



# **PHIS Pharma Profile**

**United Kingdom**

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## **Executive Summary**

### ***Health care system***

The United Kingdom (UK) has a growing population of over 61 million people. The population is ageing with average life expectancy at the highest levels on record (81.9 years for women and 77.7 for men).

The UK has a National Health Service (NHS) funded centrally mainly through general taxation. Established in 1948, it provides universal access to healthcare based on medical need rather than the ability to pay. The NHS remains free at the point of use with a few exceptions (primary care optical and dental services and prescription charges for out-patients where co-payments apply although there are exemptions on grounds of age, income, medical condition etc). Since devolution in 1999, responsibility for healthcare in Scotland, Wales and Northern Ireland has transferred to the devolved administrations. NHS services are managed separately in England, Scotland, Wales and Northern Ireland and although services remain similar in most respects, some differences have emerged in some areas.

Traditionally low by international comparisons, the government pledged in 2000 to increase spending on health care to the European average. By 2008, total health spending accounted for 8.7% of GDP in the UK, compared with an average of 9.0% across OECD countries. The public sector accounts for some 83% of total expenditure on healthcare in the UK and the private sector 17%.

In England, the Department of Health provides leadership to the NHS through the Strategic Health Authorities (SHAs), which in turn oversee the activities of trusts in their region. Primary Care Trusts (PCTs) are responsible for commissioning or providing primary medical care services for their populations and have a major role around commissioning hospital care and providing community care services. NHS hospital trusts (also known as Acute Trusts) or Foundation Trusts provide the overwhelming majority of hospital care. The devolved administrations of Scotland, Wales and Northern Ireland run their local NHS services separately.

In England, the Department of Health allocates funding to PCTs on the basis of the relative needs of their populations and the Payment by Results (PbR) tariff sets the price that PCTs pay hospital trusts out of their unified allocation for a given episode of care. The tariff price for each treatment includes the cost of the medicines used, provision, monitoring of the condition and other costs around the treatment.

Hospital doctors are employed by NHS trusts but General Practitioner (GPs) are mostly self-employed under contract to NHS trusts. Between 2000 and 2008, the number of doctors in the UK increased by 37% and the number of GPs by 23%.

## ***Pharmaceutical system***

Medicines are licensed for use by the European Medicines Agency (EMA) or the UK Medicines and Healthcare products Regulatory Agency (MHRA). The NHS list price at which medicines are reimbursed on the NHS is agreed with the Department of Health.

Over 26,000 medicines are licensed for use in the UK. Once a pharmaceutical company has obtained marketing authorisation and pricing approval, it is free to launch the medicine in the UK and in most cases it will be granted automatic full reimbursement on the NHS. Hospitals may be able to purchase medicines under contract at a discount to the NHS list price.

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance to the NHS (in England and Wales) on the promotion of good health and the prevention and treatment of ill health. It makes recommendations on the clinical and cost-effectiveness of new medicines and treatments.

The UK is home to a world-class pharmaceutical industry, which makes significant contributions not only to developing new medicines, and to the economy, but also to the UK research capacity within and beyond the NHS.

Pharmaceutical wholesalers are an essential part of the supply chain, the link between manufacturers and patients, supplying medicines to hospitals, community pharmacies and dispensing doctors.

Prescription-only medicines 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.

Total NHS expenditure on medicines in the UK is estimated at £ 14.8 billion (€ 18.6 billion) in 2008, an increase of 50% since 2000. Expenditure on medicines in England in 2008 was £ 11.6 billion (€ 14.6 billion) of which hospital expenditure was some £ 3.6 billion (€ 4.5 billion), about 30% of the total. It is estimated that around £ 3.0 billion (€ 3.8 billion) was on branded medicines with the remainder on generic medicines and pharmaceutical related products.

The UK has the among highest generic prescribing rate amongst comparable countries in Europe - in England (out-patient care) in 2008, 83% of prescriptions were written generically by volume and 65% were dispensed generically and 25% were dispensed generically by value. In hospitals, pharmacies dispense medicines generically irrespective of how they are prescribed.

The NHS is funded centrally mainly through general taxation including a proportion from National Insurance contributions with a small element coming from charges and receipts, including sales of surplus NHS land and proceeds from income generation schemes.

## ***Pricing, reimbursement and volume control in the out-patient sector***

The prices of branded prescription medicines supplied to the NHS (out-patient and in-patient sector) are controlled by the 2009 Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement negotiated between the Department of Health and the branded pharmaceutical industry. A company, which chooses not to join the PPRS, falls under the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 that form a statutory alternative to the voluntary arrangements.<sup>1</sup> The PPRS is the mechanism, which controls the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their NHS sales. The PPRS sets the NHS list price i.e. the reimbursement price which includes wholesaler and pharmacy margins. It sets a maximum price and hospitals may be able to purchase medicines under contract at a discount to the NHS list price.

The prices of generic medicines are set by the market. Generic manufacturers have freedom of pricing subject to a maximum of the reference product at the point of patent expiry.

The retail prices of medicines sold over the counter (OTC) direct to the public are not controlled. A team in Medicines, Pharmacy and Industry Group (MPIG) in the Department of Health are responsible for pricing and reimbursement of branded and generic medicines.

There are no regulated or set margins in the UK for wholesalers or pharmacies – these are negotiated by the parties in the supply chain. The Drug Tariff outlines what will be paid to pharmacists for dispensing NHS prescriptions - it includes remuneration (professional fees/allowances) for service provision and for reimbursement (the cost of the medicines, appliances etc) supplied against an NHS prescription form.

Standard rate VAT in the UK in 2010 is 17.5% (20% from 2011). Medicines dispensed by a community pharmacist against a prescription are zero-rated for VAT (which means that the patient pays no VAT and the pharmacy can recover the VAT paid when buying the medicines). Medicines supplied to hospitals and community pharmacies are subject to VAT at the standard rate. Sales of OTC medicines are also subject to VAT at the standard rate.

There are no separate pricing and reimbursement mechanisms and the great majority of new prescription medicines are granted automatic full reimbursement upon market authorisation from the EMA/MHRA and pricing approval from the Department of Health. In out-patient care, any product may be prescribed for a patient and it will be reimbursed on the NHS except for a small number on a negative list.

With the exception of charges for some prescriptions and optical and dental services, the NHS remains free at the point of use for anyone resident in the UK. In England, a fixed co-payment arrangement applies – a standard prescription charge (£ 7.20 (€ 8.40) from 1 April

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<sup>1</sup> Most of the larger companies are members of the voluntary PPRS – the last Report to Parliament in December 2009 stated that out of 205 companies, 150 had signed up to the voluntary scheme and 55 to the statutory scheme. Numbers have increased in both since then - but the majority are still in the PPRS.

2010) - is payable in respect of each item supplied. There is a system of exemptions under which items are supplied free of charge and around 90% of prescription items are not charged for at the point of dispensing in the community. Exemptions are based on one of a number of factors, for example, the age of the patient, the patient's medical condition; or the patient's income. Wales and Northern Ireland have abolished the prescription charge and Scotland has reduced the charge to £ 3 (€ 3.50) from 1 April 2010 and plans to abolish charges altogether in 2011.

The Department of Health allocates funding to PCTs on the basis of the relative needs of their populations and the money available for medicines is part of this overall allocation. The national amount to be spent on prescribing of medicines each year is managed locally by PCTs and prescribing advisers based in each PCT help prescribing doctors in their local areas to prescribe cost-effectively.

Prescribers are encouraged, but not obliged, to write prescriptions by their 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 is accepted by the majority of doctors and, as mentioned above, generic prescribing rates are the highest in Europe amongst comparator countries (82.6% in England (out-patient care) in 2008). Generic substitution is not allowed in out-patient care in the UK.

In recognition that most medicines dispensed can be purchased by a pharmacy at less than reimbursement prices, pharmacies are reimbursed the tariff price less a clawback percentage. The clawback percentage depends on the total reimbursement value of the medicines they dispense - larger pharmacies have a higher discount clawback percentage applied. The average clawback is 8.2%.

The Department of Health monitor the prices of medicines supplied to the NHS through the PPRS for branded medicines and the Drug Tariff for generic medicines. The Department of Health, SHAs and PCTs all have an interest in monitoring pharmaceutical expenditure in the NHS. Reports on prescribing data are produced by the NHS Information centre. The National Prescribing Centre (NPC) is an NHS organisation whose aim is to 'promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery'. The NPC produces a number of resources to support commissioners (purchasers) in relation to prescribing and medicines management. Medicines Use Reviews (MUR) allow a pharmacist to discuss with the patient their usage of medicines.

NICE uses health-economic analysis in the development of its guidance to the NHS on the clinical and cost-effectiveness of licensed medicines and other treatments. If a treatment receives a positive appraisal by NICE, PCTs are mandated to fund its use when it is prescribed by practitioners in the NHS. Pharmaco-economic analyses are not required to obtain a market authorisation, or pricing and reimbursement decision.

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme produces independent research information about the effectiveness, costs and



broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS. The HTA programme commissions Technology Assessment Reports on behalf of NICE to support its technology appraisals.

### ***Pricing, reimbursement and volume control in the in-patient sector***

The prices of branded prescription medicines supplied to the NHS (out-patient and in-patient sector) are controlled by the voluntary PPRS or its statutory alternative – both administered by a small team in MPIG in the Department of Health. However, hospitals may obtain a discount to the NHS list price where there is therapeutic competition.

Medicines supplied to hospitals are subject to VAT at the standard rate of 17.5% (20% from 4 January 2011) and the NHS is funded centrally by the Government to take account of VAT. The prices of hospital medicines consist of the NHS list price, plus VAT minus any discounts the hospital secures and includes a margin for distribution. There are no mandatory discounts for hospitals.

Most generic medicines in the in-patient sector are purchased locally at trust level with a significant proportion via contracts awarded by NHS Commercial Medicines Unit (NHS CMU), who manage the contracting process on behalf of hospital pharmacy purchasing groups to ensure adherence with the UK regulations that implement the EU procurement directives. The contracts that are awarded, against pre-determined award criteria, are usually framework agreements on behalf of defined geographical groupings of hospitals. Public procurement regulations restrict the length of framework agreements to a period of four years, but many products are tendered more frequently than this. Whilst hospitals remain free to carry out their own procurement, the NHS as a whole supports a consistent national procurement model.

The state funds NHS hospital care including the cost of medicines. In England, hospital trusts pay for the medicines purchased and are reimbursed by PCTs through the PbR mechanism, a tariff price for each treatment including the cost of the medicines used. NHS patients are not required to pay for medicines in hospital. NHS patients who wish to buy additional private care (e.g. buy medicines privately that are not recommended for use by the NHS) can do so as long as the private care can be delivered separately from NHS care.

Decisions concerning which medicines can be prescribed rest with local pharmaceutical and therapeutic committees (PTC) (known as drugs and therapeutic committees (DTC) in the UK), which manage formularies and include members of the pharmacy team. Formularies have been in place in the majority of NHS hospitals for many years with some hospitals sharing formularies whilst others have developed joint formularies with PCTs. Each hospital will normally have their own formulary of active substances, and as a result, the format and number of items on each list will vary significantly. Generic substitution is normally practised with these lists. The formularies are continually updated.

Data is collected monthly at trust level for England, by NHS CMU through hospital pharmacy computer systems and purchasing information. The information collected includes name, form, strength, pack size, number of packs and price per pack. Through this system, known

as PharmEx, the NHS is able to measure the performance of its procurement arrangements. Feedback is given to trusts on their performance but information is not published.

Hospital trusts expenditure on medicines is monitored closely, usually led by the Chief Pharmacist and their team. Expenditure on medicines is centrally recorded e.g. a report on Hospital Prescribing in England in 2009 was published in October 2010 by the NHS Information Centre for Health and Social Care.

Within hospitals, consumption can be analysed by the ward or department and by individual patient where electronic prescribing systems exist. Most hospital pharmacies have sophisticated stock control systems and a medicine's progress through the hospital can be monitored from ordering to administration.

There has been an extensive move to embrace and develop the role of clinical pharmacy whilst sustaining technical and supply chain expertise. The majority of pharmacists are based in clinical services specialising in specific areas of work (e.g. renal, mental health, intensive care, general surgery) and working closely with medical teams to provide patient care. Clinical pharmacy teams seek to ensure safe and effective use of medicines, implementing guidelines and individualising patients' medicines regimens.

NICE uses health-economic analysis in the development of its guidance to the NHS on the clinical and cost-effectiveness of licensed medicines and other treatments – it applies to both the hospital and community sectors. NICE appraisals are not given to all medicines, and so hospitals will often have to make decisions on clinical and cost effectiveness without NICE guidance. NICE reviews its methods approximately every 3 to 5 years.

### ***Interface management and developments***

The use of medicines by patients needs to be co-ordinated throughout the patient's journey. Many medicines are initiated in acute/specialist hospitals and subsequently prescribed in out-patient care. Medicines management and prescribing are key elements of both PCT and acute trust business. Problems with medicines often occur at the interface between health care organisations, and health and social care. This risk needs to be managed both clinically and financially, and a coordinated area wide approach to medicines management can help organisations do this.

Health economy prescribing committees (or Area Prescribing and Medicines Management Committees (APCs)) whose 'member' organisations are out-patient and in-patient care commissioners (purchasers) and providers work together to ensure a consistent health community approach to medicines management. Many were established to manage more effectively the entry of new medicines into the NHS but have evolved as forums to resolve issues around medicines safety and usage across the care interfaces.

The NPC is an NHS organisation whose aim is to 'promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient

care and service delivery'. The NPC produces resources to support commissioners (purchasers) in relation to prescribing and medicines management.

The coalition Government published a White Paper 'Equity and Excellence: Liberating the NHS' in July 2010 setting out its long-term plans to reform the NHS in England. Most significantly it plans to transfer responsibility for 80% of the NHS budget to groups of GPs (GP consortia) who would assume the healthcare commissioning role currently played by PCTs. It commits to increase health spending in real terms in each year of the Parliament but the NHS will have to make efficiency savings of £ 20 billion (€ 22.5 billion) by 2014 to be re-invested in frontline services.

In terms of medicines, the government plans to move towards a system of value-based pricing when the current PPRS expires in 2013 and published a consultation on its proposals in December 2010. As an interim measure, it is creating a new Cancer Drug Fund from April 2011 (with in the meantime additional £ 50 million (€ 58 million) funding available from 1 October 2010) to help patients get the medicines their doctors recommend.

The government is consulting on its plans for changes to be introduced over the next three years.

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| ABPI     | Association of British Pharmaceutical Industries               |
| ADTC     | Area Drug and Therapeutics Committee                           |
| AIFA     | Agenzia Italiana del Farmaco / Italian Medicines Agency        |
| APC      | Area Prescribing and Medicines Management Committees           |
| ATC      | Anatomic therapeutic chemical classification                   |
| BAPW     | British Association of Pharmaceutical Wholesalers              |
| BGMA     | British Generics Manufacturers Association                     |
| BIA      | BioIndustry Association  |
| BMG      | Bundesministerium für Gesundheit / Austrian Ministry of Health |
| CHM      | Commission on Human Medicines                                  |
| CIVAS    | Centralized Intravenous Admixtures Service                     |
| DDD      | Defined Daily Doses  |
| DG SANCO | Health and Consumer Protection Directorate General             |
| DH       | Department of Health   |
| DRG      | Diagnosis related group  |
| DTC      | Drugs and therapeutic committee                                |
| DTP      | Direct to Pharmacy   |
| EAHC     | Executive Agency for Health and Consumers                      |
| EMA      | European Medicines Agency                                      |
| EMIG     | Ethical Medicines Industry Group                               |
| EU       | European Union   |
| IHHII    | International Healthcare and Health Insurance Institute        |
| INN      | International Non-proprietary Name                             |
| GDP      | Gross domestic product   |

|          |  |
|----------|--|
| GMS      | General Medical Services   |
| GÖG/ÖBIG | Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG /<br>Austrian Health Institute |
| GP       | General Practitioner   |
| GPhC     | General Pharmaceutical Council   |
| GSL      | General sale list  |
| HE       | Health expenditure   |
| HiT      | Health systems in transition   |
| HOM      | Hospital-only medicine   |
| HPF      | Hospital pharmaceutical formularies  |
| HTA      | Health Technology Assessment   |
| MA       | Marketing authorisation  |
| MHRA     | Medicines and Healthcare products Regulatory Agency                              |
| Mio.     | Million  |
| MPIG     | Medicines, Pharmacy and Industry Group   |
| MUR      | Medicines Use Review   |
| NAS      | New active substance   |
| NCG      | National Commissioning Group   |
| NCU      | National currency unit   |
| NHS      | National Health Service  |
| NHSBSA   | NHS Business Services Authority  |
| NHS CMU  | NHS Commercial Medicines Unit  |
| NHS PASA | NHS Purchasing and Supply Agency   |
| NIC      | Net ingredient cost  |
| NICE     | National Institute for Health and Clinical Excellence                            |
| NIHR     | National Institute for Health Research   |

|       |  |
|-------|--|
| NMEs  | New molecular entities                                       |
| NPC   | National Prescribing Centre                                  |
| OECD  | Organisation for Economic Co-operation and Development       |
| OJEU  | Official Journal of the EU                                   |
| OPD   | Out-patient departments                                      |
| OPP   | Out-of-pocket payment  |
| OTC   | Over-the-counter medicine                                    |
| PAGB  | Proprietary Association of Great Britain                     |
| PAS   | Patient access schemes                                       |
| PbR   | Payment by Results   |
| PCT   | Primary Care Trust   |
| PE    | Pharmaceutical expenditure                                   |
| PHIS  | Pharmaceutical Health Information System                     |
| PMCPA | Prescription Medicines Code of Practice Authority            |
| PMS   | Personal Medical Services                                    |
| POM   | Prescription-only medicine                                   |
| PPC   | Prescription pre-payment certificate                         |
| PPP   | Purchasing power parities                                    |
| PPRI  | Pharmaceutical Pricing and Reimbursement Information project |
| PPRS  | Pharmaceutical Price Regulation Scheme                       |
| PRP   | Pharmacy retail price  |
| PSNC  | Pharmaceutical Services Negotiating Committee                |
| PTC   | Pharmaceutical and therapeutic committee                     |
| QALY  | Quality adjusted life year                                   |
| QIPP  | Quality, Innovation, Productivity and Prevention             |

|        |   |
|--------|---|
| QOF    | Quality and Outcomes Framework                                      |
| R&D    | Research and development  |
| ROC    | Return on capital   |
| ROS    | Return on Sales   |
| RPS    | Royal Pharmaceutical Society  |
| RPSGB  | Royal Pharmaceutical Society of Great Britain                       |
| SHA    | Strategic Health Authority  |
| SHI    | Social health insurance   |
| SMC    | Scottish Medicines Consortium                                       |
| SPMS   | Specialist Personal Medical Services                                |
| SUKL   | Štátny ústav pre kontrolu liečiv / State Institute for Drug Control |
| SOGETI | SOGETI Luxembourg SA  |
| THE    | Total health expenditure  |
| TPE    | Total pharmaceutical expenditure                                    |
| UK     | United Kingdom  |
| VAT    | Value added tax   |
| VHI    | Voluntary health insurance  |
| WHO    | World Health Organisation   |
| WP     | Work package  |

## Introduction

The Pharmaceutical Health Information System (PHIS) project was a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The [PHIS project management](#) was a consortium of the project leader [Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute \(GÖG/ÖBIG\)](#) a research institute situated in Vienna, Austria, and four associated partners: the [Italian Medicines Agency](#) (AIFA), Italy, the [International Healthcare and Health Insurance Institute](#) - (IHII), Bulgaria, [SOGETI Luxembourg SA.](#), Luxembourg and the [State Institute for Drug Control](#) (SUKL), Slovakia. Further key stakeholders of the PHIS project management were the [PHIS advisory board](#) covering EU Commission services and agencies and international organisations, and the [PHIS network](#), which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project aimed at increasing the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This was achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

The PHIS project ran from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website <http://phis.goeg.at>.

## PHIS Monitoring

The aim of the work package “Monitoring” was to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States and beyond.

The country-specific information was compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sectors written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sectors (also part of the PHIS Pharma Profile)
- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (<http://phis.goeg.at>) and is constantly updated.

## **PHIS Pharma Profile**

The production of the country-specific PHIS Pharma Profiles was based on three steps:

### 1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sectors. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template was based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria<sup>2</sup>) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board members. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

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<sup>2</sup> IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – [www.zdrave.net](http://www.zdrave.net) – which is an online arena of information exchange and debates in health reaching at daily average 5,000 people acting in health and pharmaceutical system.

## 2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conversation and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRi report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

## 3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHII, Bulgaria (Work Package leader of “Monitoring”) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feedback on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.





# 1 Health care system

## 1.1 Demography

The population of the UK was 61.8 million people in mid 2009. The population is ageing - over the last 25 years, the percentage of the population aged 65 and over has increased from 15% in 1983 to 16% in 2009, an increase of 1.7 million people. Over the same period, the percentage aged 16 and under decreased from 21% to 19%. This trend is projected to continue. The fastest population increase has been in the number of those aged 85 and over - since 1984 numbers have more than doubled reaching 1.4 million in 2009. Average life expectancy is at the highest levels on record at 81.9 years for women and 77.7 for men.

Table 1.1: UK – Demographic indicators 2000, 2005–2009

| Demography                      | 2000       | 2005       | 2006       | 2007       | 2008       | 2009       |
|---------------------------------|------------|------------|------------|------------|------------|------------|
| Total population <sup>1</sup>   | 58,886,100 | 60,238,400 | 60,587,300 | 60,975,400 | 61,383,200 | 61,792,000 |
| Population aged 0-14            | 11,203,700 | 10,802,500 | 10,737,400 | 10,721,100 | 10,753,800 | 10,795,600 |
| Population aged 15-64           | 38,374,500 | 39,795,700 | 40,161,900 | 40,475,300 | 40,699,500 | 40,890,600 |
| Population aged > 64            | 9,307,800  | 9,640,300  | 9,687,800  | 9,779,000  | 9,929,900  | 10,105,800 |
| Total life expectancy at birth  |            |            |            |            |            |            |
| Females                         | 80.1       | 81.3       | 81.5       | 81.6       | 81.9       | n.a        |
| Males                           | 75.3       | 76.9       | 77.2       | 77.4       | 77.7       | n.a        |
| Total life expectancy at age 65 |            |            |            |            |            |            |
| Females                         | 18.8       | 19.7       | 19.9       | 20.0       | 20.2       | n.a        |
| Males                           | 15.7       | 16.9       | 17.2       | 17.4       | 17.6       | n.a.       |

Notes:

<sup>1</sup> Due to rounding, the population figures for the different age groups do not replicate the figure for the total population.

<sup>2</sup> Life expectancy estimates are available for 3-year periods i.e. the figures for 2000 pertain to the period 1999-2001 etc. The latest available figures are for 2007-09.

n.a. = not available

Sources:

Population: Office for National Statistics, Population estimates for UK, England and Wales, Scotland and Northern Ireland - current datasets. Retrieved from

<http://www.statistics.gov.uk/statbase/Product.asp?vlnk=15106>

Life expectancy at birth: Office for National Statistics, Interim Life Tables. Retrieved from

<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=14459> (29/9/2011)

## 1.2 Organisation

The National Health Service (NHS) was established on 5 July 1948 following publication of the National Health Service Act in 1946 to provide universal access to healthcare based on medical need rather than the ability to pay. It has grown to become the world's largest publicly funded health service responsible for the great majority of healthcare in the UK. Some 12.5% of the population also have private medical insurance, generally as an add-on to the NHS. The NHS is based on a common set of principles throughout the four constituent parts of the UK. Since devolution in 1999, responsibility for healthcare in Scotland, Wales and Northern Ireland has transferred to the respective devolved administration. While some differences have emerged in recent years, the systems remain similar in most respects and continue to be referred to as belonging to a single unified system.

The Secretary of State for Health leads the Department of Health (DH), which provides overall strategic leadership to the NHS and social care organisations in England and is responsible for setting direction and priorities; supporting delivery; leading health and well-being in government; and accounting to Parliament and the public. DH does not directly deliver health and social care services to the public. These services are delivered through working with a variety of delivery partners, principally the health and social care system, which includes the NHS, local government and arms length bodies<sup>3</sup>.

In England, 10 Strategic health authorities (SHAs) provide leadership, coordination and support across a regional area and manage the performance of NHS Trusts in their region. SHAs also work with partner organisations in local government, education and charitable and voluntary organisations and are directly accountable to the Department. There are currently 152 Primary Care Trusts (PCTs) in England, which are responsible for commissioning or providing primary medical care services for their populations and have a major role around commissioning hospital care and providing community care services. PCTs control 80% of the NHS budget. There are 167 NHS hospital trusts (also known as Acute Trusts) and 129 Foundation Trusts (a new type of NHS trust with greater autonomy and freedom set against a national framework of standards and inspection), which provide the overwhelming majority of hospital care in England. Further information on the NHS in England is available at [www.nhs.uk](http://www.nhs.uk). The devolved administrations of Scotland, Wales and Northern Ireland run their local NHS services separately and information is available at [www.show.scot.nhs.uk](http://www.show.scot.nhs.uk), [www.wales.nhs.uk](http://www.wales.nhs.uk) and [www.n-i.nhs.uk](http://www.n-i.nhs.uk) respectively.

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<sup>3</sup> Stand-alone national organisations sponsored by the Department of Health to help support and manage the health and social care system.

## 1.3 Funding

### 1.3.1 Health expenditure

Spending on health care in the 1990s was low by international comparisons. In 2000, the Government pledged to increase spending to the European average. By 2008, total health spending accounted for 8.7% of GDP in the UK, compared with an average of 9.0% across OECD countries (OECD Health Data 2010).

Expenditure on healthcare in the UK was £125.4 billion (€157.5 billion) in 2008, with the public share of expenditure being 82.6% and the private share being 17.4%.

Table 1.2: UK – Health expenditure 2000, 2005–2009

| Health expenditure in NCU = £ | 2000    | 2005      | 2006      | 2007      | 2008      | 2009      |
|-------------------------------|---------|-----------|-----------|-----------|-----------|-----------|
| GDP                           | 976,533 | 1,254,058 | 1,328,363 | 1,404,845 | 1,445,580 | 1,392,705 |
| THE <sup>1</sup>              | 68.8    | 103.5     | 112.2     | 118.0     | 125.4     | n.a.      |
| - thereof public HE           | 54.5    | 84.8      | 91.8      | 96.7      | 103.6     | n.a.      |
| - thereof private HE          | 14.3    | 18.8      | 20.3      | 21.3      | 21.8      | n.a.      |
| HE in the out-patient sector  | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| - thereof public              | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| - thereof private             | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| HE in the in-patient sector   | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| - thereof public              | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| - thereof private             | n.a.    | n.a.      | n.a.      | n.a.      | n.a.      | n.a.      |
| Exchange rate (NCU per €)     | 0.61    | 0.68      | 0.68      | 0.68      | 0.79      | 0.89      |

GDP = gross domestic product, HE= health expenditure, n.a. = not available, NCU = national currency unit, THE = total health expenditure

Note:

<sup>1</sup> Estimates of annual expenditure on healthcare in the UK have been revised in 2010 so they might differ from the figures in previous reports.

Sources:

GDP: Office for National Statistics, 2010, United Kingdom National Accounts: The Blue Book, 2010 edition. Retrieved from <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=1143>

Health Expenditure: UK Centre for the Measurement of Government Activity, Office for National Statistics (April 2010), "Expenditure on Health Care in the UK". Retrieved from <http://www.statistics.gov.uk/cci/article.asp?id=2410>

Exchange Rate: HM Revenue & Customs, Foreign exchange rates: European Union. Retrieved from <http://www.hmrc.gov.uk/exrate/european-union.htm>

### **1.3.2 Sources of funds**

The NHS is funded centrally, mainly through general taxation including a proportion from National Insurance contributions with a small element (6%) coming from charges and receipts, including sales of surplus NHS land and proceeds from income generation schemes.

The NHS remains free at the point of use with relatively few exceptions (primary care optical and dental services and prescription charges for out-patient prescriptions where co-payments apply although there are exemptions on grounds of age, income, medical condition etc).

### **1.3.3 Out-patient care**

In England, PCTs are responsible for commissioning or providing primary medical care services for their population. General Practitioners (GPs) provide most services under the General Medical Services (GMS) contract, under which PCTs contract with GP practices to provide primary medical services for their population. As well as the provision of services, GMS practices are able to participate in the Quality and Outcomes Framework (QOF), which is designed to reward practices for the quality of care provided. Care is also provided through the Personal Medical Services (PMS) contract, under which PMS practices deliver a broadly similar range of services to GMS practices but enables, for example, GPs to be employed directly by PCTs, and can support an enhanced role for nurses or other health professionals in out-patient care. Specialist PMS (SPMS) has been developed as an additional, local flexibility to help to address unmet needs amongst client groups that traditionally have experienced difficulties in accessing out-patient medical services e.g. the homeless, prisoners, drug users. SPMS does not require the involvement of a GP or the provision of essential out-patient care services but must be provided by an NHS provider.

### **1.3.4 In-patient care**

The overwhelming majority of hospital care in the UK is provided by the NHS, which is funded centrally mainly through general taxation. In England, the Department of Health allocates funding to PCTs based on the relative needs of their population. A weighted capitation formula determines each PCT's target share of available resources, to enable them to commission similar levels of health services for populations in similar need. PCTs individually then calculate how much money is needed to cover health services for their population.

In England, the Payment by Results (PbR) tariff sets the price that PCTs are expected to pay hospital trusts (or any other providers) out of their unified allocation for a given episode of care. The tariff price for each treatment includes the cost of the medicines used, provision, monitoring of the condition and other costs around the treatment.

There are no out-of-pocket payments for in-patient treatment in the NHS. NHS patients who wish to buy additional private care (e.g. buy medicines privately that are not recommended for use by the NHS) can do so as long as the private care can be delivered separately from

NHS care. Guidance makes clear that patients should not be charged for NHS care and that the NHS should not subsidise private care.

## 1.4 Access to health care

### 1.4.1 Health care professions

The number of doctors in the UK increased by 37% between 2000 and 2008 and the number of GPs by 23% as the Government pledged to increase spending to the European average. The increase in the number of doctors is higher than the increase in the population - 2 doctors per 1,000 inhabitants in 2000 increased to 2.6 doctors per 1,000 inhabitants in 2008.

The Royal Pharmaceutical Society of Great Britain (RPSGB) Pharmacy Workforce Census 2008 reported that community pharmacy accounts for the largest proportion of pharmacists (71%) with 21% working in hospitals and 7% in out-patient care<sup>4</sup>. 11% of pharmacists work in more than one sector, mostly combining work in community pharmacy with work in the hospital sector or the out-patient sector.

Table 1.3: UK – Doctors and pharmacists development 2000, 2005–2009

| Health professionals                      | 2000    | 2005    | 2006    | 2007    | 2008    | 2009 |
|---|---------|---------|---------|---------|---------|------|
| Total no. of doctors <sup>1</sup>         | 117,616 | 147,154 | 145,811 | 154,460 | 160,802 | n.a. |
| - of which GPs <sup>2</sup>               | 30,252  | 35,302  | 35,369  | 35,855  | 37,213  | n.a. |
| - of which work in the out-patient sector | n.a.    | n.a.    | n.a.    | n.a.    | n.a.    | n.a. |
| - of which work in the in-patient sector  | n.a.    | n.a.    | n.a.    | n.a.    | n.a.    | n.a. |
| No. of pharmacists                        | n.a.    | n.a.    | 48,692  | 49,851  | 50,753  | n.a. |
| - of which work in community pharmacies   | n.a.    | n.a.    | n.a.    | n.a.    | n.a.    | n.a. |
| - of which work in hospital pharmacies    | n.a.    | n.a.    | n.a.    | n.a.    | n.a.    | n.a. |

n.a. = not available

#### Notes

<sup>1</sup> The figures shown are the sum of headcount figures for the four countries in the UK.

England: Figures for all NHS Hospital and Community Health Services and GPs excluding GP retainers (practitioners who provide service sessions in general practice with a maximum of 4 sessions of approximately half a day each week).

Scotland: Figures are for all medical staff (excluding medical support) which includes medical staff in the Hospital, Community and Public Health Services of the NHS and general medical services.

Wales: Figures for hospital and medical specialists, GPs and General Dental Practitioners.

<sup>4</sup> As explained in 3.3.1 prescribing advisers, mainly pharmacists, are employed at various levels in the NHS (SHAs and PCTs), having a common aim to encourage and secure rational and cost-effective prescribing.

Northern Ireland: Figures include all grades of Health Service doctor; wholly private sectors doctors and dentists are not included.

<sup>2</sup> Sum of headcount figures for the four countries in the UK.

England: Figures for General Practice doctors excluding retainers (practioners who provide service sessions in general practice with a maximum of 4 sessions of approximately half a day each week).

Scotland: Figures for all GPs.

Wales: Figures exclude GP retainers and locums (a person who stands in temporarily for someone else of the same profession, especially a GP).

Northern Ireland: Figures include unrestricted Principals only, that is, practitioners whose list of patients is not limited to any particular group of persons and who provide the full range of general medical services.

Sources:

Number of doctors:

England: NHS Information Centre (25 March 2009). NHS staff 1998-2008 (Medical and Dental). Retrieved from <http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-medical-and-dental>

Scotland: NHS Scotland Workforce Information, Medical and Dental. Retrieved from <http://www.isdscotland.org/isd/5345.html>

Wales: Welsh Assembly Government – Statswales, [001278] Hospital Medical and Dental staff (organisation, grade, specialty). Retrieved from <http://www.statswales.wales.gov.uk/ReportFolders/reportFolders.aspx> (Folder pathway: Public Reports/Health and Care/Staffing/Medical and Dental)

Northern Ireland: Medical Doctors, Hospital Dentists – Human Resource Management System; GPs and GDPs – Business Services Organisation.

Number of GPs:

England: NHS Information Centre (25 March 2009). NHS staff 1998-2008 (Medical and Dental). Retrieved from <http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers/nhs-staff-1998--2008-medical-and-dental>

Scotland: NHS Scotland Workforce Information, Medical and Dental. Retrieved from <http://www.isdscotland.org/isd/5345.html>

Wales: Welsh Assembly Government – Statswales, [001617] GP Headcount (gender, age group). Retrieved from <http://www.statswales.wales.gov.uk/ReportFolders/reportFolders.aspx> (Folder pathway: Public Reports/Health and Care/General Medical Services)

Northern Ireland: GPs and GDPs – Business Services Organisation.

No. of pharmacists:

Royal Pharmaceutical Society of Great Britain (July 2009). Pharmacy Workforce Census 2008: Main findings. Retrieved from <http://www.rpsgb.org.uk/informationresources/downloadsocietypublications> (under the heading: Research - Reports: RPSGB Research Strategy)

Pharmaceutical Society of Northern Ireland (April 2010).

## 1.4.2 Out-patient care

The NHS is divided into two sections – primary care (out-patient) and secondary care (in-patient). 'Primary care' refers to services provided by GP practices, GP-led Health Centres,

NHS walk-in centres, dental practices, community pharmacies and high street optometrists etc and is part of a wide range of community-based services (i.e. services not based in hospitals). Around 90% of people's contact with the NHS is with these community-based services.

Patients have the right to be registered with the GP surgery of their choice, as long as they live within its catchment area and have the right to change their doctor without giving a reason. However, a public consultation, which closed in May 2010, is seeking views on new proposals that give patients a much greater choice of GP practice. It sets out the different options for organising healthcare for patients; and the potential implications of their choices if the current system of GP practice boundaries is removed. GPs are employed by PCTs and act as gatekeepers arranging access to hospital treatment, apart from emergency care.

### **1.4.3 In-patient care**

The overwhelming majority of hospital care in the UK is provided by the NHS. The NHS is a devolved area of responsibility, which means that Scotland, Wales and Northern Ireland run hospital services independently of the English NHS.

There is no general technical definition of a hospital but there is a variety of subtypes, each of which have a different status in terms of autonomy, strategic focus and funding. [Similar to the OECD definitions] the NHS (in England) has a total of 1,600 hospitals (general, mental health, specialist care and foundation). Most of the hospitals in England are run by one of 167 NHS hospital (or acute) trusts or 60 mental health NHS trusts. These trusts are responsible for ensuring that hospital funding is efficiently deployed to meet demand. Some acute trusts are regional or national centres for more specialised care. Others are attached to universities and help to train health professionals. Acute trusts can also provide services in the community, for example through health centres, clinics or in people's homes.

Some of these acute and mental health trusts are Foundation Trusts. There are 129 Foundation Trusts in England. These are a newer type of NHS trust with greater financial and operational freedom to manage hospitals set against a national framework of standards and inspection. The independent sector also provides services funded through the NHS and free to patients. PCTs agree delivery of NHS funded services with providers using NHS contracts.

Since the introduction of free choice in April 2008, patients can, in most cases, choose the hospital that best suits their needs, except for mental health and maternity services.

Table 1.4: UK – In-patient care 2000, 2005–2009

| In-patient care                                     | 2000    | 2005    | 2006    | 2007    | 2008  | 2009 |
|---|---------|---------|---------|---------|-------|------|
| No. of hospitals                                    | n.a.    | n.a.    | n.a.    | n.a.    | n.a.  | n.a. |
| <i>Classified according to ownership</i>            |         |         |         |         |       |      |
| – thereof public hospitals                          | n.a.    | n.a.    | n.a.    | n.a.    | n.a.  | n.a. |
| – thereof private hospitals                         | 225     | 213     | 211     | 210     | 210   | n.a. |
| <i>Classified according to subtypes<sup>1</sup></i> |         |         |         |         |       |      |
| – thereof general hospitals                         | n.a.    | n.a.    | n.a.    | n.a.    | n.a.  | n.a. |
| No. of acute care beds                              | 188,059 | 182,885 | 176,412 | 170,619 | n.a.  | n.a. |
| – thereof in the public sector                      | 178,079 | 173,307 | 166,925 | 161,030 | n.a.  | n.a. |
| – thereof in the private sector                     | 9,980   | 9,578   | 9,487   | 9,589   | 9,489 | n.a. |
| Average length of stay <sup>1</sup>                 | 9.9     | 9.0     | 8.7     | 8.1     | n.a.  | n.a. |
| No. of hospital pharmacies                          | n.a.    | n.a.    | n.a.    | n.a.    | n.a.  | n.a. |

n.a. = not available, No. = number

<sup>1</sup> Calculated as the average of the average length of stay in hospital for Northern Ireland, Scotland, Wales and England.

Sources:

Private Hospitals and Number of acute care beds in the private sector: Laing's Healthcare Market Review 2008-09, Laing & Buisson (data on Independent acute medical/surgical hospitals, UK).

Number of acute care beds in the public sector and average length of stay: OECD HEALTH DATA 2009, November 09.

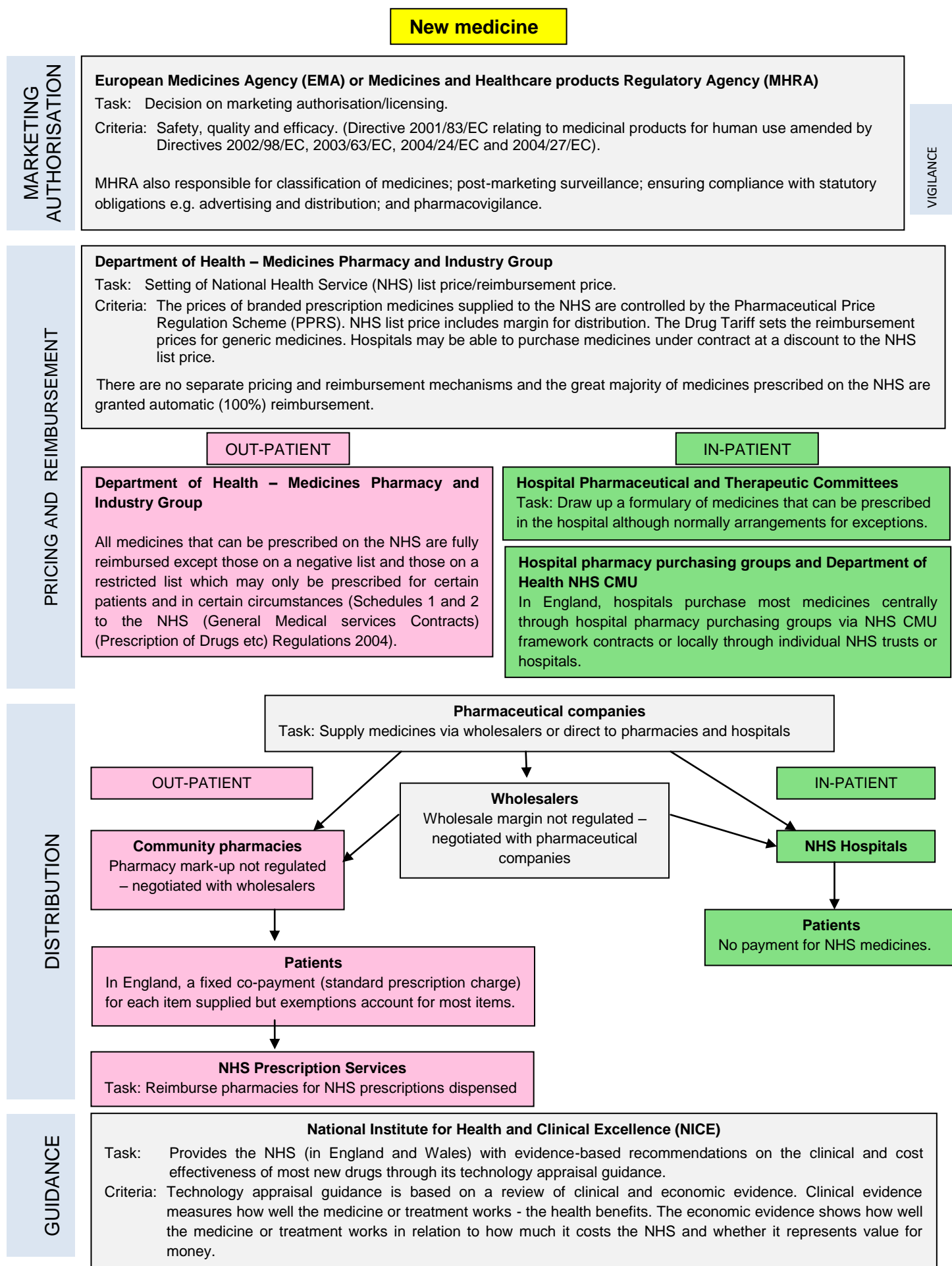


## **2      Pharmaceutical system**

### **2.1    Organisation**

The NHS is divided into primary (or community) care (out-patient) and secondary (or hospital) care (in-patient) sectors. The process of supplying medicines to patients differs between the two sectors.

Figure 2.1: UK – Flowchart of the pharmaceutical system 2010



## 2.2 Regulatory framework

Table 2.1: UK – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2010

| Fields               | Legal basis   | Coverage                   | Authorities   | Activity / responsibility in the pharmaceutical system  | Actors i  |
|----------------------|---|----------------------------|---|---|---|
| Market authorisation | The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (SI 1994/3144)<br><a href="http://tiny.cc/evfbi">http://tiny.cc/evfbi</a> | In- and out-patient sector | Medicines and Health-care products Regulatory Agency (MHRA) | Responsible for ensuring that medicines and medical devices work, and are acceptably safe.<br>Responsible for market authorisation/licensing; reclassification. | Pharmaceutical companies  |
| Pricing / Purchasing |   | In- and out-patient sector | Department of Health (DH)                                   | Responsible for overall pharmaceutical policy including pricing and reimbursement of NHS prescription medicines.  | Pharmaceutical companies<br>Association of the British Pharmaceutical Industry (ABPI)                         |
| Reimbursement        |   | In- and out-patient sector | Department of Health (DH)                                   | Responsible for overall pharmaceutical policy including pricing and reimbursement of NHS prescription medicines.  | Pharmaceutical companies<br>NHS Prescription Services<br>Pharmaceutical Services Negotiating Committee (PSNC) |

PHIS Pharma Profile 2010  
United Kingdom

| Fields       | Legal basis   | Coverage                   | Authorities   | Activity / responsibility in the pharmaceutical system   | Actors i  |
|--------------|---|----------------------------|---|--|---|
| Promotion    | Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994 (SIs 1994/1932 and 1994/1933 as amended).<br><a href="http://tiny.cc/b5gmm">http://tiny.cc/b5gmm</a><br><a href="http://tiny.cc/t1qz7">http://tiny.cc/t1qz7</a> | In- and out-patient sector | Medicines and Health-care products Regulatory Agency (MHRA) | Responsible for ensuring all promotion of medicines complies with the legal requirements.  | Pharmaceutical companies  |
| Distribution | Medicines Act 1968 as amended<br><a href="http://tiny.cc/w4mp6">http://tiny.cc/w4mp6</a>  | In- and out-patient sector | Medicines and Health-care products Regulatory Agency (MHRA) | Responsible for inspecting pharmaceutical companies and their operations to verify their compliance with the EU GDP and GMP guidelines | Pharmaceutical companies<br>Wholesalers<br>Community pharmacies<br>British Association of Pharmaceutical Wholesalers (BAPW) |
| Vigilance    | Medicines Act 1968 as amended<br><a href="http://tiny.cc/w4mp6">http://tiny.cc/w4mp6</a>  | In- and out-patient sector | Medicines and Health-care products Regulatory Agency (MHRA) | Responsible for vigilance and security concerns.   | Pharmaceutical companies  |

Source: DH,MPIG/MHRA

A medicine must have a marketing authorisation before it can be marketed. Medicines are licensed for use by the European Medicines Agency (EMA) or the UK Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health.

The NHS list price at which medicines are reimbursed on the NHS is agreed with the Department of Health (Medicines, Pricing and Industry Group).

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE produces guidance on public health, health technologies and clinical practice for the NHS in England and Wales. The Scottish Medicines Consortium (SMC) provide advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland regarding all new licensed medicines, new formulations of existing medicines and new indications for established products (licensed from 2002).

NHS Prescription Services reimburse pharmacies for prescriptions dispensed in the community. Hospitals purchase medicines locally against framework agreements awarded by the NHS Commercial Medicines Unit (NHS CMU), formerly NHS Purchasing and Supply Agency (NHS PASA) at either national or regional levels.

The National Prescribing Centre (NPC) is an NHS organisation, which promotes and supports high quality cost-effective prescribing and medicines management across the NHS.

## 2.3 Statistics

### 2.3.1 Availability of medicines

#### 2.3.1.1 Market authorisation

Table 2.2: UK – Number of medicines 2000, 2005–2010

| Medicines                    | 2000   | 2005   | 2006   | 2007   | 2008   | 2009   | 2010   | Method of counting |
|------------------------------|--------|--------|--------|--------|--------|--------|--------|--------------------|
| Authorised                   | 19,000 | 29,600 | 29,800 | 30,600 | 29,400 | 23,300 | 26,200 | -                  |
| On the market <sup>1</sup>   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | -                  |
| POM                          | 9,500  | 12,000 | 11,900 | 11,600 | 10,600 | 10,700 | 10,800 | -                  |
| Reimbursable                 | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | -                  |
| Generics <sup>2</sup>        | 4,600  | 5,800  | 5,500  | 5,400  | 5,200  | 4,700  | 4,400  | -                  |
| Parallel traded <sup>3</sup> | 5,200  | 13,200 | 13,800 | 15,300 | 15,800 | 13,900 | 11,700 | -                  |
| Hospital-only <sup>4</sup>   | 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. = not available, POM = prescription-only medicines

Data as of 1 January

- 1 Some medicines will be authorised but not marketed - no information is collected centrally on the number of medicines on the market.
- 2 Generics figure includes POMs and OTCs.
- 3 Many marketing authorisations for parallel traded medicines are not active.
- 4 No information is available on hospital only medicines as there is no such legal definition in the UK.

Source: MHRA

The numbers in table 2.2 are for marketing authorisations granted by the MHRA and exclude centralised EMA licences. Marketing authorisations include different pharmaceutical forms and different strengths but do not include different pack sizes. The total authorised represent the number of UK marketing authorisations including parallel imported products and excluding homeopathic or traditional herbal registrations.

The Medicines Act 1968 and Council Directive 2001/83/EEC control the sale and supply of medicines. The legal status of medicines is part of the marketing authorisation (MA) and products may be available either on a prescription (prescription only medicine (POM)), or available in a pharmacy without prescription, under the supervision of a pharmacist (P) or on general sale (GSL). There is no legal status of hospital only medicine. Prescriptions can be issued by doctors, dentists, nurse independent prescribers, pharmacist independent prescribers and supplementary prescribers.

The Government encourages wider availability of medicines as soon as there is adequate evidence of safety in use. New medicines are usually authorised for use as a POM. After some years' use, if adverse reactions to the medicine are few and minor, it is possible that the medicine may be safely used without a doctor's supervision. If there is sufficient evidence of safety, a medicine may be reclassified for sale or supply as a P medicine. Pharmacy medicines which have been safely used for several years may be suitable for general sale and may be reclassified as GSL.

Applications to reclassify medicines are evaluated by the MHRA, with advice from a suitable expert committee (currently the Commission on Human Medicines (CHM)), as necessary. Where it is considered that the proposed reclassification may safely be made, wide public consultation, via the MHRA website takes place. Interested organisations will be notified when a new consultation has been added to the website. Responses to the consultation are evaluated by the MHRA and advice is sought from the CHM only if a new safety issue is raised during consultation. Following a successful reclassification proposal, the change of legal status will be conferred on the product that is the subject of the application for switching.

The UK Parallel Import Licensing Scheme allows medicinal products authorised in other EU Member States to be marketed in the UK provided the imported products have no therapeutic difference from the equivalent UK products. The granting of licences in the EU for such a purpose began in 1984. The MHRA liaises closely with the relevant competent authorities to obtain the necessary information to ensure that only those products which fully comply with the stringent criteria for parallel import are granted a licence.

### 2.3.1.2 Access to medicines

No data is collected on the time between marketing authorisation and the company launching the product on the market. However, there is no regulatory delay as a result of pricing and reimbursement negotiations as under the Pharmaceutical Price Regulation Scheme (PPRS), companies have freedom of pricing when launching major new branded medicines i.e. new active substances. So once a company has obtained marketing authorisation from the EMA/MHRA and pricing approval from DH, it is free to launch the medicine in the UK and it will be granted automatic full reimbursement on the NHS.

Table 2.3: UK – Number of new molecular entities, 1999-2009

| New molecular entities                        | 1999 – 2009 | 2004 – 2009 |
|---|-------------|-------------|
| Number of new molecular entities <sup>1</sup> | 110         | 27          |

<sup>1</sup>The numbers in the table are NASs authorised by the MHRA only and exclude those authorised by the EMA.

Source: MHRA

The MHRA does not classify medicines as new molecular entities but counts the number of 'new active substances' (NAS), which include vaccines and different salts of known chemical

entities. The vast majority of NASs are now authorised via the European centralised route and this is the main reason for the low number and apparent fall in numbers.

### 2.3.2 Prescriptions

The annual number of prescription items (in the community) in the UK has been increasing at an average of 5% a year from 2000 to 2008: 682 million items were dispensed in 2000 and 1 billion items were dispensed in 2008, an increase of 50%. Between 2000 and 2008, the value per item decreased by around 1% and the number of items per head increased from 12 in 2000 to 17 in 2008.

Table 2.4: UK – Annual prescriptions 2000, 2005–2009

| Prescriptions  | 2000  | 2005  | 2006   | 2007   | 2008   | 2009 |
|--|-------|-------|--------|--------|--------|------|
| No. of prescriptions (in volume: millions of items) <sup>1</sup> | 682   | 882   | 919    | 971    | 1,025  | n.a. |
| Prescriptions in value (in GBP; million) <sup>2</sup>            | 6,879 | 9,702 | 10,029 | 10,235 | 10,206 | n.a. |

n.a. = not available

Prescription in volume = number of items prescribed.

Prescription in value = public expenditure of prescribed medicines.

Notes:

1. Volume for annual prescriptions is provided by the number of items (in millions).
2. The figures refer to the Net Ingredient Cost (NIC) – the cost of the drug before discounts and it does not include any dispensing costs or fees or any income adjustment.

Sources:

England: NHS Information Centre (29 July 2009). Prescriptions dispensed in the community – Statistics for 1998 to 2008: England. Retrieved from <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescriptions-dispensed-in-the-community-statistics-for-1998-to-2008-england>

Scotland: Information Services Division/ Healthcare Information Group/ NHS National Services Scotland, Prescribing and Dispensing Information - Volume and Cost Data. Retrieved from [http://www.isdscotland.org/isd/information-and-statistics.jsp?pContentID=2225&p\\_applic=CCC&p\\_service=Content.show&](http://www.isdscotland.org/isd/information-and-statistics.jsp?pContentID=2225&p_applic=CCC&p_service=Content.show&)

Wales: Welsh Assembly Government (25 March 2009), Statistical Release 43/2009 – Prescriptions dispensed in the community in Wales, 2000 to 2008. Retrieved from <http://wales.gov.uk/topics/statistics/theme/health/primary-care/prescribing/?lang=en>

Northern Ireland: Health and Social Care Business Services Organisation, Prescription Cost Analysis. Retrieved from <http://www.centalservicesagency.com/display/statistics>

### 2.3.3 Sales

Information is available on NHS expenditure on medicines rather than sales. Total NHS expenditure on medicines in the UK is estimated at £ 14.8 billion (€ 18.6 billion) in 2008, an increase of 50% since 2000.



Expenditure figures in the table below are for England only and are the net ingredient cost (NIC) of the medicine i.e. the basic price of a medicine excluding VAT in England as listed in the national Drug Tariff or standard price lists.

*Table 2.5: England – Pharmaceutical sales 2000, 2005–2009*

| Sales                              | 2000 | 2005   | 2006   | 2007   | 2008   | 2009   |
|------------------------------------|------|--------|--------|--------|--------|--------|
| Total expenditure                  | n.a. | 10,276 | 10,696 | 11,222 | 11,626 | 12,278 |
| – out-patient sector               | n.a. | 7,752  | 7,998  | 8,169  | 8,109  | 8,318  |
| – hospitals                        | n.a. | 2,378  | 2,542  | 2,890  | 3,346  | 3,789  |
| Sales of parallel traded medicines | n.a. | n/a    | n/a    | n/a    | n/a    | n/a    |

n.a = not available

Note: Data for England only; for pharmaceutical expenditure data for the EU; please consult Table 2.13 in section 2.5.1

Source: DH/NHS Information Centre

Expenditure on medicines in England in 2009<sup>5</sup> was £ 12.3 billion (€ 13.8 billion) of which out-patient care accounted for £ 8.3 billion (€ 9.3 billion), 68% of the total costs, and hospitals some £ 3.8 billion (€ 4.3 billion), 31% of the total. The balance (1%) is hospital prescribing but dispensed in the out-patient sector. Overall, the cost of medicines rose by 5.6% in 2009 but by 13.2% in hospitals.

Historically, the UK has been a net importer of medicines from the EU but recent shifts in the exchange rate, which have weakened Sterling and strengthened the Euro, have resulted in parallel exports becoming a significant feature of the UK market. IMS estimate that parallel exports from the UK are worth 4% of the NHS medicines bill. It is important to highlight that parallel export is not a new phenomenon, and some level of export has been a feature of the UK medicines market. Equally, parallel imports from the EU have by no means ceased since the end of 2008, and – in value terms – imports and exports remain largely balanced (July 2010).

### 2.3.4 Consumption

The NHS Information Centre is England's central authoritative source of health and social care information and publishes data on prescribing of medicines in the community and in hospitals. Prescriptions dispensed in the community, England – Statistics for 1999 to 2009<sup>6</sup> includes data on the number of prescriptions dispensed - 886 million in 2009, an increase of

<sup>5</sup> Hospital Prescribing, England 2009. Available at [http://www.ic.nhs.uk/webfiles/publications/007\\_Primary\\_Care/hospre09/Hospital\\_Prescribing\\_2009.pdf](http://www.ic.nhs.uk/webfiles/publications/007_Primary_Care/hospre09/Hospital_Prescribing_2009.pdf)

<sup>6</sup> <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescriptions-dispensed-in-the-community-england--statistics-for-1999-to-2009>

5.2% (43.5 million items) over 2008 and up from 551.8 million in 2000, an increase of 60.5%. Prescription Cost Analysis provides details on the number of items and net ingredient cost of all prescriptions dispensed in the community in England. Further information is available at <http://www.ic.nhs.uk/>

Consumption data is not held by DDD (Defined Daily Doses) nor published for the in-patient sector.

### **2.3.5 Generics**

The figures in the table below relate to reimbursement in the out-patient sector only as data is not collected centrally for in-patient care. The volume of the generics market in the out-patient sector in the UK increased by around 25% between 2005 and 2008. England accounts for around 80% of the generic prescriptions items dispensed in the UK, Scotland accounts for around 10%, Wales for 6% and Northern Ireland for around 3%. Of the four countries, Scotland has the highest generic market share in 2008 (80%), followed by England and Wales with similar generic market shares (around 65%) and then by Northern Ireland (56%).

The value of the generics market in the out-patient sector in the UK has not changed significantly between 2005 and 2008 (a 1% increase). England accounts for around 70% of the expenditure on generic prescriptions dispensed in the UK, Scotland accounts for around 23%, Wales for 5% and Northern Ireland for around 2%. Of the four countries, Scotland has the highest generic market expenditure share although it has decreased over the period – from 71% in 2005 to 67% in 2008. England and Wales follow with similar generic market expenditure shares (around 25%) and not showing significant differences from 2005 to 2008. Northern Ireland has the lowest generic market expenditure share – 15% in 2005 and 17% in 2008.

Table 2.6: UK – Development of the generic shares 2000, 2005–2009

| Generic share   | Volume <sup>1</sup> |      | Value <sup>2</sup> |      |
|---|---------------------|------|--------------------|------|
|   | 2005                | 2008 | 2005               | 2008 |
| Shares in % of total market (in-patient/ out-patient) | n.a.                | n.a. | n.a.               | n.a. |
| Shares in % of total out-patient market               | n.a.                | n.a. | n.a.               | n.a. |
| Shares in % of out-patient reimbursement market       | n.a.                | n.a. | n.a.               | n.a. |
| England   | 59%                 | 65%  | 26%                | 26%  |
| Scotland  | 78%                 | 80%  | 71%                | 67%  |
| Wales   | 59%                 | 66%  | 26%                | 25%  |
| Northern Ireland                                      | 45%                 | 56%  | 15%                | 17%  |
| Shares in % of out-patient off-patient market         | n.a.                | n.a. | n.a.               | n.a. |
| Shares in % of the in-patient market                  | n.a.                | n.a. | n.a.               | n.a. |

n.a. = not available

<sup>1</sup> Expressed in number of prescriptions

<sup>2</sup> Expressed in expenditure

Notes

**England:**

- Generic prescriptions include the number of items prescribed and dispensed generically (class 1); total prescriptions include number of items from classes 1 and 2 (medicines prescribed generically but dispensed as proprietary because a generic is not available). Classes 3 (Medicines prescribed and dispensed by proprietary brand name) and 4 (dressings and appliances) are not included.
- Expenditure is reported using the Net Ingredient Cost (NIC), which refers to the cost of the drug before discounts and does not include any dispensing costs or fees. Expenditure for generics includes the NIC for class 1 (see note 1); total pharmaceutical expenditure includes the NIC for classes 1 and 2; classes 3 and 4 are not included (see note 1).

**Scotland:**

- Generic prescriptions include the number of items prescribed and dispensed generically (class 1); total prescriptions include the number of items from classes 1, 2 (medicines prescribed generically and dispensed as proprietary) and 3 (medicines prescribed and dispensed by proprietary brand name).
- Expenditure is reported using the Gross Ingredient Cost (GIG), which refers to the cost of medicines and appliances before deduction of any discount. Expenditure for generics includes the GIG for class 1; total pharmaceutical expenditure includes the NIC for classes 1, 2 and 3 (see note 1).

**Wales:**

- Generic prescriptions include the number of items prescribed and dispensed generically (class 1). Total prescriptions include number of items from classes 1, 2 (items prescribed generically but dispensed as proprietary because a generic is not available) and 3 (branded medicines). Classes 4 (dressing and appliances) and 5 (Non proprietary drug only made by an individual manufacturer/wholesaler) are not included.

2. Expenditure is reported using the Net Ingredient Cost (NIC), which refers to the cost of the drug before discounts and does not include and dispensing costs or fees. Expenditure for generics includes NIC for class 1. Total expenditure includes NIC for class 1, 2 and 3; classes 4 and 5 are not included (see note 1).

**Northern Ireland:**

1. Generic prescriptions include the number of items dispensed generically; total prescriptions include number of items dispensed generically and as proprietary. Unclassified items, Dressings/Appliances and Elastic Hosiery are not included.
2. Expenditure is reported using the Net Ingredient Cost (NIC), which refers to the cost of the drug before discounts and does not include any dispensing costs or fees. Expenditure for generics includes the NIC for items dispensed generically; total pharmaceutical expenditure includes NIC for items dispensed generically and as proprietary. NIC for Unclassified items, Dressings/Appliances and Elastic Hosiery is not included.

Sources:

England: NHS Information Centre (29 July 2009). Prescriptions Dispensed in the Community, Statistics dispensed in the community for 1998 to 2008: England. Retrieved from <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescriptions-dispensed-in-the-community-statistics-for-1998-to-2008-england>

Scotland: Prescribing Information System – Information Services Division Scotland and PRISMS.

Wales: Health Solutions Wales (Prescribing Services Unit).

Northern Ireland: Health and Social Care Business Services Organisation of Northern Ireland - Information Research Unit (<http://www.hscbusiness.hscni.net/>).

Doctors are encouraged, but not obliged, to write prescriptions by their 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 is accepted by the majority of doctors and generic prescribing rates are high (82.8% in England (out-patient care) in 2009). Generic substitution is not allowed (out-patient area) in the UK (for further information on generic policies consult section 3.3.2).

### **2.3.6 Top 10 medicines**

The top ten medicines in the following tables are for the out- and in-patient sectors in England<sup>7</sup>. In terms of consumption in the out-patient sector in the UK, England's top ten medicines account for 82%, Scotland for 9%, Wales for 7% and Northern Ireland for 2%. In terms of expenditure, England accounts for 80%, Scotland for 10%, Wales for 6% and Northern Ireland for 4%.

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<sup>7</sup> Figures for primary care in Scotland, Wales and Northern Ireland are also available but not displayed.

Table 2.7: England – Top 10 medicines in value and volume in the out-patient sector, 2009

| Position | Top medicines used in the out-patient sector, indicated by active ingredient, ranked with regard to <u>consumption</u> | Position | Top medicines used in the out-patient sector, indicated by active ingredient ranked with regard to <u>expenditure</u> |
|----------|--|----------|---|
| 1        | Simvastatin  | 1        | Fluticasone Propionate (Inh)  |
| 2        | Aspirin  | 2        | Atorvastatin  |
| 3        | Levothyroxine Sodium   | 3        | Enteral Nutrition   |
| 4        | Bendroflumethiazide  | 4        | Clopidogrel   |
| 5        | Salbutamol   | 5        | Glucose Blood Testing Reagents  |
| 6        | Ramipril   | 6        | Budesonide  |
| 7        | Paracetamol  | 7        | Olanzapine  |
| 8        | Omeprazole   | 8        | Tiotropium  |
| 9        | Amlodipine   | 9        | Beclometasone Dipropionate  |
| 10       | Atenolol   | 10       | Venlafaxine   |

Source: NHS Information Centre (21 April 2009), *Prescription Cost Analysis 2008*. Retrieved from <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-2008>

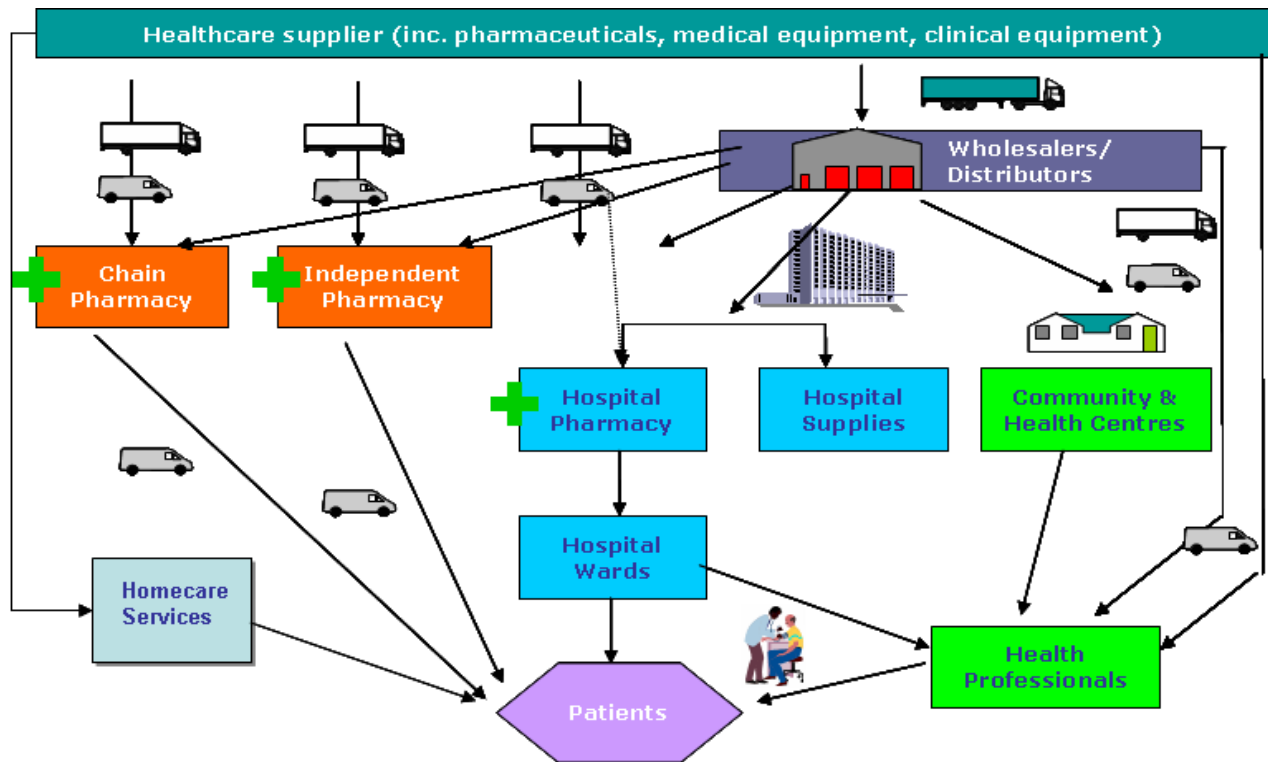
Table 2.8: England – Top 10 medicines in value and volume in the in-patient sector, 2009

| Position | Top medicines used in the in-patient sector, indicated by active ingredient, ranked with regard to <u>consumption</u> | Position | Top medicines used in the in-patient sector, indicated by active ingredient ranked with regard to <u>expenditure</u> |
|----------|---|----------|--|
| 1        | Paracetamol   | 1        | Ranibizumab  |
| 2        | Co-codamol  | 2        | Etanercept   |
| 3        | Prednisolone  | 3        | Adalimumab   |
| 4        | Diclofenac sodium   | 4        | Infliximab   |
| 5        | Codeine   | 5        | Immunoglobulin normal human  |
| 6        | Aspirin   | 6        | Rituximab  |
| 7        | Tramadol  | 7        | Trastuzumab  |
| 8        | Ibuprofen   | 8        | Tenofovir/emtricitabine/efavirenz  |
| 9        | Omeprazole  | 9        | Tenofovir/emtricitabine  |
| 10       | Flucloxacillin  | 10       | Imatinib   |

Source: DH CMU: PharmEx database

## 2.4 Market players

The flow-chart illustrates the common delivery chain for medicines for the out-patient and the in-patient sectors in the UK.



### 2.4.1 Industry

The pharmaceutical industry in the UK comprises:

- The research based sector, which is largely represented by the Association of British Pharmaceutical Industries (ABPI). The ABPI represents most pharmaceutical companies active in the UK, and it claims that its 90+ member companies research, develop, manufacture and supply more than 80% of the medicines prescribed through the NHS. It represents the industry in discussions and formal consultations with government on policy matters pertinent to the industry including negotiations on the PPRS. The BioIndustry Association (BIA) is the trade association for innovative enterprises in the UK's bioscience sector. The Ethical Medicines Industry Group (EMIG) is the trade association in the UK that represents the interests of small to medium-sized pharmaceutical companies. It claims to have 100 members (some are also ABPI members).
- The generics sector where the British Generics Manufacturers Association (BGMA) represents the interests of UK-based manufacturers and suppliers of generic medicines. The BGMA is made up of about 20 manufacturers, who between them account for more than 85% of the UK generic market by volume.

The UK is home to a world-class pharmaceutical industry, which makes significant contributions not only to developing new medicines, and to the economy, but also to the UK research capacity within and beyond the NHS. The global pharmaceutical industry's presence within the UK is a major aspect of our economy, particularly in the current economic climate. Highlights include:

- The UK pharmaceutical industry employs around 72,000 people directly and generates another 200,000 jobs in related industries.
- There was a positive trade balance in pharmaceuticals of almost £ 7 billion (€ 8 billion) in 2009.
- Pharmaceutical companies carry out more than a quarter of all industrial research and development in the UK, and spend more than 20% of their gross output on R&D.
- In 2008, the pharmaceutical industry R&D expenditure in the UK increased to over £4 billion (over €5billion) (some £ 11.8 million (€ 14.8 million) a day). This is greater than in any other country in Europe and third behind only the USA and Japan in international terms.
- The UK-based pharmaceutical industry remains among the most innovative, with 16 of the world's top-selling 75 medicines discovered and developed in the UK, more than in any other country except for the USA.

#### **2.4.2 Wholesalers**

Pharmaceutical wholesalers are an essential part of the supply chain, the link between manufacturers and patients, supplying medicines to hospitals, community pharmacies and dispensing doctors.

There are 8 full-line wholesalers operating in the UK – of these the largest three (Alliance Healthcare, AAH and Phoenix) operate at a national level whilst the remaining wholesalers are much smaller and operate on a regional basis. Some national full-line wholesalers are vertically integrated with pharmacy chains. Full-line wholesalers supply the full range of up to 20,000 pharmaceutical products including lines where there is little or no profit mark-up and deliver at least twice a day. The British Association of Pharmaceutical Wholesalers (BAPW) is the trade association for the full-line wholesalers.

Short-line wholesalers supply a narrower range of medicines and concentrate on generics, parallel imports and more profitable, frequently prescribed brands. Short-liners tend to have lower costs and deliver less frequently. A large number of companies and some pharmacies<sup>8</sup> engage in short-line wholesaling albeit on an irregular basis. According to the MHRA, over 2,600 companies held wholesaler dealer licences in 2009 and it is estimated that there are about 1,400 active short-line wholesalers in the UK, varying significantly in size and the number of product lines stocked. Historically the UK has been a net importer of medicines from the EU. However, as a result of the recent decline in pound sterling, the balance has shifted so that parallel exports are now a significant feature of the UK market. There have also been price reductions of 3.9% and 1.9% for branded medicines under the PPRS in 2009 and 2010 respectively.

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<sup>8</sup> These are pharmacies which hold a wholesaler dealer licence and which engage in parallel trade in pharmaceuticals e.g. buying stock in the UK and exporting to more expensive EU countries.

As an industry, pharmaceutical wholesaling employs almost 9,000 staff and makes more than 235,000 deliveries a week, delivering over 85% by value of medicines dispensed in community pharmacies and about 50% of medicines used in hospitals. It operates over 50 depots<sup>9</sup> nationwide and provides 50% of computer equipment used by pharmacies. 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.

However, a number of major pharmaceutical manufacturers have changed the way they distribute their products introducing Direct to Pharmacy (DTP) schemes or restricting the number of wholesalers they deal with. DTP schemes involve manufacturers selling directly to pharmacies rather than through a wholesaler and using a wholesaler as a logistics service provider to deliver medicines on their behalf in return for a fee.

*Table 2.9: UK – Key data on pharmaceutical wholesale 2000, 2005–2010*

| Wholesalers <sup>1</sup>         | 2000 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
|----------------------------------|------|------|------|------|------|------|------|
| Total number of wholesale compa- | 66   | 79   | 76   | 67   | 69   | 65   | n.a. |
| Total number of importers        | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Total number of outlets          | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |

Data as of 1 January

n.a. = not available

Notes

1. Figures for the total number of wholesale companies are based on the 99.5% panel from IMS suppliers plus the 0.5% of other suppliers notified to IMS through their pharmacy panel.

### 2.4.3 Retailers

Prescription-only medicines 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 (dispensing doctors) can dispense prescription only medicines – mainly where their patients have difficulty accessing a community pharmacy. Dispensing doctors do not provide a full pharmaceutical service and cannot supply over-the-counter medicines. Internet and mail order pharmacies are also allowed (England and Wales only) although if they want to provide state funded NHS pharmaceutical services, they cannot do this face to face at their premises and are not allowed to dispense NHS medicines.

<sup>9</sup> By depot we mean places where wholesalers store stock and from where they distribute stock to outlets e.g. community pharmacies.



### 2.4.3.1 Community pharmacies

Pharmacies' activities are governed by the following regulations:

- *Medicines Act 1968 Part IV* - there are restrictions on ownership of community pharmacies whether providing state funded pharmaceutical services for the NHS (majority) or independently. 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).
- *NHS Act 2006 and associated regulations (NHS (Pharmaceutical Services) Regulations 2005 as amended for England, NHS (Pharmaceutical Services) (Scotland) Regulations 1995 as amended, NHS (Pharmaceutical Services) Regulations 1992 as amended for Wales and Pharmaceutical Services Regulations (Northern Ireland) 1997* - if a pharmacy wishes to provide state funded NHS pharmaceutical services, it must apply to the relevant local health body for approval and be included on a pharmaceutical list.

There are 12,782 community pharmacies in the UK (as at March 2009). Most community pharmacies are privately owned although in exceptional cases PCTs can run pharmacies. There are no other restrictions on who can own a pharmacy or how many they can own, subject to competition law. Pharmacy chains are allowed. Vertical partnerships/mergers (partnership of pharmacists and "bodies corporate"), 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).

Dispensing doctors can dispense NHS prescription only medicines - mainly where their patients have difficulty accessing a community pharmacy. This is under the authority from the local health body. Dispensing doctors are reimbursed the cost of the medicine as per the Drug Tariff plus a fee subject to annual agreement as part of the General Practitioners NHS medical services arrangements. Patients pay a prescription charge, unless exempt, as they do to a community pharmacy.

The General Pharmaceutical Council (GPhC) took over as the regulator for pharmacy professionals in England, Wales and Scotland from the Royal Pharmaceutical Society of Great Britain (RPSGB) in September 2010. The Royal Pharmaceutical Society (RPS) has taken over as the body responsible for leading the profession to ensure the highest standards of professional practice. The Pharmaceutical Society of Northern Ireland carries out both functions. It also has an important role in registering, regulating and inspecting pharmacy premises.

The Pharmaceutical Services Negotiating Committee (PSNC) is recognised by the Secretary of State for Health as representative of community pharmacy on NHS matters. PSNC's main objective is to secure the best possible NHS service opportunities, remuneration, terms and conditions for NHS pharmacy contractors in England and Wales.

Table 2.10: UK – Retailers of medicines 2000, 2005–2010

| Retailers  | 2000   | 2005   | 2006   | 2007   | 2008   | 2009   | 2010  |
|--|--------|--------|--------|--------|--------|--------|-------|
| No. of community pharmacies <sup>1</sup>             | 12,302 | 12,247 | 12,407 | 12,683 | 11,647 | 12,782 | n.a.  |
| – Thereof:<br>No. of private pharmacies <sup>2</sup> | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.  |
| – Thereof:<br>No. of public pharmacies               | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.  |
| No. of hospital pharmacies for out-patients          | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.  |
| No. of dispensing GP practices <sup>3</sup>          | n.a.   | 1,153  | 1,150  | 1,138  | 1,147  | 1,114  | 1,111 |
| No. of other POM disp.,                              | 0      | 0      | 0      | 0      | 0      | 0      | 0     |
| <b>Total no. of POM dispensaries</b>                 | 12,302 | 13,400 | 13,557 | 13,821 | 12,794 | 13,896 | n.a.  |
| No. of internet pharmacies                           | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.  |
| No. of OTC disp., like drugstores                    | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.   | n.a.  |

Disp. = dispensaries, n.a. = not available, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (PHIS Glossary).

<sup>1</sup> hospital pharmacies dispensing to out-patients are not included in this figure (according to PHIS Glossary).

<sup>2</sup> Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

<sup>3</sup> Data is held on number of dispensing practices rather than individual GPs (England only)

Data as of 1 January

Sources: Community Pharmacies in England and Wales (DH Statistical Bulletin).

General Pharmaceutical Services in England and Wales (IC Statistical Bulletin).

Prescription Pricing Authority Annual Report (PPA).

Health and Personal Social Services Statistics for England (DH).

Scottish Health Statistics (ISD).

Health Statistics Wales (NAW).

Annual Statistical Report (Northern Ireland CSA).

### 2.4.3.2 Dispensing doctors

Under certain circumstances (as prescribed in the NHS (General Medical Services Contracts) Regulations 2004, the NHS (Personal Medical Services Agreements) Regulations 2004 and the NHS (Pharmaceutical Services) Regulations 2005), doctors who have contracted with their local primary care trust to provide NHS services can dispense prescription-only medicines to patients on the practice's list (dispensing doctors). These patients live in

the main in rural (controlled) areas or have serious difficulty accessing a community pharmacy.

In 2010, there were 1,111 dispensing GP practices in England (data is held on dispensing practices rather than dispensing doctors as the contractual arrangements grant dispensing rights to a contractor i.e. practice rather than an individual).

Dispensing doctors can employ staff to assist them in the provision of services e.g. dispensing, but they must ensure that those staff are suitably qualified and competent to do so.

Nurses, pharmacists and optometrists can all undertake a qualification to allow them to become independent and/or supplementary prescribers (but no dispensing). Nurses can also train to become community practitioner nurse prescribers. Chiropodists/podiatrists, physiotherapists and radiographers can train to become supplementary prescribers. Supplementary prescribing is a voluntary partnership between a doctor or dentist and a supplementary prescriber to implement an agreed patient-specific clinical management plan<sup>10</sup> with the patient's agreement.

#### **2.4.3.3 Hospital pharmacies**

Most hospitals (1,600 in England) have pharmacies, although some of the smaller ones may rely on larger hospitals or local community pharmacies for supplies. Hospital pharmacies cater for hospital in-patient and out-patients i.e. patients who attend hospital for consultation or treatment without being 'admitted' to hospital as an in-patient. Hospital pharmacies do not dispense medicines to outpatients who have a prescription from their GP (FP10 prescription form). They do not cater for patients not receiving hospital care as community pharmacies do.

In terms of the delivery chain, manufacturers, wholesalers and to a lesser extent parallel traders are all involved in supplying hospital pharmacies.

On a day-to-day basis, hospital pharmacists combine clinical and technical roles. On the one hand, they provide prescribing advice to clinicians and deliver clinical services, while on the other they are responsible for the availability, when required, of medicines of suitable quality through the management, on a day-to-day basis, of purchasing and dispensing activities. Pharmacists are supported by technically trained staff (pharmacy technicians and supporting assistant staff) who dispense, prepare, distribute medicines and, increasingly, undertake duties at the ward level.

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<sup>10</sup> A supplementary prescribing clinical management plan (CMP) will specify which medicines can be prescribed by the supplementary prescriber, including the indication and dose (or dose range). Within the scope of the CMP, the supplementary prescriber will make decisions autonomously about what to prescribe and when - they are not simply carrying out the instructions of the doctor. The CMP will also specify arrangements for review and monitoring, as well as the circumstances in which the patient will be referred back to the independent prescriber. Supplementary Prescribing arrangements can cover most categories of medicine - unlicensed, controlled drugs and off-license/off-label prescribing, for example (provided that this is specified in the CMP).

Hospital pharmacy departments vary considerably in size, with some departments having specialist units providing services to a much wider population (medicines information for example). A district general hospital has a staff of 50 to 100, a larger teaching trust a department of in excess of 200 staff. A typical ratio is 1 pharmacist to 1 technician to 1 support member of staff, but again this varies with nature of the service and extent of automation.

#### **2.4.3.4 Other POM dispensaries**

There are no other POM dispensaries.

#### **2.4.3.5 Other retailers**

Non-pharmacy retailers such as corner shops, petrol stations, supermarkets can sell OTC medicines with certain restrictions (e.g. only small pack sizes of paracetamol-based products). Such retailers are not required to be licensed.

There are 56 wholly mail order/internet pharmacies providing NHS pharmaceutical services, thus dispensing POM or selling OTC medicines, as at March 2009 in England. These must comply with the same legal requirements that apply to any community pharmacy and in addition, certain restrictions apply to their provision of NHS services under the 2005 Regulations.

### **2.4.4 Promotion**

Title VIII of Council Directive 2001/83/EC has been implemented in the UK by the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994 (SIs 1994/1932 and 1994/1933 as amended). The Regulations apply to all current methods of advertising including the Internet. Advertising to the public is permitted only for OTC medicines.

The control of medicines advertising is based on long-standing systems of self-regulation supported by the statutory role of the MHRA. The MHRA administers the UK law on behalf of Health Ministers. The self regulatory systems set up by industry include Codes of Practice covering the promotion of prescription and over the counter medicines. These are administered by the Prescription Medicines Code of Practice Authority (PMCPA) (which operates a complaint investigation system) and the Proprietary Association of Great Britain (PAGB) (which checks all advertising to the public prior to issue), respectively. There are also general controls on advertising operated by the Advertising Standards Authority with further specific controls on broadcast advertising.

The ABPI Code of Practice for the Pharmaceutical Industry, administered by the PMCPA, which operates independently from the ABPI, covers prescription medicines. The Code (available at <http://www.pmcpa.org.uk/?q=getcopiesofcode>) reflects the legal requirements and provides additional advice to ensure compliance, including the following:

- Restrictions on the supply of samples to a maximum of 10 packs/product/year and only for products on the UK market for less than 10 years.
- Restrictions on sales representatives, including limits on the number of calls so as not to cause inconvenience.
- Advice on the provision of information to the public about prescription only medicines in the UK.

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, which in turn feed into the assessment of costs and hence profits.

Information for patients on rational use of medicines is available from a number of sources including the patient information leaflet, advice from health professionals, NHS websites and patient organisations.

A public consultation has been held on the Commission proposals on information to patients. The results are available at:

<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON046657>

## **2.5 Funding**

### **2.5.1 Pharmaceutical expenditure**

Total pharmaceutical expenditure in the UK is estimated at £ 9.7 billion (€ 15.9 billion) in 2000 and at £ 14.8 billion (€ 18.6 billion) in 2008, an increase of 50%. However, this increase corresponds to an increase of 64% in the public sector and of 8% in the private sector.

Over the period 2000-2008, total pharmaceutical expenditure has been increasing at an average of 5%. The average annual increase has been of 6% in the public sector and of 1% in the private sector.

Table 2.11: UK – Total pharmaceutical expenditure 2000, 2005–2009

| Pharmaceutical expenditure   | 2000  | 2005   | 2006   | 2007   | 2008   | 2009 |
|------------------------------|-------|--------|--------|--------|--------|------|
| TPE in NCU = GBP (million)   | 9,730 | 13,240 | 13,800 | 14,400 | 14,760 | n.a. |
| –thereof public              | 7,630 | 11,030 | 11,650 | 12,040 | 12,500 | n.a. |
| –thereof private             | 2,100 | 2,210  | 2,160  | 2,360  | 2,260  | n.a. |
| PE in the out-patient sector | n.a.  | n.a.   | n.a.   | n.a.   | n.a.   | n.a. |
| –thereof public              | n.a.  | 8,317  | 8,714  | 8,765  | 8,725  | n.a. |
| –thereof private             | n.a.  | n.a.   | n.a.   | n.a.   | n.a.   | n.a. |
| PE in the in-patient sector  | n.a.  | n.a.   | n.a.   | n.a.   | n.a.   | n.a. |
| –thereof public              | n.a.  | 2,713  | 2,936  | 3,275  | 3,775  | n.a. |
| –thereof private             | n.a.  | n.a.   | n.a.   | n.a.   | n.a.   | n.a. |

n.a. = not available, NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure

Note: Figures are estimated. Out-patient/in-patient split estimated on basis of England figures in table 2.5

Source: Department of Health

## 2.5.2 Sources of funds

The NHS is funded centrally, mainly through general taxation including a proportion from National Insurance contributions with a small element (6%) coming from charges and receipts, including sales of surplus NHS land and proceeds from income generation schemes.

There are no out-of-pocket payments for inpatient treatment in the NHS but there is a prescription charge for out-patient prescriptions for medicines although there are exemptions on grounds of age, income, medical condition etc (see section 3.2.4 below). NHS patients who wish to buy additional private care (e.g. buy medicines privately that are not recommended for use by the NHS) can do so as long as the private care can be delivered separately from NHS care. Guidance makes clear that patients should never be charged for NHS care and that the NHS should not subsidise private care.

## **3 Pricing, reimbursement and volume control in the out-patient sector**

### **3.1 Pricing in the out-patient sector**

#### **3.1.1 Organisation of pricing**

The prices of branded prescription medicines supplied to the NHS (out-patient and in-patient sector) are controlled by the 2009 Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement negotiated between the Department of Health and the branded pharmaceutical industry. A company, which chooses not to join the 2009 PPRS, falls under regulations that form a statutory alternative to the voluntary arrangements. Both the 2009 PPRS and the statutory scheme are administered by a small team in Medicines, Pharmacy and Industry Group in the Department of Health.

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 to reflect developments in the NHS and the pharmaceutical industry.

The PPRS sets the NHS list price i.e. the reimbursement price to pharmacists. The PPRS allows companies freedom of pricing for new medicines (new active substances) but requires the prices of other new medicines (e.g. medicines which are not granted a new active substance marketing authorisation by EMA or MHRA e.g. line extensions) to be negotiated with the Department – usually within four weeks. The PPRS requires companies to seek the department's agreement for price increases, which are only granted if the reasons for the application meet the criteria for increases set out in the agreement.

The prices of generic medicines are set by the market. Generic manufacturers have freedom of pricing subject to a maximum of the respective in-patent product at the point of patent expiry.

There are no separate pricing and reimbursement mechanisms and the great majority of new prescription medicines are granted automatic full reimbursement upon market authorisation from the MHRA and pricing approval from the Department of Health. The NHS list price for branded medicines agreed under the PPRS and for generic medicines in the Drug Tariff is the reimbursement price in the out-patient sector. Hospitals may be able to purchase medicines under contract at a discount to the NHS list price.

Information including the indicative reimbursement price to NHS dispensing contractors for prescriptions dispensed in the community is available at [www.dmd.nhs.uk](http://www.dmd.nhs.uk) with data supplied by NHS Prescription Services of the NHS Business Services Authority (NHSBSA). It releases new prices on the first Thursday following the date a price change is applicable.

### 3.1.2 Pricing policies

The PPRS controls the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their sales to the NHS. Within this framework there are elements of free pricing, price negotiations and procurement and statutory pricing for companies which do not join the voluntary PPRS. The PPRS does not set prices at the manufacturer level. It sets the NHS list price i.e. the reimbursement price which includes wholesaler and pharmacy margins. The prices of generic medicines purchased by the pharmacy are set by the market.

Table 3.1: UK – Ways of pricing of medicines at manufacturer level, 2010

| Pricing policies                         | (Non) prescription market |     | (Non) reimbursement market |                  | Specific groups of medicine |                  |
|--|---------------------------|-----|----------------------------|------------------|-----------------------------|------------------|
|  | POM                       | OTC | Reimbursable               | Non-reimbursable | Generics                    | Parallel traded  |
| Free pricing                             | Yes <sup>a</sup>          | Yes | Yes <sup>a</sup>           | Yes              | Yes                         | Yes <sup>a</sup> |
| Statutory pricing                        | Yes <sup>b</sup>          | No  | Yes <sup>b</sup>           | No               | No                          | Yes <sup>b</sup> |
| Price negotiations                       | Yes <sup>c</sup>          | No  | Yes <sup>c</sup>           | No               | No                          | Yes <sup>c</sup> |
| Tendering                                | Yes <sup>d</sup>          | No  | Yes <sup>d</sup>           | No               | No                          | Yes <sup>d</sup> |
| Others – specify:<br>PPRS Profit Control | Yes                       | No  | Yes                        | No               | No                          | Yes              |

POM = prescription-only medicine, OTC = over-the-counter medicines

Notes

- a for new branded medicines (new active substance) within the profit control of the PPRS
- b for branded medicines from companies that have not joined the voluntary PPRS
- c within PPRS where no freedom of pricing at launch
- d vaccines

Source: MPIG-DH

#### 3.1.2.1 Statutory pricing

The statutory powers covering pharmaceutical pricing are contained in sections 260 to 266 of the National Health Service Act 2006.

A company supplying the NHS with branded medicines which has not joined the 2009 PPRS falls under *The Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008*. The regulations form the statutory alternative to the voluntary arrangements of the 2009 PPRS and, in general, the statutory scheme mirrors the provisions of the voluntary scheme.

The Regulations limit the maximum price of prescription only, branded medicines supplied to the NHS and require manufacturers and suppliers of branded medicines to provide the Department of Health with information on sales income and discounts. These legal



requirements do not apply to any company that is a member of a voluntary scheme to control the prices of branded health service medicines. As well as controlling the maximum price of existing products, the Regulations include controls on the maximum price of new products. This power will be exercised to give new products that are new active substances freedom of pricing on entering the market. However, the Secretary of State will be able to set the maximum price of products that are not new active substances by issuing a direction, having taken factors defined in the Regulations into account.

The Regulations give manufacturers the right of appeal against any decision made by the Secretary of State and any enforcement decision made under these price controls.

The Regulations include enforcement provisions, which provide for the recovery of any payments in excess of maximum prices permitted under the regulations, with an additional premium of 5% of the excess payment for the first contravention. The additional premium rises for each subsequent contravention to a maximum of 50% for the fifth or subsequent contraventions. Interest (at 2.5% above the Bank of England base rate) will be charged for late payment.

### **3.1.2.2 Negotiations**

Under the PPRS, the prices of branded prescription medicines which do not have freedom of pricing as they have not been granted an EU or UK new active substance marketing authorisation have to be agreed/negotiated with the Department.

In reaching a decision on the acceptability of a 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 medicines bill;
- the clinical need for the product;
- any exceptional costs.

### **3.1.2.3 Free pricing**

The prices of generic medicines are set by the market. Generic manufacturers have freedom of pricing subject to a maximum of the in-patent product at the point of patent expiry.

Under the PPRS, new branded products introduced following the granting of an EU or UK new active substance marketing authorisation from the appropriate Licensing Authority, may be priced at the discretion of the company on entering the market. This is conditional that it will not cause forecast profits to exceed the target profit (plus a Margin of Tolerance) under the PPRS.

Line extensions relating to such new products, granted on the basis of an abridged application, may also be priced at the discretion of the company provided that the application to

market the line extension has been submitted to the appropriate licensing authority within five years of the grant of the original authorisation of the new product.

Companies are required to give the Department a minimum of four weeks' notice before the intended date of introduction.

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 freely negotiated margin for the pharmacist.

#### **3.1.2.4 Tendering**

The Department of Health runs tendering programmes to procure vaccines for children and young adults to support the National Immunisation programme. The tenders are to procure vaccines at ex-factory price including delivery. The system has been in place since 1992. All contracts are advertised in OJEU and are procured in compliance with the EU Procurement Regulations – Restricted or Open Procedure used. Vaccines procured hold Marketing Authorisations in accordance with the Medicines Regulations. The procurement process is initiated by the Secretary of State for Health acting through NHS CMU (formerly NHS PASA). The criteria used to choose the best bid are the Most Economical Advantageous Tender (MEAT).

#### **3.1.2.5 Others**

The PPRS controls the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their sales to the NHS. For more information see section 3.1.3.4 below.

### 3.1.3 Pricing procedures

Table 3.2: UK – Pricing procedures, 2010

| Pricing procedure          | In use:<br>yes / no | Price type <sup>1</sup>                   | Scope <sup>2</sup>                                 |
|----------------------------|---------------------|---|--|
| External price referencing | No                  | -   | -  |
| Internal price referencing | No                  | -   | -  |
| Cost-plus pricing          | No                  | -   | -  |
| Indirect profit control    | Yes,<br>PPRS        | NHS List price (i.e. reimbursement price) | Branded prescription medicines supplied to the NHS |

<sup>1</sup> Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

<sup>2</sup> Scope = a pricing procedure does not always refer to all medicines: e.g. a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

Source: MPIG, DH

The 2009 PPRS is the mechanism which the Department of Health uses to control the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their NHS sales. It is a voluntary agreement between the Department and the branded pharmaceutical industry and there is a statutory alternative for companies which are not members of the voluntary scheme.

#### 3.1.3.1 External price referencing

There is no external price referencing in the UK.

#### 3.1.3.2 Internal price referencing

There is no internal price referencing in the UK.

#### 3.1.3.3 Cost-plus pricing

There is no cost-plus pricing in the UK.

#### 3.1.3.4 (Indirect) profit control

The PPRS is the mechanism which the Department of Health (on behalf of the UK health departments - England, Wales, Scotland and Northern Ireland) uses to control the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their NHS sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the ABPI – under Section 261 of the National Health Service Act 2006. 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 to reflect developments in the NHS and the pharmaceutical industry. The scheme seeks to achieve a

balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines.

The 2009 PPRS, a new five-year voluntary scheme, agreed between Government and the pharmaceutical industry commenced on 1 January 2009 in succession to the 2005 and interim 2008 schemes. As part of the agreement, there was a 3.9 per cent cut in the list price of branded medicines supplied to the NHS from 1 February 2009 and a further price cut of 1.9 per cent from 1 January 2010. The new PPRS includes for the first time support for innovation and uptake of clinically and cost effective medicines. It also includes two provisions – more flexible pricing arrangements and more systematic use of patient access schemes – aimed at increasing patient access to medicines and ensuring the prices of medicines better reflect their value.

### **Objectives**

The objectives for the 2009 scheme, as stated in the agreement, are that it should:

#### **Deliver value for money**

Deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices, and encouraging the efficient development and competitive supply of medicines.

#### **Encourage innovation**

Promote a strong and profitable pharmaceutical industry that is both capable and willing to invest in sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and industry in this and other countries.

#### **Promote access and uptake for new medicines**

The department and industry are committed to increasing uptake and patient access for new clinically and cost-effective medicines in the NHS in a sustainable manner.

#### **Provide stability, sustainability and predictability**

To help the NHS and industry develop sustainable financial and investment strategies, the UK must remain a stable and predictable market that does not place unforeseen burdens on either party over the coming years.

#### **Coverage of the Scheme**

The PPRS applies to all licensed branded prescription medicines sold to the NHS. It does not cover the prices of medicines without a brand name (generics) nor the prices of branded medicines available without a prescription (over the counter medicines) except when prescribed.

All companies, which sell branded medicines to the NHS, are covered by the scheme, although only those with sales to the NHS of over £35 million (€40 million) a year (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.

## **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 medicines bill
- the clinical need for the product
- any exceptional costs.

The PPRS sets the NHS list price. The prices 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.

## **Assessment of profitability**

Companies with NHS sales of more than £35 million (€40 million) a year are required to submit annual data to the Department on sales, costs, assets and profitability and to repay the excess where profits exceed the agreed threshold.

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

- the value of sales of branded prescription medicines to the NHS including primary care and hospital trusts;
- the level of costs appropriate for the NHS to bear. The largest element is manufacturing costs. The assessment of allowable costs includes an allowance for research and development (R&D) (up to 30% of NHS sales) and a limitation to marketing expenditure (6% of NHS sales).
- Where appropriate, the capital employed by the company in delivering NHS sales. Companies with insufficient capital are assessed on a Return on sales (ROS) basis. As companies produce products other than for sale to the NHS (e.g. over the counter medicines, exports and non-pharmaceutical products) costs and capital needs to be allocated between these activities.

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

The 2009 PPRS also included:

- Subject to discussion with affected parties, the introduction of generic substitution from January 2010 (but not introduced see section 3.3.2.1 below);
- Action to support innovation so patients have faster access to new medicines that are clinically and cost-effective;
- New and more flexible pricing arrangements that will enable pharmaceutical companies to supply medicines to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date; and
- A more systematic use of patient access schemes, which allow pharmaceutical companies to offer discounts or rebates that reduce the effective cost of a medicine to the NHS.

Further information on the PPRS is available at

<http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/PharmaceuticalPriceRegulationScheme/fs/en>

#### **3.1.3.5 Others**

There are no other pricing procedures.

#### **3.1.4 Discounts / rebates**

There are no restrictions on the type of discount (within the constraints of competition law; no predatory pricing is allowed).

The NHS list price includes a margin for distribution – this is nominally 12.5% off the NHS list price for branded medicines but it is not fixed. It is negotiated between the manufacturer and wholesaler and can vary for a number of reasons including whether the medicine is supplied to retail pharmacies, dispensing doctors or hospitals etc and on the companies' wholesaling arrangements. Changes to distribution methods including DTP schemes (cf. section 2.4.2) have made this figure even less reliable.

The 2009 PPRS introduced a more systematic use of patient access schemes (PAS), which allow pharmaceutical companies to offer discounts or rebates that reduce the effective cost of a medicine to the NHS. These include financially-based schemes where the company does not alter the list price of the drug, but offers effective discounts or rebates which may be linked to (for example) the:

- numbers or type of patients treated (e.g. price volume arrangement which may or may not be linked to use in different patient sub-groups);
- response of patients treated (there is, of course, also an “outcome” dimension to such schemes);
- numbers of doses required.

Information on all currently operational PASs is available at

<http://www.nice.org.uk/aboutnice/howwework/paslu/ListOfPatientAccessSchemesApprovedAsPartOfANICEAppraisal.jsp>

### 3.1.5 Mark-ups and taxes

There are no regulated or set margins in the UK for wholesalers or pharmacies (but see section 3.1.5.2 for discounts). As explained in 3.1.4 above, the NHS list price or reimbursement price for medicines includes a margin for wholesalers and a margin for pharmacists. These are negotiated between the parties and not set by government. Pharmacy remuneration is determined by a tariff of fees and allowances (see section 3.1.5.2)

Table 3.3: UK – Regulation of wholesale and pharmacy mark-ups, 2010

|    | Wholesale mark-up |         |        | Pharmacy mark-up |         |        |
|----|-------------------|---------|--------|------------------|---------|--------|
|    | Regulation        | Content | Scope* | Regulation       | Content | Scope* |
| UK | No                |         |        | No               |         |        |

\* Regulations concerning mark-ups do not always apply to all medicines, it may also target only POM or reimbursable medicines

Source: MPIG,DH

#### 3.1.5.1 Wholesale remuneration

The wholesale mark-up is not regulated. As explained in 3.1.4 above, the NHS list price or reimbursement price for medicines includes a margin for wholesalers and a margin for pharmacists. These are negotiated between the parties and not set by government.

#### 3.1.5.2 Pharmacy remuneration

Pharmacy mark-ups are not regulated.

The Drug Tariff, compiled monthly on behalf of the Department of Health by the Prescription Pricing Division of the NHSBSA, outlines what will be paid to dispensing contractors for dispensing NHS prescriptions. It includes remuneration (professional fees/allowances) for service provision and for reimbursement (the cost of the medicines, appliances etc) supplied against an NHS prescription form. Part II, clause 6 of the Drug Tariff outlines that pharmacy contractors will be paid the total cost of the medicines less a discount. The amount of discount deducted will depend on the total of the cost of the medicines they are to be reimbursed, however it is an average of approximately 10%. Part II also lists medicines for which a discount is not deducted when reimbursing pharmacy contractors. It is available electronically at [http://www.ppa.org.uk/ppa/edt\\_intro.htm](http://www.ppa.org.uk/ppa/edt_intro.htm).

Part II clause 8 outlines the drug price to be used for pharmacy contractor reimbursement. The price used for many generic medicines is specified in Part VIII of the Drug Tariff. Where

the price for a drug is not in Part VIII, the price used will be list price supplied by the manufacturer, wholesaler or supplier for supplying the product to the contractor.

The Government aims to reimburse pharmacies in such a way as to incentivise efficient purchasing. As part of the Contractual Framework for Community Pharmacy, pharmacies as a whole can be expected to earn about £500 million (€583 million) in margin (after the discount deduction scale has been applied). This is counted towards their remuneration. Margins are monitored periodically by examining a sample of pharmacy purchase invoices compared to reimbursement prices. Reimbursement prices are adjusted to re-align margins to target levels.

In addition, the Department conducts a rolling programme of Margin Surveys to assess the amount of margin earned on reimbursement. This survey examines the purchase prices of a random sample of medicines from invoices obtained from a sample of pharmacies to estimate an average margin across all medicines and pharmacies. The results of these surveys are then used to adjust reimbursement prices (as opposed to changing the discount claw-back). These adjustments are generally applied to medicines in Category M of the Drug Tariff, as it is these products where pharmacies can generally achieve the most margin. Under the Community Pharmacy Contractual Framework, pharmacies are allowed to earn a target of £ 500 million (€ 561 million) (nationally) in margin, and this is counted towards their remuneration. When the estimated margin differs from this amount, Category M reimbursement prices are adjusted.

### **3.1.5.3 Remuneration of other dispensaries**

The scale of fees paid to dispensing doctors for their dispensing activities are set out in annex G of the General Medical Services Statement of Financial Entitlement. The latest version can be found on the DH website at

[http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH\\_117007](http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH_117007)

Hospital pharmacy costs are met by the hospital trust.

### **3.1.5.4 Taxes**

#### **3.1.5.4.1 Value-added tax**

Standard rate VAT in the UK in 2010 is 17.5% (20% from 4 January 2011).

Medicines supplied to hospitals and community pharmacies are subject to VAT at the standard rate of 17.5% (it was reduced temporarily to 15% on 1 December 2008 because of the economic crisis but reverted to 17.5% from 1 January 2010 and will be increased to 20% from 4 January 2011). 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 (which means that the patient pays no VAT and the pharmacy can recover the VAT paid when buying the medicines). Medicines prescribed in hospital are subject to VAT at



the standard rate and 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.

#### **3.1.5.4.2 Other taxes**

There are no other taxes on medicines in the UK.

### **3.2 Reimbursement in the out-patient sector**

#### **3.2.1 Organisation**

There are no separate pricing and reimbursement mechanisms and the great majority of new prescription medicines are granted automatic full reimbursement upon market authorisation from the EMA/MHRA and pricing approval from the Department of Health.

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 the out-patient sector, any product may be prescribed for a patient and it will be reimbursed on the NHS except those listed in Schedule 1 (negative list with products not reimbursed on the NHS) to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 and those in Schedule 2 to the same regulations, which may be prescribed only for certain patients and under certain circumstances. The Secretary of State for Health takes decisions on the addition or removal of items from these schedules after a full public consultation, as required under the Transparency Directive. There is no formal appeal procedure related to this process, but manufacturers will have an opportunity to submit comments to the consultation. If a company does not agree with the decision to list their product in Schedule 1 or 2, they can challenge the decision through the Judicial Review process i.e. in the Court.

The majority of prescriptions in primary care (known as FP10s) are dispensed by community pharmacists, the others by dispensing GP practices and appliance contractors. Once prescriptions have been dispensed, they are sent to the Prescription Pricing Division of the NHSBSA. The NHSBSA reimburses community pharmacies and dispensing practices for the medicines that have been dispensed using a pricing schedule published in the Drug Tariff.

All prescriptions are coded, so that the NHSBSA can then invoice PCTs for the cost of the medicines which have been prescribed by their practices. The data collated by the Prescription Pricing Division can be used to view and analyse prescribing data and expenditure. Medicines supplied to patients by mechanisms other than FP10 prescriptions require direct reimbursement arrangements between the PCT and the provider.

NICE provides independent professional advice on clinical and cost-effectiveness of medicines and other therapeutic interventions but it has no direct effect on reimbursement status.

Note that issues related to reimbursement are the responsibility of the devolved administrations in Wales, Scotland and Northern Ireland but currently, the arrangements are identical or very similar to those in England as described above.

### **3.2.2 Reimbursement schemes**

Reimbursement in out-patient 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 prescribers in the out-patient sector 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 PPRS. Generic prices are calculated from manufacturer or market prices using a number of different formulae - using manufacturer and market prices (c.f. section 3.1) ensures that price levels are mainly controlled by competition.

Pharmacies purchase their own medicines, which they supply in response to NHS prescriptions. The NHS reimburses them for the product and remunerates them for the service provided in the provision of the product. Reimbursement is based either on Drug Tariff listings (for those items listed in the Tariff), or on manufacturer list prices. As soon as a medicine has a licence, it can be reimbursed as detailed above.

NHS eligibility relates to being 'ordinarily resident' in the UK. A person is regarded as 'ordinarily resident' in the UK if they are lawfully living in the UK voluntarily and for a settled purpose. Special regulations apply to EEA residents and visitors from bilateral healthcare agreement countries.

GPs can use their discretion regarding the treatment of overseas patients. They can register overseas visitors as temporary residents or, if they are in the UK for over 3 months, may accept them on to their practice lists. Once a person is accepted on to a practice's list, they are entitled to receive free NHS medical services.

#### **3.2.2.1 Eligibility schemes**

Eligibility for reimbursement depends on the medicine is product-specific. 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 medicines 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 medicines in this list on the NHS only in specified cir-

cumstances, and/or for specified patient groups. GPs may write a private prescription (outside the NHS and the patient has to pay for the medicine), 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 (adding products to the black or grey list) 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 Transparency Directive.

### **3.2.2.2 Reimbursement lists**

As described in section 3.2.1, a GP or other prescriber can prescribe any product considered to be a suitable treatment for his patient and it will be reimbursed on the NHS. This is subject to two provisos. Firstly that the product does not appear on a negative list (black and grey list) and secondly, GPs must be prepared to justify any challenges to their prescribing by their Primary Care Trust. Addition to or removal from the list 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 criteria under which medicines may be included in either Schedule 1 or Schedule 2 are published in Part XVIIIIC of the Drug Tariff.

Schedules 1 and 2 are replicated in the Drug Tariff, which is updated and published monthly and available for doctors and pharmacists. There is no specified frequency to how often changes are made.

Products which are too expensive, not necessary or which have no medicinal use may be considered for inclusion in Schedule 1. Products that are included in Schedule 2 are regarded to be effective for certain patients in certain circumstances and available for those patients. For any other patient, Schedule 2 products are regarded to be too expensive, not necessary or to have no medicinal use. There are no specified evaluations undertaken.

### **3.2.2.3 Reimbursement categories and reimbursement rates**

All medicines which can be prescribed on the NHS are fully reimbursable.

### **3.2.3 Reference price system**

There is no reference price system in place in the UK.

### **3.2.4 Private pharmaceutical expenses**

With the exception of charges for some prescriptions (see section 3.2.4.2) and optical and dental services, the NHS remains free at the point of use for anyone resident in the UK. NHS patients who wish to buy additional private care (e.g. buy medicines privately that are not

recommended for use by the NHS) can do so as long as the private care can be delivered separately from NHS care. Guidance makes clear that patients should not be charged for NHS care and that the NHS should not subsidise private care.

### 3.2.4.1 Direct payments

There are no particular medicines for which a patient is required to make a direct payment unless a patient chooses to purchase a medicine outside of NHS arrangements.

### 3.2.4.2 Out-of-pocket payments

Table 3.4: England – Out-of-pocket payments for medicines, 2010

| Out-of-pocket payments | Amount  | Vulnerable groups  |
|------------------------|---|--|
| Fixed co-payments      | £7.20 per dispensed item (England). (see section 3.2.4.2.1 below for other countries) | Exemptions are provided for certain income groups, on age basis (for children and the elderly) and for those suffering from certain medical conditions. Inpatients are not charged. See section 3.2.4.3 below. |
| Percentage payments    | Not applied   | -  |
| Deductibles            | Not applied   | -  |
| Reference price system | Not in place  | -  |

Source: MPIG,DH

#### 3.2.4.2.1 Fixed co-payments

In England, a fixed co-payment arrangement applies. A standard prescription charge - £ 7.20 (€ 8.40) from 1 April 2010 - is payable in respect of each item supplied. There is no limit to the number of items per prescription but the point is that a charge is payable in respect of each item. However, Wales abolished the prescription charge from 1 April 2007 and Northern Ireland from 1 April 2010; Scotland has reduced the charge to £ 3 (€ 3.50) from 1 April 2010 and plans to abolish charges altogether in 2011.

There is a system of exemptions under which items are supplied free of charge (see 3.2.4.3 below).

#### 3.2.4.2.2 Percentage co-payments

There are no percentage co-payment arrangements in the UK.

#### 3.2.4.2.3 Deductibles

There are no deductibles in place. As described below, a patient may effectively cap the total prescription charges paid by purchasing a prescription pre-payment certificate (PPC).

### 3.2.4.3 Mechanism for vulnerable groups

There is no maximum ceiling to out-of pocket payments. However, a patient may effectively cap the prescription charge paid by purchasing a prescription pre-payment certificate (PPC). PPCs are available for 3 months for £ 28.25 (€ 32.93) (from 1 April 2010) or for 12 months for £ 104.00 (€ 121.23) (from 1 April 2010). No further prescription charge is payable at the point of dispensing and the patient may have an unlimited number of prescription items during the period of the certificate.

There is 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 in England are as follows (arrangements in Scotland are different).

(1) No charge for medication for the patient (regardless of the patient's condition, age 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 a 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, e.g. supply by a hospital)
- Supplied for the treatment of tuberculosis (and no prescription form is used, e.g. supply is by a specialised clinic)
- Supplied subject to a community treatment order<sup>11</sup>, in respect of any drug supplied to that patient for the treatment of mental disorder (and no prescription form is used).
- Which is a listed medicine (Tamiflu and Relenza) supplied by controlled arrangements under specified circumstances.
- 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 month who hold a valid exemption certificate
- People who hold a valid war disablement exemption certificate (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

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<sup>11</sup> An order under §17A(1) of the Mental health Act 1983. It is an order imposed on certain categories of psychiatric in-patients at the point they are discharged from hospital. The order is designed to ensure the patient continues with their treatment when they resume living in the community.

- 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 anticonvulsive therapy
- Continuing physical disability which prevents the patient from leaving his residence without the help of another person

or

- they are undergoing treatment for cancer, the effects of cancer or the effects of current or previous cancer treatment (from 1 April 2009).

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

(a) The patient is named on an HC2 certificate for full help under the National Health Service Low Income Scheme. (This includes asylum seekers and their families if they are supported by the Immigration and Nationality Directorate). The level of help is broadly based on income support applicable amounts plus housing costs and council tax the individual/couple is liable to pay. No help is available when capital is more than £ 23,000 (€ 26,811) for people living permanently in a care home or £ 16,000 (€ 18,651) for anyone else, or

(b) Recipients of the following who do not need to make a separate NHS Low Income Scheme claim (this includes the partner and any dependant young people aged under 20 included in a benefit award)

- Income Support
- Jobseekers' Allowance Income-based
- Income-related employment and support allowance
- Pension Credit guarantee credit (for partners under 60)
- Tax credit award and the family's annual gross taxable income (from 6 April 2009) is £ 15,276 (€ 17,807) or less with:
  - child tax credit; or
  - Working tax credit with a disability, or severe disability element (and the patient is named on a tax credit exemption certificate).

### **3.3 Volume control in the out-patient sector**

#### **3.3.1 Pharmaceutical budgets**

The Department of Health allocates funding to PCTs on the basis of the relative needs of their populations and the money available for medicines is part of this overall allocation. The national amount to be spent on prescribing of medicines each year is not determined by the Department of Health but is set locally by 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. PCTs are under a statutory duty to break even as set out in the National Health Service Act, 2006. It is up to individual PCTs how they enforce their pharmaceutical budgets as part of their wider remit to break even. In case of overspending, the shortfall has to be made up elsewhere in the PCT budget.

NHS Prescription Services of the NHSBSA produce various electronic information to enable PCT prescribing advisers and others to monitor prescribing patterns (c.f. section 3.3.4.1).

### **3.3.2 Generic policies**

#### **3.3.2.1 Generic substitution**

Generic substitution is not allowed (in the out-patient sector) in the UK. Pharmacists are allowed to supply parallel imported products against prescriptions written generically and parallel imported products can be supplied against prescriptions written for a brand when the brand name on the product is the brand prescribed. The dispensing (supply) of medicines in the NHS in England is governed by the Medicines Act 1968 and the NHS Act 2006. The Medicines Act requires that, where a prescription only medicine is prescribed by a prescriber via a prescription, that medicine must be dispensed in accordance with that prescription. In the main, this has been interpreted as meaning that what is dispensed by or under the supervision of a pharmacist should be exactly what is written on the prescription and so, for example, in the case where a branded product is prescribed, the substitution of that brand by an equivalent generic product is not permitted without the prior agreement of the prescriber. The NHS (Pharmaceutical Services) Regulations 2005 and the NHS (Local Pharmaceutical Services etc.) Regulations 2006, made under the NHS Act, require the dispensing of the medicine that is ordered – and this obligation has similarly been interpreted as requiring the dispensing of a branded product, if that is what is written on the prescription.

The 2009 PPRS provides for the introduction of generic substitution in the out-patient sector in the NHS, subject to discussion with affected parties. This would have allowed a dispenser to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine in certain circumstances.

However, following a full public consultation, the Government decided not to progress any further the implementation of generic substitution. The responses to the consultation showed no clear consensus with regards to a preferred option going forward. Three key points were apparent:

- There was a strongly held perception by respondents that generic substitution posed a threat to patient safety. If the proposals were to be implemented, these concerns would arise in the frontline delivery of NHS services, impacting on the workload of health care professionals.

- The position on the cost-effectiveness of generic substitution implementation is inconclusive. There is a strong sense that the effort involved in implementing a formal generic substitution scheme was simply too great for the potential gain.
- Other, less nationally prescriptive mechanisms for further supporting the use of generic medicines can be explored.

The Coalition Government intends to stand by the 2009 PPRS agreement, which expires at the end of 2013. Instead of progressing generic substitution, the Department of Health will be looking at further ways to support the use of generic medicines in a way that is acceptable to patients, recognising that there are still some savings that can potentially be delivered in this area.

### **3.3.2.2 INN prescribing**

Doctors are encouraged, but not obliged, to write prescriptions by their generic name for both clinical and cost reasons, when appropriate, recognizing that there are occasions when it is medically appropriate to prescribe the brand. Good practice guidance from the General Medical Council states that, doctors “should take account of appropriateness, effect and cost when prescribing any medicine.” Generic prescribing is accepted by the majority of doctors and generic prescribing rates are high (82.6% in England (out-patient care) in 2008 (cf. section 2.3.5.).

Prescribing advisers undertake face to face reviews with GPs and carry out reviews of repeat prescribing etc activity.

### **3.3.2.3 Other generic promotion policies**

As explained above, GPs are encouraged to write prescriptions by their generic name for both clinical and cost reasons. 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.

Government policy is to balance the promotion of new innovative products during which originator companies make a return on their investment with the promotion of immediate generic competition on patent expiry with lower prices thus creating headroom to pay for investment in future innovation. The use of generics delivers a range of benefits including cost containment, enhanced patient access to treatment, promotion of innovation and enhanced security of supply.

### **3.3.3 Claw-backs / Pay back**

In recognition that most medicines dispensed can be purchased by a pharmacy at less than reimbursement prices, pharmacies are reimbursed the tariff price less a clawback percentage. The clawback percentage depends on the total reimbursement value of the medicines they dispense - larger pharmacies have a higher discount clawback percentage applied. There are some medicines where pharmacies cannot generally buy at a discount (Discount



Not Deducted – DND), and the clawback does not apply to these products. The clawback percentage is, therefore, applied to total reimbursement less reimbursement of DND items. The average clawback is about 8.2%. Further information is available at [http://www.ppa.org.uk/ppa/edt\\_intro.htm](http://www.ppa.org.uk/ppa/edt_intro.htm)

### **3.3.4 Monitoring**

#### **3.3.4.1 Prescription monitoring**

NHS Prescription Services of the NHSBSA produce various electronic information to enable PCT prescribing advisers and others to monitor prescribing. Prescribing advisers, mainly pharmacists, are employed at various levels in the NHS (SHAs and PCTs), 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 GPs and carry out reviews of repeat prescribing etc activity.

The National Prescribing Centre (NPC) is an NHS organisation whose aim is to „promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery“. The NPC produces a number of resources to support commissioners (purchasers) in relation to prescribing and medicines management. In addition, the NPC hosts a medicines management database of improvement examples<sup>12</sup> which allows you to search through examples of improvement that have been submitted to the NPC for sharing with the wider NHS. Further information is available at [www.npc.co.uk](http://www.npc.co.uk).

The Information Centre provides statistics and data on prescriptions. Examples of some of the reports they produce include:

- How many prescription items were dispensed?
- What was the net ingredient cost of prescriptions?
- Which NICE appraised medicines are used in hospitals?
- What is the variation in hospital supplied medicines across strategic health authorities?

The link to their website is

<http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions>

The Better Care, Better Value indicators published by the NHS Institute for Innovation and Improvement help NHS organisations make the most effective use of resources and deliver quality healthcare. For example, the quarterly indicator on statins encourages the appropriate use of therapeutically equivalent low cost generic statins in place of higher cost branded statins. The NHS Institute has other indicators relating to generic prescribing, details can be found on their website at <http://www.productivity.nhs.uk/default.aspx>

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<sup>12</sup> [http://www.npc.co.uk/mm/mm\\_improvement/mm\\_improvement.htm](http://www.npc.co.uk/mm/mm_improvement/mm_improvement.htm)

### **3.3.4.2 Price monitoring**

Medicines Pharmacy and Industry Group in the Department of Health monitor the prices of medicines supplied to the NHS through the PPRS for branded medicines and the Drug Tariff for generic medicines.

The launch prices of all branded medicines have to be notified/agreed with the Department. Subsequent price changes also have to be agreed and any price increases are only granted if the criteria set out in the PPRS are met. The Department liaises closely with the NHSBSA, responsible for reimbursing pharmacists for dispensing medicines in the out-patient sector, and receives monthly reports of price changes to ensure that the reimbursement price is the same as the NHS list price. In addition, the Department monitors the delivery of savings from the price cuts under the PPRS and receives annual audited information on prices from companies to ensure the value of the delivery.

The Department publishes a Report to Parliament on the operation of the PPRS, which includes information on the number and value of price increases, delivery of price adjustment savings from the price cuts and international price comparison. These reports are available on the department's website.

In addition, the Department conducts a rolling programme of Margin Surveys to assess the amount of margin earned on reimbursement (c.f. section 3.1.5.2).

### **3.3.4.3 Pharmaceutical expenditure monitoring**

The Department of Health, SHAs and PCTs all have an interest in monitoring pharmaceutical expenditure in the NHS. Reports on prescribing data are produced by the Information centre (see 3.3.4.1 above). The NHS Institute for Innovation and Improvement have a number of specific indicators relating to generic prescribing rates of certain medicines, including statins (see 3.3.4.1 above).

A National Audit Office report<sup>13</sup> on prescribing costs in the out-patient sector recognised the savings achieved in relation to generic prescribing and for 2009 estimated that PCTs in England achieved a total saving of £ 443 million (€ 497 million) for generic medicines. The largest savings were made on:

- Statins - £ 323 million (€ 362 million)
- Medicines for gastric problems - £ 74 million (€ 83 million)
- Medicines for high blood pressure - £ 9 million (€ 10 million).

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<sup>13</sup> [http://www.nao.org.uk/publications/0607/prescribing\\_costs\\_in\\_primary\\_c.aspx](http://www.nao.org.uk/publications/0607/prescribing_costs_in_primary_c.aspx)

### 3.3.4.4 Consumption monitoring

As described in section 2.3.4, the NHS Information Centre is England's central authoritative source of health and social care information and publishes data on prescribing of medicines in the community.

In general, the consumption of pharmaceutical items by individuals is not monitored except in a limited number of cases e.g.

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

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.

### 3.3.5 Assessment and evaluation

#### 3.3.5.1 Decision-making tools

There is no legal or regulatory use of pharmaco-economic analysis. NICE was established in 1999 and uses health-economic analysis in the development of its guidance to the NHS on the clinical and cost-effectiveness of licensed medicines and other treatments. If a treatment receives a positive appraisal by NICE, PCTs are mandated to fund its use when it is prescribed by practitioners in the NHS. Pharmaco-economic analyses are not required to obtain a market authorisation, or pricing and reimbursement decision.

#### 3.3.5.2 Evaluation of measures

Health-economic evaluations are not necessary to receive a market authorisation. The majority of NICE technology appraisal guidance relates to new branded prescription medicines.

NICE expresses the costs and health benefits of a treatment in a cost / QALY figure, which guides the decision of whether to approve the medicine. Full technical guidance can be

found at  
<http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyappraisal.jsp?domedia=1&mid=B52851A3-19B9-E0B5-D48284D172BD8459>

NICE reviews its methods approximately every 3 to 5 years. NICE develops its guidance development methods independently and in consultation with stakeholders.

### 3.3.5.3 Reports and results

The National Institute for Health Research (NIHR) Health Technology Assessment programme (HTA) produces independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS. It identifies the most important questions that the NHS needs the answers to by consulting widely with these groups, and commissions the research it thinks is most important through different funding routes. The HTA programme commissions Technology Assessment Reports on behalf of NICE to support its technology appraisals.

The HTA programme publishes its findings in its internationally acclaimed journal series, Health Technology Assessment, and guidance is also published at <http://guidance.nice.org.uk/>.

In April 2010, NICE identified 19 sets of recommendations that if fully implemented by trusts could help to save millions of pounds. The cost saving guidance, costing tools, recommendation reminders and commissioning guides are available at <http://www.nice.org.uk/aboutnice/whatwedo/niceandthenhs/UsingNICEGuidanceToCutCostsInTheDownturn.jsp>

## 3.4 Overview on policy measures in the out-patient sector

Table 3.5: UK – Policy measures in the out-patient sector, 2005–2010

| Measures  | Description  | Year      |
|---|--|-----------|
| Changes in the pricing policies (e.g. new policies or methodology and changes, external price referencing; price freezes / cuts, (obligatory) discounts | 2005 PRRS introduced a price cut of 7% on branded medicines supplied to the NHS from 1 January 2005.   | 2005      |
|   | 2008 PPRS introduced a price freeze on branded medicines supplied to the NHS from 1 September 2008.  | 2008      |
|   | 2009 PPRS introduced a price cut of 3.9% on branded medicines supplied to the NHS from 1 February 2009 and a further 1.9% price cut from 1 January 2010. | 2009      |
|   | 2009 PPRS introduced more flexible pricing arrangements and more systematic use of patient access schemes.   | 2009-2010 |
| Changes in the regulation of the mark-ups   | -  | -         |

PHIS Pharma Profile 2010  
United Kingdom

| Measures  | Description  | Year                  |
|---|--|-----------------------|
| Changes concerning the VAT rates on medicines   | VAT reduced temporarily to 15% on 1 December 2008 but reverted to 17.5% from 1 January 2010 (increased to 20 from 4 January 2011).   | 2008-2009             |
| Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)                              | -  | -                     |
| Changes regarding a reference price system (e.g. introduction, methodology changes conc. clustering and/or the reference price) | -  | -                     |
| Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)  | <p>In England, a standard prescription charge - £ 7.20 from 1 April 2010 – is payable in respect of each item supplied. The charge has been abolished in Wales and Northern Ireland and Scotland has reduced the charge to £ 3 from 1 April 2010 and plans to abolish it in 2011.</p> <p>Abolition of prescription charges for cancer patients from 1 April 2009 and a review of prescription charges for those with long-term conditions.</p> | 2007-2010<br><br>2009 |
| Changes in the generics policies (e.g. introduction of INN prescribing, generics substitution)                                  | Consultation on introduction of generic substitution   | 2010                  |
| Changes concerning monitoring of medicines (e.g. new monitoring tools)  | -  | -                     |
| Changes concerning evaluations and assessments (e.g. price review, reimbursement reviews)                                       | -  | -                     |

conc. = concerning, OPP = out-of pocket payment, VAT = value added tax

Description = please list the major measures in the field of policy measures mentioned

Year = please list the year in which the measures were taken

Source: MPIG-Department of Health

## **4 Pricing, reimbursement and volume control in the in-patient sector**

### **4.1 Pricing and procurement in the in-patient sector**

#### **4.1.1 Pricing**

##### **4.1.1.1 Framework**

The prices of branded prescription medicines sold to the NHS (in-patient and out-patient) are controlled by the 2009 Pharmaceutical Price Regulation Scheme (PPRS) (see section 3.1.3.4). It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry. A company, which chooses not to join the PPRS falls under regulations which form a statutory alternative to the voluntary arrangements. The PPRS sets the NHS list price of a medicine, a maximum price that a supplier may charge the NHS. The prices of generic (non-branded and out of patent) medicines are not controlled but are set by the market. However, in the in-patient sector, hospitals may be able to negotiate purchase prices below the NHS list price (brands) or Drug Tariff price (generics) where there is therapeutic competition.

Hospitals can choose to purchase medicines centrally via NHS Commercial Medicines Unit (CMU) contracts, via regional contracts or locally through individual NHS trusts or hospitals (see section 4.1.2.1. below). The pharmaceuticals business of NHS Purchasing and Supply Agency (PASA) transferred to NHS CMU within the Department of Health in 2010.

Hospital pharmacists, together with pharmacists in commissioning organisations, have important roles in deciding which medicines are available in hospitals locally, unless national guidance pertains. They work through therapeutic or prescribing committees. Price does influence this process, but prices across all medicines are negotiated at national, regional or individual hospital basis with only occasionally “therapeutic tenders” undertaken, that is, it is not the norm to decide between two alternate treatments based on a tendering process.

Private (non-NHS) hospitals make their own arrangements for purchasing medicines.

##### **4.1.1.2 Hospital prices**

Hospitals procure medicines via contracts following competitive tendering and may obtain a discount to the NHS list price.

Medicines supplied to hospitals (and community pharmacies) are subject to VAT at the standard rate of 17.5% in 2010 (20% from 4 January 2011). Medicines prescribed in hospital are subject to VAT at the standard rate and the NHS is funded centrally by the Government to take account of this non-recoverable VAT. Healthcare is, therefore, VAT free to the patient.

The prices of hospital medicines consist of the NHS list price, plus VAT minus any discounts the hospital secures. Prices of hospital medicines are often lower than the prices paid in the community where there is therapeutic competition. There are no mandatory discounts for hospitals. The Office of Fair Trading in its market study on the PPRS, published in February 2007, calculated that the discount obtained by hospitals on the fifty medicines on which they spent the most in 2005, was 12.3% although there was variation in the discounts obtained across medicines<sup>14</sup>.

In February 2009, a report (Analysis of Hospital Medicines) commissioned by the Danish Ministry for Health and Prevention from COWI consultants on hospital medicines included a comparison of the prices of 39 medicines in six selected countries: Denmark, Norway, England, Sweden, Germany and the Netherlands. The analysis showed that the prices of hospital medicines are lowest in England and Norway both with regard to the official list prices and with regard to the prices that are actually negotiated.

There is no legal obligation for hospital trusts to publish the prices of medicines or to notify the price to a competent authority. This information is treated as commercially confidential as discounts vary between trusts. Disclosure of this information would undermine the relationships between the parties and could inhibit or curtail negotiations. However, trusts may cooperate on these issues to some extent in consortia. As explained in section 4.1.2.1, purchasing data is collected for England, by NHS CMU at trust level, through hospital pharmacy computer systems (PharmEx). Procurement prices in the hospital sector are not published. However, information including the NHS list price is available at [www.dmd.nhs.uk](http://www.dmd.nhs.uk) with data supplied by NHS Prescription Services of the NHSBSA although it does not list all hospital only medicines.

#### **4.1.2 Purchasing policies**

##### **4.1.2.1 Tendering**

NHS Trusts (including their pharmacies) are public sector organisations, therefore, the procurement they undertake is governed by the UK regulations (The Public Contracts Regulations SI 2006 No 5<sup>15</sup>) that implement the EU procurement directives. The Public Contracts Regulations outline the procedures, which must be followed when awarding contracts above a specified financial threshold. Contracting Authorities are responsible for achieving value for money, normally through fair and open competition. Procurements must be advertised in the Official Journal of the EU (OJEU) and meet set timescales, from the initial notice to contract award, and define, for example, the minimum time during which suppliers must be allowed to respond.

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<sup>14</sup> [http://www.oft.gov.uk/shared\\_oft/reports/comp\\_policy/oft885.pdf](http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf)

<sup>15</sup> [http://www.opsi.gov.uk/si/si2006/uksi\\_20060005\\_en.pdf](http://www.opsi.gov.uk/si/si2006/uksi_20060005_en.pdf)

The contracts that are awarded, against pre-determined award criteria, are usually framework agreements on behalf of defined geographical groupings of hospitals or occasionally commitment contracts on behalf of individual hospitals or legal entities.

Most medicines in the in-patient sector are purchased locally at trust level via contracts awarded by NHS CMU, most usually at regional level.

For the most part, NHS CMU manages the contracting process on behalf of hospital pharmacy purchasing groups to ensure adherence with the UK regulations. Framework agreements for generic medicines are managed within a nationally coordinated programme that takes into account the date that products come off patent. Hospital pharmacists may dispense medicines generically (where there are no clinical considerations) and determine the award decisions for the framework agreements. Contracts for branded products are awarded as price volume matrices against which hospitals then place their prescribing commitment to achieve the discounts that are available.

Contracts are let for a period of time, which provides optimum commercial benefit to the Contracting Authority. Public procurement regulations restrict the length of Framework Agreements to a period of four years, but many products are tendered more frequently than this. Across the NHS pharmacy community there will be many procurement processes underway at any one time.

As outlined above tendering opportunities are advertised in the OJEU and once contracts are awarded a notice is posted in the OJEU containing information about the suppliers awarded the contract.

Procurement prices are not published although purchasing data is collected for England, by NHS CMU at trust level, through hospital pharmacy computer systems (PharmEx).

#### **4.1.2.2 Negotiations**

Most medicines are purchased locally at trust level via contracts awarded by NHS CMU.

#### **4.1.2.3 Other purchasing policies**

There are no other purchasing policies.

### **4.1.3 Organisation of procurement**

In the in-patient sector, locally managed NHS hospital pharmacy services supply medicines purchased against NHS CMU, regional purchasing group or local Trust contracts. Most medicines in the in-patient sector are purchased locally at trust level via contracts awarded by NHS CMU most usually at regional level.

Whilst hospitals remain free to carry out their own procurement as they wish, the NHS (in England) as a whole supports a consistent national procurement model. This involves hospitals aggregating their business on a geographical basis through hospital pharmacy purchas-



ing groups. There are six main pharmacy purchasing groups in England. The business of these groups is then competitively tendered on their behalf by NHS CMU, in line with the UK regulations and against a previously agreed timetable. When offer prices are received from the suppliers, the hospitals collectively agree the award decisions for their groups. NHS CMU then awards and manages the resulting framework agreements on behalf of the pharmacy purchasing groups.

This NHS contracting model reduces duplication of effort, optimises leverage, manages risk and offers both the NHS and its suppliers a single consistent approach through the use of one tendering and contract management system in compliance with UK regulations.

Tenders are assessed against the criteria set out in the OJEU advertisement or tender documentation. The assessment should follow the pre-defined evaluation strategy and be consistent with the ultimate objectives of the project/procurement. The final selection should be the tender that offers best overall value for money. Where offers are made, contracts are awarded to the most “economically advantageous offer” (not necessarily the cheapest).

A second route of supply has developed since 1995 supplying high-tech and low-tech technologies – products and services - to patients at home – now referred to as homecare. This has grown exponentially and is estimated to be worth around £ 1 billion (€ 1.2 billion) a year against NHS in-patient expenditure on medicines of £ 3.2 billion (€ 3.7 billion) in England. Growth has been driven as a result of meeting the legitimate healthcare needs of patients, VAT savings and manufacturers imposing direct to patient supply.

## **4.2 Reimbursement in the in-patient sector**

### **4.2.1 National framework**

In England, the state funds NHS hospital care via NHS budgets, allocated to commissioning organisations (PCTs). Funding passes to providers (hospitals) on the basis of inpatient and outpatient activity undertaken. Most of the costs are covered by a tariff price – the Payment by Results (PbR) system, which includes an element for medicines. However, high cost items i.e. those medicines with a disproportionate cost compared with the tariff price are dealt with outside the tariff.

Hospital trusts are reimbursed by PCTs for medicines purchased if the medicine has been approved for prescription. Restrictions are not placed on what can be reimbursed but on what can be prescribed. There are no national reimbursement lists for hospital care. Decisions concerning which medicines can be prescribed rest with local pharmaceutical and therapeutic committees, which manage formularies, or restricted lists, but there are normally arrangements for exceptions. In some parts of the UK, hospitals work closely with the outpatient sector to agree jointly which medicines are used or not used locally. However, positive NICE guidance on medicines appraised as being clinically and cost effective places a statutory requirement on purchasers to make funding available for clinicians to follow the guidance.

The National Commissioning Group (NCG) is responsible for commissioning services for rare diseases on a national basis for the population of England. In general, the number of patients receiving treatment from one of the NCG's services is less than 400. By concentrating the resources for these services on a national basis, the NHS is able to develop expertise in how best to commission them, to ensure safety and quality through a concentration of skills in a few centres, and to mitigate the risk to individual PCTs of unpredictable episodes of very expensive treatment. National Commissioning is a responsibility of the SHAs, and the group is hosted by NHS London on behalf of all 10 SHAs.

NHS patients are not required to pay for medicines in hospital. NHS patients who wish to buy additional private care (e.g. buy medicines privately that are not recommended for use by the NHS) can do so as long as the private care can be delivered separately from NHS care. Guidance makes clear that patients should never be charged for NHS care and that the NHS should not subsidise private care.

#### **4.2.2 Hospital pharmaceutical formularies**

Formularies have been in place in the majority of NHS hospitals for many years. Some hospitals share formularies between several NHS bodies whilst others have developed joint formularies with PCTs. As explained above, hospital trusts pay for the medicines used and are then reimbursed through the PbR mechanism (in England) or through budget allocation.

The Pharmaceutical and Therapeutic Committee (PTC) (known as drugs and therapeutic committee (DTC) in the UK) usually oversee the formulary system and members of the pharmacy team update the documentation/electronic system. The topics discussed in building formulary lists will normally include issues around cost and clinical-effectiveness, safety, efficacy, and whether there are benefits compared to existing medicines on the formulary list.

Each hospital will normally have their own formulary of active substances, and as a result, the format and number of items on each list will vary significantly - as a minimum medicines approved by NICE are on this list. Generic substitution is normally practised with these lists, with the exception of products with narrow therapeutic indices and variable bioavailability. The formularies are continually updated, and depending on hospital policy, are overhauled every 1 to 2 years.

Some hospitals allow specialists (e.g. consultants, senior doctors in charge of a patient's treatment) to override these lists; others only allow such an override in specially approved circumstances. Formularies are developed locally and may be made available in paper and electronic forms. Electronic copies are available on 'intranets' for organisational use and some are available on the publicly accessible internet e.g

<http://www.mtw.nhs.uk/pharmacy/formulary.asp>

### **4.2.3 Pharmaceutical and Therapeutic Committees**

The role of Pharmaceutical and Therapeutic Committees (PTCs) (known as drugs and therapeutic committees (DTCs) in the UK) varies - some are advisory, others are decision makers. The PTC manages entry to the formulary but also supports safe and effective prescribing – often with oversight of guidelines, medicines documentation and so on. The National Prescribing Centre has produced helpful guidance on prescribing committees<sup>16</sup>.

The membership of PTCs varies but comprises a multi-professional group with a mix of doctors, pharmacists, nurses and others. For an area PTC, GPs are also represented, as are pharmacists working in primary care organisations.

On a day-to-day basis, hospital pharmacists combine clinical and technical roles. On the one hand, they provide prescribing advice to clinicians and deliver clinical services, while on the other they are responsible for the availability, when required, of medicines of suitable quality through the management, on a day-to-day basis, of purchasing and dispensing activities.

## **4.3 Volume control in the in-patient sector**

### **4.3.1 Monitoring**

#### **4.3.1.1 Price monitoring**

Prices of medicines in the in-patient sector are monitored. Data is collected monthly at trust level for England, by NHS CMU through hospital pharmacy computer systems and purchasing information. The information collected includes name, form, strength, pack size, number of packs and price per pack. Although not all trusts provide data, currently 95% of available purchasing information available from acute trusts is collected in this way through a system known as PharmEx. Through this system, the NHS is able to measure the performance of its procurement arrangements. Feedback is given to trusts on their performance but information is not published.

#### **4.3.1.2 Pharmaceutical expenditure**

Hospital trusts expenditure on medicines is monitored closely, usually led by the Chief Pharmacist and their team. Budgets are usually devolved to “business units” within trusts (such as General Surgery or Acute Medicine) but with close involvement of the pharmacy team. A minority of hospitals have e-prescribing systems, therefore linking spend to specific case mix and tends to be reserved for particular analyses – perhaps where spending is growing or concerns are raised on usage. Monthly monitoring is the usual approach but process and extent varies markedly between organisations.

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<sup>16</sup> [http://www.npc.co.uk/policy/local/apc\\_guide.htm](http://www.npc.co.uk/policy/local/apc_guide.htm)

As explained above, data is also collected for England at trust level, by NHS CMU through a system known as PharmEx on a monthly basis. Feedback is given to trusts on their performance but information is not published.

Expenditure on medicines is centrally recorded e.g. a report on Hospital Prescribing in England in 2009 was published in October 2010 by the NHS Information Centre for Health and Social Care. This report revealed that expenditure on medicines in England in 2009 was £ 12.3 billion (€ 13.8 billion) of which out-patient care accounted for £ 8.3 billion (€ 9.3 billion), 68% of the total costs, and hospitals some £ 3.8 billion (€ 4.3 billion), 31% of the total. The balance (1%) is hospital prescribing but dispensed in the out-patient area. Overall, the cost of medicines rose by 5.6% in 2009 but by 13.2% in hospitals. This report is publicly available<sup>17</sup>. Note that the costs for hospital use are provided by IMS Health who collect volume data from a large sample of hospitals and cost this using the Drug Tariff and standard price lists. This means that the costs are not necessarily what the hospitals paid, as they are often able to negotiate a discount. Some national work led by the National Cancer Director has also been produced – examining uptake of NICE approved cancer medicines – comparing network uptake per population<sup>18</sup>.

There has been extensive work on cost-effectiveness in hospitals, some examples of initiatives (majority are widespread):

- Clinical pharmacy services – individualising patient care for safety and cost-effectiveness
- Generic substitution
- Therapeutic substitution (more limited – selected products where junior medical staff requests are converted to alternate products as agreed by a PTC)
- Formularies
- Tendering/procurement exercises

During 2010, work on promoting cost-effective medicines use has been included in DH's Quality, Innovation, Productivity and Prevention (QIPP) initiative. By offering a range of advice and support to the NHS, the "QIPP Medicines use and procurement workstream" aims to improve quality of care and release substantial efficiency savings by:

- improving cost-effective prescribing in the out-patient sector;
- improving medicines management in the in-patient sector;
- supporting patients to get maximum benefit from their medicines; and
- improving patient safety.

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<sup>17</sup> Hospital Prescribing, England 2009. Available at

[http://www.ic.nhs.uk/webfiles/publications/007\\_Primary\\_Care/hospre09/Hospital\\_Prescribing\\_2009.pdf](http://www.ic.nhs.uk/webfiles/publications/007_Primary_Care/hospre09/Hospital_Prescribing_2009.pdf)

<sup>18</sup>[http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_098856](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_098856)

#### 4.3.1.3 Consumption monitoring

Monitoring pharmaceutical usage at a national level has been problematic, but work is undertaken on a regular basis. As described above, for England, the NHS Information Centre for Health and Social care publishes details; the 2009 report<sup>19</sup> was published in October 2010. Some national work led by the National Cancer Director has also been produced – examining uptake of NICE approved cancer medicines – comparing network uptake per population<sup>20</sup>.

Data on consumption in Trusts in England is collated through PharmEx data, as explained at section 4.1.2.1. PharmEx data is not publicly available. Hospital services normally administer medicines to their patients within the confines of their own clinical environment. However, on some occasions the supply and administration of medicines is provided to the patient whilst in their own home. The use of services is expanding, and it is estimated that in the English NHS 120,000 plus patients are now receiving their medicines via the homecare route. The value of medicines being supplied by this route is estimated to be around £ 1 billion (€ 1.2 billion) and is expected to increase substantially as more clinical services move away from hospitals to the community. This data is not fully captured in PharmEx data.

Within hospitals, consumption can be analysed by the ward or department (some are identified by the consultant's name - senior doctor who is a specialist in particular field responsible for a patient's treatment - rather than the unit) and by individual patient where electronic prescribing systems exist.

Whilst computerised stock tracking is common in hospitals, e-prescribing is limited. Most hospital pharmacies have sophisticated stock control systems. A medicine's progress through the hospital can be monitored from ordering to administration. Generally the pharmacy computer system will order pharmaceutical goods automatically based upon need and send these orders (after authorisation) to wholesalers and manufacturers electronically. When the stock arrives it is checked and then entered into the system against the original order, batch numbers and expiry dates can be entered as appropriate. The medicine is then either booked out to a specific patient, this is recorded automatically in the notes, then dispensed, and sent to the ward or stock is ordered for a particular ward and administered. Eventually e-prescribing will allow hospitals to monitor individual doses administered to patients and record to the patient's notes. A daily stock take should occur as good practice, here a few items will be checked and discrepancies investigated, and annually a full stock take should take place for audit.

In the UK there has been an extensive move to embrace and develop the role of clinical pharmacy whilst sustaining technical and supply chain expertise. There is also a very strong medicines information network as well as underpinning pharmacy education services based

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<sup>19</sup> Hospital Prescribing, England 2009. Available at [http://www.ic.nhs.uk/webfiles/publications/007\\_Primary\\_Care/hospre09/Hospital\\_Prescribing\\_2009.pdf](http://www.ic.nhs.uk/webfiles/publications/007_Primary_Care/hospre09/Hospital_Prescribing_2009.pdf)

<sup>20</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_098856](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_098856)

in hospital care and linking with Higher Education. Pharmacists are supported by technically trained staff (pharmacy technicians and supporting assistant staff) who dispense, prepare, distribute medicines and, increasingly, undertake duties at the ward level.

Parenteral nutrition, radiopharmaceuticals, centralised intravenous additive service (CIVAS) and cytotoxic chemotherapy are prepared locally – either under a Medicines Act exemption (supervised by a pharmacist) or in a unit licensed by the MHRA (again with pharmacist leadership). There are medicines, particularly those of lower risk, reconstituted at ward level by medical and nursing staff.

Pharmacy team size varies across organisations, larger trust will provide their own services but there can be collaboration between organisations. Support services include education, computer/IT and procurement specialists. Teams may include or be led by technicians rather than pharmacists. On a “regional” basis there will also be specialist leads in these and other areas. Quality Assurance/Quality Control pharmacists are usually linked to production/aseptic dispensing facilities but there are also regional leads.

The majority of pharmacists are based in clinical services. Pharmacists specialise in specific areas of work (renal, mental health, intensive care, general surgery for example) and work closely with medical teams to provide patient care. There are now around 40 “consultant pharmacists” in England – these are holders of posts approved as meeting Department of Health requirements around expert practice, they work with specific patient groups or in defined areas of practice. Pharmacists at lower grades, in development posts, also undertake routine clinical pharmacy duties.

Clinical pharmacy teams seek to ensure safe and effective use of medicines, implementing guidelines and individualising patients’ medicines regimens. Pharmacists do accompany medical team rounds – but not all rounds and not in all hospitals; they counsel patients on their medicines, and this is supported in some hospitals by technical staff. Pharmacists can now prescribe and undertake this in a number of specialities.

Pharmacists undertake a number of “clinic” type roles, for example managing anticoagulation, supporting cancer therapies. Medicines information services provide enquiry answering and active dissemination of information, critical appraisal of evidence and electronically available information. There is an active network of MI pharmacists – UK Medicines Information. Pharmacists support formulary development, monitoring and implementation. There has been particular work on antibiotic stewardship with pharmacists contributing significantly – guidelines, feedback on use, training, monitoring, joint ward rounds with microbiologists.

There are close working relationships between medical, nursing and pharmacy staff. Pharmacists are active in the education of junior medical staff.

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## **4.3.2 Assessment and evaluation**

### **4.3.2.1 Decision-making tools**

NICE uses health-economic analysis in the development of its guidance to the NHS on the clinical and cost-effectiveness of licensed medicines and other treatments – it applies to both the hospital and community sectors. NICE appraisals are not given to all medicines, and so hospitals will often have to make decisions on clinical and cost effectiveness without NICE guidance.

### **4.3.2.2 Evaluation of measures**

As described in section 3.3.5.2, the majority of NICE technology appraisal guidance relates to new branded prescription medicines.

NICE expresses the costs and health benefits of a treatment in a cost / QALY figure, which guides the decision of whether to approve the medicine. Full technical guidance can be found at

<http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyappraisal.jsp?domedia=1&mid=B52851A3-19B9-E0B5-D48284D172BD8459>

### **4.3.2.3 Reports and results**

Health-economic analysis is necessary for approval by NICE and, if a treatment receives a positive appraisal by NICE, PCTs are mandated to fund its use when it is prescribed by practitioners in the NHS. Health economic analysis for NICE guidance is provided by either the drug manufacturer or an independent HTA centre. The analysis is then reviewed by appropriate clinical and health economic experts. The majority of NICE technology appraisal guidance relates to new branded prescription medicines. For medicines and treatments that have not been considered by NICE, PCTs are required to make funding decisions rationally and on the basis of the available evidence.

As described in section 3.3.5.3, the National Institute for Health Research (NIHR) HTA programme produces independent research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS. It identifies the most important questions that the NHS needs the answers to by consulting widely with these groups, and commissions the research it thinks is most important through different funding routes. The HTA programme commissions Technology Assessment Reports on behalf of NICE to support its technology appraisals.

The HTA programme publishes its findings in its internationally acclaimed journal series, Health Technology Assessment, and guidance is also published at <http://guidance.nice.org.uk/>.

#### 4.4 Overview of policy measures in the in-patient sector

Table 4.1: UK – Policy measures in the in-patient sector, 2005–2010

| Measures  | Description   | Year          |
|---|---|---------------|
| Changes in the pricing framework (e.g. change pricing regulation with relevance for the in-patient sector, change in hospital specific mark-up / VAT which is relevant for the in-patient sector) | 2009 PPRS included 3.9% cut in the list price of branded medicines from 1 February 2009 and a further 1.9% from January 2010 to deliver 5% savings a year in out- and in-patient sectors over the five year scheme.<br>More systematic use of patient access schemes with discounts/rebates off the NHS list price. | 2009 and 2010 |
| Changes in procurement (e.g. establishment of new procurement agency, change in relevance of tendering vs. negotiations etc.)   | Establishment of NHS CMU in place of NHSPASA  | -             |
| Changes regarding the reimbursement lists (e.g. concerning a national hospital list, the HPF, ...)  | -   | -             |
| Changes in funding (e.g. specific budgets for specific medicines, concerning OPP in the in-patient sector)  | PbR (England only)  |               |
| Changes concerning evaluations and assessments  | -   | -             |

CMU = Commercial Medicines Unit, HPF = hospital pharmaceutical formulary, NHS = National Health Service, NHSPASA = NHS Purchasing and Supply Authority, OPP = out-of pocket payment, PbR = Payment by Results, VAT = value added tax

Description = please list the major measures in the field of policy measures mentioned

Year = please list the year in which the measures were taken

Source: MPIG DH



## 5 Interface management and developments

### 5.1 Interface management

Hospitals have been asked to take into account the impact of their prescribing on the out-patient sector and joint PTCs have been established to support this. There are examples of hospitals switching and controlling specific medicines to support cost-effective prescribing in the out-patient sector.

Some hospitals minimise out-patient prescribing and provide recommendations to GPs instead. Shared care arrangements are sometimes in place to help GPs prescribe more complex medicines (e.g. disease modifying agents in rheumatoid arthritis) rather than continuing prescribing from hospitals.

The use of medicines by patients needs to be co-ordinated throughout the patient's journey. Most patients have their care delivered by more than one health care organisation. Many medicines are initiated in acute/specialist hospitals and subsequently prescribed in the out-patient sector. Medicines management and prescribing are key elements of both PCT and acute trust business. Issues relating to medicines and technologies also interface with a number of other areas including specialist commissioning, finance, clinical networks, clinical effectiveness and public health. Problems with medicines often occur at the interface between health care organisations, and health and social care. This risk needs to be managed both clinically and financially, and a coordinated area wide approach to medicines management can help organisations do this.

Health economy prescribing committees (sometimes referred to as Area Prescribing and Medicines Management Committees (APCs)) whose "member" organisations are primary and secondary care commissioners (purchasers) and providers work together to ensure a consistent health community approach to medicines management. Many were established to manage more effectively the entry of new medicines into the NHS. Now, however, the functions and forms of many APCs go far beyond this original remit. In particular, they can be used as forums to resolve issues around medicines safety and usage across the care interfaces, for example from the out-patient to in-patient sector.

There are clear benefits to patients and organisations of having an effective and influential APC, for example, an APC can:

- promote co-operation and consistency of approach in the commissioning process
- prevent duplication of professional and managerial effort by ensuring local joint working
- ensure that robust standards and governance underpin community wide decision making
- enable key stakeholders, working in the NHS locally, to exert an influence on the prioritisation, improvement and development of healthcare delivery
- co-ordinate the safe and effective use of medicines across a health community

The National Prescribing Centre (NPC) is an NHS organisation whose aim is to “promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery”. The NPC produces a number of resources to support commissioners (purchasers) in relation to prescribing and medicines management. In addition, the NPC hosts a medicines management database of improvement examples<sup>21</sup>, which allows you to search through examples of improvement that have been submitted to the NPC for sharing with the wider NHS. Further information is available at [www.npc.co.uk](http://www.npc.co.uk)

## 5.2 Developments in the out-patient and the in-patient sectors

Table 5.1: UK – Measures in the pharmaceutical system, 2010

| Measures   | Under discussion  | Under implementation  |
|--|---|---|
| General health reforms (e.g. changes in responsibilities and institutions) | <p>Introduction of e-prescribing and wider automation.</p> <p>More contracting out of pharmacy services (especially supply), rather than services always provided within the organisation</p> <p>The responsible pharmacist legislation.</p> <p>Planned review of the Medicines Act.</p> <p>Modernising Pharmacy Careers Programme.</p> | <p>Hospitals gaining more financial autonomy by moving to foundation trust status in England (ongoing since 2004)</p> <p>Pharmacy White Paper (2008) gave an emphasis on pharmacy leading for safety in organisations</p> <p>Introduction in England of the Payment by Results system and ex-tariff over a four year period to 2008-2009</p> <p>Increased emphasis on antibiotic stewardship<sup>22</sup></p> <p>Pharmacists as prescribers from 2006</p> |
| Pricing policies in general  | -   | 1.9% price cut (branded medicines) January 2010   |
| Mark-ups   | -   | -   |
| Taxes  | Increase in VAT to 20% from 4 January 2011 (applies to hospital medicines purchases except for zero rated or exempt items)  | -   |

<sup>21</sup> [http://www.npc.co.uk/mm/mm\\_improvement/mm\\_improvement.htm](http://www.npc.co.uk/mm/mm_improvement/mm_improvement.htm)

<sup>22</sup> [http://www.bma.org.uk/health\\_promotion\\_ethics/diseases/tacklinghcais.jsp](http://www.bma.org.uk/health_promotion_ethics/diseases/tacklinghcais.jsp)

PHIS Pharma Profile 2010  
United Kingdom

| Measures                                  | Under discussion                       | Under implementation |
|---|--|----------------------|
| Reimbursement policies                    | -                                      | -                    |
| Out-of pocket payments                    | -                                      | -                    |
| Generic policies                          | Generic substitution consultation 2010 | -                    |
| Reforms targeted at the in-patient sector | -                                      | -                    |
| Evaluation & assessment                   | -                                      | -                    |

Source: MPIG – Department of Health

The new coalition Government published a White Paper “Equity and Excellence: Liberating the NHS” in July 2010 setting out its long-term plans to reform the NHS in England. Most significantly it plans to transfer responsibility for 80% of the NHS budget to groups of GPs (GP consortia) who would assume the healthcare commissioning role currently played by PCTs. It commits to increase health spending in real terms in each year of the Parliament but the NHS will have to make efficiency savings of £ 20 billion (€ 22.5 billion) by 2014 to be re-invested in frontline services. The government is consulting on its plans for changes to be introduced over the next three years.

In terms of medicines, the government plans to move towards a system of value-based pricing when the current PPRS expires in 2013. The Department of Health published a consultation on its proposals for value-based pricing for branded medicines in December 2010. The consultation runs until 17 March 2011. As an interim measure, it is creating a new £ 200 million (€ 225 million) a year Cancer Drug Fund from April 2011 (with in the meantime an additional £ 50 million (€ 56 million) available from 1 October 2010) to help patients get the medicines their doctors recommend.

## **6 Bibliography**

### **6.1 Literature**

#### *Studies / Books:*

Analysis of Hospital Medicines, commissioned by the Danish Ministry for Health and Prevention from COWI, February 2009.

Pharmaceutical Pricing and Reimbursement Information (PPRI): Pharma Profile UK 2008. Vienna: ÖBIG. In online: <http://ppri.goeg.at/>

Pharmaceutical Price Regulation Scheme 2009 Department of Health, December 2008.

Pharmaceutical Price Regulation Scheme Tenth Report to Parliament Department of Health, December 2009.

Pharmacy Workforce Census 2008. Royal Pharmaceutical Society of Great Britain July 2009

Prescribing Costs in Primary Care. National Audit Office May 2007

### **6.2 Legislation**

The National Health Service Act 1977 as amended (and associated regulations).

The National Health Service Act 2006 as amended (and associated regulations).

The Medicines Act 1968 as amended (and associated regulations).

### **6.3 Web links**

Department of Health <http://www.dh.gov.uk/>

The NHS in England [www.nhs.uk](http://www.nhs.uk)

The NHS in Scotland [www.show.scot.nhs.uk](http://www.show.scot.nhs.uk)

The NHS in Wales [www.wales.nhs.uk](http://www.wales.nhs.uk)

The NHS in Northern Ireland [www.n-i.nhs.uk](http://www.n-i.nhs.uk)

The NHS Information Centre <http://www.ic.nhs.uk/>

The National Prescribing Centre [www.npc.co.uk](http://www.npc.co.uk)

National Institute for Health and Clinical Excellence <http://www.nice.org.uk/>

NHS Institute for Innovation and Improvement <http://www.productivity.nhs.uk/default.aspx>

The Medicines and Healthcare Products Regulatory Agency <http://www.mhra.gov.uk/>

The Prescription Medicines Code of Practice Authority <http://www.pmcpa.org.uk/>

Dictionary of medicines + devices [www.dmd.nhs.uk](http://www.dmd.nhs.uk)

The PPRS

<http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/PharmaceuticalPriceRegulationScheme/fs/en>

Drug Tariff [http://www.ppa.org.uk/ppa/edt\\_intro.htm](http://www.ppa.org.uk/ppa/edt_intro.htm)