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Pharmaceutical Pricing and Reimbursement Information project

United Kingdom

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Pharma Profile

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PPRI Participant(s)

Department of Health (DH): Danny Palnoch

PPRI Pharma Profile - Authors

Department of Health (DH): Danny Palnoch, David Kullman, John Sherriff, Eunice Barnor, Michael Baxter, Judy Carter, Giles Crompton-Howe, Diana Kenworthy, Rebecca Blessing
National Health Service (NHS):Howard Stokoe
Medicines and Healthcare products Regulatory Agency (MHRA): Michael Derbyshire

PPRI Pharma Profile - Editorial team

WHO Regional Office for Europe: Trine Lyager Thomson (editor-in-chief)

Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Barbara Fröschl, Claudia Habl

Executive Summary

Background

The UK has a population of just over 60 million people, with a life expectancy of 81 years for women and 76.6 for men. It has amongst the highest GDP per head.

The Health System

The UK has a National Health Service funded through general taxation. Entitlement is not based on taxes paid or contributions made. With relatively small exceptions (primary care eye and dental services, and prescription charges, where co-payments apply – though there are exemptions for the poor and other vulnerable groups), health services are free at the point of use..

Health policy is the jurisdiction of the devolved administrations in England, Scotland, Wales and Northern Ireland.

Historically, NHS hospital Trusts have received an annual ex-ante fixed budget which is used to fund all their services. This system remains in place in Northern Ireland, Scotland and Wales. In England, a system has been introduced where hospital services are commissioned by PCTs (which in turn have fixed budgets) through General Practitioners. Hospitals are then remunerated for each outpatient and inpatient episode by a nationally set tariff. The tariffs apply at DRG level and are set by taking an average of the costs from hospitals that provide the DRG activity.

Pharmaceutical System

Organisation

For new (in patent) medicines, the MHRA or EMEA decides whether to grant a market authorisation for a new product. Reimbursement prices must be agreed with the Department of Health before launch, but there is freedom of pricing for new chemical entities.

For generic medicines, prices are set at prevailing market levels, plus a margin (which is counted towards pharmacy remuneration). Periodic surveys of pharmacy invoices are used to assess the amount of margin earned. These functions are carried out by the Department of Health.

Industry

The UK has a strong research based pharmaceutical industry presence, contributing significantly to GDP. The main organisations representing the industry are the Association of British Industries (ABPI) and the Bioindustry Association (BIA). The ABPI represents the R&D based industry in dialogue, formal consultations, and negotiations on the Pharmaceutical Price Regulation Scheme.

The generics industry is represented by the British Association of Generics Manufacturers, though only a small amount of manufacturing takes place in the Uk.

Wholesaling

Wholesales buy medicines from manufacturers and then sell them to pharmacies (note margins are not regulated), though there are some vertically integrated (pharmacy – wholesaler) companies. Wholesaling can be divided into two main groups. Full-line wholesalers generally stock a full range of medicines. They are represented by the British Association of Pharmaceutical Wholesalers. Short-line wholesalers deal mostly with generics and parallel imports, and may carry a less than comprehensive range of medicines, generally competing on high volume generics.

Pharmaceutical Outlets / Retailers.

Prescription-only drugs are normally dispensed from a registered pharmacy premises by or under the supervision of a pharmacist in response to a prescription issued by an appropriate practitioner. Under certain circumstances, primary care doctors can dispense prescription only medicines – mainly where their patients have difficulty accessing a community pharmacy. Internet and mail order pharmacies are also allowed.

There are 11,642 community pharmacy outlets in Great Britain (excludes Northern Ireland). Vertical partnerships/mergers, i.e. with pharmacy wholesalers and drug producers are allowed subject to the Competition Act and mergers can be referred to the appropriate competition authorities. Apart from any relevant planning or building conservation laws, there are no legal controls over the location of pharmacies in respect of, for example, setting a minimum distance between pharmacies. However, if a pharmacy wishes to provide state funded NHS pharmaceutical services, (and most do) it must apply to the relevant local health body for approval (called the “control of entry” system.

Hospitals

As at June 2006 there were 172 NHS trusts which provided acute services. It is usual for acute trusts to have a pharmacy and for those which comprise more than one site there may be multiple pharmacies. The pharmacy will typically dispense medicines for individual in-patients, provide medicines to wards and dispense medicines to outpatients who have attended the hospital’s outpatient clinics and who have received a prescription. All acute trusts have a committee responsible for making decisions on medicines use within the trust, often referred to as the Drug and Therapeutics Committee

Evaluation

There is no organisation tasked specifically with evaluating drugs policy. However, government ministers are responsible to parliament, and as a result, policy on medicines can be subject to public scrutiny, in the main through the House of Commons Health Select Committee and the National Audit Office. They have conducted a number of studies related to pharmaceutical policy including. The Office for Fair Trading has also conducted a number of market studies related to pharmaceuticals

Pricing

Branded Medicines

The prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (NHS) are regulated by the Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS covers all licensed, branded, prescription medicines sold to the NHS

A new five-year PPRS commenced on 1 January 2005 in succession to the 1999 scheme. The 2005 scheme included a 7% price reduction. There have been a series of voluntary agreements with the industry since 1957 to limit branded medicine prices and profits, each lasting five years or so, although the details of these agreements have evolved over time.

The PPRS sets the NHS list price at which pharmacists are reimbursed. This is a maximum price as pharmacists are able to purchase at a discount and hospitals can purchase medicines under contract at a discount.

There is freedom of pricing at launch for new active substance. Where a new branded product has not been subject to a new active substance marketing authorisation, companies must seek the Department's agreement to the price of the new product. In reaching a decision on the acceptability of the proposed price, the Department may take into account a number of factors (see section 3.3.4)

Thereafter he PPRS allows companies to increase prices subject to the Department's agreement. These are only allowed if the reasons for the application meet the criteria for increases set out in the agreement i.e. that profits are forecast to be below 40% of their profit target (in practice there are few price increases).

Assessment of profitability - There are three main elements to the Department's assessment of a company's profit:

- the value of its sales of branded prescription medicines to the NHS including primary care and hospital trusts;
- an assessment of the company costs that would be appropriate for the NHS to bear. The largest element is manufacturing costs. The assessment of allowable costs includes an allowance for research and development (up to 28% of NHS sales) and a limitation to marketing expenditure (6% of NHS sales);
- the capital employed by the company in delivering NHS sales. As pharmaceutical companies produce products other than for sale to the NHS (e.g. over the counter medicines, exports and non-pharmaceutical products) capital needs to be allocated between these activities.

Where profits are assessed as exceeding the return on capital (ROC) target plus a margin (almost 30% of ROC), the excess has to be repaid to the Department or prices reduced.

Generics

For generic medicines, prices are set at prevailing market levels, plus a margin (which is counted towards pharmacy remuneration). Periodic surveys of pharmacy invoices are used to assess the amount of margin earned.

In secondary care, hospitals may be able to negotiate a discount on community prices for both branded and generic medicines..

The retail prices of medicines sold over the counter (OTC) direct to the public are not controlled by the Government.

Pharmacy Remuneration

The remuneration of pharmacies is provided under a contractual framework for community pharmacies. This framework is negotiated with the Pharmaceutical Services Negotiating Committees – the organisation that represents the interests of community pharmacies.

In broad terms, the framework provides for a target level of funding across all pharmacies for a given year, paid for via:

- fees and allowances (the bulk of which are related to the number of items dispensed)[1],
- payments for specific services (e.g. Medicines Use Reviews)[1],
- and margins earned on the difference between reimbursement prices and prices actually paid. A survey of pharmacy invoices is used to monitor pharmacy margins. If pharmacy margins are found to diverge from the target that is set within the contractual framework, reimbursement prices for generic medicines (where the bulk of the margins occur) are adjusted accordingly. Margins are not regulated directly.

Dispensing Doctors are paid through an item fee. Hospital pharmacies are funded directly through the hospital Trust concerned.

VAT

Medicines dispensed by a community pharmacist against a prescription are zero-rated for VAT while medicines prescribed in hospital are subject to VAT at the standard rate of 17.5%

Discounts / Rebates

The NHS list price of branded medicines includes a margin for distribution through wholesalers. For branded medicines and generics the level of discount is negotiated between the manufacturer and wholesaler and pharmacy and varies over time, from product to product and company to company. There are no restrictions on the type of discount (within the constraints of competition law).

[1] Details of pharmacy remuneration and prices of medicines and other healthcare products are published in the Drug Tariff (produced by the NHS Business Services Authority – Prescription Pricing Division) which is updated on a monthly basis. – see http://www.drugtariff.com/

Reimbursement

In primary care, restrictions are placed not on what can be reimbursed but on what can be prescribed. All items which can be prescribed on the NHS are fully reimbursable. All items may be prescribed for all patients, except those listed in schedule 1 of the National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, as amended, and those in Schedule 2 of the same Regulations, which may be prescribed only for certain patients and under certain circumstances.

In hospitals anything can be prescribed, although local restrictions may apply (for example those established by the hospital's drugs and therapeutics committee).

Co-Payments

In England, fixed co-payment arrangements apply. A standard prescription fee - GBP6.65 from 1 April 2006 – is payable in respect of each item supplied.

There is also a system of exemptions under which items are supplied free of charge. The exemption is based on one of a number of factors: the method of delivery, the type of medication, the age of the patient, the patient's condition; or the patient's income.

Out-patients do not pay a prescription charge for any medicines which are administered to them at the hospital. For medicines which out-patients are prescribed to take at home then the same rules apply as for medicines prescribed in the community,

Rational Use of Pharmaceuticals

Impact of Pharmaceutical Budgets

The Department of Health do not determine a national amount to be spent on prescribing each year, this is locally determined by Primary Care Trusts (PCTs) within an overall budget. Prescribing advisers based in each PCT help set budgetary constraints for prescribing doctors in their local areas.

Prescribing Guidelines

There are no direct controls on the amount of promotional expenditure that a pharmaceutical company may undertake. However, there are limits set out in the PPRS Agreement, which in turn feed into the assessment of costs and hence profits. [Refer to PPRS document]. The pharmaceutical companies are bound by a voluntary Code of Practice on sales promotion drawn up by the Association of the British Pharmaceutical Industry (ABPI) and breaches are reported to the Prescription Medicines Code of Practice Authority, which operates independently from the ABPI.

Pharmaco-economics

NICE in its assessment of clinical and cost effectiveness makes use of heath economic analyses and uses Quality Adjusted Life Year data on which it bases its recommendations (though in practice NICE will take on board other factors). However, these recommendations are for the NHS in reaching decisions, both clinical and managerial, on the use of pharmaceuticals and devices. Guidance applies to both the hospital and community setting.

The provision of health-economic analyses is not necessary for obtaining market authorization, pricing approval, nor reimbursement status. However, NICE may provide guidance on whether a product should be used in the NHS, where the price will have an bearing

Generics

Pharmacists must dispense the brand if that is what has been written on the prescription by the prescriber. In the in-patient setting, local arrangements may allow hospital pharmacists to substitute a generic for a brand, according to locally developed policies. Doctors are encouraged, but not obliged, to write prescriptions by generic name for both clinical and cost reasons, when appropriate. Local primary Care Organisations can develop incentive schemes for their prescribers, and these vary from place to place. In addition, most Primary Care Organisations will have performance management arrangements that monitor local prescribing.

Current Challenges and future Developments

The main challenge facing the UK system is how to respond to the Office of Fair Trading market study report. This report has produced far reaching recommendations that, if implemented, would require considerable change to the current system – see section 6.1. The government is considering the OFT recommendations and will respond in due course.

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List of abbreviations

ABPI	Association of British Pharmaceutical industries
BGMA	British Association of Generics Manufacturers
BAPW	British Association of Pharmaceutical Wholesales
BIA	Bioindustry Association
MHRA	Medicines and HealthCare products Regulatory Agency
NICE	National Institute for Health and Clinical Excellence
NHS	National Health Services
OFT	Office of Fair Trading
PCT	Primary Care Trust
PPRS	Pharmaceutical Price Regulation Scheme
ROC	Return on Capital Employed

Introduction

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.

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.

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

Chapter 1 aims to provide an overview on the country, in particular on the health care system. As the focus on the PPRI Pharma Profiles is on pharmaceutical pricing and reimbursement, the authors of this Profile did not write a full chapter like for the following ones, but opted for the presentation of some key figures on health care systems presented in 2 tables.

Table 1.1: United Kingdom – Key figures on the healthcare system 1995, 2000 - 2005

Variable	1995 [1]	2000 [1]	2001[1]	2002[1]	2003[1]	2004[1]	2005[1,2]	Source
Total population (millions)	58.025	58.886	59.113	59.322	59.554	59.834	60.209	Office for National Statistics
Life expectancy at birth, total	NA	NA	NA	NA	NA	NA	NA	
Life expectancy at birth, females	79.1	79.9	NA	NA	NA	NA	81.0	ONS
Life expectancy at birth, males	73.8	75.0	NA	NA	NA	NA	76.6	ONS
GDP in GBP	719.747	953.227	996.987	1048.767	1110.296	1176.527	1224.715	ONS
GDP in Billion €	857.075	1565.389	1603.853	1668.483	1605.044	1734.083	1791.636	Calculated
GGE in GBP	142.898	181.851	194.503	212.464	232.699	250.708	269.491	ONS
GGE in € [3]	170.163	298.636	312.897	338.009	336.390	369.519	394.238	Calculated
THE in GBP	45.469	62.444	68.008	74.166	81.223	88.787	95.582	ONS
THE in Mio. € [3]	54.144	102.546	109.404	117.991	117.416	130.863	139.827	Calculated
Public Health Expenditure in GBP	38.469	53.236	58.032	63.388	69.888	76.855	83.579	ONS
Public Health Expenditure in Mio. €	45.809	87.424	93.356	100.844	101.030	113.277	122.268	Calculated
Private Health Expenditure in GBP	7.000	9.208	9.976	10.778	11.335	11.932	12.003	ONS
Private Health Expenditure in Mio. €	8.336	15.121	16.048	17.147	16.386	17.587	17.559	Calculated
Total number of NHS Trust sites	NA	NA	NA	NA	NA	NA	9,503	NHS
Number of acute care beds	108,296	107,956	108,535	108,706	109,793	109,544	108,113	NHS
Total number of doctors[4]	84,459	97,436	100,319	104,460	109,964	117,806	122,987	NHS
Number of visits to GPs per patient per year	4	4	4	4	4	4	4	General Household Survey
Exchange rate (GBP per €)1	1.1908	1.6422	1.6087	1.5909	1.4456	1.4739	1.4629	ONS

GDP = Gross Domestic Product, GGE = General government expenditure, GBP = British Pounds, THE = Total Health Expenditure

[1] As at 30th of June.

[2] If the latest available year is not 2005, please provide the year by means of a footnote.

[3] Excluding retired and non-practising doctors or indicate the exact composition of the number of doctors.

Table 1.2: United Kingdom - Diseases with highest morbidity and the leading causes of mortality

Males	**Top 5 diseases with highest morbidity (1 = most common)**	**ICD-10 code**	**No.**	**Top 5 leading causes of mortality (1 = most common)**	**ICD-10 code**
1			1	Ischaemic heart disease	120-125
2			2	Cerebrovascular diseases	160-169
3			3	Malign neoplasm of trachea, bronchus & lung	C33, C34
4			4	Chronic lower respiratory disease	J40-J47
5			5	Influenza & Pneumonia	J10-J18
Females		**ICD-10 code**	**No.**		**ICD-10 code**
1			1	Ischaemic heart disease	120-125
2			2	Cerebrovascular diseases	160-169
3			3	Influenza & Pneumonia	J10-J18
4			4	Dementia and Alzheimer's Disease	F01, F03, G30
5			5	Chronic lower respiratory disease	J40-J47
Source: ONS			Source: ONS		
Year: 2005			Year: 2005		

2 Pharmaceutical system

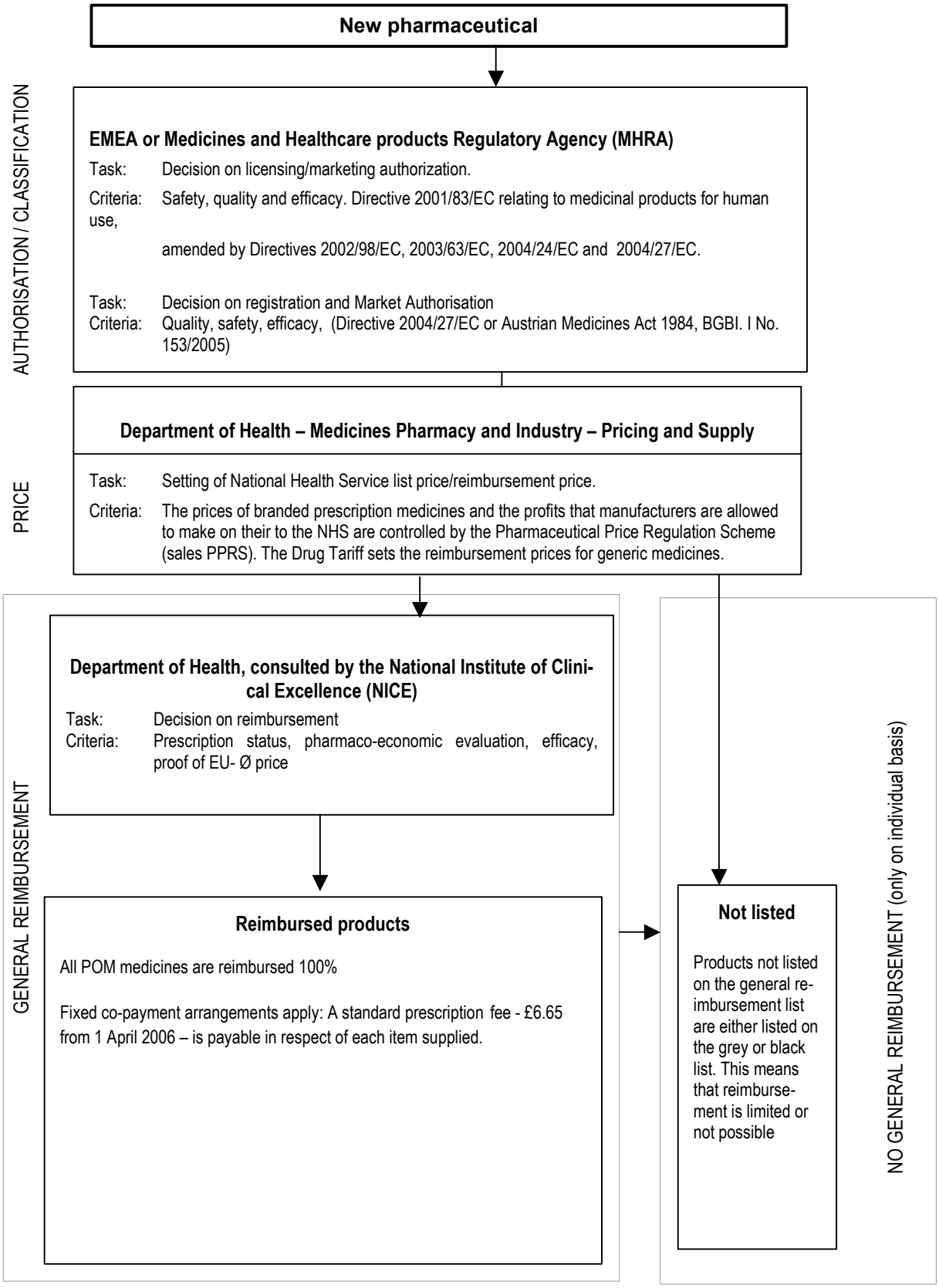
This chapter provides an overview of the pharmaceutical system.

2.1 Organisation

This section describes, on one hand, the regulatory framework (legal basis, main authorities and their tasks), and, on the other hand, the pharmaceutical market (data, key players).

Figure 2.1 shows an overview of the UK pharmaceutical system.

Figure 2.1: United Kingdom – flowchart of pharmaceutical system



2.1.1 Regulatory framework

This section includes a description of the legal framework for the pharmaceutical policy, the principal authorities and important players in this framework and their roles.

2.1.1.1 Policy and legislation

The major laws / regulations that are relevant for the pharmaceutical sector are listed below.

Acts

Year/Chapter	Title
1968 chapter 67	Medicines Act
1971 chapter 69	Medicines Act

Statutory Instruments

Year/No	SI Title
1970/1256	Medicines (British Pharmacopoeia Commission) Order
1971/972	Medicines (Standard Provisions for Licences and Certificates) Regulations
1971/973	Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations
1971/974	Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations
1971/1200	Medicines (Control of Substances for Manufacture) Order
1971/1267	Medicines (Surgical Materials) Order
1971/1326	Medicines (Importation of Medicinal Products for Re-exportation) Order
1971/1410	Medicines (Exemption from Licences) (Foods and Cosmetics) Order
1971/1445	Medicines (Retail Pharmacists - Exemptions from Licensing Requirements) Order
1971/1447	Medicines (Applications for Product Licences of Right and Clinical Trial and Animal Test Certificates of Right) Regulations•
1971/1448	Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences of Right) Regulations •
1971/1450	Medicines (Exemption from Licences) (Special and Transitional Cases) Order
1972/1198	Medicines (Termination of Transitional Exemptions)(No. 1) Order
1972/1199	Medicines (Exemption from Licences) (Manufacture and Assembly Temporary Provisions) Order •
1972/1200	Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order
1972/2076	Medicines (Data Sheet) Regulations
1973/367	Medicines (Extension to Anti-microbial Substances) Order

• SIs 1971/1447 and 1971/1448 are spent as the date by which applications must have been made is past. They have not been revoked.

• SI 1972/1199 is spent as the final date for application of the temporary provisions is past. It has not been revoked.

Year/No	SI Title
1973/1822	Medicines (Pharmacies) (Applications for Registration and Fees) Regulations
1974/316	Medicines (Exemption from Licences) (Emergency Importation) Order
1974/832	Medicines (Renewal Applications for Licences and Certificates) Regulations
1974/1149	Medicines (Termination of Transitional Exemptions)(No. 2) Order
1974/1150	Medicines (Exemption from Licences) (Ingredients) Order
1975/298	Medicines (Advertising of Medicinal Products) Regulations
1975/533	Medicines (Dental Filling Substances) Order
1975/761	Medicines (Termination of Transitional Exemptions)(No. 3) Order
1975/762	Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery) Order
1975/1326	Medicines (Advertising of Medicinal Products) (No. 2) Regulations
1976/968	Medicines (Specified Articles and Substances) Order
1976/1726	Medicines (Labelling) Regulations
1977/161	Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order
1977/670	Medicines (Bal Jivan Chamcho Prohibition) (No. 2) Order
1977/1038	Medicines (Manufacturer's Undertakings for Imported Products) Regulations
1977/1055	Medicines (Leaflets) Regulations
1977/1399	Medicines (Certificates of Analysis) Regulations
1977/1488	Medicines (Breathing Gases) Order
1977/2130	Medicines (Retail Sale or Supply of Herbal Remedies) Order
1977/2131	Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order
1978/40	Medicines (Fluted Bottles) Regulations
1978/41	Medicines (Labelling and Advertising to the Public) Regulations
1978/1004	Medicines (Radioactive Substances) Order
1978/1006	Medicines (Administration of Radioactive Substances) Regulations
1978/1421	Medicines (Collection and Delivery Arrangements – Exemption) Order
1979/1585	Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order
1979/1759	Medicines (Contact Lens Fluids and other Substances) (Labelling) Regulations
1980/1467	Medicines (Intra-Uterine Contraceptive Devices)(Termination of Transitional Exemptions) Order
1980/1923	Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations
1980/1924	Medicines (Pharmacy and General Sale – Exemption) Order
1981/1690	Medicines (Contact Lens Fluids and Other Substances) (Termination of Transitional Exemptions) Order
1984/673	Medicines (Exemption from Licences) (Importation) Order
1984/187	Medicines (Cyanogenetic Substances) Order
1985/1403	Medicines (Control of Substances for Manufacture) Order
1986/1761	Medicines Act 1968 (Hearings by Persons Appointed) Rules
1989/684	Medicines (Fixing of Fees in Relation to Medicinal Products for Human Use) Order
1990/566	Medicines (Exemption from Licences) (Wholesale Dealing) Order
1992/605	Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations

Year/No	SI Title
1992/2844	Medicines (Exemption from Licensing) (Radiopharmaceuticals) Order
1993/2538	Medicines (Applications for Grant of Product Licences – Products for Human Use) Regulations
1994/105	Medicines (Homeopathic Medicinal Products for Human Use) Regulations
1994/1932	Medicines (Advertising) Regulations
1994/1933	Medicines (Monitoring of Advertising) Regulations
1994/3144	Medicines for Human Use (Marketing Authorisations Etc.) Regulations
1995/309	Medicines (Advisory Board on the Registration of Homeopathic Products) Order
1995/449	Medical Devices (Consultation Requirements) (Fees) Regulations
1995/1116	Medicines (Products for Human Use – Fees) Regulations
1997/1830	Prescription Only Medicines (Human Use) Order
1999/3106	Good Laboratory Practice Regulations
2001/1841	Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order
2002/618	Medical Devices Regulations
2002/3170	Medicines for Human Use (Kava-kava) (Prohibition Order)
2003/1076	Medicines and Healthcare Products Regulatory Agency Trading Fund Order
2003/1680	Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations
2003/2317	Medicines (Child Safety) Regulations
2004/1031	Medicines for Human Use (Clinical Trials) Regulations
2005/50	Blood Safety and Quality Regulations
2005/765	Medicines for Human use (Prescribing) Order
2005/1094	Medicines (Advisory Bodies) Regulations
2005/2750	Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005
2005/2754	Medicines (Advisory Bodies) (No.2) Regulations
2005/2788	Medicines (Advisory Bodies) (Terms of Office of Members) Regulations
2005/2789	Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations
2005/2791	Herbal Medicines Advisory Committee Order

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI) – under Section 33 of the Health Act 1999. It gives powers to impose statutory price and profit controls on those companies, which elect not to sign up to the scheme. The statutory powers covering pharmaceutical pricing are contained in sections 33 to 38 of the Health Act 1999. All major companies elected to join the 1999 and 2005 PPRS.

2.1.1.2 Authorities

Table 2.1 United Kingdom - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language	Name in English	Description	Responsibility
Department of Health (DH)	Department of Health	The Department of Health (DH) is a Department of State (a Government organisation).	DH is responsible for carrying out the decisions of ministers who represent the public as democratically elected Members of Parliament (MPs). DH's overall purpose is to help improve the health and wellbeing of everyone in England by leading and supporting NHS and social care organisations. Overall pharmaceutical policy. Pricing of NHS prescription medicines.
Strategic Health Authorities (SHAs)	Strategic Health Authorities (SHAs)	Local headquarters of the NHS	There are 10 Strategic Health Authorities who manage the NHS locally on behalf of the Secretary of State. They are a key link between the Department of Health and the NHS. They hold all local NHS organisations (apart from NHS Foundation Trusts) to account for performance.
NHS Foundation Trusts	NHS Foundation Trusts	Type of NHS Hospital	Foundation Trusts are a new type of NHS hospital run by local managers, staff and members of the public which are tailored to the needs of the local population. Foundation Trusts have been given much more financial and operational freedom than other NHS Trusts and have come to represent the Government's commitment to de-centralising the control of public services. These Trusts remain within the NHS and its performance inspection system.

Primary Care Trusts (PCTs)	Primary Care Trusts (PCTs)	Local National Health body	Primary Care Trusts (PCTs) work with local authorities and other agencies that provide health and social care locally to make sure that local community's needs are being met. PCTs are at the centre of the NHS and get 75% of the NHS budget. PCTs hold provider organisations (including NHS Foundation Trusts) to account for the delivery of services which they have commissioned.
Medicines and Healthcare products Regulatory Agency (MHRA)	Medicines and Healthcare products Regulatory Agency	An executive agency of the Department of Health	The MHRA is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. Department of Health Ministers act as the Licensing Authority. *See the divisional descriptions for further information. Only those divisions covering medicines related activities or support services are included
National Health Service Purchasing and Supply Agency (NHS-PASA)	National Health Service Purchasing and Supply Agency	An executive agency of the Department of Health	Procurement/tendering of pharmaceuticals in hospitals. Act as a centre of expertise, knowledge and excellence in purchasing and supply matters for the health service. As an integral part of the Department of Health, the NHS Purchasing and Supply Agency is in a key position to advise on policy and the strategic direction of procurement, and its impact on developing healthcare, across the NHS.
The Prescription Pricing Division (PPD) of the NHS Business Services Authority (NHSBSA)	The Prescription Pricing Division (PPD) of the NHS Business Services Authority (NHSBSA)	An Arm's Length Body (ALB)	The PPD of the NHS BSA is the main processing facility and centre of excellence for payment, reimbursement, remuneration and reconciliation for NHS patients, employees, and other affiliated parties.
National Institute for Health and Clinical Excellence (NICE)	National Institute for Health and Clinical Excellence	Department of Health, Arms Length Body, (non-regulatory, independent)	Gives advice to the NHS on best clinical practice including the clinical and cost effectiveness of drugs and other treatments.

MHRA Divisional Descriptions

Name	Description	Responsibility
Department of Health	Department of State	The Government organisation responsible for carrying out the decisions of ministers, with the purpose of helping to improve the health and wellbeing of everyone in England.
Medicines and Healthcare products Regulatory Agency (MHRA)	Regulatory Body	The MHRA is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. Department of Health Ministers act as the Licensing Authority.
Agency Board	The Agency Board comprises the Chairman, Chief Executive Office and six Non-Executive Members. The Finance Director and Director of Policy also attend.	Advises on the strategic development of the Agency and ensures that targets set out in our Business Plan and endorsed by Ministers are met.
Risk and Audit Committee	Advisory Committee	Provides independent feedback to the Chief Executive, who is also the Accounting Officer, and the Management Board on the effectiveness of our risk management processes
Commission on Human Medicines	Advisory Committee	Advises the Licensing Authority on matters relating to human medicinal products. This includes advice in relation to the safety, quality and efficacy of human medicinal products.
Advisory Board on the Registration of Homeopathic Products	Advisory Committee	Provides advice with respect to safety and quality in relation to any homoeopathic medicinal product for human use in respect of which a certificate of registration could be granted, or homoeopathic veterinary product
Herbals Medicines Advisory Committee	Advisory Committee	Provides advice with respect to herbal medicinal products
Independent Review Panel for Advertising	Advisory Committee	Considers written representations from pharmaceutical companies as to the conformity of their advertising and promotional material with the Regulations. It also advises Health Ministers on the conformity of advertising and promotional material with the Regulations before a final decision is made by Health Ministers.
Independent Review Panel on the Classification of Borderline Products	Advisory Committee	Considers written and oral representations from companies against a provisional determination by the MHRA, on behalf of the Licensing Authority, that a product is a medicinal product. It also advises Licensing Authority whether or not the MHRA's provisional determination should be confirmed.
British Pharmacopoeia		Collection of standards for UK medicinal substances
Laboratory of the	Laboratory	The laboratory performs the majority of the

Name	Description	Responsibility
Government Chemist		MHRA physico-chemical analysis of medicinal products
Licensing Division	MHRA Division	Licensing Division has a diverse range of responsibilities. In general it is responsible for assessing and approving applications for marketing authorisations.
Vigilance and Risk Management of Medicines (VRMM) Division	MHRA Division	The objective of the VRMM organisation is to protect public health by promoting the safe use of marketed medicines, and by supporting this with high quality product information
Inspection and Standards Division	MHRA Division	Inspection and Standards Division is responsible for ensuring compliance with the standards that apply to the manufacture and supply of medicines on the UK market.
Enforcement and Intelligence Group	MHRA Division	Enforcement and Intelligence Group is responsible for investigating suspected illegal advertising, manufacture, importation and sale or supply of medicines for human use and initiating legal proceedings in appropriate circumstances.
Policy Division	MHRA Division	Policy Division is responsible for taking an overview of policy across the Agency.
Information Management Division	MHRA Division	Information Management Division has an overall responsibility for Information Management, including the development and implementation of the Agency's Information Management Strategy, eBusiness, Information Technology, the General Practice Research Database (GPRD), initial processing of licence submissions and the Agency's delegated authority for Crown copyright.
Human Resources Division	MHRA Division	Human Resources (HR) Division works in partnership with MHRA managers and staff to provide professional and efficient HR services including the facilitation of a continuous learning and development culture.
Finance Division	MHRA Division	Finance Division is responsible for providing the financial infrastructure to help the Agency achieve its objectives and serve all its customers.
Communications Division	MHRA Division	Communications Division ensures that internal and external communication is clear, accurate and timely.

The MHRA's aims and objectives and corporate governance arrangements

Aims

MHRA aims to:

- Protecting public health through regulation, with acceptable risk: benefit profiles for medicines and devices.

- Promoting public health by helping people who use these products to understand their risks and benefits.
- Improving public health by encouraging and facilitating developments in products that will benefit people.

MHRA Objectives

MHRA key objectives are to:

- maintain rigorous authorisation and inspection programmes;
- maintain and develop pro-active surveillance and enforcement programmes;
- communicate authoritative and reliable information and advice to improve public and professional awareness;
- engage with and influence other Government bodies and European and worldwide regulators concerned with medicines or medical devices;
- support innovation and product development, offering constructive and impartial advice to scientific communities and health services;
- minimise the cost of regulation so far as is compatible with our public health role; and
- run a successful business with a skilled and equipped workforce dedicated to the Agency’s aims.

Corporate governance

The following structures and processes are designed to ensure accountability and give the Agency a framework for risk management:

- The Agency Board is made up of a non-executive Chairman, six non-executive members and the Agency's Chief Executive Officer.
- The Agency's Chief Executive is responsible for service delivery and resources.
- The Executive Board, consisting of the Agency's directors, takes overall responsibility for day-to-day management, strategic decision-making, line management, and all financial, policy, operational and resource management issues.
- The Risk and Audit Committee provides independent feedback to the Chief Executive, who is also the Accounting Officer, and the Management Board on the effectiveness of our risk management processes. The Committee is supported by the Agency's Risk Management Team.

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: United Kingdom - Number of pharmaceuticals 1995, 2000 - 2006

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	11292	11991	12229	12490	12758	12762	12866	11633
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM	6938	7916	8157	8491	8702	8785	8951	8204
Reimbursable	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Generics	2171	4008	4264	4542	4733	4854	5115	4634
Parallel traded	1769	3693	4700	5856	7240	9059	10088	10217
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Others	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, POM = Prescription-Only Medicines

[1] as of 1 January

Source: MHRA Sentinel Database

Points to note are that these numbers represent the number of Marketing Authorisations with a status of 'granted' at 1st January of each year. The numbers therefore include different pharmaceutical forms and different strengths and different brands and different marketing authorisation holders but will not include different pack sizes or different dosages. Centralised (European) licenses are not included as our database is not reliable and the EU system counts each pack size as a different authorisation therefore numbers are not compatible.

To calculate the 'generics' all marketing authorisations with a work type of 'Abridged' have been counted.

No information is collected centrally on the number of pharmaceuticals currently on the market. Some medicines will be authorized, but not be marketed. All medicines are reimbursable, except a small number listed in parts XVIIIA and XVIIIC of the Drug Tariff. No information is available on Hospital only medicines.

2.1.2.2 Market data

Will be completed.

Table 2.3: United Kingdom - Market data 1995, 2000 – 2005 (figures relate to prescriptions reimbursed by the NHS / to be completed

In million GBP / €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescription by volume (1)							
No. of annual prescriptions by value							
Pharmaceutical sales							
Sales at ex-factory price level							
Sales at wholesale price level							
Sales at pharmacy retail price level							
Sales at hospitals							
Sales of generics							
Sales of parallel traded pharmaceuticals							
Exports and imports							
Total pharmaceutical exports *							
Total pharmaceutical imports*							

* Please indicate if this is finished products and / or raw material

Source:

Table 2.4: Top 10 best selling pharmaceuticals, by active ingredient, 2005 or latest available year / to be be completed.

Position	Pharmaceutical, by active ingredient
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

Source:

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 for 5 more years under a Supplementary protection certificate.

Under the recently adopted EU legislation authorities are also obliged to provide for data protection for an 8 + 2 + 1 year period. This provides for an additional protection period for patented drugs. Only after 8 years the medicines agency can process application for generic medicines under the EU Bolar amendment, 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).

Compulsory Licensing: Section 48 of UK Patent Act 1977 allows for applications to be made for a licence after 3 years of the grant of a patent if the patented invention is not being worked or the needs of the public are not being met. In general, compulsory licensing provision has been directed towards the use of a patent within the domestic market. Following the introduction of TRIPS and discussion at the Doha round, an EU directive is being progressed to allow for a license to permit manufacture of a pharmaceutical for export to a country which does not itself have facilities for manufacture where the pharmaceutical is required on public health grounds.

Parallel Imports: Once a good marketed in the UK has been put on the market by the rights holder (whether it is patent, trademark etc) third parties are then free to buy and resell the good without infringing the patent or trademark rights of the rights holder. Under EU law, the jurisdiction has been extended to the good being placed on sale for the first time anywhere in an EU country. Where goods intended to be marketed in one EU country but resold in another, labelling and instructions may need to be translated for pharmaceuticals for safety reasons. Imports from outside the EU are deemed to be an infringement of rights.

2.1.3 Market players

2.1.3.1 Industry

The pharmaceutical industry comprises of two main elements.

The research based sector, which is largely represented by the Association of British Pharmaceutical Industries. The ABPI represents most pharmaceutical companies active in the UK, and it represents the industry in discussions and formal consultations with government on policy matters pertinent to the industry. The ABPI also represents the industry in negotiations with the government on the Pharmaceutical Price Regulation Scheme. The Biotechnology sector is represented by the Bioindustry Association (BIA).

The Generics Manufacturers are represented by the British Generics Manufacturers Association, which represents the larger manufacturers.

The distribution channel normally comprises of manufacturers (research based or generic) selling to wholesalers who sell on the pharmacies. Some research based manufacturers have their

own distribution arrangements. Wholesaling is split in to two sectors – full-line wholesalers, which supply a full range of medicines, and short-line wholesalers, which tend to specialise in supplying a smaller range of high volume generic medicines. In addition, some pharmacy changes are part of vertically integrated companies comprising wholesale and retail pharmacy.

The pharmaceutical industry contributing a trade surplus of GBP3.5bn in 2005, the UK share of world R&D investment was 8.5% in 2005 (more than any other country outside the US and Japan).

UK headquartered companies have, for several years, been producing around one fifth of the worlds leading 75 global medicines – second only to the US.

The pharmaceutical industry contributed 0.61 per cent of the UK's national income, and directly employed 68,000 people in 2005.

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

Will be completed

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies							
- research-oriented							
- generic producers							
- biotech							
Number of persons employed[2]							

[1] as of 1 January

[2] counted per head

Source:

2.1.3.2 Wholesalers

In the pharmaceutical distribution chain, wholesalers supply pharmacies, dispensing doctors and hospitals with medicines. They buy the medicines then sell them on with a margin. They sometimes also act as distributing agents for manufacturers, particularly in generic medicines. In addition to these, wholesalers provide both suppliers and clients information on demand and supply stock levels. There are more than 2,000 companies with wholesale licenses but not many of these are engaging in wholesaling regularly.

There are two types of wholesalers:

- **Full-line wholesalers** supply the whole range of pharmaceutical products; branded medicines, generic medicines and parallel imports (PIs). This includes both frequently prescribed and infrequently prescribed medicines as well as many other products supplied by pharmacies. Full-liners have relatively higher market shares in branded medicines. They consist of both national and regional wholesalers and deliver up to 4 times a day. Some national full-line wholesalers are vertically integrated with pharmacy chains. Comparatively, full-liners invest more in storage and distribution facilities than the short-liners. They also offer services such as IT equipment, loan guarantee and advisory services to pharmacies in return for pharmacies purchasing certain minimum percentages

of their turnovers from them. Ownership patterns see increasing levels of European integration. Mawdsleys Group includes Doncaster Pharmaceuticals; a specialist in PIs giving the group access to the European market. The association that represents full-line wholesalers is the British Association of Pharmaceutical Wholesalers. It has 11 full members.

- **Short-line wholesalers** deal mostly in parallel imports and generics. They concentrate more on profitable frequently prescribed products, though some short-liners supply the full range of generic medicines. Short-liners tend to have lower costs and deliver less frequently. A large number of companies and some pharmacies engage in short-line wholesaling albeit on an irregular basis. Short-line wholesalers are represented by two associations; the British Association of Generic Distributors has 3 members with some of its members holding a few marketing authorisation licenses, and the British Association of European Pharmaceutical Distributors represents 14 companies.

Wholesale licensing: There are three classes of wholesale license; a full license, a license restricted to general sales list products and a license allowing importation. In addition every site of a license-holder is licensed for certain product categories.

Wholesalers influence on policy through their associations: Views of the trade associations of the pharmaceutical wholesalers were sought in consultation exercises on the January 2005 Pharmaceutical Price Regulation Scheme (for branded medicines) and the New Long-term Arrangements for Reimbursement of Generic Medicines introduced in April 2005. Some of these stakeholders were also involved in discussions on these new pricing schemes.

2.1.3.3 Pharmaceutical outlets / retailers

POM are normally dispensed from a registered pharmacy premises by or under the supervision of a pharmacist in response to a prescription issued by an appropriate practitioner. In addition, within the NHS or in certain independent healthcare sectors, prescription medicines can be supplied direct to patients (but not to the public at large) by certain registered health professionals, including pharmacists, nurses, dentists, doctors. Veterinary surgeons are also able to dispense certain medicines.

The Medicines Act 1968 and regulations made under the Act governs the manufacture and supply of medicines.

Under certain circumstances (as prescribed in the NHS (Pharmaceutical Services) Regulations 2005, doctors can dispense prescription-only medicines to patients (dispensing doctors). These patients live in the main in rural (controlled) areas or have serious difficulty accessing a community pharmacy. Hospital pharmacies have not traditionally acted as community pharmacies but this is possible.

In the UK, the term "OTC" refers to drugs with a Pharmacy (P) legal status and those with General Sales List (GSL) status.

P medicines can only be supplied from registered pharmacy premises by or under the provision of a pharmacist. GSL medicines can be sold from retail premises such as supermarkets, garage

forecourts without the involvement of a pharmacist. In addition, within the NHS or in certain independent healthcare sectors, medicines can be supplied direct to patients (but not to the public at large) by certain registered health professionals.

2.1.3.3.1 Pharmacies

There are 11,642 community pharmacy outlets in Great Britain (excludes Northern Ireland). This breaks down as England and Wales = 10,477 and Scotland ISD 1,165.

There are restrictions on ownership of community pharmacies. Retail premises must be registered and owned by a pharmacist, a partnership of pharmacists (in Scotland one or more partners must be a pharmacist) or by a 'body corporate' – for example a limited company. In addition, a representative of the pharmacist may carry on the business in the event of death, bankruptcy or disability. A pharmacist partnership or limited company can own an unlimited number of pharmacies (subject to competition laws). As a result, the community pharmacy network in the UK consists of a number of large and medium sized chains owning between 20 and 2,000 pharmacies and smaller businesses, including sole traders. The Medicines Act 1968 Part IV covers ownership and registration of pharmacies.

Vertical partnerships/mergers, i.e. with pharmacy wholesalers and drug producers are allowed subject to the Competition Act and mergers can be referred to the appropriate competition authorities. Pharmacists cannot enter into vertical partnerships/mergers with insurance companies and primary medical care practitioners (doctors).

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practice. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

All pharmacists must register with the Society to be able to practice pharmacy. The Society has regular meetings with policy-makers and is consulted regularly on all aspects of pharmacy and medicines policy.

The Pharmaceutical Society of Northern Ireland (PSNI) is the professional and regulatory body for pharmacists in Northern Ireland.

Pharmacies are paid by means of fees and allowances that are largely based on, but not confined to, the number of items dispensed. In addition, they earn income from margins on the medicines they dispense (target of GBP500m for all community pharmacies in England) – reimbursement prices are adjusted to hit this target margin. Margins are not regulated. See section 3.5.2.

Apart from any relevant planning or building conservation laws, there are no legal controls over the location of pharmacies in respect of, for example, setting a minimum distance between pharmacies. However, if a pharmacy wishes to provide state funded NHS pharmaceutical services, (and most do) it must apply to the relevant local health body for approval (called the "control of entry" system). This is covered by the NHS (Pharmaceutical Services) Regulations 2005 in England. Local health bodies are able to invite applications to open pharmacies in more rural and socially deprived areas.

In Scotland, as a result of the provisions of the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), the current control of entry requirements will be replaced. Instead, Health Boards will be required to establish, publish and review regularly a plan for the supply of Pharmaceutical Care Services (PCS) and arrange the awarding of contracts based on that identified need[2]. A commencement date for the PCS provision has yet to be set.

Table 2.6: United Kingdom - Retailers of pharmaceuticals 1995, 2000 - 2006[1]/to be completed

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies[2]								
No. of private pharmacies								
No. of public pharmacies								
Number of hospital pharmacies for outpatients								
Number of other POM dispensaries: _____								
Total number of POM-dispensaries[1]								
No. of internet pharmacies								
No. of OTC dispensaries, like drugstores: _____								

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

POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

[1] as of 1 January

[2] The text of the Act can be found at http://www.opsi.gov.uk/legislation/scotland/acts2005/20050013.htm.

[2] incl. branch pharmacies

Source:

2.1.3.3.2 Other pharmacy outlets (see 2.3.3)

2.1.3.3.3 Internet pharmacies

Distance-selling pharmacies of medicines is allowed in the UK, however pharmacy websites must clearly display the name of the owner of the business, the address of the pharmacy at which the business is conducted and where applicable the name of the superintendent pharmacist. Details of how to confirm the registration status of the pharmacy and pharmacists must be provided. In England, they cannot provide NHS pharmaceutical services unless they have premises in England and are placed on the pharmaceutical list of their local Primary Care Trust.

Pharmacists, their staff and premises must act in accordance with the Medicines Act 1968. Pharmacists must be registered with the RPSGB/PSNI.

There was 21 wholly mail order or internet-based pharmacies in England as at 31 March 2006.

2.1.3.3.4 Dispensing doctors

Under certain circumstances (as prescribed in the NHS (Pharmaceutical Services) Regulations 2005), doctors can dispense prescription-only medicines to patients (dispensing doctors). These patients live in the main in rural (controlled) areas or have serious difficulty accessing a community pharmacy. Hospital pharmacies have not traditionally acted as community pharmacies but this is possible.

2.1.3.4 Hospitals

As at June 2006 there were 172 NHS trusts which provided acute services. It is usual for acute trusts to have a pharmacy and for those which comprise more than one site there may be multiple pharmacies. The pharmacy will typically dispense medicines for individual in-patients, provide medicines to wards and dispense medicines to outpatients who have attended the hospital's outpatient clinics and who have received a prescription.

All acute trusts have a committee responsible for making decisions on medicines use within the trust, often referred to as the Drug and Therapeutics Committee. The committee provides a mechanism for securing the agreement and commitment of clinicians to a rationalized system of medicines usage. Decisions reached by the Drug and Therapeutics Committee are used to inform the trust's preferred list of medicines, usually referred to as 'The Formulary'. The Formulary will contain medicines that the trust has identified as necessary to meet the clinical needs of its patients. Generally the committee takes responsibility for decisions on new drugs but it will also review the use of existing approved drugs.

The membership of the Drug and Therapeutics Committee is multidisciplinary and, as well as representatives from the trust there will usually be input from the local health community (GP and pharmaceutical adviser) as well as a patient representative or lay member.

The National Institute for Health and Clinical Excellence (NICE) issues technology appraisals on the use of new and existing medicines within the NHS. Hospital Drug and Therapeutics Committees are expected to follow NICE's recommendations on whether or not it is cost effective to use certain medicines. NICE only appraises certain medicines, not all.

NHS Primary Care Trusts purchase care from NHS acute trusts. The contract price includes the full package of care including the purchase of medicines. However, certain medicines in some specialist areas, such as chemotherapy, are excluded from this system and in these cases a price for the medicines would need to be negotiated between the acute trust and the primary care trust.

Primary care representation on the hospital's Drug and Therapeutics Committee enables the committee to take account of wider implications of hospital prescribing decisions for the local health economy. See above paragraph for the development of hospital formularies.

Hospitals are reimbursed for the medicines they supply in a different way to community pharmacies. (See previous point)

2.1.3.5 Doctors

The two main doctors associations in the United Kingdom (UK) are the British Medical Association (BMA) and the General Medical Council (GMC). The British Medical Association is an independent trade union/professional association for doctors (over 139,000 members) and the General Medical Council (GMC) is the regulatory body for doctors in the UK. Doctors must be registered with the GMC to practice medicine in the UK. The GMC also set the standards and outcomes for basic medical education in the United Kingdom (UK). This covers undergraduate education and the first year of training after graduation. They also run a quality assurance programme for UK medical schools to ensure those standards and outcomes are achieved.

These associations are both large and powerful. Representatives are often involved in discussions with the Department of Health and other stakeholders about pharmaceutical policy making. They also formally contribute to public consultations on relevant issues.

Doctors are responsible for deciding the best treatment for their patients. They are required to exercise their clinical judgment, in consultation with the patient and informed by a patient's medical history. These decisions are frequently complex and may need to take account of a range of factors, including the ability of the patient to benefit from the treatment proposed. Responsibility for prescribing rests with the doctor who has clinical responsibility for that particular aspect of a patient's care.

See section 5.2 if appropriate.

2.1.3.6 Patients

Which medicines a prescriber will prescribe is a joint decision to be made between the prescriber and the patient. If a patient receives an NHS prescription there is standard charge (currently GBP 6.65) for each prescription item dispensed by a pharmacist. If the item that has been prescribed is not a prescription only medicine then it can sometimes be bought from the pharmacist at a lower price. Members of the public can purchase Pharmacy (P) and General Sales List (GSL) items over the counter. Pharmacies can set the prices for these products themselves so customers may “shop around” for the best price.

Most people have no particular requirement to look for or receive information on the price of pharmaceuticals. Information about the actual cost of items to the NHS is detailed in a publication called the ‘Drug Tariff’ which includes a wealth of information about the pricing of pharmaceutical items. It is available on the internet and in many hard copy publications[3].

There are a large number of patient groups in the UK some of which receive funding/sponsorship from the pharmaceutical industry. Representatives of patient groups are often involved in discussions with the Department of Health and other stakeholders about pharmaceutical policy making. They also formally contribute to public consultations on relevant issues.

See section 5.3 Information to patients / doctors if appropriate.

2.2 Funding

This chapter will be completed

[3] Can be accessed at the following web address: www.ppa.org.uk

2.2.1 Pharmaceutical expenditure

Table 2.7: United Kingdom - Total pharmaceutical expenditure 1995, 2000 – 2005 /to be completed

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in GBP							
TPE in % of Total Health Expenditure							
TPE per capita[1] in GBP							
Public PE in % of THE							
Private PE in % of THE							

GBP = British Pounds, GDP = Gross Domestic Product, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

Source:

2.2.2 Sources of funds

2.3 Evaluation

The NHS and Social Care information centre (http://www.ic.nhs.uk/) is responsible for providing most of the centrally collected data on prescribing and dispensing for England. They produce regular bulletins and periodic publications examining trends in prescribing.

There is no organisation that is tasked specifically with evaluating drugs policy. However, government ministers are responsible to parliament, and as a result, policy on medicines can be subject to public scrutiny, in the main through the House of Commons Health Select Committee and the National Audit Office.

The Health Select Committee is appointed by the House of Commons “to examine the expenditure, administration, and policy of the Department of Health, and its associated bodies”. It has recently examined a number of topics related to the pharmaceutical industry. Recent Inquiries include:

- The Influence of the Pharmaceutical Industry (March 2005)
  http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf
- NHS Charges (including prescription charges
  http://www.publications.parliament.uk/pa/cm200506/cmselect/cmhealth/815/815-i.pdf
- and is currently undertaking an enquiry into the National Institute for Health and Clinical Excellence (NICE). A press release covering the terms of reference can be found at http://www.parliament.uk/parliamentary_committees/health_committee/hcpn070202.cfm

The National Audit Office is totally independent of government and scrutinises public spending on the behalf of Parliament, reporting on the economy, efficiency, and effectiveness with which government departments and other bodies have used their resources. The NAO has recently published a report on Prescribing costs in Primary Care
http://www.nao.org.uk/publications/nao_reports/06-07/0607454.pdf

The Office for Fair Trading conducts Market Studies to investigate markets that do not appear to be meeting the needs of consumers, and publishes the results of these inquiries.

- A recently announced market study into the distribution of medicines in the UK – to determine how recent, and proposed changes to distribution arrangements may affect competition, the NHS and patients. See
  http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft914.pdf
- Report on the Pharmaceutical Price Regulations Scheme. It has recommended a number of far reaching reforms to the Pharmaceutical Price Regulation Scheme. (See section 6.1 for further details). See http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation
- A report on the control of entry regulations in the community pharmacy sector.
  http://www.oft.gov.uk/advice_and_resources/publications/reports/competition-policy/oft609

3 Pricing

3.1 Organisation

The prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (NHS) are regulated by the Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI). Section 33 of the Health Act 1999 gives powers to impose statutory price and profit controls on those companies, which elect not to sign up to the scheme.

Reimbursement prices for generic medicines are set and published monthly in the Drug Tariff (DT). The DT has three main categories, namely category M, A and C. Category M covers 84% by net ingredient cost of generics reimbursed in the NHS. The basic prices of Category M medicines reflect the average manufacturers' market prices after discount, and data to amend prices in line with market changes is provided by members of two new voluntary Schemes (M and W), backed by section 33 of the Health Act 1999. Scheme M applies to manufacturers and Scheme W applies to wholesalers.

Both schemes are administered by officials in Pricing and Supply, Medicines, Pharmacy and Industry Group of the Department of Health.

There are no separate reimbursement decisions in the UK. The NHS list price for branded medicines agreed under the PPRS and for generic medicines in the DT is the reimbursement price in primary care. In secondary care, hospitals may be able to negotiate a discount.

3.2 Pricing policies

The prices of branded prescription medicines supplied to the NHS are controlled through the Pharmaceutical Price Regulation Scheme (PPRS), which regulates the profits that companies can make on these sales. A new five-year PPRS commenced on 1 January 2005 in succession to the 1999 scheme. There have been a series of voluntary agreements with the industry since 1957 to limit branded medicine prices and profits, each lasting five years or so, although the details of these agreements have evolved over time.

The PPRS allows companies to increase prices subject to the Department's agreement. These are only allowed if the reasons for the application meet the criteria for increases set out in the agreement i.e. that profits are forecast to be below 40% of their profit target. However, only a few price increases have been allowed (mainly to small companies) since 1999. Companies may also modulate the prices of products provided that the effect of the modulation is cost neutral to the NHS.

Table 3.1: United Kingdom - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	The retail prices of medicines sold over the counter (OTC) direct to the public are not controlled by the Government.		
Statutory Pricing	Not applicable but The Health Act 1999 gives powers to impose statutory price and profit controls on those companies, which elect not to sign up to the voluntary schemes.		
Voluntary agreement	Prices of branded prescription medicines regulated through Pharmaceutical Price Regulation Scheme (PPRS) and generic medicines - Category M – through Schemes M and W.		
Discounts / rebates	A nominal 12.5% distribution margin for branded medicines. Discounts are not regulated.		
Public Procurement	Mainly relevant for products used in hospitals (through NHS PASA)		
Institution in charge of pricing	Department of Health – Pricing and Supply, Medicines Pharmacy and Industry Group		
Legal Basis	Health Act 1999		

source: Department of Health –MPIG

The last three PPRS agreements introduced price cuts on branded medicines - 2.5% from 1 October 1993, 4.5% from 1 October 1999 and 7% from 1 January 2005. No price increases were permitted for the first 12/15 months i.e. 1 January following the introduction of the price cut.

The PPRS sets the NHS list price at which pharmacists are reimbursed. This is a maximum price as pharmacists are able to purchase at a discount and hospitals can purchase medicines under contract at a discount.

Reimbursement prices for generic medicines are set and published monthly in the Drug Tariff (DT). The DT has three main categories, namely category M, A and C. Reimbursement prices of category M medicines are set quarterly based on manufacturers' prices after discount. Category M covers 84% by net ingredient cost of generics reimbursed in the NHS. Category A prices are based on list prices of a basket of 2 main full-line wholesalers and 3 manufacturers. Category C products are not readily available and their prices are based on a particular brand or manufacturer.

Further information at 3.4.2 below.

3.2.1 Statutory pricing

The Health Act 1999 gives powers to impose statutory price and profit controls on those companies, which elect not to sign up to the voluntary schemes, and to make regulations setting out penalties for contraventions of the schemes. However, all major companies elected to join the 2005 PPRS (for branded medicines) and Schemes M and W (for generic medicines) and have complied with their provisions.

3.2.2 Free pricing

The retail prices of medicines sold over the counter (OTC) direct to the public are not controlled by the Government. Retailers are able to set their own prices competitively and can choose to sell at a price above or below the retail price recommended by the manufacturer. The recommended retail price includes VAT and a margin for the pharmacist.

3.3 Pricing procedures

Table 3.2: United Kingdom - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing	No	n/a	n/a
External price referencing	No	n/a	n/a
Cost-plus pricing	No	n/a	n/a
Other, e. g. indirect profit control	Yes - Profit control (PPRS)	NHS list price	Branded prescription medicines sold to the NHS

Source: Medicines Pricing and Industry Group, Department of Health

3.3.1 External price referencing

Not Applicable

3.3.2 Internal price referencing

Not Applicable

3.3.3 Cost-plus pricing

Not Applicable

3.3.4 (Indirect) Profit control via the the Pharmaceutical Price Regulation Scheme (PPRS)

3.3.4.1 Introduction

The prices of branded prescription medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (NHS) are regulated by the Pharmaceutical Price Regulation Scheme (PPRS).

It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI) – under Section 33 of the Health Act 1999.

There have been a series of voluntary agreements with the industry since 1957 to limit branded medicine prices and profits, each lasting five years or so, although the details of these agreements have evolved over time.

A new five-year scheme negotiated with the ABPI commenced on 1 January 2005 in succession to the 1999 scheme. It includes a price reduction of 7% in the prices of branded prescription medicines supplied to the NHS as part of a package of measures, which provide stability for the industry and reward innovation and research while keeping public expenditure under control.

3.3.4.2 Aims

The objectives for the 2005 scheme are unchanged from those for the 1999 scheme and, as stated in the agreement, continue to be to:

- secure the provision of safe and effective medicines for the NHS at reasonable prices;
- promote a strong and profitable pharmaceutical industry in the United Kingdom capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
- encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

3.3.4.3 Coverage of the Scheme

The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter (OTC) medicines) except when prescribed. It is a UK wide scheme and covers around 80% by value (some GBP8 billion) of the medicines used in the NHS in both primary and secondary care.

All companies, which sell branded medicines to the NHS, are covered by the scheme, although only those with sales to the NHS of over GBP25 million a year (some 36 companies) are required to provide annual financial data on sales, costs, capital employed and profits. Smaller companies are not usually required to submit detailed information but have to abide by the provisions of the scheme including seeking agreement to any price increases.

3.3.4.4 Pricing

On market entry, companies have freedom of pricing for major new products i.e. those introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Licensing Authority within the constraint of their profit target. Line extensions

relating to such new products, granted on the basis of an abridged application within five years of the grant of the original authorisation of the new product also have freedom of pricing.

Where a new branded product has not been subject to a new active substance marketing authorisation, companies must seek the Department's agreement to the price of the new product. In reaching a decision on the acceptability of the proposed price, the Department may take into account factors such as the following:

- the price of other presentations of the same medicine or comparable products
- forecast sales and the effect on the NHS drugs bill
- the clinical need for the product
- any exceptional costs]

The NHS list price of existing products may only be increased with the Department's agreement if the criteria for price increases set out in the agreement are met.

3.3.4.5 Assessment of profitability

There are three main elements to the Department’s assessment of a company's profit:

- the value of its sales of branded prescription medicines to the NHS including primary care and hospital trusts;
- an assessment of the company costs that would be appropriate for the NHS to bear. The largest element is manufacturing costs. The assessment of allowable costs includes an allowance for research and development (up to 28% of NHS sales) and a limitation to marketing expenditure (6% of NHS sales);
- the capital employed by the company in delivering NHS sales. As pharmaceutical companies produce products other than for sale to the NHS (e.g. over the counter medicines, exports and non-pharmaceutical products) capital needs to be allocated between these activities.

Where profits are assessed as exceeding the return on capital (ROC) target plus a margin (almost 30% ROC), the excess has to be repaid to the Department or prices reduced.

Main features of the 2005 scheme

A price reduction of 7% on all products covered by the scheme from 1 January 2005 will deliver annual savings of GBP370 million for the NHS in England. Companies have the option of delivering the reduction by price modulation.

A five year voluntary agreement which provides stability for the industry.

Increased allowances for research and development (R&D) to a maximum of 28% of NHS sales (up from 23%) with greater incentives for R&D of new medicines including those for children.

Significant level of support for R&D above the global average of company expenditure of 16-17% (source: Scrip Pharmaceutical Industry League Tables).

Continues to allow companies freedom of pricing for new medicines (new active substances) launched in the UK. No change to target rate of return on capital (21%).

The Government is currently consulting on a proposal that 'standard' branded generics will no longer be covered by the PPRS and will be reimbursed at the Drug Tariff price of the comparable true generic[4].

3.4 Exceptions

3.4.1 Hospitals-only

Not applicable

3.4.2 Generics

As explained above, the system for pricing generics is different from that for branded medicines

Turbulence in the generics market in 1999 caused significant increases in the prices of generics and various supply problems. As a result, the Government took the following actions to stabilize the generics market;

- Commissioning the Oxford Economic Research Associates (OXERA) to investigate future long-term options for price control and supply of generics
- Introducing the Maximum Price Scheme on 3 August 2000 as a temporary measure to limit the prices of the most commonly dispensed generic medicines.

Following consultations and discussions, in April 2005, the Department introduced new long-term arrangements for the reimbursement of generic medicines. The Drug Tariff introduced a new Category M of generic medicines under Part VIII. The basic prices of Category M medicines reflect the average manufacturers' market prices after discount, and data to amend prices in line with market changes is provided by members of two new voluntary Schemes (M and W), backed by section 33 of the Health Act 1999. Scheme M applies to manufacturers and Scheme W applies to wholesalers. The new arrangements replace the Maximum Price Scheme.

3.4.3 Over-The-Counter pharmaceuticals

The retail prices of medicines sold over the counter (OTC) direct to the public are not controlled by the Government. Retailers are able to set their own prices competitively and can choose to

[4] Further information is available at www.dh.gov.uk

sell at a price above or below the retail price recommended by the manufacturer. The recommended retail price includes VAT and a margin for the pharmacist.

3.4.4 Parallel traded pharmaceuticals

The NHS list price of branded prescription medicines are set by the PPRS and those for generic medicines by the Drug Tariff. These are the prices at which pharmacists are reimbursed irrespective of whether the product is sourced domestically or parallel imported.

3.4.5 Other exceptions

3.5 Margins and taxes

There are no regulated or set margins in the UK for wholesalers or pharmacies.

Table 3.3: United Kingdom - Regulation of wholesale and pharmacy mark-ups 2005

Wholesale mark-up			Pharmacy mark-up		
Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
No			No		

Source: Medicines Pricing and Industry Group, Department of Health

3.5.1 Wholesale remuneration

The NHS list price of medicines includes a margin for distribution through wholesalers. The level of discount is negotiated between the manufacturer and wholesaler and wholesaler and pharmacy. This varies over time, from product to product and company to company.

3.5.2 Pharmacy remuneration

The remuneration of pharmacies is provided under a contractual framework for community pharmacies. This framework is negotiated with the Pharmaceutical Services Negotiating Committees – the organisation that represents the interests of community pharmacies.

In broad terms, the framework provides for a target level of funding across all pharmacies for a given year, paid for via:

- fees and allowances (the bulk of which are related to the number of items dispensed)[5],
- payments for specific services (e.g. Medicines Use Reviews)[1],
- and margins earned on the difference between reimbursement prices and prices actually paid. A survey of pharmacy invoices is used to monitor pharmacy margins. If pharmacy margins are found to diverge from the target that is set within the contractual framework, reimbursement prices for generic medicines (where the bulk of the margins occur) are adjusted accordingly. Margins are not regulated directly.

3.5.3 Remuneration of other dispensaries

Dispensing Doctors are paid through an item fee[6] and hospital pharmacies are funded directly by the hospital Trust concerned.

3.5.4 Value-added tax

Standard rate VAT in the UK is 17.5%. Pharmaceuticals supplied to hospitals and community pharmacies are subject to VAT at the standard rate of 17.5% but VAT on supplies to patients differs depending on the circumstances. Medicines dispensed by a community pharmacist against a prescription are zero-rated for VAT while medicines prescribed in hospital are subject to VAT at the standard rate of 17.5%. The NHS is funded centrally by the Government to take account of this non-recoverable VAT. Healthcare is, therefore, VAT free to the patient.

Sales of OTC medicines are subject to VAT at the standard rate of 17.5%.

3.5.5 Other taxes

There are no other taxes.

3.6 Pricing related cost-containment measures

The following section includes a description of the price control mechanisms currently used in the United Kingdom.

[5] Details of pharmacy remuneration and prices of medicines and other healthcare products are published in the Drug Tariff (produced by the NHS Business Services Authority – Prescription Pricing Division) which is updated on a monthly basis. – see http://www.drugtariff.com/

[6] Details can be found at http://www.dh.gov.uk/assetRoot/04/13/29/33/04132933.pdf

3.6.1 Discounts / Rebates

The NHS list price of branded medicines includes a margin for distribution through wholesalers. For branded medicines and generics the level of discount is negotiated between the manufacturer and wholesaler and pharmacy and varies over time, from product to product and company to company. There are no restrictions on the type of discount (within the constraints of competition law).

Note: there is a specific paragraph on claw back in the section on reimbursement, cf. 4.6.4 Claw-backs).

3.6.2 Margin cuts

As noted in section 3.5.2, A survey of pharmacy invoices is used to monitor pharmacy margins. If pharmacy margins are found to diverge from the target that is set within the contractual framework, reimbursement prices for generic medicines (where the bulk of the margins occur) are adjusted accordingly

3.6.3 Price freezes / Price cuts

The 2005 PPRS (a voluntary scheme) introduced a price cut of 7% on all branded products from 1 January 2005. It applies to the NHS list price of branded prescription medicines on the market on 31 December 2004. The aim is to effect a corresponding reduction in NHS expenditure on branded medicines.

Companies have the option of delivering the 7% price reduction by variable reductions to the prices of different products (modulation) or up to 2% by repayment, provided that the overall effect is a price reduction of 7%. No price increases were permitted for the first 12 months until 31 December 2005. Manufacturers, wholesalers and pharmacists are all affected by the price reduction.

Companies are required to submit audited data on the actual savings achieved in each of the 5 years of the scheme.

The 1993 PPRS introduced a price cut of 2.5% on all branded products from 1 October 1993. The 1999 PPRS introduced a price cut of 4.5% on all branded products from 1 October 1999.

Turbulence in the generics market in 1999 caused significant increases in the prices of generics and various supply problems. As a result, the Government introduced the Maximum Price Scheme on 3 August 2000 as a temporary measure to limit the prices of the most commonly dispensed generic medicines. In April 2005, the Department introduced new long-term arrangements for the reimbursement of generic medicines. The Drug Tariff introduced a new Category M of generic medicines under Part VIII. The basic prices of Category M medicines reflect the average manufacturers' market prices after discount, and data to amend prices in line with market changes is provided by members of two new voluntary Schemes (M and W),

backed by section 33 of the Health Act 1999. Scheme M applies to manufacturers and Scheme W applies to wholesalers. Category M will remove some GBP300 million from the distribution chain to be channelled back to pharmacy services as part of the new pharmacy contract arrangements. The new arrangements replace the Maximum Price Scheme, which had secured annual savings of some GBP330 million when compared with expenditure that would have been incurred if prices had remained at March 2000 levels. The actions taken by the Department in 2003 and 2004 to reduce the reimbursement prices of four new generic medicines to align them more closely with widely available market prices continue to deliver annual savings of some GBP300 million.

3.6.4 Price reviews

The PPRS (for branded medicines) and Schemes M and W (for generic medicines) are 5 year voluntary agreements and include provision for any party to the agreements to request a review. The schemes are also reviewed internally by the Department of Health.

4 Reimbursement

4.1 Organisation

Restrictions are placed not on what can be reimbursed but on what can be prescribed. All items which can be prescribed on the NHS are fully reimbursable.

In hospitals anything can be prescribed, although local restrictions may apply (for example those established by the hospital's drugs and therapeutics committee). In primary care, all items may be prescribed for all patients, except those listed in schedule 1 of the National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, as amended, and those in Schedule 2 of the same Regulations, which may be prescribed only for certain patients and under certain circumstances.

Decisions on the addition or removal of items from these Schedules (thereby changing the reimbursement status of the item) are taken by the Secretary of State. Addition or removal may be influenced by a number of factors, including changes in price or availability, professional advice, and lobbying from patient groups or other interested parties.

The National Institute for Health and Clinical Excellence (NICE) provides independent professional advice on clinical and cost-effectiveness of drugs and other therapeutic interventions. However, NICE advice on a particular item has no direct effect on reimbursement status.

4.2 Reimbursement schemes

Reimbursement in primary care is based on a scheme authorised by a combination of the National Health Service Act 1977, the National Health Service (Pharmaceutical Services) Regulations 2005, as amended (plus similar Regulations for other pharmacy services providers), the National Health Service (General Medical Services Contracts) Regulations 2004, as amended (plus similar Regulations for primary care prescribers operating under alternative NHS contracts) and the Drug Tariff.

The scheme covers all healthcare professionals operating under these Regulations, and all patients who receive NHS services provided under them. This amounts to the vast majority of GP practices and community pharmacies in England.

The scheme establishes reimbursement prices for both branded and generic medicines. Branded prices are controlled through the Pharmaceutical Price Regulation Scheme (PPRS). Generic prices are calculated from manufacturer or market prices using a number of different formulae. Using manufacturer and market prices ensures that price levels are mainly controlled by competition.

Pharmacies purchase their own drugs, which they supply in response to NHS prescriptions. The NHS reimburses them for the product and remunerates them for the service provided in the pro-

vision of the product. Remuneration is based either on Drug Tariff listings (for those items listed in the Tariff), or on manufacturer list prices.

4.2.1 Eligibility criteria

The Department of Health has the power under section 28U of the NHS Act 1977 to prohibit or impose restrictions on the prescribing by GPs (and others entitled to prescribe within General Medical Services contracts) of specified drugs on the NHS. The prohibited list or so-called “blacklist” is contained in Schedule 1 of the NHS (GMS Contracts) (Prescription of Drugs etc) Regulations 2004. The restricted list or “grey list” is contained in Schedule 2 of the same regulations. GPs may prescribe the drugs in this list on the NHS only in specified circumstances, and/or for specified patient groups. GPs may write a private prescription, without charge, for their own NHS patients for any schedule 1 drug, and may write a private prescription for a schedule 2 drug providing the patient is not eligible for an NHS prescription because of his or her condition. A listing on Schedules 1 or 2 does not prevent GPs from issuing private prescriptions to patients other than their NHS patients.

The process of scheduling is not straightforward. A prerequisite is a period of public consultation with the interested parties – manufacturers, professional bodies and patients – under a criterion developed for the purposes of the European Transparency Directive.

4.2.2 Reimbursement categories and reimbursement rates

All POMs are fully reimbursable. Those items which are not to be prescribed and those which are to be prescribed under certain circumstances only are listed in schedules 1 and 2, respectively, of the National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, as amended.

4.2.3 Reimbursement lists

See section 4.2.1

4.3 Reference price system

No reference price applies.

4.4 Private pharmaceutical expenses

4.4.1 Direct payments

There are no particular medicines where patient payment is required except under circumstances where the drug is black listed or grey listed (see sections 4.2 and 4.2.1.

4.4.2 Out-of-pocket payments

4.4.2.1 Fixed co-payments

In England, fixed co-payment arrangements apply. A standard prescription fee - GBP6.65 from 1 April 2006 – is payable in respect of each item supplied.

There is also a system of exemptions under which items are supplied free of charge. The exemption is based on one of a number of factors: the method of delivery, the type of medication, the age of the patient, the patient's condition; or the patient's income. The details are as follow.

The basis of exemption from prescription fees in England

(1) No charge for medication for the patient (regardless of patient's status or income):

- supplied to hospital inpatients
- supplied on discharge following inpatient treatment
- supplied and administered personally by a GP
- supplied by a GP for immediate treatment (and no prescription form is used)
- administered at a hospital or walk in centre
- supplied for personal administration by person making the supply in accordance with a patient group direction
- supplied for the treatment of a Sexually Transmissible Infection (and no prescription form is used, eg supply is by a hospital)
- which is a prescribed contraceptive (oral or listed appliances)

(2) No charge for any prescriptions for patients who are in one of the following categories:

- Children under 16
- Young people aged 16, 17 18 receiving qualifying full-time education
- Men and Women aged 60 and over
- Pregnant women and women who have had a child in the previous twelve months who hold a valid exemption certificate
- People who hold a valid exemption certificate for a War Disablement Pension (but only in respect of medication for the accepted disablement)
- People suffering from the following conditions who hold a valid exemption certificate
  - Permanent Fistula (including caecostomy, colostomy, laryngostomy, or ileostomy) which requires continuous surgical dressing or requires an appliance
  - forms of hypoadrenalism (including Addison's disease) for which specific substitution therapy is essential
  - diabetes insipidus or other forms of hypopituitarism
  - diabetes mellitus (except where treatment is by diet alone)
  - hypoparathyroidism
  - myasthenia gravis
  - myxoedema
  - epilepsy requiring continuous anti-convulsive therapy
  - continuing physical disability which prevents the patient from leaving his residence without the help of another person.

(3) No charge for any prescriptions for patients who are not in any of the above groups but who have a low income.

(a) The patient is named on an HC2 charges certificate for full help under the National Health Service Low Income Scheme. Either partner (including civil partners from December 2005) may make the claim. The level of help is based on a comparison between income and requirements of the individual/couple at the time a claim is made (or a charge was paid). "Requirements" are the same as income support applicable amounts plus housing costs and council tax the individual/couple is liable to pay. The level of income at which help ceases will depend on the individual's/couple's circumstances. No help is available when capital is more than GBP21,000 for people loving permanently in a care home or GBP16,000 for anyone else. Or

(b) Recipients of the following who do not need to make a separate Low Income Scheme claim:

- Income Support
- Jobseekers' Allowance Income-based
- Pension Credit guarantee credit (for partners under 60, recipient will be entitled on age grounds)
- Tax credit awarded and family's annual gross taxable income (from 6 April 2006) is GBP15,050 or less with:
  - working tax credit and child tax credit, or
  - working tax credit with a disability, or severe disability, element, or
  - child tax credit and not eligible for working tax credit

(and the patient is named on a tax credit exemption certificate)

4.4.2.2 Percentage co-payments

There are no percentage co-payment arrangements in place in England.

4.4.2.3 Deductibles

There is no specific maximum to out of pocket expenses. However, a patient may effectively cap the prescription fees payable by purchasing a prescription pre-payment certificate (PPC). PPCs are available for 4 months for a fee of GBP34.56 (from 1 April 2006) or for 12 months for a fee of GBP95.30 (from 1 April 2006). No further prescription fee is payable at the point of dispensing and the patient may obtain an unlimited number of prescribed items during the period of the certificate. A patient may specify the start date of a PPC as up to one month before, or one month after the date of application.

4.5 Reimbursement in the hospital sector

Hospital pharmaceuticals are paid for by the hospital. In turn NHS hospital funding derives from the purchase of medical services by NHS Primary Care Trusts.

Out-patients do not pay a prescription charge for any medicines which are administered to them at the hospital. For medicines which out-patients are prescribed to take at home then the same rules apply as for medicines prescribed in the community.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

Not Applicable

4.6.2 Introduction / review of reference price system

Not Applicable

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

Not Applicable

4.6.4 Claw-backs

Claw-backs are not an explicit feature of the UK system. However, pharmacies have an amount deducted from their overall reimbursement (circa 10% on average) which varies depending on the size of pharmacy. In addition, reimbursement prices are reviewed in the light of evidence on the amount of margin earned by pharmacies.

Also, under the PPRS, pharmaceutical companies that earn profits in excess of those set out in the PPRS Agreement must either reduce prices, or make a repayment to the Department of Health. [See section 3.3.4 above]

4.6.5 Reimbursement reviews

Will be completed.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

As with any organisation, there are pressures on the National Health Service (NHS) to ensure that they provide a full range of services within budget. The Department of Health do not determine a national amount to be spent on prescribing each year, this is locally determined by Primary Care Trusts (PCTs). Prescribing advisers based in each PCT help set budgetary constraints for prescribing doctors in their local areas. Strategic Health Authorities (SHAs) hold all local NHS organisations (apart from NHS Foundation Trusts) to account for performance, including coming in on budget.

The Prescription Pricing Division (PPD) of the NHS Business Services Authority produces various electronic information to enable PCT prescribing advisers and others to monitor prescribing patterns. Prescribing advisers, mainly pharmacists, are employed at various levels in the NHS (Strategic Health Authority (SHA) and Primary Care Trust (PCT)), having a common aim to encourage and secure rational and cost-effective prescribing. There are now more than 1,200 advisers many of whom undertake face to face reviews with General Practitioners (GPs) and carry out reviews of repeat prescribing etc. activity.

There are no special prescribing procedures in the inpatient sector. Area prescribing committees do, however, cross-fertilise ideas and information between primary and secondary care settings. Please also see 5.2.

5.2 Prescription guidelines

The pharmaceutical companies are bound by a voluntary Code of Practice on sales promotion drawn up by the Association of the British Pharmaceutical Industry (ABPI) and breaches are reported to the Prescription Medicines Code of Practice Authority, which operates independently from the ABPI. The code is accepted by virtually all companies operating in the UK including most non-ABPI member companies. Companies which are found to be in breach of the code have to undertake that the promotional activity or use of the material in question will cease and take steps to avoid a similar breach in the future and pay an administrative charge. Serious breaches can result in a published reprimand and expulsion from the ABPI (expulsions or temporary suspensions are rare, but have occurred). All cases considered by the Authority are published in quarterly reports.

5.3 Information to patients / doctors

The pharmaceutical companies are bound by a voluntary Code of Practice on sales promotion drawn up by the Association of the British Pharmaceutical Industry (ABPI) and breaches are reported to the Prescription Medicines Code of Practice Authority, which operates independently from the ABPI. The code is accepted by virtually all companies operating in the UK includ-

ing most non-ABPI member companies. Companies which are found to be in breach of the code have to undertake that the promotional activity or use of the material in question will cease and take steps to avoid a similar breach in the future and pay an administrative charge. Serious breaches can result in a published reprimand and expulsion from the ABPI (expulsions or temporary suspensions are rare, but have occurred). All cases considered by the Authority are published in quarterly reports.

There are no direct controls on the amount of promotional expenditure that a pharmaceutical company may undertake. However, there are limits set out in the PPRS Agreement, which in turn feed into the assessment of costs and hence profits. [Refer to PPRS document]

Please also see 2.1.3.1 and 2.1.3.6.

5.4 Pharmaco-economics

NICE in its assessment of clinical and cost effectiveness makes use of heath economic analyses and produces Quality Adjusted Life Year data on which it bases its recommendations. However, these recommendations are for the NHS in reaching decisions, both clinical and managerial, on the use of pharmaceuticals and devices. Guidance applies to both the hospital and community setting.

NICE has indicated that the threshold cost per QALY is in the range of „20,000 to GBP30,000, however it will also take other factors into account.

The provision of health-economic analyses is not necessary for obtaining market authorization.

The provision of health-economic analyses is not required in the decision on the price of a pharmaceuticals, nor on reimbursement status. However, NICE may provide guidance on whether a product should be used in the NHS, where the price will have an bearing. This guidance is generally reviewed after 5 years. Please see 4.6.

5.5 Generics

There are no legal regulations on the use of generics. Generics represent best value for money as branded medicines are generally more expensive than their generic counterparts. Prescribers are encouraged to prescribe by chemical name in most circumstances, unless there is a medical reason not to do so. Prescribing by chemical name is also recommended on grounds of safety, where confusion may occur if different brands of the same chemical may occur.

The use of generics is still relevant in the inpatient sector.

Table 5.1: United Kingdom - Development of the generic market in the out-patient sector, 2000 – 2005

Will be completed.

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)						
Value						

Please indicate source: _____

5.5.1 Generic substitution

Pharmacists must dispense the brand if that is what has been written on the prescription by the prescriber. However, they are allowed to dispense a parallel import.

In the in-patient setting, local arrangements may allow hospital pharmacists to substitute a generic for a brand, according to locally developed policies.

Local primary Care Organisations can develop incentive schemes for their prescribers, and these vary from place to place. In addition, most Primary Care Organisations will have performance management arrangements that monitor local prescribing.

Pharmacists must dispense what is written on the prescription. Some, limited substitution may occur in the hospital setting according to well defined, locally developed formulary arrangements.

5.5.2 Generic prescription

Doctors are encouraged, but not obliged, to write prescriptions by generic name for both clinical and cost reasons, when appropriate, recognizing that there are occasions when it is medically appropriate to prescribe the brand. Generic prescribing rates are high at 80%.

Prescribers, in the main, do not benefit personally from prescribing generic medicines.

Generic prescribing is easily accepted by the majority of doctors. Good practice guidance from the General Medical Council sates that, doctors ".should take account of appropriateness, effect and cost when prescribing any medicine."

5.5.3 Generic promotion

Local primary Care Organisations can develop incentive schemes for their prescribers, and these vary from place to place. In addition, most Primary Care Organisations will have performance management arrangements that monitor local prescribing.

5.6 Consumption

In general, the consumption of pharmaceutical items by individuals is not monitored, and there is no collection of consumption data on a national basis. There are, however, a limited number of cases in which individual patient consumption is monitored:

Administration of methadone: Pharmacists may be commissioned to supervise the consumption of methadone by patients who are prescribed it by their GP.

Medicines Use Review (MUR): This is a service designed to allow a pharmacist to discuss with the patient their usage of medicines. The aims of the service are to establish the patient's actual use of medicines; to discuss any problems the patient may have, and to improve effective use of medicines and reduce waste.

The review involves asking the patient about medicines they are taking, including not only prescription items but also those bought over the counter, including herbal and other alternative therapies, and those bought online. There is no way of gathering this information unless it is volunteered by the patient. MUR is a voluntary service, and records kept of consultations are shared only with the patient and their GP.

Monitoring of consumption in hospitals: Records are kept of medicine administration to hospital inpatients.

GPs are responsible for taking into account compliance requirements of individual patients, and prescribe accordingly, and the pharmacist will be reimbursed the cost of the medicines they dispense Pharmacists also have a responsibility to ensure that patients are able to take their medicines, and to take reasonable steps to ensure that compliance aids are provided where appropriate.

6 Current challenges and future developments

This chapter covers the most oppressing pharmaceutical challenges for the health care system and the future plans to meet these challenges.

6.1 Current challenges

The Office for Fair Trading has recently reported the findings of its study into the regulation of branded pharmaceutical prices in the UK. The OFT report has recommended a number of far reaching reforms that would involve considerable change to the way that pricing is determined.

The main recommendations are that

- All reimbursement prices should be set in such a way to reflect the added value of the product (compared to its most appropriate comparator). An organisation such as NICE would undertake the cost-effectiveness analysis in order to advise on the price, and another body, initially the Department of Health, but subsequently an independent body, would negotiate a price.
- This would also involve resetting the reimbursement price of an in-patent product if its comparator goes out of patent, and a cheaper generic becomes available.
- All out of patent products to have their reimbursement prices set in accordance with the systems in place for generic medicines, irrespective of whether it is the originator brand.
- Risk-Sharing schemes should be put in place where there is insufficient certainty about the effectiveness of the product at the time the assessment is made.
- Non-Linear pricing such as Price – volume agreements should be put in place to deal with products that have different levels of effectiveness in different population sub-groups.

The government is considering the OFT recommendations and will respond in due course.

6.2 Future developments

The OFT report on the PPRS is likely to result in changes in the way in which pharmaceutical prices are developed. The government has not yet responded, so it is not possible to give a clear indication of the scope of such changes.

The government awaits the results of the OFT market study into the distribution of medicines in the UK, which is due to be published by the end of 2007.

7 Appendixes

7.1 References

Further information can be found at the following web addresses.

Department of Health – Medicines, Pharmacy and Industry

http://www.dh.gov.uk/en/Policyandguidance/Medicinespharmacyandindustry/index.htm

NHS and Social Care Information Centre

http://www.ic.nhs.uk/

The Drug Tariff

http://www.drugtariff.com/

Prescription Pricing Division of the NHS Business Services Authority

http://www.epact.ppa.nhs.uk/index.htm

7.2 Detailed description of the authors

David Kullman (MPI-PPS, Department of Health)

John Sherriff (MPI-CCE, -, Department of Health)

Howard Stokoe (NHS Purchasing and Supply Agency)

Eunice Barnor (MPI-PPS, Department of Health)

Michael Baxter (MPI-Analysts, Depratment of Health)

Judy Carter (MPI-PPS, Department of Health)

Giles Crompton-Howe ((MPI-CCE, -, Department of Health)

Diana Kenworthy (MPI-Pharma, Department of Health)

Rebecca Blessing (MPI-CCE, -, Department of Health)

Michael Derbyshire (Medicines and Healthcare products Regulatory Agency)