumption, as surveillance of antibiotic consumption has been identified as a key component in antimicrobial resistance strategies. The HSE Primary Care Reimbursement Service provides detailed information on the GMS and Community Drug Schemes including by different ATC levels.

Current challenges and future developments

In A Business Appraisal of Private Medical Insurance in Ireland (DoH&C 2007a), the need for rebalancing of costs from public to private care has been signposted. These factors will tend to lead to significant real increases in the cost of insurance, although the document's authors believe that competition can mitigate these to a limited extent.

The Government's Hospital Co-Location Initiative (HSE 2007) envisages that private providers will supply a significant proportion of additional capacity in the acute hospital system in future. Government policy will aim to incentivise and attract private providers to develop private facilities, thereby freeing up capacity in public hospitals to treat public patients.

The Health Information and Quality Authority (HIQA) was formally established (DOH&C 2007b) to ensure that high quality information is available to the health care system. The Health Act 2007 replaced the Interim Authority in order to place on a permanent footing delivery of high quality services that are based on evidence-supported best practice.

Dramatic changes in pharmaceutical markets, according to Perry 2006, have conditioned generic medicines producers to co-operate with governments to create optimal conditions for developing, manufacturing and marketing their products.

The European Commission's initiative, the Pharmaceutical Forum, closed its public consultation process in May 2007 and its scheduled meetings will continue into 2008.

By no means on its own among European countries with least generic market penetration in Europe, Ireland has since September 2006 embarked on a new policy of price reductions that will apply to specific dosage forms of patent expired medicines, under the IPHA and APMI Agreements where the identical pharmaceutical form of that medicine, approved by the Irish Medicines Board or EU Commission, is available for prescription. To that extent, measuring the outcomes from this process is a future development.

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List of Abbreviations

AGP	Association of General Practitioners
All ER	All England Reports (a series of law reports)
ALOS	Average Length of Stay
APMI	Association of Pharmaceutical Manufacturers of Ireland
ATC	Anatomic Therapeutic Chemical classification
Ch	Chancery Division of the High Court (England and Wales)
CLR	Commonwealth Law Reports (official law reports for the High Court of Australia)
CSO	Central Statistics Office
DG SANCO	Health and Consumer Protection Directorate General
DoH&C	Department of Health and Children
DPS	Drugs Payment Scheme
DTSS	Dental Treatment Services Scheme
EEA	European Economic Area
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPO	European Patents Office
EU	European Union
EWHC	England and Wales High Court (in media neutral citation)
FCA	Federal Court of Australia (in media neutral citation)
GDP	Gross Domestic Product
GGE	General Government Expenditure
GMS	General Medical Services
GP	General Practitioner
GPVC	General Practitioner Visit Card
HE	Health Expenditure
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information and Quality Authority
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
HPAI	Hospital Pharmacists Association Ireland
HPSC	Health Protection Surveillance Centre
HPSG	Hospital Procurement Services Group
HSE	Health Service Executive
HTA	Health Technology Assessment
HTD	High Tech Drugs (a Scheme)
HTMP	High Tech Medicinal Products (a Scheme)
ICGP	Irish College of General Practitioners
IDTS	Indicative Drug Target Scheme
IESC	Irish Supreme Court (in media neutral citation)
IHCA	Irish Hospital Consultants Association
IMO	Irish Medical Organisation

IMB	Irish Medicines Board
Inc	Incorporated
INN	International Non-proprietary Name
IPA	Irish Patients' Association
IPHA	Irish Pharmaceutical Healthcare Association
IPU	Irish Pharmaceutical Union
Ltd	Limited (as in Limited Company)
LTI	Long Term Illness (a Scheme)
LLC	Limited Liability Company (as in Australia, United States)
MR	Mutual Recognition
NCAOP	National Council on Ageing and Older People
NCHD	Non Consultant Hospital Doctor
NCPE	National Centre for Pharmacoeconomics
NCU	National Currency Unit
NHO	National Hospitals Office
NHS	National Health Service
NMIC	National Medicines Information Centre
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
Ors	Others
OTC	Over-The-Counter pharmaceuticals
PCCC	Primary, Community and Continuing Care (Directorate of the HSE)
PCRS	Primary Care Reimbursement Service
PDF	Pharmaceutical Distributors Federation
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PPRS	Prescription Price Regulation Scheme (UK)
PRP	Pharmacy Retail Price
PRSI	Pay Related Social Insurance
PSI	Pharmaceutical Society of Ireland
Pty	Propriety (as in company descriptions, e.g. in Australia and South Africa)
QALY	Quality Adjusted Life Year
S1A	Schedule 1 Part A
S1B	Schedule 1 Part B
S1C	Schedule 1 Part C
SHI	Social Health Insurance
SIGN	Scottish Intercollegiate Guidelines Network
SPC	Supplementary Protection Certificate
TD	Teachta Dála (Deputy in the Lower House of Ireland's Parliament)
THE	Total Health Expenditure

TIPPSA	Technical Industrial Pharmacists and Pharmaceutical Scientists Association
TPE	Total Pharmaceutical Expenditure
UK	United Kingdom
VAT	Value Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organisation
WP	Work Package

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Disclaimer

While all reasonable care has been taken in researching and preparing this Pharma Profile, neither the Health Service Executive nor the authors accept any responsibility for errors or omissions.

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at http://ppri.oebig.at. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

The total population of Ireland in 2006 is 4,234,925 (CS 2006a). (The most recent population census was taken in April 2006 and preliminary results were published in July 2006. Dissemination of the definitive population figures will commence in April 2007). Data from the previous census in 2002 will be used in this report, until the more recent data (2006) is published in full.

The over all population density for 2002 was 56 persons per square kilometer. Dublin city had the highest population density with 4,215 persons per square kilometer, whereas Leitrim had the lowest population density of 16. In 2002, Dublin had the youngest population in the country whereas Leitrim had the oldest population (average age 38.5 years). Approximately 60% of the population lives in urban areas. A map of the population density of electoral divisions in 2002 is available at: http://www.cso.ie/census/documents/vol1_map2.pdf.

Although Ireland's population is ageing, in comparative terms it remains relatively young. In 2002, the proportion of Ireland's population aged 65 years and over was 11.1%. According to population projections prepared for the National Council on Ageing and Older People (NCAOP), this proportion will rise to between 14.8% and 15.3% by 2021(NCAOP 2006; Connell P, Pringle D. 2004). The number of Irish people aged 80 and over is projected to increase quite steeply; from 100,583 in 2002 to 137,305 in 2021(NCAOP 2006; Connell P, Pringle D. 2004). The National Health Strategy: "*Quality and Fairness – A health System for You"* addresses services for older people and the development of an action plan to meet their needs (DoH&C 2001a).

The NCAOP is a statutory agency, funded by the Department of Health and Children (DoH&C). It was established in 1997, in succession to the National Council for the Elderly (1990-1997) and the National Council for the Aged (1981-1990). The Council has published a wide range of reports including a position statement in June 2005, to address policy, planning and strategy setting for the care of older people in an ageing population (NCAOP 2006).

Life expectancy at birth has improved, rising from 73.0 to 75.1 years for males and from 78.5 to 80.3 years for females between 1996 and 2002 (CSO 2006). Nevertheless, life expectancy at age 65 still compares unfavorably with our EU partners.

Diseases of the circulatory system are the single largest cause of death in Ireland (36% of deaths in 2005), followed by cancer (28% of deaths in 2005) and respiratory disease (14% of deaths in 2005) respectively. In relation to morbidity, the Hospital In-Patient Enquiry (HIPE) system shows that in 2002 there were 895,050 discharges (direct age standardized rate 23,183 per 100,000) from hospitals in Ireland. Diseases of the digestive system accounted for over 1 in 9 hospital discharges; neoplasms for 1 in 11 discharges and diseases of the circulatory system for 1 in 12 discharges.

The population of Ireland increased by 318,000 persons between 2002 and 2006, representing an 8.1% increase over a 4-year period. The 2006 population was last exceeded in 1861 when the recorded population was 4.4 million[1]. The highest rate of increase occurred in the counties with the youngest age profiles and the lowest in counties with the oldest age profiles. Migration has played a key influence in determining population change in Ireland. On average there were 46,000 more immigrants than emigrants over the 2002-2006 periods with an annual excess of births over deaths of 33,000. The corresponding figures for the 1996-2002 periods were 26,000 and 23,000 respectively.
From a 10 year perspective, Ireland's population increased at an annual average rate of 1.6% between 1996 and 2006. This is the largest population growth in the EU.

Table 1.1: Ireland - Demographic indicators 1995, 2000, 2003 and 2005

Variable	1995	2000	2003	2005
Total population (in thousands)	3,601.30	3,789.50	3,978.90	4,130.70
Population density per km^2	n/av	n/av	56 (2002)	n/av
Population aged 0-14 (in thousands)	878	828	833.8	853.3
(% of total)	24.38%	21.85%	20.96%	20.66%
Population aged 15-64 (in thousands)	2312.1	2536.8	2702.3	2816.7
(% of total)	64.20%	66.94%	67.92%	68.19%
Population aged >64 (in thousands)	411.3	424.7	442.8	460.7
(% of total)	11.42%	11.21%	11.13%	11.15%

Sources: Irish Central Statistics Office (www.cso.ie) Health Statistics 2002– Department of Health and Children (www.dohc.ie)

1.2 Economic background

In Ireland, there has been a period of unprecedented economic growth over the last decade, which is reflected in the increase in GDP per capita which has more than doubled over this period. In 2004, Ireland recorded the third highest GDP per capita in the world. However, the use of the GDP measure may not give the most accurate indication of living standards for Ireland. GDP includes the substantial profits made by foreign multinationals, much of which is repatriated. GNP may give a better indication of income and hence living standards for the Irish case. The difference between the two output measures is stark in the Irish case with GNP accounting for just 79% of GDP in 2004 (ESRI 2006).

Ireland is one of the fastest growing economies in the developed world. In recent decades the Irish economy has been transformed from being traditionally manufacturing based to one increasingly based on the hi-tech and internationally traded services sectors. There have been many reasons advanced for Ireland's success, which include EU membership and access to the Single Market; Ireland's low corporation tax rate and a large multinational presence; a high proportion of the population of working age; increased participation in the labor market especially

by females; a reversal of the trend of emigration toward immigration; sustained investment in education and training and a more stable public finance position (ESRI 2006). However, to maintain this dynamic economy, Ireland faces challenges to continue strong productivity growth and increase labor supply. Furthermore, Ireland is going through a transition phase in upgrading its social services, infrastructure levels need to catch up with the boom in activity and population that has occurred over this period.

Table 1.2: Ireland - Macroeconomic indicators 1995, 2000 - 2005

Variable (in NCU or percentage)	1995	2000	2001	2002	2003	2004	2005
GDP i(€m)	53,147	104,379	117,114	129,947	138,941	147,569	161,163
GDP / capita (€m)	14,757	27,544	30,441	33,173	34,919	36,493	39,016
GDP / capita in PPPa	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Growth rate	8.2%	9.2%	6.2%	6.1%	4.4%	4.5%	5.1%
General government expenditure (GGE)	20,276	32,211	38,112	42,537	45,403	48,711	53,837
GGE in % of GDP (€m)	38.15%	30.86%	32.54%	32.73%	32.68%	33.01%	33.41%
Exchange rate (NCU per €), annual rate	n/ap	n/ap	n/ap	n/ap	n/ap	n/ap	n/ap

GDP = Gross Domestic Product, GGE = General government expenditure, NCU = National Currency Unit, PPPa = Purchasing Power Parity

Sources: Irish Central Statistics Office (www.cso.ie); Department of Finance (www.finance.gov.ie)

1.3 Political context

Ireland is a parliamentary democracy. The Irish Constitution is the fundamental legal document that sets down how Ireland should be governed. It was enacted in 1937. The two houses of the Oireachtas (Parliament) are Dáil Éireann (House of Deputies) and Seanad Éireann (the Senate). The Government is chosen by and is collectively responsible to the Dáil. In June 2007, the Government was led by the Taoiseach (Premier) Mr. Bertie Ahern and Tánaiste (Vice-Premier) Mr. Brian Cowen, who was also Minister for Finance.

Each of the Dáil's 166 members is a Teachta Dála (TD). The TDs are directly elected by the people. General elections take place at least once every five years, the latest held in May 2007. The Ceann Comhairle (Speaker) of Dáil Éireann is returned unopposed, leaving 165 contested seats in constituencies each ranging from three to five seats, weighted by population size. The electoral system is proportional representation by single transferable vote.

The Seanad has 60 members; 11 are nominated by the Taoiseach, the rest from a number of vocational panels and by graduates of universities. The Seanad can initiate or revise legislation, but the Dáil has the power to reject these proposals or amendments.

The President, the Head of State, is directly elected by Irish citizens. The President does not have an executive or policy role but has the absolute discretion to refuse the dissolution of the Dáil when the Taoiseach has ceased to retain a majority in the house. The President can also refer a Bill – other than a 'money' (budgetary) Bill - to the Supreme Court for a judgment on its constitutionality.

There are 15 Government Departments, each headed by a Minister. The present Government is a coalition between Fianna Fáil , the Green Party and the Progressive Democrats, supported by Independent TDs. Fianna Fáil has been the largest party in the Dáil since 1932. It is part of the Union for Europe of the Nations group in the European Parliament. The largest opposition party is Fine Gael, a member of the Christian Democrat group in the European Parliament. The Labour Party is a member of the Socialist group in the European Parliament.

The local government system is administered by 114 local authorities and is undergoing a process of renewal and reform. Local government is funded partly by central government and partly by local sources including motor tax proceeds, rates on commercial property, and local charges such as refuse and rents.

1.4 Health care system

1.4.1 Organisation

The structure of the health services in Ireland has recently undergone a process of reform. The previous system was designed over 30 years ago when the scale of activity and the number of services provided were considerably smaller. More effective ways of organizing the healthcare system are now required to meet the demand and expectations of the twenty-first century.

In June 2003 the government announced the Health Service Reform Programme (www.dohc.ie) initiating an unprecedented change for the Irish healthcare system.

There are three main organizations within the restructured health service:

a) The Department of Health and Children (DoH&C): The DoH&C has a dual role within the new structure which includes focusing on strategic and policy issues and having ultimate responsibility for holding the service delivery system to account for its performance.

b) Health Service Executive (HSE): The HSE functions as a single national agency that delivers services, specified by the DoH&C, within budget. There are two main bodies within the HSE:

- The National Hospitals Office (NHO) which is responsible for the management and co-ordination of the acute hospital sector nationally;
- The Primary, Community and Continuing Care (PCCC) Directorate, which is responsible for the management and delivery of non-hospital services.

- The Primary Care Reimbursement Service (PCRS) is responsible for making payments to health professional contractors of PCCC.

c) Health Information and Quality Authority (HIQA): The HIQA was established to ensure that high quality information is available to the health care system and thus, to facilitate delivery of the key policy aim of the National Health Strategy 2001 i.e. to deliver high quality services that are based on evidence-supported best practice. The HIQA is responsible for developing health information, promoting and implementing quality assurance programs nationally and overseeing HTA.

1.4.2 Funding

Health care funding is mainly derived from taxation (75%) with private funding via insurance agents accounting for 11% and patient co-payment the remainder. The overall funding level for the health services is determined in negotiations between the Department of Finance and the DoH&C. In recent years, coincident with increased economic prosperity, public expenditure on healthcare in Ireland has increased considerably from €3.7 billion in 1997 to an estimated €11 billion in 2005.

Table 1.3: Ireland- Health expenditure, 1995, 2000 - 2005

Health expenditure	1995	2000	2001	2002	2003	2004	2005
THE in €	€4,097 m	€7,391 m	€9,042 m	€10,32 8m	n/av	n/av	n/av
THE in % GDP	6.7%	6.3%	6.8%	7.2%	7.2%	7.1%	n/av
THE per capita in €	€1138	€1950	€2350	€2637	n/av	n/av	n/av
Public HE in % of THE	71.60%	73.30%	75.60%	75.20%	78.00%	79.50%	n/av
Private HE in % of THE	28.40%	26.70%	24.40%	24.80%	22.00%	20.50%	n/av

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure

Sources: 1. Expenditure Statistics, Department of Health and Children (www.dohc.ie); 2. OECD Health data 2006 (www.oecd.org).

1.4.3 Access to health care

There are two categories of entitlement to healthcare in Ireland (DOH&C 2006):

Category I: below an income threshold all inpatient and outpatient services including pharmaceutical therapy are free under the General Medical Services (GMS) Scheme. The GMS Scheme is also known as the medical card scheme and covers approximately 30% of the Irish population.

Category II: the rest of the population receives free inpatient treatment with a levy but they are not entitled to free GP services or prescribed medicines. Pharmaceutical expenditure is reimbursed above a threshold of €85 under the Drugs Payment Scheme (DPS). There is now a sub-

category of persons who hold a GP Visit Card. Such persons are entitled to GP consultations without charge although they are still liable to the €85 co-payment for prescribed medication.

In June 2005 the GP Visit Card was implemented. This is a new initiative to assist those who do not qualify for a medical card on income grounds but for whom the cost of visiting a GP is often prohibitively high. Eligibility is means tested and the scheme is estimated to benefit approximately 200,000 people who do not have a medical card.

Therefore the entire population is entitled to a core publicly funded service, including hospital inpatient services. Day care is also considered an inpatient service. In addition, the HSE has the discretion to provide services free of charge in cases of hardship to people who are not normally eligible for particular services[7]. There is, however, a mix of public and private care in the system, which is reflected in the fact that voluntary private insurance is an established part of arrangements used to meet the cost of hospital services. Approximately 45% of the Irish population hold private medical insurance, despite universal access to the public health care system (Mossialos et al. 2004).The number of insured persons has been rising, principally, it seems, because of the speed and certainty of access to care, as well as quality of care, which the holding of insurance is perceived to provide (Harmon C et al. 2000).

1.4.3.1 Outpatient care

Outpatient care is practiced in primary care by General Practitioners (GP's) and by specialists in secondary care. The GP acts as a gatekeeper for access to specialist outpatient and inpatient care. There is a free choice of GP. However, public patients must register with a GP and the GP is paid an annual capitation fee for each patient. Private patients pay out-of-pocket fees for GP services. However, tax relief may be claimed for these expenses (DOH&C 2006). The majority of GPs and hospital consultants provide services to both public and private patients.

Out-patient services in hospitals include accident and emergency services as well as planned services provided on an out-patient basis (e.g. a patient may be referred by their GP for specialist assessment by a consultant) (DOH&C 2006). In general, a patient may refer themselves to the out-patients department of a public or voluntary hospital but they do not incur hospital charges if referred by a GP. Public patients do not have to pay for consultants' services and do not have a choice of consultants. Private patients must be referred to the consultant by their GP and pay the full cost involved. Private health insurance may cover some of this cost (DOH&C 2006).

Table 1.4: Ireland - Outpatient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Total number of doctors[1]	n/av	n/av	n/av	n/av	15479
Number of doctors per 1,000 inhabitants[2]	n.a.	2.2	2.4	2.8	n/av
Total number of outpatient doctors					
thereof General Practitioners[3]	1652	1798	2134	2210	2257
thereof dentists[3]	903	1206	1349	1340	1394
Number of out patient doctors per 1,000 inhabitants[4]	n/av	100113	n/av	n/av	n/av
Number of out-patient clinics departments ("ambulatories")[4]	1890702	2042567	n/av	n/av	n/av

Sources:

1. Medical Council (www.medicalcouncil.ie) – refers to number of doctors fully registered in Ireland.
2. OECD Health Data 2006 (www.oecd.org) – refers to number of physicians entitled to practice rather than only practicing.
3. Doctors and dentists with public contracts: General Medical Services (Payments) Board Financial and Statistical Analysis of Claims and Payments 1995, 2000, 2002; HSE National Shared Services Primary Care Reimbursement Service 'Statistical Analysis of Claims and Payments 2005'
4. Health Statistics 2002, Department of Health and Children (www.dohc.ie).

1.4.3.2 Inpatient care

There are three different types of hospital in Ireland but there is very little difference in practice between the first two types (which can be referred to as public hospitals):

- Health Service Executive hospitals, owned and funded by the Health Service Executive
- Voluntary public hospitals, most of whose income comes directly from the government. Voluntary public hospitals are sometimes owned by private bodies, i.e., religious orders. Other voluntary public hospitals are incorporated by charter or statute and are run by boards often appointed by the Minister for Health and Children
- Private hospitals, which receive no state funding. There are a small number of private hospitals in Ireland. Private hospitals are free to set their own charges and patients must pay these charges**.** It is not possible to avail of public services in a private hospital**.**

Most of the public hospitals also provide private health care but they must clearly distinguish between public and private beds (approximately one-fifth of the beds are private) (Wiley M. 2000). Half of the private beds in the country are provided in public hospitals (Turner B. 2004). Therefore, those with private insurance generally receive private care in private or semi-private rooms, and choose their own consultant, but much of this care is delivered in public hospitals[9]. Public patients may not choose their own consultant.

Some hospitals are specialist e.g. maternity hospitals, psychiatric hospitals, while others are general. The large general and regional hospitals in Ireland provide a broad range of services.

The fee for public inpatient services is €60 per day up to a maximum of €600 per year. Thee fee does not apply to medical card holders and certain other groups. Private patients attending either public or private hospitals must pay for maintenance and treatment. Private health insurance may cover some or all of the costs (DOH&C 2006). Doctors are employees of the hospital and are paid on a fee for service basis for private consultations, via the health insurers e.g. VHI.

In relation to funding, Ireland operates a unique “budget neutral” case mix policy, with the inefficient hospitals losing funding and the efficient hospitals gaining additional funding annually. The National Case mix Program was established in Ireland in 1991. Budget adjustments are based on the complexity of the annual hospital patient caseload. Estimates of the case mix budget adjustment draw on two main data sources:

- Hospital inpatient activity data (HIPE) (http://www.esri.ie)
- Hospital cost data: Expenditure data by speciality is provided to the National Case mix Unit of the Do H&C. The Australian Related-Diagnosis Related Group (AR-DRG) system is used in Ireland.

The number of acute hospital inpatient beds in Ireland decreased from 17,665 in 1980 to 11,832 in 2000. The number of day beds increased from 26 in 1980 to 562 in 2000 (DOH&C 2002). In patient activity levels have been maintained primarily through a steady decline in average length of stay (ALOS). The ALOS appears to have stabilized at 6.5 days, reduced from 9.7 days in 1980. However, due to population growth, the number of inpatients has increased with the consequence that occupancy levels in many acute hospitals are very high. There has been a dramatic increase in the volume of hospital based care which is provided on a day basis. In 1980, day activity constituted 2% of all non-outpatient care in hospitals. In 2000, 38% of all non-outpatient care, exclusive of obstetric care, was provided on a day basis. The number of outpatients seen in the acute hospitals is approximately 2 million per annum (a 37% increase since 1980) (DOH&C 2002).

Table 1.5: Ireland - Inpatient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2003	2005
Number of inpatient doctors [1,2]	3637	4678	n/av	5663	6117
Number of inpatient doctors per 1,000 inhabitants[2]	1.01	1.23	n/av	1.42	1.48
Number of acute hospitals [3,4]	62 (1997)	60	n/av	59	53
Number of acute care beds	11,861	11,891	n/av	12,299	13,771
thereof in private sector	n/av	n/av	n/av	n/av	n/av
Acute care beds per 1,000 inhabitants [1]	3.29	3.14	n/av	3.09	3.33
Average length of stay in hospital (days) [3,5]	6.5	6.4	n/av	6.5	6.56

Sources

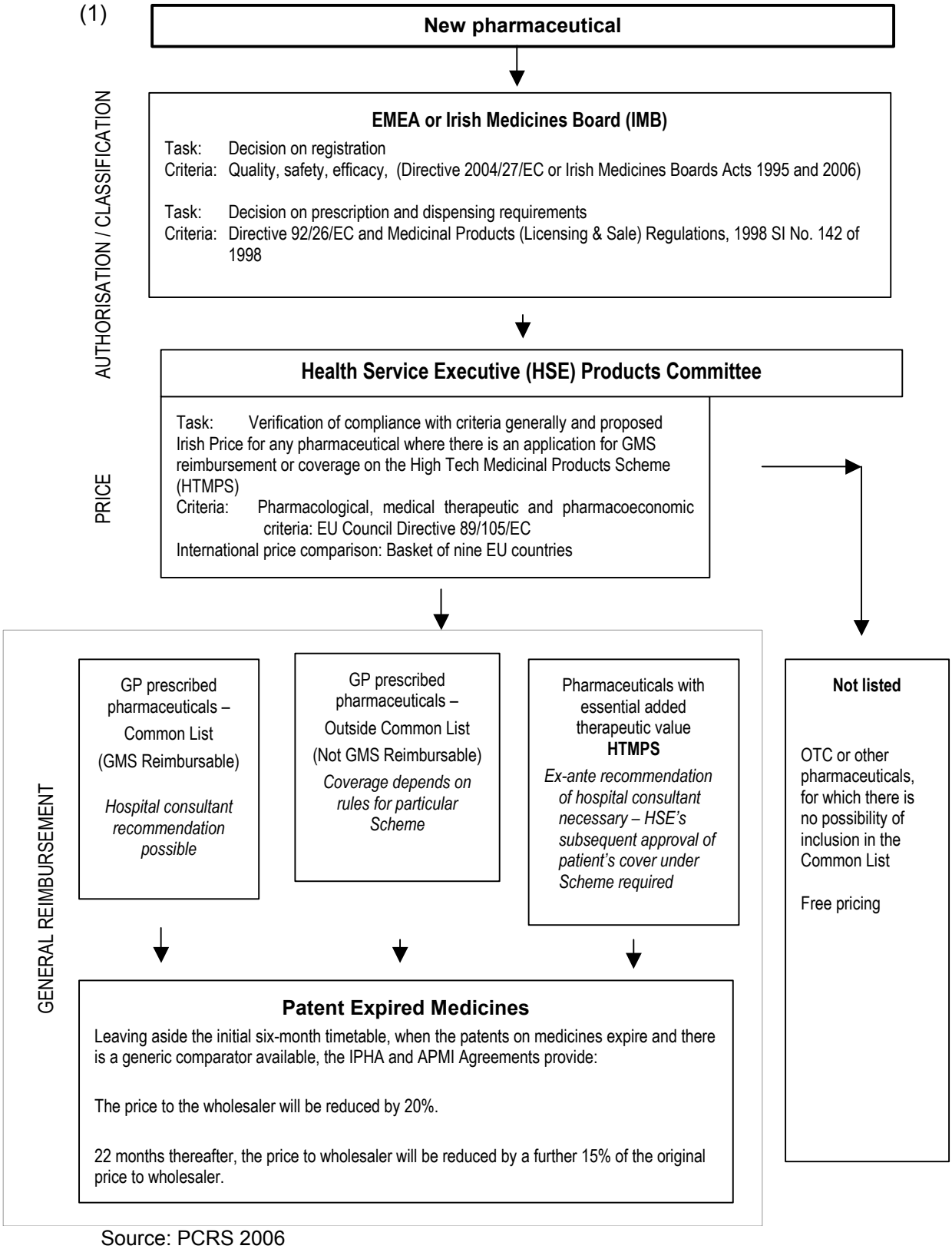
1. Report on Consultant Staffing 2005. National Hospitals Office, Health Service Executive (www.hse.ie).
2. Report of the National Task Force on Medical Staffing. June 2003 (www.dohc.ie).
3. Health Statistics 2002. Department of Health and Children (www.dohc.ie).
4. Annual Report and Financial Statement 2004. Health Service Executive (www.hse.ie).
5. National Service Plan 2006. Health Service Executive (www.hse.ie).

2 Pharmaceutical system

2.1 Organisation

This section describes the Irish pharmaceutical system's regulatory environment and pharmaceutical market, its actors and key data.

Figure 2.1: Ireland - Flowchart of the pharmaceutical system 2006



Source: PCRS 2006

2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

The following are the major laws relevant to the pharmaceutical sector:

Medicines are classified according to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 SI No. 540 of 2003 and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 SI No. 510 of 2005, which are to be construed as one piece of legislation.

The main purpose of the 2003 Regulations is to consolidate and to update the controls applicable to the prescription and supply of medicinal products to the public in accordance with the requirements of E.U. Directive 2001/83/EC of 6th November 2001 insofar as that Directive relates to the classification for the supply of medicinal products for human use (OJ No L311, 28.11.2001, p67). The Regulations also set out the classification for supply of medicinal products to the public as required by that Directive.

The Regulations apply an up-to-date and comprehensive system of control to medicinal products and identify those products which may only be supplied on medical prescription. The circumstances excluding medicinal products from prescription-only control are also specified and incorporate a pharmacy-only category into which most such non-prescription products fall.

The Regulations up-date the list of medicinal products subject to prescription control and deregulate certain other products, which were previously subject to prescription control. In recognition of Ireland's position as part of the E.U. Internal Market, the term "supply" is defined in the broader context, so that the controls apply equally to supplies made to persons in the State and to persons who may at the time be in another Member State of the European Union. In this connection also, the supply of medicinal products by mail order is prohibited, as is the supply by means of automatic vending machines.

The purpose of the 2005 Regulations is to update the controls in respect of the supply of medicinal products as set out in the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

The Regulations provide for: (a) clarification with regard to the administration of medicinal products; (b) clarification of the role of authorized persons with regard to supervision of the supply of prescription - only medicinal products; (c) the availability of certain medicinal products in non – pharmacy outlets; (d) further restrictions on certain medicinal products containing Isotretinoin; (e) clarification on the record keeping requirements in respect of pharmacies; (f) the exemption of non – prescription medicinal products from the prohibition on the sale of medicinal products by mail order; (g) the extension of the availability of fluorescein sodium to optometrists and dispensing opticians for professional use; (h) the availability and use of certain medicinal products by various grades of ambulance personnel; (i) the addition of certain products to the schedules of prescription only medicinal products; (j) the correction of certain minor errors and omissions which have come to light since publication of the principal Regulations.

The Medicinal Products (Licensing & Sale) Regulations, 1998 (SI No. 142 of 1998) provide for a licensing scheme for medicinal products for human use and related matters as required by EU Council Directives. The Medicinal Products (Licensing and Sale) (Amendment) Regulations, 2001 (SI No. 512 of 2001) amend the Medicinal Products (Licensing and Sale) Regulations, 1998 (which requires persons importing and selling (which includes distributing) medicinal products to hold product authorizations in respect of those products) to facilitate the obtaining and making available of such medicinal products that have not been authorized in this country, to meet the needs of a national emergency or other circumstances of extreme urgency.

Legislation, Regulations and Guidelines Relating to Medicinal Products for Human and Veterinary Use are available from the Irish Medicines Board website, the URL is: http://www.imb.ie/inner.asp?nav=5,52

Consultation on 2001 Review of Pharmaceutical Legislation Implementation of Directive 2001/83/EC (as amended by Directives 2002/98/EC, 2004/24/EC and 2004/27/EC) relating to the placing on the market of medicinal products for human use. (DoH&C 2001b) This implementation embraces Titles III (placing on the market), V manufacture), VII (on wholesaling), VIII and VIIIa (on advertising) of Directive 2003/2001/EC (as amended by Directive 2004/27/EC): (labelling and packaging), VI (classification of medicinal products) and IX (pharmacovigilance) of Directive 2001/83/EC) Implementation of Titles IV (on manufacture), VII (on wholesaling), VIII and VIIIa (on advertising) of Directive 2003/2001/EC (as amended by Directive 2004/27/EC)

The IMB has put project teams in place to oversee the implementation of Directive 2004/27/EEC, 2004/28/EEC and Regulation 726/2004. These teams are currently developing implementation plans that will, in time, include guidance on particular sections of the legislation. As soon as such guidance is available, including any received from the European Commission, the IMB will make it available on its web site.

There is no special regime for “essential products” in Ireland.

There is no current legislation for regulating competition between pharmacies and for deciding where pharmacies may locate, geographically or demographically. Pricing matters are not government regulated and are framed in Agreements with the pharmaceutical industry.

2.1.1.2 Authorities

Table 2.1: Ireland - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Department of Health and Children (DoH&C)	—	Regulatory body	Overall planning and legislative authority, including pharmaceutical classifications (e. g. concerning prescription status, hospital-only or not)
Irish Medicines Board (IMB)	—	Medicines Agency (subordinate to the Department of Health and Children)	In charge of market authorization, classification, vigilance, licensing wholesalers (distribution).
Health Service Executive (HSE)	—	Healthcare and Personal Social Services Provider (subordinate to the Department of Health and Children)	Application of Agreements with Pharmaceutical Industry and with Wholesalers. In charge of the reimbursement decision. Public procurement and tendering of pharmaceuticals.
HSE Primary Care Reimbursement Service (PCRS)	—	Third Party Payer (within the HSE)	In charge of the reimbursement of pharmaceuticals in the outpatient sector. Aiding the Department of Health and Children and the HSE to monitor pharmaceuticals consumption.

Sources: PCRS 2006

In determining the safety, quality and efficacy of medicinal products the Irish Medicines Board draws upon the expertise of its assessors and its Advisory Committee for Human Medicines (appointed by the Minister for Health & Children). Expert advisory panels also meet on an as required basis. The statutory role of the advisory committees is to provide advice in cases where it is proposed to refuse to grant a license for a medicinal product. (IMB 2006).

During 2005, the IMB output for new product applications was 942. This comprised 328 new nationals, 318 new EU mutual recognition (MR), 29 new EU centralized[1] and 267 transfer applications. While this represents an increase on previous years, the IMB continues to place a high priority on reducing the backlog of national applications. The total number of applications still in progress decreased to 318 in December 2005 from a total of 495 applications in progress in December 2004.

The median time for new product authorizations issued (excluding transfers) in 2005 was 27 weeks, which is an improvement on the 2004 figure of 34 weeks. This reflects the significant improvements in timelines by the IMB in 2005 (IMB 2005).

[1] *Total number of centralized applications complete in 2005, not all may be authorized by the European Commission at this point.*

The Health Service Executive (HSE) is responsible for providing Health and Personal Social Services for everyone living in the Republic of Ireland. As outlined in the Health Act, 2004, the objective of the Executive is to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.

The establishment of the HSE represents the beginning of the largest programme of change ever undertaken in the Irish public service. Prior to this, services were delivered through a complex structure of ten regional Health Boards, the Eastern Regional Health Authority and a number of other different agencies and organizations. The HSE replaces all of these organizations. It is now the single body responsible for ensuring that everybody can access cost effective and consistently high quality health and personal social services. The service will be delivered making best use of resources allocated by Government. The largest employer in the State, the HSE employs more than 65,000 staff in direct employment and a further 35,000 staff are funded by the HSE. The budget of almost €12 billion is the largest of any public sector organization (HSE 2006).

2.1.2 Pharmaceutical market

This section gives an overview on the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

Table 2.2: Ireland - Number of pharmaceuticals 1995, 2000 - 2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised[1]	n/av	n/av	7189	7794	n/av	n/av	n/av	7309
On the market	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
POM	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Reimbursable[2]	n/av	n/av	n/av	n/av	n/av	n/av	n/av	3389
Generics[3]	n/av	n/av	n/av	n/av	n/av	n/av	n/av	728
Parallel traded[1]	n/av	n/av	n/av	n/av	n/av	n/av	n/av	376
Hospital-only	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Others *(please include further lines if necessary)*	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av

POM = Prescription-Only Medicines; n/av = not available

[1] IMB as of 1 January; including different dosages and pharmaceutical forms

[2] PCRS as of December

[3] Reimbursable generics as of December

Sources: IMB 2006; PCRS

Differences may exist between the number of pharmaceuticals registered and the number of pharmaceuticals on the market for reasons that may include the following. Pharmaceutical companies may delay the introduction, or cause the early departure, of an individual, already licensed, pharmaceutical from the Irish market, for commercial reasons, including relatively low sales volume and costs associated with continued participation in the regulatory affairs process.

Legal Classification of Medicines in Ireland: examples of Prescription-Only Medicines (POM)

Schedule 1 Part A (S1A)

POM (restricted repeat)*

Examples: Antimicrobial agents; Methotrexate / ciclosporin: All parenteral medicines**; Benzodiazepines***

*repeated only if prescription specifically worded

** except insulin which is in Schedule S1B

***flunitrazepam/temazepam also subject to prescription writing requirements under the Misuse of Drugs Regulations

Schedule 1 Part B (S1B)

POM (repeatable X 6mths.)

Examples: Antihypertensive agents; NSAIDs; Proton pump inhibitors.

Schedule 1 Part C (S1C)

S1C indicates a prescription that may only be dispensed in a 'hospital' setting (e.g. radio-pharmaceuticals) and therefore is not used in the primary care setting.

Sources:
http://www.stjames.ie/ClinicalInformation/NationalMedicinesInformationCentre/NMICBulletins/2004/MedicationSafetyVol10No62004/file,17217,en.pdf

Medicinal Products (Prescription and Control of Supply) Regulations 2003 SI No. 540 of 2003

Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 SI No. 510 of 2005

There are no country-specific classifications in Ireland such as *Ethicas* and *Especialidadas Farmaceuticas Publicitarias* in Spain

On-patent / off-patent pharmaceuticals and generics are to be subject to price reductions in certain circumstances. Parallel traded pharmaceuticals are regarded as similar to the originator

Switches (change from POM to OTC) are facilitated by each set of *Medicinal Products (Prescription and Control of Supply)* Regulations, on the basis of those available or pending in the (small) Irish OTC market, at the time the Regulations are made. To say that a manufacturer switches a pharmaceutical may be misleading in that it is possible for a reimbursable prescription pharmaceutical to co-exist with a similar OTC product provided that the names and packaging are different. There are Pharmacy Only OTCs and OTCs, which can be dispensed outside pharmacies (e.g. paracetamol tablets in small pack sizes).

2.1.2.2 Market data

Table 2.3 contains pharmaceutical market data for Ireland in the years 1995 and 2000 to 2005 inclusive. Total pharmaceutical sales at wholesale level rose between 2004 and 2005 by 12.8%: the corresponding percentage for 2000 to 2001 was 18%. The growth in pharmaceutical sales at ex-factory level between 2003 and 2004 was 15.7%. Sales of generics as a percentage of sales at ex-factory price level fell marginally from 7.1% in 2000 to 6.9% in 2005. The Table shows clearly the outcome from a significant level of foreign direct investment and the role of indigenous manufacturers that Ireland is a major net exporter of pharmaceuticals.

Table 2.3: Ireland - Market data 1995, 2000 - 2005

Pharmaceutical industry in million €	1995	2000	2001	2002	2003	2004	2005
Pharmaceutical sales							
Sales at ex-factory price level	293	595	702	816	973	1126	1271
Sales at wholesale price level	345	700	826	960	1145	1325	1495
Sales at pharmacy retail price level	356	730	870	1015	1200	1377	1533
Sales at hospitals	57	115	126	140	170	205	245
Sales of generics	21	42	47	52	62	72	89
Sales of parallel traded pharmaceuticals	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Exports and imports							
Total pharmaceutical exports *	1609	5312	8975	15675	13612	15155	14425
Total pharmaceutical imports*	553	1525	1915	2069	2168	1970	1992

* Not differentiated between finished products (the great majority) and raw materials

Source: Irish Pharmaceutical Healthcare Association

Table 2.4: Ireland -Top 10 pharmaceuticals in ingredient cost, by active ingredient, GMS Scheme 2005

Position	Pharmaceutical, by active ingredient - GMS Scheme	ATC Code	Ingredient Cost (€)
1	Atorvastatin	C10AA05	36,471,497
2	Pravastatin	C10AA03	24,213,944
3	Omeprazole	A02BC01	23,661,509
4	Salmeterol and other drugs for obstructive airway diseases	R03AK06	17,927,868
5	Olanzapine	N05AH03	16,133,693
6	Lansoprazole	A02BC03	15,652,447
7	Clopidrigel	B01AC04	15,364,632
8	Esomeprazole	A02BC05	13,289,470
9	Amlodipine	C08CA01	10,501,365
10	Alendronic Acid	M05AB04	9,508,652

Sources: HSE National Shared Services Primary Care Reimbursement Service 'Statistical Analysis of Claims and Payments 2005'; WHO Collaborating Centre for Drug Statistics Methodology, Oslo 'ATC Index with DDDs 2005'

2.1.2.3 Patents and data protection

Patent protection is harmonized under the European Patent Convention and ensures original pharmaceuticals market protection for 20 years. Under EU legislation, there is a possible extension of patent protection for a period not exceeding 5 years under a Supplementary Protection Certificate (SPC), which may only be obtained at national level, as the European Patents Office (EPO) does not issue SPCs. Under the recently adopted EU legislation, authorities are also obliged to provide for data protection for an 8 + 2 + 1 year period. This provides an additional protection period for patented pharmaceuticals. (Human Medicines Directives 2001/83/EC and 2004/27/EC)

The EU legislated the so called 'Bolar Amendment' in order to address the difficulty flowing from the US Federal Circuit Court decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984). In *Bolar*, it was held that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval.

Only after 8 years the medicines agency can process an application for generic medicines under the EU Bolar amendment, *"Conducting the necessary studies and trials […] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for those medicinal products."* which can then be marketed when the 10-year data protection period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and therewith delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

In general, and not merely in relation to access and public health issues, there is an explicit provision for *compulsory licensing* contained in Section 70 of the Patents Act 1992.

If a medicinal (or any) product is the "object" of patent protection in Ireland, and European Union law does not otherwise provide, the sale of a *parallel import* may be legally blocked under Irish national law.

"Government use" of patented products is provided for in Part V of the Patents Act 1992:

PART V USE OF INVENTIONS FOR THE SERVICE OF THE STATE
Section 76 Assignment of invention, application, or patent to Minister of Government.
Section 77 Right to use inventions for service of State.
Section 78 Use of inventions pursuant to section 77; supplementary provisions.

In Ireland, there is no overriding legal provision for "State lockdown" of a patent, in the national interest, as may be exercised in the USA and in the UK, for example.

There has been no recently reported Irish case on the legal point of 'ever greening'. At the time of writing, the authors are unaware of any pending litigation in the patent protection area.

An Irish Court may view the decisions of Courts in other Common Law Jurisdictions as having "persuasive authority" to the extent that such judicial decisions are not inconsistent with European Union Law, the Constitution of Ireland or the Court's own jurisprudence (i.e. decisions of an Irish Court having equal or greater jurisdiction, which bind the Court in hearing and deciding a given case).

In relation to other recent controversies around patent protection, the Irish Supreme Court said in *Ranbaxy Laboratories Ltd & Ors v. Warner Lambert Company* [2005] IESC 81 that the evidence of the patentee or the inventor himself is not admissible as an aid to construction of claims in a patent. What is admissible is the evidence of a person to whom the patent is addressed as to such person's opinion of the meaning of the claim. The Irish Court adopted the principle confirmed in the *speech* (judgment) of Lord Hoffman in *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Ltd & Ors* [2005] 1 All ER 667, at Page 680 (UK House of Lords).

The case of *Ranbaxy Australia Pty Ltd v Warner-Lambert Company LLC (No 2)* [2006] FCA 1787 (20 December 2006) (Federal Court of Australia) dealt with the question of who is the skilled addressee in patent legislation. As patent specifications and claims must be construed in light of the common general knowledge of a person skilled in the art before the priority date, it is necessary to ask who the skilled addressee is. The Federal Court said that axiomatically, the identity of the person who is skilled in the art would vary with the nature of the invention and the field with which it is concerned. The level of skill, which can properly be attributed to the skilled addressee, will be an important determinant of his or her common general knowledge. The qualifications of the skilled addressee, the setting in which and the resources with which he or she operates, and the practices and techniques that he or she regards as commonplace and known will also be important considerations: see *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 ('Alphapharm') at 465 [153] per Kirby J.

Mention is made also of a recent English case *SanDisk Corporation v Koninklijke Philips Electronics and Ors* [2007] EWHC 332(Ch), Pumfrey J. (27 February 2007), from the Chancery Division of the High Court. The judge held that where a claimant alleged that defendant foreign companies held a dominant position in the licensing of patents in a defined market and that they had abused that position, the High Court only had jurisdiction to adjudicate on the alleged abuses pursuant to art 5(3) of Council Regulation (EC) 44/2001 ("the Brussels Regulation") if the event setting the tort in motion was in England and Wales, or the claimant was the immediate victim of that abuse suffering direct harm in England and Wales. It remains to be seen if such reasoning is followed in legal systems other than that of England and Wales. Since a domestic appeal may lie from a decision of the English High Court to the Court of Appeal and ultimately to the House of Lords, any extrapolations from this judgment may be premature. See section 7.2 for links to the European Patent Office and the Irish Patents Office.

2.1.3 Market players

This section describes the key players in the pharmaceutical system except from the authorities which have been introduced in section 2.1.1.2 Authorities. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy making.

2.1.3.1 Industry

PharmaChemical Ireland comprises of approximately fifty-five pharmaceutical and chemical companies and is staffed by a full time executive staff. PharmaChemical Ireland is a major sector within The Irish Business and Employers Confederation (IBEC) and has access to the various back-up and research facilities that IBEC provides for its membership (PI 2006): The usual distribution channel is via wholesale. Direct distribution by manufacturers is very much a minority situation.

Established in 1994, Forfás is the national policy and advisory board for enterprise, trade, science, technology and innovation. Forfás reports that Ireland has succeeded in attracting a large pharmaceutical manufacturing sector with 80 employers. Nine of the top ten companies in the world have manufacturing operations in Ireland. Of the present global pharma-products, an estimated 16 per cent are of biotechnological origin or are related to biotechnology; this [was] expected to rise to 30 per cent by 2005 (Forfas 2006).

Ireland has two major pharmaceutical industry associations. The Irish Pharmaceutical Healthcare Association (IPHA) represents pharmaceutical companies many of which are transnational in organization. The Association of Pharmaceutical Manufacturers of Ireland (APMI) counts in membership Irish based companies with a focus largely on generic medicinal products.

Industry's involvement in pricing and reimbursement is through the framework agreements between industry (the IPHA Agreement and the APMI Agreement) and the HSE. Industry has no representation on the Pricing Committee. There is no cap or "tax" imposed on promotional expenditure. Promotional activities are supposed to comply with the (voluntary) IPHA Code of Marketing Practice for the Pharmaceutical Industry with a view to securing high standards of conduct in the marketing of medicinal products to health professionals, whether intended for use under medical supervision or otherwise.

There is no ad hoc offering or demanding lower prices in return for reimbursement, as all products that meet the criteria are eligible. Please see section 5.3 Information to patients / doctors.

Table 2.5: Ireland - Key data on the pharmaceutical industry 1995 - 2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	70	76	76	75	74	76	76
- research-oriented	n/av	n/av	n/av	n/av	n/av	n/av	n/av
- generic producers	n/av	n/av	n/av	n/av	n/av	n/av	n/av
- biotech	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Number of persons employed[2]	10500	16000	18000	20000	21000	26000	25000

[1] as of 1 January

[2] counted per head

Source: Irish Pharmaceutical Healthcare Association

2.1.3.2 Wholesalers

The major pharmaceutical wholesalers are United Drug plc, Celesio and Uniphar

United Drug plc reported a Group Turnover of €1,326m (Annual Report 2005 http://www.united-drug.ie/investor_relations3.asp). The average number of persons employed by the Group (including executive directors) during the year was 2004.

For 2005, Celesio reported revenue of €255.4m for the three branches of its Irish wholesaler entity, Cahill May Roberts, which had then 219 employees (Celesio 2006) Celesio reported revenue of €145m in their Irish wholesale operations for the first six months of 2006: (NCB 2006).

Uniphar, in its 2005 Annual Report, announced Group Turnover of €618m, while profit before tax was €15.6m (www.allphar.ie/dynamic/pdf/Uniphar%20Annual%20Report%202005.pdf). The average number of persons employed by the company (including directors) during 2005 was 519. In 2005, five of the ten Uniphar Directors were community pharmacists.

A recognized feature of EU competition policy, parallel trade wholesalers have operated in Ireland for over 20 years. It is not usual for a parallel trade wholesaler to advertise its services extensively, which may indicate that it can achieve a satisfactory pharmacy customer base.

The Pharmaceutical Distributors Federation (PDF) is the wholesaler association within Ireland, which promotes its members' interests.

Uniphar reported for 2005 the complete integration into its operations of new customers, who were the former clientele of the smaller wholesaler, Boileau & Boyd, which Uniphar had earlier acquired.

Table 2.6: Ireland - Key data on pharmaceutical wholesale 1995 - 2005[1]

Wholesalers	1999	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	58	73	84	122	125	141	139
Total number of outlets	n/av	n/av	n/av	71	55	66	72

[1] as of 1 January

Source: Irish Medicines Board

2.1.3.3 Pharmaceutical outlets / retailers

Pharmacies notified to the Pharmaceutical Society of Ireland as "keeping open shop" in accordance with the Pharmacy Acts 1875-1977. This means mainly community pharmacies but also some pharmacies located in hospitals engaged in the supply of medicines to persons other than in-patients.

Others entitled to supply medicines are medical practitioners and dentists to patients in their care and veterinary practitioners for animals under their professional care. Licensed merchants can supply a limited range of veterinary medicinal products. Any outlet can supply a limited range of medicinal products e.g. paracetamol (maximum pack size of 500mg tablets/capsules is 12) and aspirin.

There are no legal prerequisites for the functioning of other dispensaries than community pharmacies, if allowed (e. g. if there are no community pharmacies in the area). If one is a medical practitioner, dentist etc dispensing to a patient in one's own professional care, there is no applicable legal provision. There are no restrictions on what a pharmacy notified as "keeping open shop" with the Pharmaceutical Society of Ireland can dispense or supply.

2.1.3.3.1 Pharmacies

The Pharmacy Acts 1875-1977 together with the Regulations of the Pharmaceutical Society of Ireland 1977-2002 govern the establishment, ownership and operation of pharmacies.

Community pharmacies may be owned by a pharmacist or by a body corporate (i.e. company). There is no requirement for a pharmacist(s) to have a majority shareholding in a company owning a pharmacy.

Pharmacy chains are permitted. Nearly 90% of pharmacies are owned by bodies corporate, which are currently mainly controlled by pharmacists.

No information is available on the total share of pharmaceuticals dispensed in pharmacies.

There are a number of important associations of pharmacists as follows:

Pharmaceutical Society of Ireland (PSI): This body as established by law regulates the practice and profession of pharmacy in Ireland. In order to practice pharmacy in Ireland, pharmacists must be registered with the PSI. Pharmacies "keeping open shop" in accordance with the Pharmacy Acts 1875-1977 must be notified to the PSI.

Irish Pharmaceutical Union (IPU): This body represents the commercial and other interests of community pharmacists, particularly pharmacy owners.

Hospital Pharmacists Association Ireland (HPAI): representative organization for hospital pharmacists.

Technical Industrial Pharmacists and Pharmaceutical Scientists Association (TIPPSA): professional association for those pharmacists who work in the pharmaceutical industry.

Influence of associations on policy making:

The PSI would have an advisory role to the Department of Health & Children on the regulation of the profession and practice of pharmacy in Ireland

Remuneration of Irish Pharmacies:

GMS Scheme
Standard Fee-Per-Item (Note 1) €3.26
Extemporaneous Fee €6.28
Extemporaneous dispensing and compounding of
- Powders €18.83
- Ointments and Creams €12.56
Controlled Drugs €5.07
Non-Dispensing - exercise of professional judgment €3.14
Phased Dispensing - each part of phased dispensing €3.14
Urgent/Late Dispensing
Additional fee for Urgent/Late dispensing other than between 00:00 and 08:00 (Note 2) €8.81
Additional fee for Urgent/Late dispensing between 00:00 and 08.00 €18.24

Note 1 €2.78 basic fee and €0.48 allowance for containers, obsolescence etc.

Note 2 Urgent fee prescriptions are those so specified by the prescriber and necessarily dispensed outside normal hours. Late fee prescriptions are those which, though not marked urgent, are in exceptional circumstances necessarily dispensed outside normal hours by the Pharmacist, having regard to the person's requirements.

Note 3 A Standard Fee-Per-Item is also payable on prescription forms issued by Dentists under the DTS Scheme.

Note 4 A Fee-Per-Item of €4.21 is also payable on prescription forms in respect of persons aged 70 years and over issued with a medical card for the first time regardless of income.

Supplies to Dispensing Doctors Pharmacies supplying Dispensing Doctors are reimbursed on the basis of the basic trade price with the addition of 25% on cost.

DPS/LTI/EEA and Health (Amendment) Act 1996

Reimbursement of ingredient cost plus 50% mark-up on ingredient cost plus Standard Fee - €2.86 (Note 1)

20% mark-up on Incontinence Products and Dressings under DP Scheme

Extemporaneously dispensed preparations are reimbursed at current private prescription rates. In the case of the Drugs Payment Scheme, the PCRS makes payments to Pharmacies in respect of authorized Patients whose monthly costs of prescribed drugs and medicines are in excess of the specified monthly amount **(currently €85)** payable to the Pharmacy by an individual or family.

Note 1 The standard fee is an all-inclusive fee which includes container and broken bulk allowance.

Patient Care Fee: €54.82 per month.

High Tech Medicinal Products Scheme

Patient Care Fee: Up to a Maximum of €54.82 per month.

Note 1 The standard fee is an all-inclusive fee which includes container and broken bulk allowance.

Patient Care Fee: €54.82 per month.

Methadone Treatment Scheme

Patient Care Fee: Up to a Maximum of €54.80 per month.

There are no provisions in place to regulate the establishment of new pharmacies in Ireland based on geographic location, population etc. There are no incentives in place to encourage the establishment of pharmacies in rural areas. There is no differentiation in Ireland among pharmacies along the line of branch pharmacies etc. It is possible for a community pharmacy to be located in proximity to a hospital, although the owner or operator must have a Community Pharmacy Contractor Pharmacy Agreement in order to participate in the GMS and Community Drug Schemes. As at 31st October 2006, there are 1487 community pharmacies in Ireland. That is approx 0.37 pharmacy per 1000 inhabitants (based on a population of 4.15 million).

There is evidence of vertical integration of wholesalers and pharmacies already in Ireland. Celesio, a German company owns one of the major wholesalers Cahill May Roberts Ltd. and the Unicare chain of pharmacies in Ireland. Another leading wholesaler Uniphar Ltd. owns IPOS Ltd., a company which purchases pharmacies with the aim to provide an ownership buy out scheme for young pharmacists to acquire such pharmacies.

The mail order supply of prescription only medicines (POMs) is prohibited in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2005. This prohibition previously applied to all medicinal products but was restricted to POMs only on foot of the ruling of European Court of Justice in *Deutscher Apothekerverband eV v DocMorris NV and Jacques Waterval* (Case C-322/01).

Discounts/Rebates for pharmacies

There is no provision in the IPHA and APMI Agreements for discounts or rebates to pharmacists.

Hospital pharmacies acting as community pharmacies
Hospital pharmacies are limited by section 56(1) of the Health Act 1970: for the purposes of this section "out-patient services" means institutional services other than in-patient services provided at, or by persons attached to, a hospital or home and institutional services provided at a laboratory, clinic, health centre or similar premises, but does not include the giving of any drug, medicine or other preparation, except where it is administered to the patient direct by a person providing the service or is for psychiatric treatment, or dental, ophthalmic or aural services (ISB 2006).

Table 2.7: Ireland - Retailers of pharmaceuticals 1995, 2000 - 2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies	1178	1244	1268	1279	1277	1306	1468	1487
No. of private pharmacies	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
No. of public pharmacies	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Number of hospital pharmacies for outpatients	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
Number of other POM dispensaries: Dispensing Doctors only	215	179	136	148	156	143	135	n/av
Total number of POM-dispensaries[1]	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av
No. of internet pharmacies	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed
No. of OTC dispensaries, like drugstores: _____	n/av	n/av	n/av	n/av	n/av	n/av	n/av	n/av

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number

[1] As at 1st October in any given year.

Source: Pharmaceutical Society of Ireland; General Medical Services (Payments) Board Financial and Statistical Analysis of Claims and Payments (1995 to 2004); HSE National Shared Services Primary Care Reimbursement Service 'Statistical Analysis of Claims and Payments 2005'

The number of (rural) dispensing doctors is quite low, both in absolute terms and by comparison with other countries. Dispensing doctors are not a feature of general practice in urban areas.

2.1.3.3.2 Other pharmacy outlets

Medical practitioners and dentists are entitled to dispense medicines to patients in their professional care and veterinary practitioners for animals under their professional care. This provision includes both POMs and OTC medicines. The law does not provide for regulation of outlets from which medical practitioners or dentists supply medicines.

The premises from which a veterinary practitioner practices veterinary medicine is regulated by the Veterinary Practitioners Act 2005 but does not have specific provision addressing the supply of medicines from such premises.

The premises of licensed merchants supplying animal remedies are regulated under the Animal Remedies Regulations 2005. These Regulations address the premises mainly.

Outlets supplying general sale medicinal products are not regulated.

None of these outlets would be considered to be in any way a pharmacy under Irish law.

The regulation of outlets other than pharmacies insofar as pharmacy staff is required is not equivalent to that of normal conventional pharmacies.

2.1.3.3.3 Internet pharmacies

Purchasing of pharmaceuticals via mail order or Internet is not allowed under Regulation 19 (Prohibition of mail order supply of medicinal products) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003.

2.1.3.3.4 Dispensing doctors

Dispensing doctors are a feature of the GMS Scheme only. In the GMS Scheme, rural dispensing is at the patient's election. Where the patient attends a doctor's practice centre that is more than three miles distant (approximately five kilometers - the criteria date from the 1970s) from the nearest pharmacy participating in the GMS Scheme, and the patient elects to have approved pharmaceuticals dispensed by the doctor, the patient may be assigned to the doctor's dispensing panel. But for individual patients' applications to the Local Health Office to avail a dispensing doctor service, such a service would not exist in a given locality. A doctor cannot acquire the status of dispensing doctor where there is no local demand from GMS eligible persons. However, since 1999, it is possible for a GP to opt out of rural dispensing, although this rarely occurs.

Being paid on a fee basis, the dispensing-doctor does not profit from dispensing pharmaceuticals, which are obtained on a stock order through a community pharmacy.

Many GMS participating GP practices include a practice nurse. Currently there is no framework for independent nurse practitioner prescribing and dispensing in the GMS Scheme or otherwise. During 2006, the Department of Health and Children published a consultation document on midwife (obstetric nurse) practitioner prescribing.

2.1.3.4 Hospitals

2.1.3.5 Doctors

The statutory regulatory body for registered medical practitioners is the Medical Council, which has disciplinary powers including erasure of a doctor's name from the register for misconduct. The Irish College of General Practitioners (ICGP) is the major vocational training and accreditation body for GPs.

The three organizations that interact with central government and the HSE are the Irish Hospital Consultants Association (IHCA) (which has the membership that its name implies), the Irish Medical Organisation (IMO) and the Association of General Practitioners (again the membership category is clear from the organization's title).

Hospital consultants are represented by the IHCA and IMO. The IMO also represents Non Consultant Hospital Doctors (NCHDs), who are generally pursuing postgraduate medical or surgical training.

From the perspective of general practice, the IMO represents the majority of GPs who hold contracts in the GMS Scheme.

2.1.3.6 Patients

Until recently, there has been no special feature to the patient's role in deciding which medicines will be prescribed and /or dispensed. Clause 3 of the IPHA Agreement refers to patient choice. The objective is to enhance the ability of patients to have a greater say in the prescribing process with a view to choosing, in consultation with the prescriber, the medicine that best meets their needs and delivers best value for money. Recognizing that patients have a right to freely choose from among the different treatments, on the basis of adequate patient information, the HSE will seek to increase patient awareness of the range of available prescription options. Prescribers may, in consultation with their patients, prescribe the medicines of their choice from the list of medicines available under the Schemes as appropriate. The HSE reserves the right to influence the prescribing habits of prescribers.

The prices of medicines are generally similar in pharmacies, although some pharmacies promote price reductions on selected OTC items. Therefore patients have some incentive to "shop around" for pharmaceuticals other than prescription medicines.

The Irish Patients' Association (IPA) is the main patient representative body representing patients in Ireland. For its website, parts of which are currently under development, is http://www.irishpatients.ie/. The IPA is engaged in advocacy and consultation with Government, the HSE, health professional bodies and the pharmaceutical industry on a wide range of matters that affect the IPA's membership.

IPHA has produced an Industry Guide to working with Patient Associations (December 2004)[2].

2.2 Funding

2.2.1 Pharmaceutical expenditure

In Ireland, pharmaceutical expenditure is diffuse in nature. For example, statistics for occupationally based reimbursement schemes are not published and some expenditure below the DPS co-payment threshold may not be captured at all. Accordingly, it is possible to quantify Total Pharmaceutical Expenditure (TPE) only from public sources, though not possible to state with precision the proportions of TPE comprised by the various sources of funds (public and private). The Total Pharmaceutical Expenditure in the year 2004 has been quantified with 1,306 Euros respectively 267.98 Euros per capita (OECD Health Data Base 2006).

[2] http://www.ipha.ie/htm/info/download/Publications/Industry%20Guide%20to%20working%20with%20Patient%20Associations.pdf

2.2.2 Sources of funds

The main funding sources of public pharmaceutical expenditure are national taxation and Pay Related Social Insurance (PRSI) contributions. Most employed people over 16 years of age contribute to Social Insurance. The amount paid is based on earnings and the type of work done (Social Insurance Class). PRSI Class A applies to most people in Ireland, i.e. those in industrial, commercial and service type employment who are employed under a contract of service with a reckonable pay of €38 or more per week from employment. It also includes civil and public servants recruited from 6 April 1995. The law makes the employer responsible for PRSI, though workers may have to pay an 'employee's share'. Regional income taxes do not exist in Ireland.

Private pharmaceutical expenses:

Health insurance companies currently operate a number of reimbursement systems for members' claims arising from an in-patient setting. The majority of pharmaceutical costs are not reimbursed on an itemized basis. They are rather built into the general reimbursement mechanism for private hospitals. Because of the structure of public hospital charges, and because of the insurers' reimbursement mechanism for private hospitals, it is not possible to isolate the benefit insured persons receive towards private pharmaceutical expenses.

For all tax payers, tax relief on medical (including pharmaceutical) expenses not reimbursed through any other source is available, subject to an annual deductible. Persons who care for a dependent person may qualify for tax relief, although this is not connected with expenses on pharmaceuticals.

The member(s) of a household seeking to avail of the Drugs Payment Scheme (DPS) are liable for a maximum charge of €85 per calendar month for prescribed medicines appliances covered by the Scheme. There is no minimum co-payment (threshold) in the DPS. There is no deductible regime for reimbursed pharmaceuticals in Ireland. Apart from self-medication, patients are not faced with direct payments for pharmaceuticals. It is not possible to state the average amount paid for such pharmaceuticals.

2.3 Evaluation

The NCPE reviews the cost-effectiveness and budget impact of individual pharmaceuticals in the Irish healthcare setting in response to requests from the Department of Health & Children. Evaluations of budget impact analyses have been informed by pharmaceutical utilisation data extracted from the GMS and the Community Drugs Schemes databases, as appropriate. Evaluations of cost-effectiveness models have been enhanced by the inclusion of Irish cost data as available.

In common with other countries, in Ireland, there is no permanently operating programme for pharmaceutical policy evaluation, in its totality, on a continuous basis. Universities and other research establishments evaluate some aspects of pharmaceutical policy.

3 Pricing

3.1 Organisation

The legal framework in Ireland for pricing of pharmaceuticals consists of the Agreements between the HSE on the one part and the representative associations of the pharmaceutical industry (IPHA or APMI) on the other part. There is no statutory framework to underpin such agreements. The pricing criteria have been determined as part of those agreements.

There is a Products Committee (currently comprised of DoH&C and HSE staff members), which meets monthly in order to decide on applications for reimbursable status in the GMS and Community Drug Schemes. The Products Committee examines the applications with particular reference to the pricing provisions of the IPHA and APMI Agreements.

The new IPHA and APMI Agreements represent major changes in the organization of pricing, as the HSE has taken over the role of the DoH&C as a lead partner in the Agreements. The HSE retains overall responsibility for pricing and reimbursement. Decisions on pricing and reimbursement form part of the same procedure. Please see the PRICE process description in the Flowchart (Figure 2.1 in Chapter 2).

The HSE Primary Care Reimbursement Service performs the reimbursement function.

Since the new Agreements are the first to set time limits, it is not possible at this early stage to say how long the process takes on average. New medicines, including new presentations and applications, granted a marketing authorization by the Irish Medicines Board or European Commission will become reimbursable in the Schemes, within 60 days of the date of the reimbursement application, subject to the provisions on pharmacoeconomic assessment prior to reimbursement (within 90 days of the receipt of the reimbursement application, with a further 90-day period in the event of an appeal) and setting the price of new pharmaceuticals (within 90 days of the date of the reimbursement application).

3.2 Pricing policies

Table 3.1: Ireland - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Not applicable	Not applicable	Free pricing for OTC sold within or outside pharmacies
Statutory Pricing	Not applied, but price of reimbursable pharmaceuticals (POM and OTC) may be indirectly influenced via the reimbursement system (reimbursement price)		
Price Negotiations	Manufacturers and wholesalers negotiate their share of the wholesale price (which is set by the manufacturer/importer, cf. above). The IPHA and APMI Agreements operate at the wholesale price level.		Not applicable
Discounts / rebates	Cost related discounts may be possible	Cost related discounts may be possible	No claw back applied
Public Procurement	➢ Mainly relevant for products used in hospitals ➢ Not relevant in out-patient sector, except for vaccinations and certain blood products		Not applicable
Institution in charge of pricing	HSE		Not applicable
Legal Basis	Pricing and reimbursement have not been placed on a statutory basis. The legal framework is the Agreements between the HSE and IPHA and APMI.		

Source: PCRS (2006)

The current pricing system was implemented with effect from September 2006. The price setting procedures are independent of the type of pharmaceutical e. g. prescription-only pharmaceuticals, me-too products, generics, parallel traded pharmaceuticals?

Pricing decisions are made at the wholesale price level. The price to wholesaler of each item of medicine covered by the new Agreement will not be increased for the term of the Agreement - save as might be required under Clauses 5.3 (Price Monitoring and Review), 5.4 (Price Modulation) and 11.3 (Exceptional Circumstances) of the IPHA Agreement.

The HSE decides on price changes. Save as might be required for Price Monitoring and Review, Price Modulation and Exceptional Circumstances, the price to wholesaler of each item of medicine covered by the new Agreement will not be increased for the term of the Agreement. Price decreases are allowed in accordance with Clause 6 of the IPHA Agreement (Patent Expired Medicines).

Product price modulation will be permitted under the new Agreement, on an exceptional basis and on condition that any such product price modulation will be demonstrably cost neutral for the State in each year of this new Agreement.

The HSE may require audited documentation of any price modulation and shall have the sole discretion to accept, reject or seek variation in any modulation application and to seek an appropriate refund if the terms of this clause are not adhered to.

3.2.1 Statutory pricing

Statutory pricing is not applicable to Ireland.

3.2.2 Negotiations

The IPHA and APMI Agreements apply, at the wholesale price level, to all medicines granted a marketing authorization by the Irish Medicines Board or European Commission, that can be prescribed and reimbursed in, and supplied to the GMS Scheme and the Community Drug Schemes, including the Drugs Payment Scheme, the Long Term Illness Scheme, the High Tech Scheme and the European Economic Area Scheme (the Schemes) and all medicines supplied to the HSE, State-funded hospitals and to State Agencies whose functions normally include the provision of medicines.

The HSE and IPHA or APMI are the parties to the negotiations. In September 2006, a system of external price referencing with a basket of nine EU Member States was introduced.

The legal framework is contained in the Agreements: there is no parliamentary or delegated legislation applicable to the price negotiations. The current Agreements are the latest in a line that has continued over decades. In the IPHA Agreement Clause 7.4 (Special Supply Arrangements), the HSE reserves the right to negotiate special arrangements for supply to the HSE, State funded hospitals and State agencies whose functions normally include the supply of medicines, with individual manufacturers or agents, designed to secure more favorable terms than those referred to in Clause 7.1 (Supply Arrangements from Wholesalers).

3.2.3 Free pricing

Effectively, free pricing exists for OTC pharmaceuticals alone. The IPHA and APMI Agreements apply to all medicines granted a marketing authorization by the Irish Medicines Board or European Commission, that can be prescribed and reimbursed in, and supplied to the GMS Scheme and the Community Drug Schemes and all medicines supplied to the HSE, State-funded hospitals and to State Agencies whose functions normally include the provision of medicines. Over many years, the price level of OTC pharmaceuticals has been influenced by market forces in that segment of the pharmaceuticals marketplace in Ireland.

3.2.4 Public procurement / tendering

Clause 11.2 (Vaccines) of the IPHA Agreement provides that the Agreement will not prevent arrangements being made for the supply of vaccines or similar products for the Healthcare Services. The authors have no information concerning the operation of this Clause at this time.

3.3 Pricing procedures

New features of the IPHA and APMI Agreements, compared with their predecessors, are that they provide for reductions in the price of existing pharmaceuticals and those coming off patent, and for a wider basket of countries for pricing new pharmaceuticals coming on the market. Also, for the first time, reimbursement of new pharmaceuticals coming onto the Irish market can now be informed by pharmacoeconomic assessment, in line with other EU member States. The new basket will include some traditionally lower priced countries, including Spain, which should benefit consumers over the medium term.

Clause 5.3 (Price Monitoring and Review) in the IPHA Agreement provides:

"The price to wholesaler of any new medicine introduced to Ireland under the new Agreement shall be realigned to the currency-adjusted average price to wholesaler in the nominated EU member states in which the medicine is then available, two years and four years following the commencement of the new Agreement. Price changes (if any) resulting from these realignments will be implemented within 60 days of the realignment date. No realignment will be required within 12 months of the date of reimbursement approval."

Table 3.2: Ireland - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing	No		
External price referencing	Yes	Wholesale	GMS Scheme and the Community Drug Schemes, medicines supplied to the HSE, State-funded hospitals and to certain State Agencies
Cost-plus pricing	No		
Other, e. g. indirect profit control	No		

Source: PCRS (2006)

3.3.1 External price referencing

External price referencing is applied to POM (including generic) pharmaceuticals, at the wholesale price level. OTC pharmaceuticals are not generally covered by the Agreements. While there are no laws or decrees for external price referencing, the IPHA and APMI Agreements contain the formal rules to be applied.

For inclusion in the basket for external price referencing, the nominated EU States are Belgium, Denmark, France, Germany, the Netherlands, Spain, the UK, Finland and Austria. These countries were chosen in the negotiations between the parties that negotiated the IPHA and APMI Agreements.

The price to wholesaler of any new medicine, introduced to Ireland following the commencement of the Agreement, shall not, on the date of initial price notification to the HSE, exceed the currency adjusted average price to wholesaler in the nominated EU member states.

If any new medicine is not available in all nominated EU states on the date of initial price notification to the HSE, the Irish price to wholesaler shall not exceed the currency adjusted average price to wholesaler in the nominated EU States in which the new item of medicine is available.

If a new medicine is not available in any of the nominated EU states, the Irish price to wholesaler will be agreed between representatives of the manufacturer/ importer concerned and the HSE within 90 days of the date of the reimbursement application.

The IPHA Agreement Clause 5.5 (Applicable Exchange Rates) provides that the applicable exchange rates for initial price notification of medicines will be the exchange rates published by the Central Bank of Ireland, on the date of price notification or realignment. Purchasing power parity comparisons are not a feature of the IPHA and APMI Agreements.

The manufacturer or agent provides the country price information. It is the responsibility of the Products Committee to check its accuracy, which it may do by checking published information from other EU State (s) and, if necessary, contacting a corresponding organization in the other EU State (s) in order to confirm the pricing data’s accuracy.

IPHA Agreement Clause 5.1 (Price Freeze) provides for no price increases for the duration of the Agreement.

Clause 5.2 (Price of New Medicines) of the IPHA Agreement states that the price to wholesaler of any new medicine, introduced to Ireland following the commencement of the Agreement, shall not, on the date of initial price notification to the HSE, exceed the currency adjusted average price to wholesaler in the nominated EU member states.

If any new medicine is not available in all nominated EU states on the date of initial price notification to the HSE, the Irish price to wholesaler shall not exceed the currency adjusted average price to wholesaler in the nominated EU States in which the new item of medicine is available.

If a new medicine is not available in any of the nominated EU states, the Irish price to wholesaler will be agreed between representatives of the manufacturer/ importer concerned and the HSE within 90 days of the date of the reimbursement application.

IPHA Agreement Clause 5.7 (Nominated EU States) provides that the nominated EU States are Belgium, Denmark, France, Germany, the Netherlands, Spain, the UK, Finland and Austria.

Price movements in other EU States might conceivably be a factor in an application under Clause 5.4 (Price Modulation).

Product price modulation will be permitted under the Agreement, on an exceptional basis and on condition that any such product price modulation will be demonstrably cost neutral for the State in each year of this new Agreement. The HSE may require audited documentation of any price modulation and shall have the sole discretion to accept, reject or seek variation in any modulation application and to seek an appropriate refund if the terms of this clause are not adhered to.

3.3.2 Internal price referencing

Internal price referencing is not applicable to Ireland's situation.

3.3.3 Cost-plus pricing

Cost-plus pricing is not operated in Ireland.

3.3.4 (Indirect) Profit control

Indirect profit control, such as the British PPRS Scheme, is not applied in Ireland.

3.4 Exceptions

Under Clause 5.4 (Price Modulation) of the IPHA Agreement, product price modulation will be permitted under the Agreement, on an exceptional basis and on condition that any such product price modulation will be demonstrably cost neutral for the State in each year of this new Agreement.

The HSE may require audited documentation of any price modulation and shall have the sole discretion to accept, reject or seek variation in any modulation application and to seek an appropriate refund if the terms of this clause are not adhered to.

3.4.1 Hospitals-only

The IPHA and APMI Agreements cover hospital pharmaceuticals. Under Clause **7**.4 (Special Supply Arrangements) in the IPHA Agreement, the HSE reserves the right to negotiate special arrangements for supply to the HSE, State funded hospitals and State agencies whose functions normally include the supply of medicines, with individual manufacturers or agents, designed to secure more favorable terms than those referred to in Clause 7.1 above.

Hospitals, particularly voluntary hospitals, sometimes contract out their pharmaceutical procurement to other (larger) hospitals. The Hospital Procurement Services Group (HPSG) is an alliance of voluntary hospitals, which has not yet become involved in pharmaceuticals procurement. Hospitals carrying out their own procurement under the auspices of the HSE achieve lower prices than those in the outpatient sector.

Price-changes are not currently monitored and evaluated on a collective basis. The authors have no information on prices for pharmaceuticals in hospitals or how price-changes are monitored and evaluated in hospitals.

The IPHA and APMI Agreements are the foundation for pricing of pharmaceuticals in hospitals. The HSE reserves the right to negotiate special arrangements for supply to … State funded hospitals … with individual manufacturers or agents, designed to secure more favorable terms than those referred to in the Agreements' general pricing provisions.

3.4.2 Generics

In Ireland, originator pharmaceuticals and generics are reimbursable on substantially the same basis: the IPHA and APMI Agreements contain provisions that make this the position.

3.4.3 Over-The-Counter pharmaceuticals

In general, OTC pharmaceuticals are not reimbursable and are therefore amenable to free pricing. POM and OTC products are not reimbursable unless these come within the criteria pursuant to Council Directive 89/105/EEC. Products for smoking cessation are exempt from the general restriction on the advertising of GMS reimbursable products to members of the public.

3.4.4 Parallel traded pharmaceuticals

The system for the pricing of parallel traded pharmaceuticals does not differ from other pricing procedures for medicinal products. Parallel imports that comply with the criteria are separately identified from the originator product and reimbursed on the GMS Scheme.

Given Ireland's peripheral location in the EU and its proximity to a larger market with a shared official language, there has been concern that parallel exportation from Ireland to the UK would cause shortages of medicinal products in Ireland. These anxieties should have lessened some-

what with the European Court of Justice (ECJ) decision in SIFAIT v GlaxoSmithKline (Case C-53/03). Here the Court stated that the refusal by a dominant pharmaceutical company to fulfill all orders from wholesalers does not automatically constitute an abuse of a dominant position, despite such refusal clearly limiting parallel trade of the products in question.

Parallel traded pharmaceuticals are not treated like generics, because in most cases the parallel import arises while patent protection still subsists.

3.4.5 Other exceptions

3.5 Margins and taxes

Table 3.3: Ireland - Regulation of wholesale and pharmacy mark-ups 2006

	Wholesale mark-up			Pharmacy mark-up		
	Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
Ireland	No	Fixed percentage	All pharmaceuticals	No	Fixed percentage	All pharmaceuticals

*For OTC there is free pricing.

Source: PCRS (2006)

3.5.1 Wholesale remuneration

Prior to the new IPHA and APMI Agreements, the wholesale mark up was uniformly 17.66%.

Since September 2006, the wholesale mark up is 15% for all new products and new presentations of existing products. However, the level (or levels) of the wholesale mark up may be the subject of a future review.

The government does not regulate margins so as to limit the wholesaler's profit.

3.5.2 Pharmacy remuneration

Remuneration of Irish Pharmacies:

GMS Scheme

Standard Fee-Per-Item (Note 1) €3.26

Extemporaneous Fee €6.28

Extemporaneous dispensing and compounding of

- Powders €18.83

- Ointments and Creams €12.56

Controlled Drugs €5.07

Non-Dispensing - exercise of professional judgment €3.14

Phased Dispensing - each part of phased dispensing €3.14

Urgent/Late Dispensing

Additional fee for Urgent/Late dispensing other than between 00:00 and 08:00 (Note 2) €8.81

Additional fee for Urgent/Late dispensing between 00:00 and 08.00 €18.24

Note 1 €2.78 basic fee and e0.48 allowance for containers, obsolescence etc.

Note 2 Urgent fee prescriptions are those so specified by the prescriber and necessarily dispensed outside normal hours. Late fee prescriptions are

those which, though not marked urgent, are in exceptional circumstances necessarily dispensed outside normal hours by the Pharmacist,

having regard to the person's requirements.

Note 3 A Standard Fee-Per-Item is also payable on prescription forms issued by Dentists under the DTS Scheme.

Note 4 A Fee-Per-Item of €4.21 is also payable on prescription forms in respect of persons aged 70 years and over issued with a medical card for

the first time regardless of income.

Supplies to Dispensing Doctors

Pharmacies supplying Dispensing Doctors are reimbursed on the basis of the basic trade price with the addition of 25% on cost.

DPS/LTI/EEA and Health (Amendment) Act 1996

Reimbursement of ingredient cost plus 50% mark-up on ingredient cost plus Standard Fee - €2.86 (Note 1)

20% mark-up on Incontinence Products and Dressings under DP Scheme

Extemporaneously dispensed preparations are reimbursed at current private prescription rates. In the case of the Drugs Payment Scheme

the PCRS makes payments to Pharmacies in respect of authorized Patients whose monthly costs of prescribed drugs and medicines are

in excess of the specified monthly amount **(currently €85)** payable to the Pharmacy by an individual or family.

Note 1 The standard fee is an all inclusive fee which includes container and broken bulk allowance.

Patient Care Fee: €54.82 per month.

High Tech Medicinal Products Scheme

Patient Care Fee: Up to a Maximum of €54.80 per month.

Note 1 The standard fee is an all inclusive fee which includes container and broken bulk allowance.

Patient Care Fee: €54.82 per month.

Methadone Treatment Scheme

Patient Care Fee: Up to a Maximum of €54.80 per month.

Pharmacists are remunerated on a fee-for service basis for the GMS Scheme. There is a 25% on cost allowance for items supplied to Dispensing Doctors on a Dispensing Doctors Stock Order Form. On the DPS and other Community Drug Schemes, remuneration includes a standard fee and a 50% mark-up. On the High Tech Medicinal Products Scheme, the only remunerative heading is a Patient Care Fee, since the wholesaler or pharmaceutical company invoices PCRS directly.

In the reimbursement context, there are no contractual relations between wholesalers and pharmacies. However, subject to applicable laws, a wholesaler is free to hold a beneficial interest in a pharmacy and vice versa and, like in other EEA Member States, this does occur.

Pharmacy mark-ups / margins and / or fees are not regulated by law / decree, rather they have been set by various agreements that have been reached over many years.

There are no current proposals to alter the margin system or refunding system for pharmacists. However, the position may come to be reviewed in any future consultation on pharmacy contracts.

Table 3.4: Ireland - Pharmacy mark-up scheme 2006

Ireland			
GMS Scheme		**DPS/LTI Schemes Etc.**	
Pharmacy Purchase Price (PPP) €	**Pharmacy Mark-up Coeffi-cient in % of PPP**	**Pharmacy Purchase Price (PPP) €**	**Pharmacy Mark-up Coefficient in % of PPP**
rish Trade Price	Zero%	Irish Trade Price	50%

NCU = National Currency Unit

Sources: PCRS (2006)

3.5.3 Remuneration of other dispensaries

Rural dispensing doctors receive a capitation fee in respect of persons on their GMS panel for whom they have a liability to dispense pharmaceuticals. No margin is payable to the dispensing doctors, since pharmacists (holding a contact for services in the GMS Scheme) supply the pharmaceuticals to those GPs.

Hospital pharmacies in Ireland do not generally perform remunerable services to which a margin or fee payment would apply.

For drugstores and other non-pharmacy outlets, the question of remunerable services does not arise.

3.5.4 Value-added tax

Since 1973, oral medicines have been VAT zero-rated. Some ostomy and urinary appliances are also zero-rated. Medicines for external use or application are liable to 21% VAT.

3.5.5 Other taxes

There are no further taxes or other fiscal charges on pharmaceuticals in Ireland.

3.6 Pricing related cost-containment measures

3.6.1 Discounts / Rebates

In Ireland, there is no administrative law procedure, referable specifically to the GMS and Community Drug Schemes, governing the granting of discounts or their claw back. Statutory discounts are not applied. “Settlement discounts” for regular and timely payment, set at a modest proportion of the customer’s relevant indebtedness to the supplier, are a recognized business practice.

No information is available on the discounts that hospitals receive from wholesalers and manufacturers. These discounts will not necessarily be uniform countrywide because of the rights reserved in the IPHA and APMI Agreements to negotiate special arrangements for supply to State funded hospitals (including on a national or regional basis). Sales based ex-post discounts ("solidarity contributions") are not a structural feature of the Irish healthcare system.

The HSE will advise each manufacturer or importer of each quantity and value of his/her medicines dispensed under the GMS Scheme each month and each manufacturer/importer will rebate to the HSE an amount equal to 3.53% of the value (at price to wholesaler) of all medicines dispensed in the GMS Scheme.

3.6.2 Margin cuts

The current position in Ireland is that there is no imposed change wholesaler or pharmacy margins or mark-ups.

3.6.3 Price freezes / Price cuts

There is currently a price freeze applied in Ireland, which has a history of such price standstills by agreement, rather than by statutory regulation. The price to wholesaler of each item of pharmaceutical covered by the IPHA Agreement will not be increased for the term of the Agreement - save as might be required under Clauses 5.3 (Price Monitoring and Review), 5.4 (Price Modulation) and 11.3 (Exceptional Circumstances) of the IPHA Agreement. Similar provisions exist in the APMI Agreement. With the aim of cost containment, he current price freeze is in place since September 2006. At this time, an evaluation process for that price freeze is premature.

A price increase may be sought through price modulation, which will be permitted under the IPHA and APMI Agreements, on an exceptional basis and on condition that any such price modulation will be demonstrably cost neutral for the State in each year of this new Agreement.

Patent expired medicines (including generics) are set for price cuts in accordance with the IPHA and APMI Agreements. Please see also section 4.1.

3.6.4 Price reviews

The duration of the Agreement is four years from the date of commencement. Twelve months' notice to re-negotiate may be given by either party after three years. In the IPHA Agreement there is provision in Clause 11.3 (Exceptional Circumstances) to deal with a situation where a supplier is oppressed by the terms of the Agreement. Direct representations may be made to the HSE for variation of any term of this Agreement including its price terms.

In the interests of continuity of supply, where it becomes uneconomic for a supplier to supply a particular dosage form under the terms of this Agreement, direct representations may be made to the HSE for variation of any term of this Agreement, in relation to that product, including its price terms.

The HSE shall have the final decision on whether to vary the terms of this Agreement in any case but will consult with IPHA before reaching its decision.

4 Reimbursement

4.1 Organisation

The legal framework is contained in the IPHA and APMI Agreements. There is no parliamentary or delegated legislation applicable to reimbursement policy.

POM and OTC products are not reimbursable unless these come within the criteria pursuant to Council Directive 89/105/EEC. Products for smoking cessation are exempt from the general restriction on the advertising of GMS reimbursable products to members of the public.

The Agreements between the HSE and IPHA and the APMI cover the supply terms, conditions and prices of medicines supplied to the Health Services. That is to say the GMS and Community Drug Schemes, the HSE, State funded hospitals and State Agencies the functions of which normally include the supply of medicines.

The HSE has the decision-making power in relation to whether or not a pharmaceutical is reimbursed.

Pharmaceuticals must have a current EU Commission Marketing Authorization (MA) or a Product Authorization (PA) issued by the Irish Medicines Board (IMB).

The price of a pharmaceutical must comply with the pricing structure of the IPHA Agreement (Agreement between the HSE and the Irish Pharmaceutical Healthcare Association).

Products must belong to a category eligible for reimbursement under the GMS Scheme, pursuant to EU Council Directive 89/105/EC.

The overall reimbursement status of a pharmaceutical (i.e. covered under a Scheme or not), subject to routine deletions, will not change for the duration of the Agreement. However, the price may be reduced for patent expired medicines in the following manner.

The price reductions will apply to specific dosage forms of patent expired medicines where the identical pharmaceutical form of that medicine, approved by the Irish Medicines Board or EU Commission, is available for prescription.

Existing patent expired medicines and medicines due to go off patent within 6 months of the commencement of the Agreement

For patent expired medicines or medicines the patents of which expire in the 6 months period following the commencement of the Agreement, 6 months following the commencement of the Agreement, the price to wholesaler will be reduced by 20% and 22 months after the first price reduction, the price to wholesaler will be reduced by a further 15% of the original price to wholesaler.

Medicines due to go off patent from 6 months following the commencement of the new Agreement.

For medicines the patents of which expire beyond 6 months following the commencement of the new Agreement, the price to the wholesaler will be reduced by 20% and 22 months thereafter, the price to wholesaler will be reduced by a further 15% of the original price to wholesaler.

Clause 6.3 (Implementation of Price Reductions) specifies that the HSE will notify the manufacturer/importer of the availability of an identical pharmaceutical form from another manufacturer and the new discounted price applicable in accordance with the requirements of Clauses 6.1 and 6.2 of the IPHA Agreement.

Products shall not trigger the price reductions specified in Clauses 6.1 and 6.2 unless the manufacturers/importers can satisfy the HSE of their ability to maintain continuity of supply of these products for Irish patients. 20 months after the initial HSE notification, the HSE will confirm to the manufacturer/importer, the continuing availability for prescription in the Schemes of the identical pharmaceutical form.

The price reductions will be implemented on the required dates as set out in Clause 6.1 and 6.2 or within 60 days of the date of the relevant HSE notification, whichever is the later. Clause 8 of the IPHA Agreement concerns the Rebate on pharmaceuticals supplied under the GMS Scheme. The HSE will advise each manufacturer or importer of each quantity and value of his/her medicines dispensed under the GMS Scheme each month and each manufacturer/importer will rebate to the HSE an amount equal to 3.53% of the value (at price to wholesaler) of all medicines dispensed in the GMS Scheme.

During the course of this Agreement, the HSE may introduce a rebate across all the Schemes following consultation with IPHA. Any such rebate will not exceed the value of the 3.53 % GMS Scheme rebate at the time of the introduction of the new rebate.

No rebate will be payable on the specific dosage forms of medicines which are the subject of the price reductions applied under Clause 6, i.e. patent expired medicines.

Price changes do not constitute a change in reimbursement status. Medicines normally reimbursable in the Schemes at the date of commencement of the new Agreement will, subject to routine deletions, and provided that they conform with the Agreements and the reimbursement criteria published by the Minister, pursuant to EC Directive 89/105/EC, remain reimbursable in the Schemes for the duration of the Agreement.

4.2 Reimbursement schemes

The General Medical Services (GMS) Scheme was established to provide, free of charge, both a general practitioner (GP) service and medication dispensed by a community pharmacy, to persons who cannot afford such services from their own resources without undue hardship. All persons aged 70 years and over receive a free general medical service. Based on the CSO offi-

cial population estimate of 4,130,700 (April 2005), 29.50% of Ireland's population was eligible for GMS services at December 2005 (PCRS Statistical Analysis of Claims and Payments 2005).

Under the Drugs Payment Scheme (DPS) persons who are ordinarily resident in the State and who do not have a current medical card can benefit - an individual or family has now to pay no more than €85 in a calendar month for approved drugs, medicines and appliances for themselves or their families. In order to benefit under this Scheme a person must register themselves and their dependants with their HSE Local Health Office.

The General Practitioner Visit Card (GPVC) is available to certain people in Ireland who do not qualify for a medical card. Such persons may apply to the HSE for a GP Visit Card. GP Visit Cards allow individuals and families who qualify, to visit their General Practitioner for free. All GP claims are processed and paid by the PCRS.

Persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the Long Term Illness (LTI) Scheme.

The Long Term Illness (LTI) Scheme covers 15 diseases or disabilities of a permanent or long term nature:

- Mental Handicap
- Hydrocephalus
- Cerebral Palsy
- Muscular Dystrophy
- Haemophilia
- Diabetes Mellitus
- Diabetes Insipidus
- Epilepsy
- Multiple Sclerosis
- Parkinsonism
- Cystic Fibrosis
- Phenylketonuria
- Acute Leukaemia
- Mental Illness (Under 16 years of age)
- Spina Bifida

Medicines and appliances necessary for the treatment of the long term condition are supplied free of charge by a Community Pharmacy.

High Tech Medicinal Products (HTMP) Scheme

Commenced in November 1996, the Scheme provides for the supply and dispensing of high-tech medicines through Community Pharmacies. The medicines are purchased by the HSE and supplied through Community Pharmacies for which pharmacies are paid a patient care fee by the PCRS each month. Examples of high-tech drugs are: anti-rejection drugs for transplant patients, chemotherapy and growth hormones. The patient's primary eligibility (GMS or other Scheme) determines whether there is a charge.

The statutory basis for the GMS and Community Drug Schemes is to be found in section 59 of the Health Act, 1970 (as amended).

The IPHA and APMI Agreements are the first to set time limits: it is therefore not possible at this early stage to say how long the process of obtaining reimbursement takes on average. New medicines, including new presentations and applications, granted a marketing authorization by the Irish Medicines Board or European Commission will become reimbursable in the Schemes, within 60 days of the date of the reimbursement application, subject to the provisions on pharmacoeconomic assessment prior to reimbursement (within 90 days of the receipt of the reimbursement application, with a further 90-day period in the event of an appeal) and setting the price of new pharmaceuticals (within 90 days of the date of the reimbursement application).

4.2.1 Eligibility criteria

Through the IPHA Agreement, Clause 4.3 (Pharmacoeconomic Assessment prior to Reimbursement), the HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be high cost or have a significant budget impact on the Irish healthcare system.

In the case of new medicines, assessment may be conducted prior to reimbursement, in parallel with the IMB/EU Commission process, to ensure speed of access to market. To this end, suppliers should notify the HSE (using the official form in Appendix xxx) when (or as soon as possible after) applying for a marketing authorization, of intention to seek reimbursement approval.

Assessments will be conducted in accordance with the existing agreed Irish Healthcare Technology Assessment Guidelines. Any new guidelines will be agreed between IPHA and the HSE

Where a new medicine is subject to assessment, the reimbursement decision will be notified within 90 days of the receipt of the reimbursement application. Should reimbursement be refused appeal may be made to an expert committee, the membership of which will be agreed between the HSE and IPHA. In reaching its decision, the expert committee will consider views of relevant stakeholders. The expert committee's decision will be made within a further 90 days and will be accepted as binding.

Where reimbursement of a new medicine is refused on appeal, and where significant new evidence becomes available subsequently, it will be open to the applicant to seek a new pharmacoeconomic assessment in accordance with the foregoing procedures.

There are no patients specific or disease specific criteria applied to reimbursement policy.

4.2.2 Reimbursement categories and reimbursement rates

Ireland does not operate a system of differential reimbursement rates.

4.2.3 Reimbursement lists

For the GMS Scheme, there is a positive as opposed to a negative list, indicating reimbursable pharmaceuticals. The GMS List is updated on a monthly basis. Other Schemes (HTM and DTSS) are updated less frequently, since there may be no change in the pharmaceuticals covered in any given month.

Council Directive of 12 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC).

Pursuant to Article 11.2 of the above Directive, the Minister for Health and Children hereby advises that the following criteria apply in respect of the consideration of applications from pharmaceutical companies concerning the inclusion of medicinal products in the General Medical Services Scheme (GMS) and the Drugs Payment Scheme (DPS):

1. The product must be an 'allopathic' medicinal product which is the subject of a current product authorization granted by the Irish Medicines Board under the Medicinal Products (Licensing and Sale) Regulations, 1998 (S.I. No. 142 of 1998) or an authorization granted or renewed by the European Commission in accordance with Consolidated Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC, Directive 2004/24/EC and Directive 2004/27/EC.;

2. The product must be such that it is ordinarily supplied to the public only on foot of a medical prescription;

3. The product should be one which may be used under the supervision of a general medical practitioner and which is not restricted to hospital or medical specialist use;

4. The product should not be advertised or promoted to the public excluding special arrangements made with regard to nicotine replacement therapy;

5. The product should not be one for the purpose of obtaining a cosmetic effect (e.g. hair restorers);

6. The price of the product should be in accordance with the agreements in place between the Department of Health and Children and the pharmaceutical industry;

7. Notwithstanding paragraph 2, products in the following categories which otherwise comply with these criteria are eligible for inclusion in the GMS Scheme-

- anthelmintics;
- anti-diarrhoeals;

- non-sedating oral liquid antihistamines and other antihistamines in solid unit dosage forms;
- products authorized and recommended for the treatment of scabies;
- products authorized and recommended for the treatment of psoriasis;
- vitamin drops intended for infants;
- iron drops intended for infants;
- iron and folic acid in solid unit dosage forms;
- products containing iron salts as their single active component;
- products (not being antacids) authorized and recommended for the treatment of ulcers in the gastrointestinal tract;
- medicinal products authorized and recommended as phosphate-binding agents in the treatment of renal failure in patients on renal dialysis;
- bulk forming products authorized and recommended for colostomy or ileostomy control;
- products, being antacids, acting in the gastro-intestinal tract (in all forms);
- products, (in solid unit dosage forms) being analgesics, acting on the central nervous system;
- medicinal products which are specifically authorized and recommended for use in the treatment of chronic constipation;
- folic acid tablets, 400 mcg specifically authorized and intended only for the prevention of Neural Tube Defects in children;
- products containing calcium and vitamin D, specifically authorized and intended for the prophylaxis and treatment of osteoporosis and osteomalacia;
- products for nicotine replacement therapy.

8. Where under the forgoing criteria products in a particular therapeutic category have been deleted from the GMS and DPS Schemes except for product(s) in that category which are present by virtue only of their prescription classification, and the said product(s) have a recognized abuse potential by virtue of their being controlled drugs under the Misuse of Drugs Acts, 1977 and 1984, then those product(s) shall, in those circumstances, not be eligible for inclusion in the GMS and DPS Schemes.

Doctors and pharmacists are updated monthly of changes to the List of GMS Reimbursable Items. It is proposed to examine the feasibility of placing and updating the List of GMS Reimbursable Items on an Internet site.

There is no procedure in place in order to add pharmaceuticals, which do not completely fulfill the inclusion criteria, to the list.

The reimbursement system is not designed to accommodate pharmaceuticals used in hospitals or nursing homes. Inpatients will have their medication supplied by the hospital authorities. Nursing home residents may be entitled to avail of a particular Scheme on the same eligibility criteria as persons generally.

4.3 Reference price system

Ireland does not utilize a reference price system for pharmaceuticals under the current IPHA and APMI Agreements and has not done so previously.

4.4 Private pharmaceutical expenses

Private Hospitals:

Three health insurance companies currently operate a number of reimbursement systems for members' claims arising from an in-patient setting. The majority of pharmaceutical costs are not reimbursed on an itemized basis. They are rather built into the general reimbursement mechanism for private hospitals. For example, a considerable number of hospital benefits are now paid on a packaged price basis. This means that a single all-inclusive benefit is determined for surgical or diagnostic procedures. In non-surgical (medical) cases, the daily rate of benefit is either all-inclusive or will permit separate reimbursement of additional technical costs, such as pathology and radiology, although not pharmaceuticals.

Some cancer chemotherapy pharmaceuticals (infused cytotoxic medication) may be reimbursed on an itemized basis in private hospitals only. The responsibility for decisions in respect of such claims may be reserved to the insurer's medical director.

Because of the structure of public hospital charges, and because of the insurers' reimbursement mechanism for private hospitals, it is not possible to isolate the benefit insured persons receive towards private pharmaceutical expenses.

Health insurance companies have as their objective cost minimization for the benefit of all their members and they do not have mechanisms in place to reimburse vulnerable groups preferentially. Members will decide on the level of cover that best meets their needs and which they can afford.

For all tax payers, tax relief on medical (including pharmaceutical) expenses not reimbursed through any other source is available, subject to an annual deductible. Persons who care for a dependent person may qualify for tax relief, although this is not connected with expenses on pharmaceuticals.

Rational consumption mechanisms aimed at patients would only be suitable for pharmaceuticals that patients can take at home. Not all health insurers offer reimbursement for out-patient pharmaceutical expenses.

Health insurers negotiate contracts with hospitals on an annual basis. There is an awareness that some hospitals can achieve economies from bulk purchasing pharmaceuticals, which will influence the insurers' price setting process.

All-inclusive reimbursement mechanisms and Package Procedure benefits encourage private hospitals to manage their costs effectively, for example through using low-cost generic pharmaceuticals and curbing over-prescribing.

In recent years there has been a very significant increase in the development of new pharmaceuticals primarily for treating cancerous conditions: most come at a very high cost. It will be some time before generic versions become available because of intellectual property rights.

4.4.1 Direct payments

Apart from self-medication, patients are not faced with direct payments for pharmaceuticals. It is not possible to state the average amount paid such pharmaceuticals.

4.4.2 Out-of-pocket payments

The member(s) of a household seeking to avail of the Drugs Payment Scheme (DPS) are liable for a maximum charge of €85 per calendar month for prescribed medicines appliances covered by the Scheme. There is no minimum co-payment (threshold) in the DPS.

4.4.3 Fixed co-payments

The member(s) of a household seeking to avail of the Drugs Payment Scheme (DPS) are liable for a maximum charge of €85 per calendar month for prescribed medicines appliances covered by the Scheme. There is no minimum co-payment (threshold) in the DPS.

4.4.3.1 Percentage co-payments

There is no fixed co-payment percentage in Ireland.

4.4.3.2 Deductibles

There is no deductible regime for reimbursed pharmaceuticals in Ireland.

4.5 Reimbursement in the hospital sector

The concept of reimbursement generally exists in the outpatient sector only. In the inpatient sector, patients in a publicly funded hospital will not be required to pay for the cost of their medication: pharmaceuticals for inpatient care are fully resourced by the hospital authorities. Patients in a private hospital may be billed for their medication: no information on the extent of such a practice is available.

The main "payer" for pharmaceuticals in hospitals is the HSE.

There is no cooperative funding for the reimbursement of pharmaceuticals, as for example in the Netherlands, since the HSE is the funding body for both the inpatient and outpatient sectors.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

There have been no major changes in reimbursement lists in Ireland. Medicines normally reimbursable in the Schemes at September 2006 under the IPHA and APMI Agreements will, subject to routine deletions, and provided that they conform with the relevant Agreement and the reimbursement criteria published by the Minister, pursuant to EC Directive 89/105/EC, remain reimbursable in the Schemes for the duration of the Agreement.

4.6.2 Introduction / review of reference price system

Ireland does not operate a reference price system.

4.6.3 Introduction of new / other out-of-pocket payments

Ireland has introduced no new / other out-of-pocket payments in the last five to ten years.

4.6.4 Claw-backs

Ireland does not utilize a claw-back mechanism of cost containment.

4.6.5 Reimbursement reviews

Reimbursement reviews are not a routine occurrence in Ireland.

Clause 4.1 (Existing Medicines) in the IPHA Agreement provides that pharmaceuticals normally reimbursable in the Schemes at the date of commencement of the Agreement will, subject to routine deletions, and provided that they conform with this Agreement and the reimbursement criteria published by the Minister, pursuant to EC Directive 89/105/EC, remain reimbursable in the Schemes for the duration of the Agreement.

Clause 4.3 facilitates pharmacoeconomic assessment prior to reimbursement

The HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be high cost or have a significant budget impact on the Irish healthcare system.

Where a new medicine is subject to assessment, the reimbursement decision will be notified within 90 days of the receipt of the reimbursement application. Should reimbursement be refused appeal may be made to an expert committee, the membership of which will be agreed between the HSE and IPHA. In reaching its decision, the expert committee will consider views of relevant stakeholders. The expert committee's decision will be made within a further 90 days and will be accepted as binding.

Where reimbursement of a new medicine is refused on appeal, and where significant new evidence becomes available subsequently, it will be open to the applicant to seek a new pharmacoeconomic assessment in accordance with procedures specified in Clause 4.3.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

Indicative Drug Target Scheme (IDTS)

Currently in a period of suspension pending review (since 2005), the primary objective of the IDTS has been to encourage GPs to prescribe economically by allowing them to invest savings made through more economic prescribing in practice development whilst recognizing clinical independence. The (national) scheme provided for the calculation of monetary prescribing targets for each GMS Scheme general practitioner, taking into consideration the makeup of his/her patient panel with regard to the age and gender of the patients. In each year, certain specialist and high cost drugs were excluded from the target setting process and are treated on a budget neutral basis. The Scheme has been voluntary and general practitioners retain the right and obligation to prescribe, as they consider necessary in the best interests of their patients. There have been no sanctions in place for those who fail to meet their target. Savings have been encouraged through the form of incentives.

Doctors receive an evaluation of their prescribing habits through PCRS prescribing reports.

Hospitals may operate formularies. Consultants wishing to introduce a new pharmaceutical may be required to seek approval from a ‘new product committee’, which is convened for the purpose of reviewing such novel entities. Certain pharmaceuticals, e.g. radiological contrast media, are confined to the hospital milieu.

The existence of a special prescribing procedure in Ireland does not really influence the prescribing habits of GPs because the GP’s practice output, in financial terms, is unaffected: the arrangements described below are budget neutral for the purposes of the GP’s Indicative Drug Target (IDT). There are arrangements for the supply and dispensing of pharmaceuticals, under the High Tech Drugs (HTD) Scheme, through Community Pharmacies, which are generally only prescribed or initiated in hospital. These would 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 Health Service Executive and supplied through Community Pharmacies for which Pharmacists are paid a patient care fee: the cost of the medicines and patient care fees are paid by the Primary Care Reimbursement Service. The prescription is written or initiated by a hospital consultant. Once initiated, the prescription may then be issued on further occasions by a GP.

5.2 Prescription guidelines

The National Medicines Information Centre (NMIC) is based at the St. James’s Hospital complex in Dublin. As part of its role in disseminating information to health professionals, NMIC bul-

letins are published every two months and the newsletter Therapeutics Today is published monthly. The NMIC web address is the following: fhttp://www.stjames.ie/ClinicalInformation/NationalMedicinesInformationCentre/Introduction/.

There is no mandatory national treatment guideline system in Ireland, which is a country in the relatively fortunate position of not necessarily having to develop specific national treatment guidelines when relevant international guidelines, from countries with similar health challenges, are available in the English language. As part of their professional training, many hospital clinicians will have worked in other English speaking countries and be aware of current practice trends. For example, in the United Kingdom, there is a Guidelines Finder (http://www.library.nhs.uk/guidelinesFinder/); a database of UK approved evidence-based clinical guidelines available on the Internet in full-text, and associated information. It is maintained by the Sheffield Evidence for Effectiveness and Knowledge service (SEEK) in partnership with the NHS National Library for Health (NLH). The Guidelines Finder is available from http://www.shef.ac.uk/seek/

One resource well known in Ireland is the Scottish Intercollegiate Guidelines Network (SIGN) (www.sign.ac.uk/). The membership of SIGN includes all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, patients, health service managers, social services, and researchers. Since January 2005, SIGN has been part of NHS Quality Improvement Scotland. SIGN guidelines are presented for download in full or as a Quick Reference Guide from http://www.sign.ac.uk/guidelines/published/index.html. Current SIGN guidelines include Management of stable angina, Hypertension in older people, Management of obesity in children and young people.

Monitoring of the sizes of the packages prescribed does not really cause concern in Ireland today, as there are fewer dispensing pack sizes than in former years and newer requirements for information to be readily accessible to patients.

The ICGP has plans to carry out regular clinical audit of doctors. ICGP has recently run some quality in practice initiatives, which already have shown that many practices are streamlining their services with new systems to assist optimal patient care.

The Irish Government has funded global access to the Cochrane Collaboration for health professionals in the State.

5.3 Information to patients / doctors

The Department of Health and Children and the Irish Medicines Board (IMB) are responsible for the implementation of the Marketing Directives, as stated in Directive 2001/83/EC.

Direct advertising of OTC pharmaceuticals to patients is allowed, provided that the pharmaceuticals are not reimbursable, with the exception of pharmaceuticals for smoking cessation.

In Ireland, pursuant to the provisions of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003, S.I. No. 540 of 2003, as amended by S.I. 510 of 2005, it is required

to have a prescription issued by a registered medical practitioner or registered dentist before a prescription-only medicinal product can be supplied by a registered pharmacy. Furthermore, the supply of prescription only or unauthorized medicinal products by mail order is prohibited by the same Regulation.

www.medicines.ie/emc/assets/o/html/**Code**_of_**Marketing**_6th.doc

The Irish Pharmaceutical Healthcare Association (IPHA) has produced a (voluntary) Code of Marketing Practice for the Pharmaceutical Industry with a view to securing the universal acceptance and adoption of high standards of conduct in the marketing of medicinal products to health professionals, whether intended for use under medical supervision or otherwise.

The advertising of medicinal products for human use in the European Union Member States is governed by Council Directive 2001/83/EC of 6 November 2001 as amended by Council Directive 2004/27/EC of 24 March 2004[3]. This Code of Practice fits into the general framework established by Article 97 Paragraph 5 of Directive 2001/83/EC, which recognizes the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies.

The IPHA Code emphasizes the importance of providing health professionals with accurate, fair and objective information about medicinal products so that rational decisions can be made as to their use. Moreover, the IPHA Code accepts the principle that such information must be presented in a form and by ways and means, which conform not only to legal requirements but also to professional standards of ethics and good taste.

Acceptance and observance of the provisions of the Code are a condition of membership of the Irish Pharmaceutical Healthcare Association. Companies observing the Code also acknowledge that its provisions are to be applied in spirit, as well as in the letter.

The provisions of the Code fully reflect the standards of the 2004 edition of the EFPIA “Code of Practice on the Promotion of Medicines” which is published by the European Federation of Pharmaceutical Industries and Associations (EFPIA). IPHA is a member of EFPIA. Compliance with the European Code is a requirement of all member associations of EFPIA.

5.4 Pharmaco-economics

The national legal source for health-economic analysis is to be found in the Agreements between the HSE and IPHA and APMI.

No health-economic analyses are necessary for obtaining a marketing authorization.

There is no stipulation in the Agreements for the provision of health-economic analyses necessary in the decision on the price of a pharmaceutical.

[3] Available to download at http://pharmacos.eudra.org/F2/eudralex/vol-1/home.htm

The provision of health-economic analyses may be necessary in order to obtain reimbursement status: IPHA Agreement, Clause 4.3 Pharmacoeconomic Assessment prior to Reimbursement.

The HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be of high cost or have a significant budget impact on the Irish healthcare system.

The possibility to apply health-economic analyses, on a systematic basis, first arose in September 2006 and these are to be performed by the NCPE.

An overview of the content of the pharmaco-economic guidelines is available from: http://www.ncpe.ie/category.php?cid=26

At this time, it has not been considered necessary to update those guidelines, which may be evaluated by the HSE and IPHA.

Ireland does not take the approach of declaring a maximum amount that the health system will pay for one QALY. No fixed threshold has been specified below which the cost per QALY is acceptable in the context of health funding.

The inpatient sector is not exempted from the application of these health-economic analyses, as the IPHA and APMI Agreements cover hospitals too.

5.5 Generics

Legal restrictions on the use of generics in Ireland tend not to be codified or consolidated in one statute. Rather, the major considerations are contractual (e.g. in the Community Pharmacy Contractor Agreement: supply against a properly prescription such medicines as may be ordered) and relating to the duty of care (not substituting of one pharmaceutical for another, which the medical practitioner has not authorized expressly or by implication).

While on one level it may appear that generics are mainly a cost-containment tool, it is the case in Ireland that originators and generics are reimbursable on substantially the same basis. Prescribers may, in consultation with their patients, prescribe the medicines of their choice from the list of medicines available under the Schemes as appropriate. The HSE reserves the right to influence the prescribing habits of prescribers.

5.5.1 Generic substitution

The following quotation (emphasis added) is taken from the document, *Information and Administrative Arrangements For Pharmacists* (Page 48):

“Doctors 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.

"Where a Doctor prescribes a medicinal product without specifying a manufacturer's name or brand and the pharmacist receives such prescriptions with reasonable frequency the pharmacist will be expected to dispense one of the less expensive, if not the least expensive, of the preparations of the drug properly available to the market."

An *aut idem* rule, i.e. mandatory generic substitution unless the GP specifies the originator product (brand) in writing on the prescription, as in Finland and Germany for instance, would require legislation and consequential changes to GP and pharmacist procedures.

Pharmacies are allowed to substitute a generic for a branded pharmaceutical, if the doctor has written the prescription with its International Non-proprietary Name (INN), unless the doctor has explicitly indicated that the pharmaceutical should not be substituted.

The patient may oppose substitution, although this is not thought to occur frequently. GMS eligible persons are not required to make any payment for pharmaceuticals. DPS eligible persons may face higher co-payment, if they have not already exceeded the €85 for the calendar month. In the GMS Scheme, the cost of a pharmaceutical, where substitution has been opposed, may increase the GP's outturn for comparison with the doctor's Indicative Drug Target and increase the pharmacist's outlay for the same professional fee. In the DPS, the cost of a pharmaceutical, where substitution has been opposed, is not referable to the GP and does not adversely affect the pharmacist's turnover.

There are no direct financial incentives for generic substitution.

Pharmacies are not permitted to perform analogous (as opposed to homologous) substitution i. e. to dispense a pharmaceutical with equal therapeutic benefits. Any suggestion of using an analogous pharmaceutical would require the prescription to be amended (with countersignature to the alteration) or issued anew by the doctor.

Pharmacies are allowed to substitute parallel imported pharmaceuticals for originators on the same basis as generic pharmaceuticals for originators.

5.5.2 Generic prescription

Doctors, while encouraged to do so, are not obliged to write prescriptions generically in Ireland. There is no personal gain through the healthcare system to GPs from prescribing generic pharmaceuticals. Any savings realized from generic prescribing, in the context of the Indicative Drug Target, will be available for investment in practice development for the benefit of the GP's patients.

Opposition to generic prescribing from doctors is seldom encountered, as GPs are at liberty to prescribe, with primary regard to their patients' interests, either by the International Non-proprietary Name (INN) or by a "brand' name.

5.5.3 Generic promotion

There is no current official campaign to promote the use of generic pharmaceuticals directly to patients, although there is a good degree of public awareness on the topic. Doctors are advised of the Trade Price of each newly reimbursable GMS item, which assists them in selecting a pharmaceutical for prescription to their patients.

The use of generic pharmaceuticals is promoted to ensure access of patients to a greater variety of pharmaceuticals, while facilitating a cost-containment approach.

5.6 Consumption

The National Centre for Pharmacoeconomics (NCPE) was established in Ireland in 1998 and is funded by the DOH&C.The aim of the centre is to promote expertise in Ireland for the advancement of the discipline of pharmacoeconomics through practice, research and education. Activities of the centre include economic evaluation of pharmaceutical products and the development of cost effective prescribing. In addition, the research of the centre focuses predominately on the economic analysis of high cost areas e.g. peptic ulcer disease, HIV therapy, lipid lowering therapy, heart failure.

The Health Protection Surveillance Centre (HPSC) has the objectives to improve the health of the Irish population by provision of the best possible information on disease including infectious diseases through surveillance and independent advice, epidemiological investigation, research and training. One of its activities is measuring antibiotic consumption, as surveillance of antibiotic consumption has been identified as a key component in antimicrobial resistance strategies, including the WHO Global Strategy of Containment of Antimicrobial Resistance and the Strategy for Antimicrobial Resistance in Ireland.

The National Shared Services Primary Care Reimbursement Service Statistical Analysis of Claims and Payments 2005 (PCRS 2006) provides detailed information on the GMS and Community Drug Schemes including by different ATC levels. Such publications have been of great interest to healthcare professionals and managers, academics and industry. Information on market data and sales are given in section 2.1.2.2 Market data.

Purchasing of pharmaceuticals via mail order or Internet is not permitted under Regulation 19 (Prohibition of mail order supply of medicinal products) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003. Therefore, the question of healthcare provider monitoring of such activities does not arise.

There is no system to monitor individuals' pharmaceutical consumption data. In the GMS Scheme and Community Drug Schemes, as operated nationally, individual reimbursement decisions do not generally arise. However, a person may be in a position to apply for further assistance from the HSE at local level.

No Essential Drug Policy exists in Ireland, since all pharmaceuticals that comply with the criteria will be reimbursable on the Scheme concerned.

6 Current challenges and future developments

6.1 Current challenges

The authors express herein no personal views on the current challenges faced by the pharmaceutical system.

In A Business Appraisal of Private Medical Insurance in Ireland (DoH&C 2007a), the trend for unit costs in the field of medicine to increase more rapidly than general inflation is said to be observable worldwide. Additionally, in Ireland there is some need for rebalancing of costs from public to private care. Furthermore, the population profile in Ireland is likely to be aging for the foreseeable future. These factors will tend to lead to significant real increases in the cost of insurance, although the document's authors believe that competition can mitigate these to a limited extent.

The Government's Hospital Co-Location Initiative (HSE 2007) envisages that private providers will supply a significant proportion of additional capacity in the acute hospital system in future. Government policy will aim to incentivise and attract private providers to develop private facilities, thereby freeing up capacity in public hospitals to treat public patients. The public sector will also procure a greater degree of services from the private sector. The Finance Acts provide for capital allowances over a seven-year period for the construction of private hospitals provided they meet certain criteria. This has already led to the construction and planning of a number of private hospital developments.

To facilitate delivery of the key policy aim of the National Health Strategy 2001, the Health Information and Quality Authority (HIQA) was formally established (DOH&C 2007b) to ensure that high quality information is available to the health care system. The Health Act 2007 replaced the Interim Authority in order to place on a permanent footing delivery of high quality services that are based on evidence-supported best practice. The HIQA is responsible for developing health information, promoting and implementing quality assurance programs nationally and overseeing HTA.

6.2 Future developments

The authors express herein no personal views on future developments in the pharmaceutical system except to state that some overlap with current challenges exists.

Generics

Dramatic changes in pharmaceutical markets, according to Perry 2006, have conditioned generic medicines producers to co-operate with governments to create optimal conditions for developing, manufacturing and marketing their products.

The G10 Medicines initiative was established by EU Commissioners Liikanen and Byrne in 2001. The European Commission's follow-up initiative, the Pharmaceutical Forum, closed its public consultation process in May 2007 and its scheduled meetings will continue into 2008.

According to Perry, policies employed by national authorities that reflect a government's choice between a more or a less interventionist approach to creating a robust environment for promoting generics. Countries are generally clustered in three groups according to their market shares:

- Less than 10 per cent market share by value: Austria, Belgium, Finland, France, Ireland, Italy, Portugal, Spain;
- Between 10 and 40 per cent market share by value: Denmark, Estonia, Netherlands, Slovak Republic, Slovenia, Sweden, Turkey, the United Kingdom;
- Greater than 40 per cent market share by value: Croatia, Czech Republic, Germany, Latvia, Lithuania, Hungary, Poland.

By no means on its own in the cluster of countries with least generic market penetration, Ireland has since September 2006 embarked on a new policy of price reductions that will apply to specific dosage forms of patent expired medicines, under the IPHA and APMI Agreements where the identical pharmaceutical form of that medicine, approved by the Irish Medicines Board or EU Commission, is available for prescription. To that extent, measuring the outcomes from this process is a future development.

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