Annexe A

Markets for prescription pharmaceuticals in the NHS

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EXECUTIVE SUMMARY

This annexe examines competition within markets for prescription medicines in the UK.

We estimate that the NHS spent about £11 billion on pharmaceuticals across the UK in 2005, of which about £3 billion was spent on generics and £8 billion on branded pharmaceuticals (covered by the PPRS). Of this £8 billion, around £6 billion was spent in primary care and £2 billion in hospitals. Patients pay directly for only a small part of this (around five per cent) through prescription charges.

Demand for drugs within the NHS (particularly in primary care) is characterised by a complex set of principal-agent relationships, in which:

• the person who consumes the drug (the patient) neither decides nor, in most cases, pays
• the person who decides which drug should be used (the prescribing doctor) neither pays nor consumes, and
• the institution that pays for the drug (the NHS / Government) neither consumes nor decides.

The PPRS is a means by which one component of that demand – the payer – seeks to constrain the prices of branded prescription medicines. Therefore, despite its name, the PPRS is not truly a regulatory mechanism (that is, one that constrains commercial relations between two third parties). Rather, it represents an attempt to exercise buyer power in the purchase of prescription medicines across the UK. In this regard it operates alongside numerous other demand-side controls and incentives at national and local levels of the NHS.

Primary care sector

In the primary care sector, it is important to distinguish between competition to influence GPs when they write a prescription, and competition to supply pharmacies when they dispense a prescription written by a GP.

Competition to influence GPs is between branded manufacturers and occurs when (as is usually the case) more than one drug can be used to treat a given condition. As drugs are imperfect substitutes for one another and GPs’ prescribing tends not to be price sensitive, price competition is on the whole fairly weak. However, branded manufacturers have strong incentives to expand market share by vigorously marketing in-patent drugs to GPs1. In-patent drugs are therefore characterised by competition on marketing to a much greater extent than on price.

The weak price competition in the market to influence GPs is seen most clearly when the first in a group of similar drugs goes off-patent. The generic price of that drug tends to decline sharply but the prices charged by branded manufacturers, both of the off-patent drug itself and of substitute drugs (which remain in-patent), do not decline to anything like the same extent. Volumes of most substitutes are also typically unaffected. As set out in Annexe M, this results

1 Given the high rate of generic prescribing, this incentive is much reduced once a drug goes off-patent.
in large differences between the generic price of the off-patent drug and the prices of the branded manufacturers, and has major implications for the value the NHS obtains from its expenditure on drugs.

As regards competition to supply pharmacies, the current reimbursement arrangements mean that pharmacies are strongly incentivised to negotiate competitive prices with suppliers. Competition depends on how the drug is reimbursed:

- when a drug is reimbursed as a brand (as is the case for reimbursement of branded prescriptions and generic prescriptions when there is only one manufacturer, including in-patent drugs), competition is between the branded manufacturer and parallel importers to supply the pharmacy. Competition from parallel imports depends on the manufacturer setting lower prices in other EEA countries and on the availability of supplies in those countries. These factors vary between drugs. On average, parallel importers currently have a UK branded share of about 18 per cent, and

- when a drug is reimbursed as a generic (as is the case for reimbursement of generic prescriptions of most off-patent drugs\(^2\)), competition is primarily between generic manufacturers through Category M (but may also come from branded suppliers). Generic manufacturers compete vigorously on price, and branded manufacturers may match the generic price through brand equalisation deals. Data from the BGMA suggest that, through such deals, branded manufacturers take about 10 to 15 per cent of generic dispensing.

Under the current reimbursement system, pharmacy margins on supplies reimbursed as a brand are on average considerably lower than on those dispensed generically, which gives strong advantages to brands competing with generics in markets for GP prescriptions.

Hospitals

Hospitals can control prescribing with more certainty than primary care organisations—hospital doctors are employees so adherence to formularies, or guidance can be made a contractual term of employment. Hospitals purchase their own drugs and, to the extent they successfully control prescribing, are able to bargain on price with manufacturers of drugs with therapeutic substitutes, for example by offering a higher volume in exchange for a lower price.

Consequently, competition on price between manufacturers of in-patent drugs is likely to be more important in the hospital sector than in primary care. The extent of price competition in the hospital sector will depend on the extent to which a drug has substitutes. We carried out some limited analysis which suggested the closeness of therapeutic substitutes was an important factor in explaining the size of hospital discounts.

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\(^2\) In some cases, off-patent drugs are not reimbursed generically—for example: modified release and other products, when there may be problems in switching patients to a generic product; products where generic manufacturers cannot enter the market because a separate patent remains (for example on the delivery method); and products where the market is not large enough to induce entry by a generic manufacturer.
1 INTRODUCTION

1.1 This annexe examines competition within markets for prescription medicines in the UK. It identifies the range of markets affected by the Pharmaceutical Price Regulation Scheme (PPRS) and considers the relevant features of supply and demand that influence competitive processes in those markets. This analysis is a prerequisite for understanding the role the PPRS, its likely effects (considered in greater detail in Annexes H and J) and the case for reform of the scheme (set out in Annexe L).

1.2 This annexe focuses on price competition within existing markets for branded drugs in the UK. It does not explicitly address dynamic competition ‘for’ markets, that is, the drivers of innovation and new product development. Given the cost structure of the pharmaceutical industry those drivers are largely international in nature – and are detailed in Annexe D of this report.

1.3 The structure of this annexe is as follows:

- Chapter 2 outlines UK expenditure on medicines prescribed in the NHS, setting out recent trends. This gives an idea of the amount of public money affected by the PPRS
- Chapter 3 presents an overview of the process by which prescription drugs are supplied to patients in the NHS. It identifies the markets within which suppliers compete at each stage of the supply chain and describes the financial flows and regulatory controls that affect the nature of competition within these markets. This establishes the context for the analysis of competition that follows
- Chapters 4 and 5 consider competition in primary care. Chapter 5 examines how suppliers of prescription medicines compete to influence GPs to prescribe. Chapter 6 assesses competition to supply pharmacies to dispense against GP prescriptions at the level of primary care, to influence GPs. Both of these chapters consider in some detail the effect of NHS demand-side controls and reimbursement arrangements on the nature of competition, and
- Chapter 6 assesses the nature of competition to secure prescriptions within and supply drugs to the hospital sector.

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3 Here, as elsewhere in the report, the term 'market' should be understood in a general sense, as referring in broad terms to the processes by which companies compete to supply a particular component of demand. Unless otherwise stated in the text no inferences should be drawn from these statements as to the precise market definition that might apply in any particular Competition Act 1998 or merger investigation, as this will depend on the circumstances of each case.
2 EXPENDITURE ON PRESCRIPTION MEDICINES IN THE NHS

The NHS drugs bill

2.1 In total, we estimate that the NHS spent about £11 billion in 2005 on pharmaceuticals across the UK, reflecting both reimbursement of pharmacies for dispensing drugs in primary care and direct expenditure by hospitals. Of this total, we estimate that roughly £8 billion was spent on branded drugs and £3 billion on generics.

2.2 Table 2.1 shows how this expenditure breaks down by country and into branded and generics spend for the primary sector. Data is less readily available for hospitals but Table 2.2 provides our estimates of expenditure in the secondary sector. Data are from 2005, which is the last year for which data are available across the UK.

Table 2.1: Expenditure on prescription medicines in primary care in the UK, 2005

<table>
<thead>
<tr>
<th>£ millions</th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>N Ireland</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generics</td>
<td>1,979</td>
<td>132</td>
<td>330</td>
<td>51</td>
<td>2,492</td>
</tr>
<tr>
<td>Brands</td>
<td>5,522</td>
<td>402</td>
<td>554</td>
<td>286</td>
<td>6,764</td>
</tr>
<tr>
<td>Total</td>
<td>7,501</td>
<td>534</td>
<td>884</td>
<td>337</td>
<td>9,256</td>
</tr>
<tr>
<td>Total (minus clawback)*</td>
<td>6,800</td>
<td>500</td>
<td>800</td>
<td>300</td>
<td>8,300</td>
</tr>
</tbody>
</table>

*Estimates quoted to nearest £100 million.
Source: prescriptions statistics; and OFT calculations. The figures may differ slightly from those quoted elsewhere. Totals may not equal sum of constituents due to rounding errors.

2.3 Table 1 shows that primary care expenditure at list / Drug Tariff prices totalled £9.2 billion in 2005. As explained in Chapter 5, the amount actually paid is somewhat less than this due to ‘clawback’ of pharmacy margins. After allowing for clawback, total expenditure reduces to about £8.3 billion. On this basis, total primary care expenditure on brands was about £6.1 billion in 2005.

Table 2.2: Estimated expenditure on prescription medicines in secondary care in the UK, 2005

<table>
<thead>
<tr>
<th>£ millions</th>
<th>England*</th>
<th>Wales</th>
<th>Scotland</th>
<th>N Ireland†</th>
<th>Total*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generics</td>
<td>400</td>
<td>24</td>
<td>43</td>
<td>8</td>
<td>500</td>
</tr>
<tr>
<td>Branded</td>
<td>1,600</td>
<td>104</td>
<td>183</td>
<td>62</td>
<td>2,000</td>
</tr>
<tr>
<td>Total†</td>
<td>2,000</td>
<td>128</td>
<td>225</td>
<td>70</td>
<td>2,400</td>
</tr>
</tbody>
</table>

*Figures quoted to nearest £100 million.
† N. Ireland figures exclude VA
Source: various; and OFT estimates. Totals may not equal sum of constituents due to rounding errors.

4 Prescription cost analysis (PCA) data provided by the Prescription Pricing Authority (England), Health Solutions Wales, the Information Services Division Scotland and the Central Services Agency (Northern Ireland).
2.4 The data for hospital expenditure are estimates of the amounts hospitals paid wholesalers (or sometimes the manufacturer directly) for drugs. Availability of these data varies from country to country and in some cases we have had to make estimates of hospital branded and generic expenditure. In total, about £2.4 billion was spent in hospitals, of which we estimate that roughly £2 billion was spent on branded drugs at manufacturers’ selling prices.

2.5 It is not possible to make an accurate estimate of hospital spend on branded drugs in all cases because hospital data sometimes only record drugs purchased by chemical name, whether orders are for branded or generic products. Disaggregated data were only available for Northern Ireland. In Table 2.2, we have estimated the proportion of expenditure on branded drugs using data from a sample of English NHS trusts. This estimated proportion has been used to provide estimates for spending on branded drugs and generics in England, Scotland and Wales. These are fairly broad brush estimates, as there is likely to be some variation between countries in the proportion of hospital expenditure on branded drugs.

**Expenditure covered by PPRS**

2.6 In Paragraph 2.3, we estimated branded reimbursement expenditure of about £6.1 billion for 2005. The reimbursement data includes expenditure on non-PPRS products (for example homeopathic remedies and health food supplements) and reimbursement of any ‘out of pocket’ expenses incurred by pharmacies in obtaining drugs. Excluding these categories reduces expenditure on branded medicines to about £5.7 billion. PPRS price and profit controls between them apply to almost all this expenditure in the UK. However, as explained in Annexes H and J, the different controls apply to different levels of expenditure in the NHS.

2.7 PPRS price controls apply to the list price and therefore have an influence on all the £5.7 billion of primary care branded expenditure in the UK. They have a less certain influence on hospital expenditure since hospitals purchase at transaction prices rather than list price.

2.8 PPRS profit controls apply to revenue accruing to UK-based manufacturers direct from sales to primary and secondary care. They therefore do not include drugs supplied through parallel trade and are net of wholesaler and pharmacy margins. Sales to the

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5 Hospital data for N. Ireland were provided by the Regional Pharmaceutical Procurement Service. The aggregate hospital expenditure figure for Wales was calculated from the Medusa database via Health Solutions Wales. For England, aggregate hospital expenditure has been estimated by applying an estimated average hospital discount of 20 per cent to our estimate of aggregate hospital expenditure at Drug Tariff prices.

6 The proportion of hospital expenditure spent on prescription drugs that was spent on generic drugs is estimated to be 19 per cent.

7 Some very small firms are exempt from the price cut but the levels of expenditure involved are negligible on a UK level. All branded pharmaceuticals are subject to controls on changes to list price over time.
NHS of AFR companies\(^8\) were about £5.3 billion in 2004, the last year for which verified AFR data were available to us (see Annex H).\(^9\)

### The drugs bill relative to other NHS expenditure

2.9 Across the UK, expenditure on prescription medicines consumes a significant proportion of annual NHS income paid by government. In 2005, the drugs bill was in the range 12 to 18 per cent of NHS expenditure on services in all four countries of the UK. In England, for example, our estimate of a net drugs bill of £8.8 billion (£6.8 billion for primary care and £2 billion for hospitals) represents about 13 per cent of aggregate net expenditure on NHS services, which was around £66 billion.

### Growth of prescribing expenditure

2.10 Expenditure on prescription medicines has been rising at a steady rate, despite the seven per cent price cut imposed across branded products in 2005. The recent growth of expenditure in the community (where most of the drugs bill is incurred and data tend to be more comprehensive) is shown below.

#### Table 2.3 Growth of the community drugs bill in the UK, 2000 to 2005

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>N Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average annual growth (nominal)</td>
<td>7.3 per cent</td>
<td>12.8 per cent</td>
<td>7.0 per cent</td>
<td>8.0 per cent</td>
</tr>
</tbody>
</table>

Source: see Table 2.1.

2.11 DH analysis for England suggests that most of the increase (5.0 per cent) has been due to an increasing numbers of prescriptions per head of the population rather than increases in the cost per prescription (1.7 per cent). Trends in the average cost per prescription reflect a number of factors, including substitution of generics for more expensive branded drugs as drugs go off patent. Trends in the cost per prescription of branded drugs are discussed in Annexe J.

### Breakdown of the drugs bill over branded medicines and generics

2.12 The total drugs bill has risen in recent years. However, in 2005 there was a slight reduction, caused largely by the seven per cent PPRS price cut imposed in 2005. The proportion of expenditure on generics has doubled over the last ten years. The situation in the community in England is depicted below.

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\(^8\) AFR companies are those with sales to the NHS in excess of £25 million which are required to submit annual financial returns (AFRs) to DH.

\(^9\) Total sales of AFR companies excludes sales of branded medicines by companies with sales to the NHS of less than £25 million and also excludes parallel imports. Sales of branded medicines in 2005 are likely to have been somewhat lower than in 2004 due to the effects of the seven per cent price cut in January 2005 (see Figure 2.1).
The contribution of patients

2.13 Prescription drugs, like most other NHS expenditure, are mainly funded from general taxation. The contribution made by patients is small.

2.14 The prescription charge is collected in the community by pharmacies and remitted to central government. It is currently £6.65 in England, Scotland and Northern Ireland, and £4.00 in Wales. Prescription charges are not levied in hospitals.

2.15 However, the majority of community prescriptions do not attract the charge due to exemptions (for example, for the elderly, young, unemployed) and the charge will be phased out altogether in Wales from April 2007. In England, for example, only 12.4 per cent of prescription items dispensed (accounting for 14.9 per cent of the drugs bill) attracted the charge in 2005.

2.16 The part of the community drugs bill that was paid for by prescription charges in 2004 is shown below:
Table 2.4 Prescription charge receipts as a proportion of the community drugs bill, 2004

<table>
<thead>
<tr>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>N Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.6 per cent</td>
<td>3.2 per cent</td>
<td>4.6 per cent</td>
<td>3.6 per cent</td>
</tr>
</tbody>
</table>

Source: PPA, HSW, ISD Scotland and CSA Northern Ireland; and OFT calculations\(^{10}\)

2.17 These are very low levels of contribution by international standards. As discussed in Annexe K, almost all countries in the world have a higher proportion of patient contributions (with the exception of the Netherlands).

2.18 This fact is central in understanding the functioning of markets to prescribe and dispense drugs in the NHS, which is the main focus of analysis in the following chapters of this annexe.

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\(^{10}\) In 2004 the prescription charge was £6.40 in all countries except for Scotland where it was £6.00. The table captures revenues from prepayment certificates (covering patients for all prescriptions needed during three-month and twelve-month periods) as well as charges levied at the point of dispensing in community pharmacies.
3 MARKETS FOR PRESCRIPTION MEDICINES IN THE NHS

Introduction

3.1 The NHS can be split up into primary (or ‘community’) care and secondary (or hospital) care segments.\(^{11}\) The process of supplying drugs to patients differs between these two segments.

3.2 In primary care, GPs write prescriptions for drugs, which a patient then takes to a pharmacy. The pharmacy dispenses the drug in question, either at the flat prescription rate or, more commonly, for free. Pharmacies are responsible for purchasing the drugs either directly from manufacturers or through wholesalers. They are reimbursed by the NHS for the cost of these drugs.

3.3 In secondary care, a hospital clinician will prescribe a drug, which is then dispensed by the hospital pharmacy. Hospitals are responsible for purchasing drugs. Unlike primary care pharmacies, however, they are not reimbursed directly for doing so – they must draw on the overall NHS revenues they receive for treating patients. Patients do not pay for drugs supplied in hospitals.

3.4 As these brief descriptions suggest, demand for drugs within the NHS (particularly in primary care) is characterised by a complex set of principal-agent relationships, in which:

- the person who consumes the drug (the patient) neither decides nor, in most cases, pays
- the person who decides which drug should be used (the prescribing doctor) neither pays nor consumes, and
- the institution that pays for the drug (the NHS / Government) neither consumes nor decides.

3.5 The PPRS is a means by which one component of that demand – the payer – seeks to constrain the prices of branded prescription medicines. As discussed elsewhere in this report, the constraints include a series of price controls and a cap on profits that companies can earn on the sale of branded drugs to the NHS.

3.6 Therefore, despite its name, the PPRS is not truly a regulatory mechanism (that is, one that constrains commercial relations between two third parties). Rather, it represents an attempt to exercise buyer power in the purchase of prescription medicines across the UK. In this regard it operates alongside numerous other demand-side controls and incentives at national and local levels of the NHS.

\(^{11}\) There is also tertiary care. This is specialised consultative care, usually on referral from primary or secondary care personnel, by specialists working in a centre that has personnel and facilities for special investigation and treatment. Cancer treatment centres are an example.
The structure of NHS demand

3.7 The diagram overleaf provides an overview of financial flows and control mechanisms relating to expenditure on branded pharmaceuticals in the NHS.

Demand for drugs in primary and secondary care

3.8 In all four countries, the delivery of frontline healthcare, including medicines, is centred on primary care organisations (PCOs), a general term for English Primary Care Trusts and what are usually referred to as Health Boards in Wales, Scotland and Northern Ireland.

3.9 Collectively, PCOs receive around 80 per cent of NHS funds and manage the delivery of most health care to populations\(^{12}\) of 100,000 to 300,000. Each PCO’s share of available funds is determined by the demographics and relative health needs of its local population, using assessment methodologies that vary across the four countries. PCOs provide care in the community ('primary care') through GPs, nurses, dentists, other professionals and services such as NHS walk-in centres. They provide 'secondary care' by commissioning services from hospitals.

3.10 With regard to primary care prescribing, PCOs manage GPs under the terms of a UK-wide General Medical Services (GMS) contract. They manage pharmacies under the terms of a Pharmacy contract with small variations between the four countries. GPs prescribe medicines that pharmacies dispense at the NHS flat-rate charge or for free before being reimbursed by the PCO\(^{13}\). PCOs seek to encourage GPs to prescribe cost effectively through local incentive schemes and other arrangements. Designing financial incentives for pharmacies, on the other hand, is mostly the domain of central governments. The link between PCOs, GPs and pharmacies is the main agency relationship in primary care prescribing and a major focus of this annexe (in particular chapters 4 and 5).

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\(^{12}\) Populations covered by some English PCTs expanded after a number were merged during 2006.

\(^{13}\) Different reimbursement arrangements apply according to the type of drug dispensed (branded or generic), how GPs prescribed and availability of drugs in the market place. The diagram only shows reimbursements for branded drugs.
3.11 Hospitals buy, prescribe and dispense their own drugs – and the doctors and pharmacists who carry out those functions are direct employees rather than contractors. Hospitals around the UK procure drugs in quite similar ways, often independently but increasingly through (local, regional and national) purchasing consortia. Hospitals are not usually remunerated directly for this expenditure but, rather, view it as an input cost to the healthcare interventions they carry out for PCOs. Hospitals may choose independently of PCOs which drugs they use to treat given conditions, though this is changing. They also take advice from the same national-level sources as PCOs.

3.12 In England, PCTs commission services from hospitals in an ‘internal market’. Many NHS hospital trusts obtain revenues solely by performing healthcare interventions for PCTs, which are priced at a standard National Tariff (subject to exclusions and regional variations) that is being progressively rolled out. Scotland, Wales and Northern Ireland have not employed the market model for hospital commissioning. In Scotland, Area Health Boards receive combined budgets for primary and secondary care, and funds are allocated to hospitals on the basis of local needs. In Wales and Northern Ireland hospitals are more independent of PCOs but are to some extent joint-managed with them.
3.13 Hospital prescribing and procurement behaviour is considered in chapter 6 of this annexe.

National level institutions and policies

3.14 Prescribing in primary care and hospitals is also influenced by national bodies and policies that attempt variously to contain the drugs bill, to ensure medicines meet acceptable standards of safety and to improve the clinical and cost effectiveness of prescribing.

Licensing

3.15 Initial access to the market for prescription medicines is controlled by the UK licensing authority, the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA licenses drugs on the grounds of their efficacy against placebo, safety and quality of manufacture. These are frequently thought of as absolute hurdles though in practice trade-offs can be made, for example between safety and efficacy to promote innovation in treatments for particularly serious or terminal conditions.

3.16 The MHRA participates in the centralised European licensing system coordinated by the European Medicines Agency (EMEA). It is also part of the Mutual Recognition procedure. Manufacturers can opt to submit new drugs for licensing by individual Member States (whereupon the Mutual Recognition procedure may or may not be triggered) or by the centralised procedure.14

Pricing schemes

3.17 As already noted, the PPRS is one of the major national instruments employed to help secure value for money for the NHS. The mechanisms it employs to control the price of branded drugs are analysed in Annexes H, I and J. The main instrument used to set the reimbursement price of generic drugs is Category M, which is based on surveys of transaction prices between manufacturers, wholesalers and pharmacies. This is discussed in chapter 5 of this annexe. It is worth noting here, however, that, because they are based on very different principles, the two schemes can result in widely varying prices for off-patent brands (set under PPRS) and bioequivalent generics (set through Category M).

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14 Under the centralised licensing system, EMEA passes a candidate product to a Member State designated by the manufacturer to act as ‘lead rapporteur’. The lead’s designated authority assesses the product which, if it is passed and subject to the decision being ratified by some centralised committees representing other Member States, is then automatically licensed across the Union. There is some specialisation amongst States as to which types of products they typically lead on. The MHRA is the most popular lead rapporteur.
Guidance

3.18 There are several national bodies that assess the cost effectiveness of drugs, issue clinical guidelines on the best-practice use of drugs and that disseminate guidance around the NHS. The most widely discussed of these bodies are the cost effectiveness watchdogs: the National Institute of Clinical and Health Excellence (NICE) in England, the Scottish Medicines Consortium (SMC) and the All-Wales Medicines Strategy Group (AWMSG).

3.19 In each country the government department in charge of the NHS receives a fixed budget which is used to maximise national health outcomes. Since resources are limited, this calls for trade-offs between different treatments for a given condition and even between the treatment of different medical conditions. This is shown explicitly in the work of NICE, SMC and AWMSG which issue decisions on cost effectiveness grounds as to which medicines and other treatments the NHS should be required to fund.

3.20 In England, when a NICE Technology Appraisal recommends the use of a drug in an indication PCTs are required to provide funding within three months if GPs – who are not bound by NICE guidance – choose to prescribe. In Wales, LHBs must fund positive guidance from AWMSG in the same manner. In Scotland, SMC approvals place this obligation on AHBs only for drugs rated 'unique' therapeutic advances. Northern Ireland implements guidance from NICE and sometimes SMC.

3.21 In view of their importance in the delivery of value for money to the NHS, we consider the role of NICE, SMC and AWMSG separately, in Annexe B of this report. In short, while we find that the technical expertise that these bodies bring to bear in conducting cost effectiveness assessments is of world class standard, we have identified a number of issues to address to ensure this expertise is put to the best possible use in ensuring NHS resources are used cost effectively.

3.22 The long-term take-up of medicines in the NHS is affected by other organisations and policies that operate at the national level. These include:

- organisations that publish clinical guidelines on how to integrate drug therapies into the broader delivery of health care. These are NICE (in another function), the Scottish Intercollegiate Guidelines Network (SIGN) and the All-Wales Prescribing Advisory Group (AWPAG)

- National Service Frameworks: initiatives that require primary care organisations to achieve uniformly high standards of care in a number of major conditions (for example, coronary heart disease, cancer). An implicit objective is to make populations healthier and healthcare cheaper in the long run, though this could plausibly involve greater use of drugs in the short run
• the NHS Health and Social Care Information Centre in England and equivalent bodies in Scotland, Wales and Northern Ireland\textsuperscript{15}. These disseminate a wide range of data around the NHS, including prescription cost information for peer-review purposes, and

• the National Prescribing Centre (NPC) is a health service organisation, formed in April 1996 by the Department of Health. Its 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'.\textsuperscript{16}

3.23 The 'public health and strategic advisory' bodies marked on the diagram are an intermediary layer between national arrangements and PCOs. In England 28 Strategic Health Authorities were created in 2002 and on 1 July 2006, this number was reduced to 10. These authorities manage the local NHS on behalf of the Secretary of State and are a key link between the Department of Health and the NHS.\textsuperscript{17} The National Public Health Service for Wales performs a similar function in the Principality.\textsuperscript{18} There are no equivalent bodies in Scotland or Northern Ireland.

**Demand-side incentives and competition in the NHS**

3.24 From the structure of NHS prescribing budgets and financial flows outlined above, the following table identifies the main types of market relevant to the supply of prescription pharmaceuticals to patients in primary and secondary care. At each level, it shows the incentives of NHS agents in terms of how they are remunerated for prescribing or purchasing decisions and the price they or the NHS pay and identifies the types of companies competing to supply.

3.25 PPRS price controls constrain the manufacturer’s list price, which is highlighted in the table in bold. The table therefore emphasises the particular role of the PPRS in constraining financial flows relevant to prescribing brands. The list price of a branded

\textsuperscript{15} The Information Services Division Scotland, Health Solutions Wales and the Central Services Agency in Northern Ireland.

\textsuperscript{16} The NPC delivers a wide range of activities and support through a coordinated work programme, comprising six main elements: education and development, medicines management services, publications on medicines and prescribing related issues, collaborative schemes to inform purchasers of new medicines which may have a significant impact, non medical prescribing support and more locally focussed support to healthcare organisations.

\textsuperscript{17} Strategic Health Authorities are responsible for:
• Developing plans for improving health services in their local area
• Making sure local health services are of a high quality and are performing well
• Increasing the capacity of local health services - so they can provide more services
• Making sure national priorities - for example, programmes for improving cancer services - are integrated into local health service plans.

\textsuperscript{18} The National Public Health Service for Wales (NPHS) delivers a full range of public health services, seeking to:
• Improve the health and wellbeing of the people of Wales and reduce inequalities in health
• Protect against existing, new and emerging diseases and health threats, and
• Contribute to improvement in health and social care services.
drug at the time it goes off patent also imposes a UK-wide ceiling on the price at which manufacturers of the equivalent generic product sell to wholesalers.

3.26 The remainder of the annexe assesses competition within these markets in primary and secondary care. At each level it explains how features of demand and supply combine to affect competition within the relevant markets.
### Table 3.1 Summary of competition in drugs markets in the UK

<table>
<thead>
<tr>
<th>Agent</th>
<th>Share NHS demand</th>
<th>How reimbursed for pharmaceutical expenditure</th>
<th>Price paid for pharmaceuticals</th>
<th>Parties competing to supply</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCOs</td>
<td></td>
<td>Formula based on population characteristics produces unified budget from which PCO apportions drug spend</td>
<td>Manufacturer’s list price less average clawback</td>
<td>Manufacturers of all therapeutically substitutable products compete to secure GP’s prescription</td>
</tr>
<tr>
<td>GPs</td>
<td></td>
<td>GPs do not pay for drugs and so are not reimbursed for drug spend.(^{[a]}) Some contractual incentives relate to list price and Drug Tariff price</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacies</td>
<td>c. 80 per cent</td>
<td>List price less clawback based on volumes</td>
<td>Market but list price imposes ceiling(^{[b]})</td>
<td>Manufacturer of brand (either directly or through a wholesaler) competes with parallel importers to supply pharmacy</td>
</tr>
<tr>
<td>Pharmacies</td>
<td></td>
<td>Drug Tariff price (primarily Category M)(^{[c]}) less clawback</td>
<td>Market but list price of originator on patent expiry imposes ceiling</td>
<td>Suppliers of all chemically identical drugs (brand and generic manufacturers) compete to supply pharmacy</td>
</tr>
<tr>
<td><strong>Secondary Care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>c. 20 per cent</td>
<td>England - National Tariff for healthcare interventions. W and NI – commissioning revenues (no tariff). Sc – funds agreed with AHB. DH pays for some high-cost drugs directly</td>
<td>Market (but list price imposes a ceiling)</td>
<td>Manufacturers of all therapeutically substitutable products (subject to clinician compliance with formulary) including parallel importers</td>
</tr>
</tbody>
</table>

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\(^{[a]}\) With the exception of Dispensing Doctors, who pay market prices and are reimbursed at list / Drug Tariff price, hence gaining from any margin.

\(^{[b]}\) Pharmacies typically purchase domestically-sourced drugs from wholesalers at list price minus about 10.5 per cent. The supply chain is described in chapter 6.

\(^{[c]}\) Drug Tariff Part VIII lists reimbursement prices for generic drugs (Categories M, A, B and C).
4 COMPETITION IN PRIMARY CARE TO INFLUENCE GPS

4.1 This chapter reviews the nature of competition between drug manufacturers to secure a GP's prescription. We consider the factors that influence GP prescribing behaviour, present the results of new research into GP price sensitivity and highlight key outcomes.

4.2 First, as useful background for both chapters 5 and 6, we present an overview of prescribing in primary care and identify the three main types of market that are relevant to this analysis.

Overview of prescribing within primary care

4.3 In all four countries, the delivery of frontline healthcare, including medicines, is centred on primary care organisations (PCOs), a general term for English Primary Care Trusts and what are usually referred to as Health Boards in Wales, Scotland and Northern Ireland.

4.4 Collectively, PCOs receive around 80 per cent of NHS funds and manage the delivery of most health care to populations of 100,000 to 300,000. Each PCO’s share of available funds is determined by the demographics and relative health needs of its local population, using assessment methodologies that vary across the four countries.

4.5 With regard to primary care prescribing, PCOs manage GPs under the terms of a UK-wide General Medical Services (GMS) contract. PCOs seek to encourage GPs to prescribe cost effectively through local incentive schemes and other arrangements.

Relevant markets in primary care

4.6 It is possible to identify three broad types of market of relevance to prescribing and dispensing in primary care. These are shown in figure 4.1.
4.7 At the upstream level in this supply chain, GPs make decisions on how to treat a particular condition and can issue a prescription. Within this market, competition is from all therapeutically similar treatments that the GP could prescribe. Pharmaceutical firms are active in this market to try and persuade GPs of the benefits of their products, to get them prescribed. Competition at this level is the focus of the rest of this chapter.

4.8 Once the GP has written the prescription, there are two types of downstream markets in which suppliers compete to supply pharmacies to dispense drugs against this prescription. These differ depending on whether the prescription written by the GP is for a branded drug, or whether it is written generically (that is, by chemical name) and the drug in question is off-patent. The nature of competition in these downstream markets is analysed in Chapter 5.

**GP prescribing behaviour**

4.9 To treat a given condition, GPs choose between groups of medicines that are therapeutically substitutable. Depending on the patient’s medical history and condition, the range of appropriate medicines may be broad or narrow. Often, but by no means always, the list of products appearing in a relevant 'Paragraph' of the British National Formulary (BNF) represents the available scope for choice.

**Markets to secure a GP’s prescription**

4.10 BNF Paragraphs can contain one or two, and up to sometimes ten or more, medicines with somewhat different chemical actions, interactions, side-effects and evidence
bases, and which may be on- or off-patent. Members of the same BNF Paragraph are, however, all designed to treat the same condition of a specific part or system of the body (though some may have alternative uses, licensed or unlicensed).

4.11 A BNF Paragraph can therefore in some cases be considered to constitute a ‘market’ for drugs to treat a given medical condition. However, it is important to note that in Competition Act 1998 investigations or merger decisions, appropriate market definitions may be wider or narrower than the Paragraph according to the individual circumstances and the specific question being addressed. This is discussed in the box below.

**Box 4.1: Market definitions relevant to prescribing behaviour**

A standard approach to defining markets for drugs (taken by the European Commission, for example) is to use the Anatomical Therapeutic Chemical (ATC) classification devised by the European Pharmaceutical Marketing Research Association (EphMRA). The World Health Organisation maintains a similar classification.

Within the ATC system, drugs are grouped according to the organ or system on which they act – the first level of analysis – and their therapeutic, pharmacological and chemical properties – the second, third, fourth and sometimes fifth levels of increasingly specific classification. An example from EphMRA is:

<table>
<thead>
<tr>
<th>ATC Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Nervous system</td>
</tr>
<tr>
<td>N6</td>
<td>Psychoanaleptics excluding anti-obesity preparations</td>
</tr>
<tr>
<td>N6A</td>
<td>Anti-depressants and mood stabilisers</td>
</tr>
<tr>
<td>N6A4</td>
<td>SSRI anti-depressants</td>
</tr>
<tr>
<td>Prozac®</td>
<td>(A branded product, chemical name: fluoxetine)</td>
</tr>
</tbody>
</table>

The European Commission considers the third level of analysis – ATC3 – (in the above example ‘C10A’) to be a suitable starting point for market definitions in competition cases. However, the Commission regularly carries out analyses at other ATC levels, or a mixture thereof, recognising that relevant economic markets can be wider or narrower than ATC3, or do not fit neatly into one of the ATC levels. The guiding principle is that products should be included in the same market if they are substitutable for the same purpose.

Often, markets are judged to be narrower than ATC3 or even ATC4. Even medicines with identical active ingredients may have distinct therapeutic uses according to their delivery technology, their side-effects resulting from the presence of chemicals other than the active ingredient, their reputation and other factors influencing their functional substitutability in the eyes of clinicians. The OFT took these factors into account in the Competition Act 1998 decision concerning Napp pharmaceuticals. There, the market relevant to the undertaking’s brand was narrowly defined as ‘sustained-release morphine tablets and capsules’. Other factors in addition to therapeutic substitutability will also inform market definition, such as price.

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19 Decision of the Director General of Fair Trading No CA98/2/2001, 30 March 2001, Napp Pharmaceutical Holdings Limited and Subsidiaries. This decision was appealed to the Competition Appeal Tribunal on 29 May 2001. On 15 January 2002 the Competition Appeal Tribunal upheld substantially the Director General of Fair Trading’s decision on liability.
The analysis presented later in this annexe uses the British National Formulary, which organises drugs in a similar but not identical way to the EphMRA scheme. The BNF uses Chapters, Sections, Paragraphs and Sub-paragraphs that are equivalent to ATC levels 1 to 4 above.

Generic prescribing

4.12 It is important to note that GPs are encouraged to write prescriptions using the drug’s chemical name, whether or not the product in question is out of patent. This is typically known as ‘generic prescribing’ and is encouraged throughout a product’s life cycle to ensure GPs do not need to change prescribing behaviour when a drug goes off patent, thereby facilitating generic entry. As discussed in the box below, generic prescribing has improved markedly over the past ten year in most countries of the UK. However, there is still significant expenditure on off-patent brands for which equivalent generics are available at much cheaper prices. This is discussed at the end of this chapter.

Box 4.2: Generic prescribing

Not all the policies that encourage GPs to prescribe cost effectively are locally implemented. One UK-wide measure that is intended to save money on GPs’ decisions is a long-standing drive for generic prescribing.

Doctors are now encouraged (and taught in medical school) to prescribe drugs by their chemical (generic) name unless there are specific clinical reasons not to. This policy is motivated by both safety and cost concerns. There are sometimes many brand names for one medicine and possible confusion or mistakes are reduced if all doctors use the same names when discussing and prescribing drugs. Also when a branded medicine’s patent expires generic equivalents that appear in the market are usually cheaper for the NHS but, for a pharmacist to be able to dispense a generic, a prescription must be written by a drug’s chemical name. NHS regulations prohibit pharmacists from dispensing a generic drug when a GP has written a prescription for a specific branded product.

The chart below shows how generic prescribing has increased in England over the last ten years for which data is available:
The component of expenditure that was "prescribed generically but only available as a brand" relates to prescriptions written by generic name for medicines that were still covered by patent protection. In total, prescribing by chemical name (sum of the two green bars) accounted for about 70 per cent of primary care expenditure. The overall generic prescribing rate and breakdown are similar in Scotland and Wales but Northern Ireland has an overall generic prescribing rate of only 45 per cent.

For certain drugs, doctors may decide not to prescribe generically. The British National Formulary prints advice about generic prescribing with each drug entry. For example, the BNF recommends against prescribing calcium channel blockers (used to treat hypertension, angina and some arrhythmias) or certain anti-epileptic drugs by generic name. This is because the chemical properties of these drugs make it difficult for any two manufacturers to achieve a great enough (over 98 per cent) 'bioequivalence' between their products – and switching patients between two even marginally different formulations could have dangerous clinical consequences.

4.13 In conclusion, in each individual case, the market for a GP’s prescription will be defined according to concepts of substitutability: where products are considered substitutable, this will lead to a broader market definition. However broadly or narrowly the market is defined, the main form of competition is between suppliers of substitutable drugs in each market to influence GPs’ prescribing decisions. In the following sections we consider the various influences on these decisions.

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20 It is primarily demand side substitutability that is relevant for GPs’ decision making. Supply side substitutability is only likely to be relevant in relation to off-patent brands, for considering possible generic entry.
Factors influencing GP prescribing behaviour and price sensitivity

4.14 This section summarises the various influences that are brought to bear on GPs’ prescribing behaviour. This issue is of key importance as over 80 per cent of NHS pharmaceutical expenditure occurs in primary care.

4.15 In understanding influences on GPs, it is important to note that their interests are not always closely aligned with those of PCOs. PCOs have relatively strong motivations to control expenditure on drugs. This is because their budgets are fixed by governments over several years on a needs basis according to a principle known as ‘weighted capitation’ which does not directly reimburse them for drug expenditure. In England in particular, PCTs stand to lose from overspending on drugs because the methodology by which needs-based funds are paid does not include historical prescribing costs as a budgetary need.

4.16 PCOs choose freely how to allocate funds across expenditure items to achieve healthcare outcomes but have duties not to exceed budgets. In recent years, however, a number of PCOs have been running financial deficits. According to DH, one in four English Primary Care Trusts failed to balance their books in 2005 whilst Audit Scotland has found that numerous Area Health Boards have gone into deficit. Still, PCOs should have every motivation to contain drugs spend since performance is monitored and failing organisations can in principle see their management boards disciplined or be merged with better performing peers.

4.17 However, as discussed above, PCOs neither decide which drugs should be prescribed in primary care nor directly purchase the drugs that are prescribed. Rather, pharmacies acting as independent contractors buy the medicines that GPs and other professionals prescribe. This leads to clear principal-agent issues, since GPs make decisions that PCOs fund. The problem from a PCO’s point of view is that GPs’ clinical decisions are complex and GPs take many varied incentives into account when deciding how to prescribe, not just those of the PCO.

4.18 The many influences that act on GPs’ prescribing decisions (and their assessments of cost and clinical effectiveness) include:

- guidance from national bodies such as NICE, SMC and SIGN, AWMSG and AWPAG, etc

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21 Weighted capitation converts each PCO’s local population into a weighted population that may be higher or lower than the true number according to how local health needs (e.g. demographics and the measured occurrence of certain major medical conditions) relate to national averages. Each PCO’s funding allocation is then obtained by multiplying its weighted population by [total NHS funds earmarked for primary care divided by the sum of all PCO weighted populations]. The formulae by which weighted populations are obtained are complex and different in each of the four countries of the UK.

22 However, historical drugs spending does increase the budgetary allocations to PCOs in Scotland and Northern Ireland.

23 Source: DH document ‘NHS organisations forecast surplus and deficits 2005-06: Month 6’.

24 See www.audit-scotland.gov.uk/publications/audithealth05.htm for specific AHB reports. However, this issue is partly due to some AHBs taking on the liabilities of failing local hospitals.
• the General Medical Services (GMS) contract which determines GPs' working conditions and provides a framework for their remuneration across the UK
• local measures implemented by PCOs, including prescribing incentive schemes, local formularies and advice from prescribing advisers
• peer pressure, informed by prescribing trend information made openly available within the NHS and the practice of hospital consultants
• the marketing activities of pharmaceuticals manufacturers
• their own, independent assessment of clinical evidence published in scientific journals, and
• pressure from patients who may have an attachment to a particular brand.

4.19 Incentives for dispensing doctors, who act as pharmacists to procure and dispense some of the medicines they prescribe, may also include profit.

**NICE, SMC and AWMSG**

4.20 The influence of NICE, SMC and AWMSG on prescribing decisions is discussed in Annexe B of this report. The bodies are considered a trusted source of advice by GPs and they have certainly helped improve awareness of the importance of cost effectiveness. However, their guidance is not always followed in practice and NICE at least does not look at all drugs. Implementation is not helped by the fact that in some cases guidance is not fully reflected in incentives contained in the GMS contract, which, as discussed below, is a major influence on GP behaviour.

**GMS contract**

4.21 Discussions with stakeholders suggested that the GMS contract exerts the strongest influence on GPs' prescribing behaviour, and that its net effect is probably to dull price sensitivity. This is because the contract offers many and varied financial rewards to GPs who meet certain clinical standards. The responsibility for containing cost is left to PCOs to organise locally.

4.22 Many objectives in the contract relate to prescribing. For example, one best-practice target is to place all post heart-attack cases on a course of statins (to manage cholesterol), beta-blockers (to manage blood pressure) and aspirin (to improve circulation). Manufacturers’ sales forces are reported to highlight incentives in the contract when encouraging GPs to prescribe well-known branded medicines.

**Box 4.3: The General Medical Services (GMS) contract**

The current GMS contract was negotiated in 2003 between the NHS Confederation, representing the Department of Health for England and the health departments of the devolved administrations, and the British Medical Association, representing GPs. It applies across the UK. Implementation began in 2004 and the contract has recently undergone a review, with some changes taking effect from April 2006.
The contract is between PCOs and GP practices rather than individual doctors. Resources are allocated to practices through three main funding streams that are paid by PCOs:

- the global sum, to cover practice running costs
- a system of quality rewards, the Quality and Outcomes Framework (QOF)
- payments for ‘enhanced services’, available to practices that opt to carry out functions beyond the minimum required in the contract.

The second two streams were new in the latest contract. The needs-based funding paid to PCOs to cover all their operations was increased to fund the new streams. Two-thirds of the uplift was earmarked for the QOF.

The QOF rewards practices for meeting clinical, organisational and patient-experience standards, as well as for offering additional services beyond the contractual minimum. Practices earn entitlements to payment under the QOF by accumulating points for meeting national targets. The value of each point is determined nationally but rewards are paid by local PCOs. Amendments to the GMS contract that took effect in 2006 include the addition of new clinical targets to those already attracting quality rewards.

The QOF was intended to give GPs the professional freedom to decide which standards they wish to aspire to and how to organise their work to meet them. Other measures in the contract were designed to attract and retain GPs, such as a Minimum Practice Income Guarantee and the system of enhanced services, which allows practices to specialise in certain clinical areas and control workload by opting out from providing services such as out-of-hours care.

The GMS contract is not the only NHS employment contract in existence for GPs. The Personal Medical Services (PMS) contract can be agreed locally between PCOs and practices. However, the terms of the PMS contract have generally been altered to match those of the GMS contract so that, in practice, there is little difference to the incentives faced by GPs.

### Prescribing incentives implemented by PCOs

**4.23** The influences that PCOs can bring to bear on GPs locally include prescribing incentive schemes, local formularies and organised peer pressure. Such measures vary substantially in use and effectiveness around the UK. In England, there is also the new system of Practice-Based Commissioning.

**4.24** Prescribing incentive schemes pay rewards to practices that contain their expenditure on drugs within agreed annual budgets. Schemes may also set targets in specific areas, such as to reduce the prescribing of antibiotics. PCOs around the UK have usually been required by local NHS regulations to operate a scheme though the details of design have been left open. Wales and Northern Ireland have experimented with national template schemes. Discussions with stakeholders suggested that schemes vary widely in their comprehensiveness and strictness. Moreover they have tended to
wither in recent years as the cost to PCOs of generating incentives to offset the rewards in the GMS contract has become prohibitive.\textsuperscript{25}

4.25 Local formularies – lists of approved prescription drugs – have been employed to some extent in primary care and perhaps more in Scotland than the other countries. Data on compliance are scant but suggest that many GPs view formularies as a source of advice rather than a hard behavioural constraint. However, the success of individual arrangements around the UK is variable. In our research we found one particularly well developed initiative, which also encompasses secondary care, in Northern Ireland. It is detailed in the box below.

<table>
<thead>
<tr>
<th>Box 4.4: Integrated formularies in Northern Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>The United Hospitals Trust in Antrim, in collaboration with its local NHS Board, has introduced a system of integrated medicines management for primary and secondary care. Among other objectives, the system is intended to coordinate GP prescribing and hospital practice.</td>
</tr>
<tr>
<td>The STEPS (Safe Therapeutic Economic Pharmaceutical Selection) system manages medicines selection, procurement, prescription and review. The aim is to use medicines in the Antrim area in a consistent way so that both patients and healthcare system performance can benefit. In secondary care, the length of hospital stays and readmission rates can be reduced when patients receive the most appropriate medication, whilst in primary care prescription wastage and treatment check-ups can also be minimised.</td>
</tr>
<tr>
<td>Typically the STEPS system recommends a single medicine for the management of a given condition, which most clinicians – GPs consultants and others – are expected to prescribe except in special circumstances.\textsuperscript{26}</td>
</tr>
<tr>
<td>The STEPS steering group has taken the view that the unnecessary use of different chemicals can lead to inconsistent therapeutic outcomes whilst sourcing from different providers of a given generic may confuse patients and affect compliance. There is also a concern that, between primary and secondary care, outpatients should usually continue to take the same medication they were started on in hospital – but at the same time community prescribing should be cost effective for the local health economy as a whole. Across the UK suppliers are sometimes observed to offer drugs to hospitals at 'loss-leader' prices in the anticipation of earning higher NHS list prices in primary care. Consequently, the STEPS system brings primary care prices into the decision-making process for hospital tenders.</td>
</tr>
<tr>
<td>The core of the STEPS system is an evaluation procedure that is applied to therapeutic categories. Therapeutically substitutable products within a category are assessed by a local expert panel for efficacy, side-effects, interactions with other drugs, available formulations, the available evidence base and other criteria. Comparable drugs are ranked and prices for each drug in primary and secondary care are then considered before a procurement choice is made.</td>
</tr>
</tbody>
</table>

\textsuperscript{25} Probably the most recent comprehensive and independent survey of prescribing incentive schemes to be carried out is OHE (2002), 'Influencing Prescribing in a Primary Care Led NHS: A Review of the Management of Prescribing and Findings from the MANMED Survey'. Conversations that we held with primary care organisations suggested that prescribing incentive schemes are now less central to PCOs' efforts to manage prescribing than at the time of the MANMED survey. Advice from prescribing advisers has become the principal means of influencing GPs in many localities.

\textsuperscript{26} Issues of individual patient tolerance may require that second-line products also be provided for.
A drug selected in this way becomes the principle item purchased by hospital contracts and is actively recommended by prescribing advisers to GPs in the community. The final selection is informed by meetings with key stakeholders, including hospital consultants, prescribing advisers, local GP representatives, pharmacists and representatives of the industry (ABPI). Decisions are also informed by broader NHS policies so, for example, drugs are assessed for their efficacy in achieving clinical outcomes stipulated in the Quality and Outcomes Framework of the GMS contract. Procurement decisions are then fed through to other policy areas: for example, they are reflected in regional prescribing incentives schemes.

STEPS and similar initiatives around the UK are a welcome response to the fact that the various organisations and contractors that make up the NHS need to offer joined-up care. As regards value for money, however, there are limitations to what formulary approaches can achieve. Whilst some savings can be obtained by switching patients to a preferred medicine, it is unlikely that any local procurement initiative would have the negotiating power to affect companies’ decisions over NHS list prices for major products that continue to be required by the NHS in significant volumes.

4.26 Complementing formal measures such as incentive schemes and formularies, organised peer pressure is perhaps the most cost effective means by which PCOs can influence GPs. It is clear from publicly available data if any one practice is putting strain on a local health economy, for example by ‘over-prescribing’ for minor conditions. More generally, peer pressure is often said to be a major factor in GPs’ decisions due to their professional liability: lawsuits are a genuine threat against which the defence is assisted by following conventional practice.

Access to information

4.27 The awareness of and sensitivity to drugs prices among GPs is determined by the balance of all their incentives and influences such as those outlined above. However, even if GPs had appropriate incentives to take into account costs, they typically have insufficient time to acquaint themselves with data on the relative cost and clinical effectiveness of different drugs.

4.28 The problems faced by GPs in assimilating all information that may be relevant to prescribing decisions should not be underestimated. Work undertaken by the National Prescribing Centre27 to advise clinicians on the efficient use of information observes that the journal articles and NHS guidance pertaining to any individual clinical decision can run into many thousands of pages, and can be updated dynamically. It is by no means obvious how clinicians should interpret knowledge from many diverse sources and the difficulties that can arise in trying to make the most appropriate decisions have been addressed by many authors.28 Such concerns were also taken up by the Health Select Committee Report in 2004-05 on the influence of the pharmaceutical industry,

27 Discussed with Dr Neal Maskrey.
where concerns were voiced that ‘there is little independent and easily digestible information reaching and influencing busy GPs and other prescribers.’

Marketing activities

4.29 It is perhaps GPs’ absence of time above all other factors that makes prescribers susceptible to the marketing strategies of drug companies (which include the use of advertising on certain types of prescribing software). Companies spent some £850 million on marketing activities in 2004. As noted in Annexe L, we believe that current linear price structures create in part the incentive to incur this expenditure, as they give companies rewards for every extra unit prescribed that are far in excess of costs – and possibly value to the NHS.

Evidence on GP price sensitivity

4.30 The awareness of and sensitivity to drug prices among GPs is therefore shaped by the incentives they are given, the influences that are bought to bear on them and the information to which they have access. Price sensitivity among GPs is particularly important because when drugs lose patent protection the prices of generics can be at substantial discounts to the incumbent brand.

4.31 Consistent with many of the above observations, previous studies have found GPs’ awareness of and sensitivity to drugs prices to be low. In 2002, a joint study by the Department of Health and the Association of British Pharmaceutical Industries (ABPI) investigated GPs’ knowledge of the relative prices of drugs within five therapeutic classes. Face-to-face interviews were conducted with 200 English GPs. They uncovered considerable variation in price awareness across therapy groups. Overall, participants got around 50 per cent of pair-wise choices between the prices of products in the same therapy class correct, which is consistent with guessing. The same study also reported that, at the time, English GPs deemed cost to be a lower priority than clinical concerns.

4.32 Since the last survey of GP price sensitivity was carried out, there have been some important changes that may plausibly affect GP price awareness, such as the bedding down of NICE and SMC and the onset in some areas of England of Practice-Based Commissioning. For this reason, the OFT collaborated with the National Audit Office to conduct an up-to-date survey, which is summarised in Box 4.5 below and described in more detail in Annexe C.

Box 4.5: Recent evidence on price sensitivity among GPs

This box describes the results of research into GPs’ knowledge of the prices of a number of commonly prescribed drugs. The results are taken from a survey of 1,000 English GPs.

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29 Point 379 of the report, available on the House of Commons website.

conducted as part of ongoing research by the National Audit Office into value for money in primary care. The exercise outlined below is described in greater detail in Annexe C of this report.

As part of its survey of GPs, the NAO kindly agreed to the inclusion of a test of price sensitivity designed by the OFT. We asked GPs to rank branded drugs within each of six therapeutic areas in order of price. The areas tested were:

- proton pump inhibitors
- statins
- ACE inhibitors and angiotensin II receptor antagonists (considered together)
- SSRI antidepressants
- other antidepressants, and
- non-steroidal anti-inflammatory drugs.

These groups were included because they are commonly prescribed and familiar to most clinicians. Each group is a major expenditure area containing drugs that are widely agreed to be quite close therapeutic substitutes. Two of the groups – the statins and the proton pump inhibitors – account for respectively the most and second-most NHS expenditure of any chemical class. All of the six groups are consistently among the ten largest components of the drugs bill.

Each of the groups contains numerous drugs in many presentations. We selected for inclusion the most commonly prescribed branded drugs, forms, strengths and pack sizes, with a view to providing GPs with a manageable list of around six highly recognisable products to rank in each group. There was no attempt to select items that would be especially easy or difficult to assess for price.

Looking at the exercise as a whole, GPs' ability to rank branded drugs in order of price proved no better than chance. There were, however, differences between the results for different groups: in several groups results were significantly better than would be expected by chance and in others much worse.

Results were best for NSAIDs (where over 70 per cent of all possible pair-wise comparisons between included drugs were correct) and worst for the PPIs and statins (with success rates around 30 per cent). Across classes, it appeared that in groups where branded drugs had generic alternatives this sometimes contributed to the difficulty of making correct ranking assessments.

The results suggest that GPs may have a systematic perception that off-patent brands have the lowest prices of all brands in a therapeutic group – implying a belief that when a drug goes off patent it lowers its price in response to generic entry. But in fact off-patent brands often do not significantly fall in price in this way.

Looking at the ability to rank prices in relation to other factors, we found no compelling evidence that any demographic group of doctors that could be identified in the survey was better or worse at ranking prices than others.

4.33 These results provide strong evidence of poor price awareness in some major areas of pharmaceutical spend. However, it should not be concluded that this applies to all GPs and for all products. Competition between off-patent brands has been suggested to us
as an area in which there might be greater than average sensitivity to price. Some new entrant brands have, for example, been able to compete with originator brands through offering a price discount, and marketing their products to PCTs and GPs accordingly. It is perhaps unsurprising that price can be a more important factor for competition between off-patent brands, since the products contain the same active substance, such that quality differences between them will be less significant than for therapeutic competition (that between brands with different active substances).

4.34 PCTs may also be more able to influence behaviour where GPs are not subject to strong countervailing marketing from pharmaceutical companies. For example several PCTs have been successful in persuading GPs to prescribe a branded generic instead of generic simvastatin, which – as it is produced generically - is not specifically marketed to GPs by any one company.  

4.35 There is also some evidence, discussed below, that prescribing volumes of a drug can increase following dramatic falls in price. To take the statins as a case in point, total prescribing volumes for simvastatin increased markedly when it lost patent protection in 2003 and its price fell accordingly. Of course, there are many other factors that combine to explain this outcome. Use of all statins has increased greatly in recent years as medical opinion has begun to reach a consensus about the therapeutic value of the class as a whole, for example. But the example is also consistent with some degree of sensitivity to significant price changes in major drugs. Presumably this sensitivity is mediated through a variety of the channels discussed above such as prescribing advisers and national guidance bodies.

4.36 It is also worth noting that price awareness might be expected to increase with the introduction of Practice-Based Commissioning in England. Practice-Based Commissioning was first mooted by the Department of Health in late 2004. Under the system GP practices will be able to execute the entire commissioning role of PCTs for their local patient lists. Practices will receive needs-based funding to allocate across prescribing, other primary care delivery, hospital commissioning, etc, and may be allowed to reinvest savings back into their businesses. It seems that PCTs will be liable for overspends, though practices failing to break even over a budget cycle would lose budget-holding rights. The precise effect of Practice-Based Commissioning on the sensitivity of GPs to drug prices will not be known for some years as the system has only recently begun.

4.37 In conclusion, while there is variation between individuals and between products, awareness of and sensitivity to the relative price of some major branded drugs is fairly weak among primary care prescribers. This is one of the reasons supplementary

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31 As discussed in Annexes J and L, the supply of branded generics can be profitable because the pharmacy earns a significant margin on true generics but not on brands (including branded generics).

32 Universal coverage will be achieved when all PCTs have put in place the arrangements to facilitate Practice Based Commissioning. The DH expected all PCTs to have done so by 31 December 2006. This would involve all practices receiving information about their referrals, information on their allocation of the PCT budget, the offer of support from their PCT, and details of the local governance arrangements.
influences and controls such as the PPRS are required in other parts of the NHS. Of course, that price alone is not the only criterion prescribers should take into account. Efficient prescribing behaviour requires a consideration of price relative to the benefits a drug produces – or cost effectiveness. As suggested at the end of this chapter, there is strong evidence that current prescribing practices in the UK do not always meet this criterion.

**Static and dynamic measures of market concentration**

4.38 The focus of this annexe is on the demand side of pharmaceuticals markets in the UK. Annexe D considers features relevant to the supply side – that is, the process of developing and marketing drugs, the nature of the costs involved and companies’ global investment incentives and pricing strategies. As noted in that annexe, pharmaceuticals markets are characterised by significant barriers to entry, reflecting the high fixed costs required to develop a drug and intellectual property rights companies are granted to protect their investments. Accordingly, one would expect pharmaceuticals markets in most countries to be fairly concentrated (that is, that individual companies will have fairly high market shares). Particular outcomes in any one country will be a function both of these supply side factors and key characteristics of demand, of the sort discussed above in the context of the NHS.

4.39 This section provides an overview of evidence on concentration in markets to secure primary care prescriptions in the UK. It begins with a static analysis – a snapshot of concentration at a particular point in time – before looking at how prices and volumes of drugs change over time in response to events such as new entry and substitute products going off patent.

**Static analysis**

4.40 As discussed above, the fundamental nature of competition at the GP level is that companies seek to gain market share by convincing GPs that their products are more clinically effective than rival products for a particular condition (or, to the extent that GPs are price sensitive, more cost effective than rival products). Accordingly, drugs markets are routinely defined according to the principle of therapeutic substitutability.

4.41 The tables below show the degree of concentration in UK drugs markets defined at the level of the BNF Paragraph. As discussed above, markets at this level are for groups of typically five to ten quite closely substitutable products, such as ‘tricyclic and related antidepressants’ (one of several classes of antidepressant) or ‘proton pump inhibitors’ (for stomach ulcers).

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33 Even if prescribers were fully aware of prices, there would be strong arguments for the centralisation of certain functions within the NHS, such as the assessment of cost effectiveness (economies of scale arising from the complexity of the analysis involved) and the negotiation of prices (effective use of NHS buyer power).
We use the BNF because UK data is most readily available in BNF format, which both DH and the ABPI have set precedents for using. We consider BNF Paragraphs which approximate to the ATC3/4 level, and have generated for each of England, Scotland and Northern Ireland summaries of the concentrations of markets so defined. It is important to reiterate that in many cases markets may be defined at very different levels to these. The analysis here is simply intended to give a broad brush overview of the extent of competition across all Paragraphs of the BNF.

Table 4.1(a) Value and share of sales by concentration of markets: England, 2005

<table>
<thead>
<tr>
<th>C1</th>
<th>NIC (£, 000s)</th>
<th>NIC Share per cent</th>
<th>Number of Markets</th>
<th>per cent of Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>192,247</td>
<td>2.5</td>
<td>56</td>
<td>16.3</td>
</tr>
<tr>
<td>&gt;0.9</td>
<td>362,072</td>
<td>4.7</td>
<td>85</td>
<td>24.8</td>
</tr>
<tr>
<td>&gt;0.8</td>
<td>410,363</td>
<td>5.4</td>
<td>102</td>
<td>29.7</td>
</tr>
<tr>
<td>&gt;0.7</td>
<td>836,803</td>
<td>10.9</td>
<td>123</td>
<td>35.9</td>
</tr>
<tr>
<td>&gt;0.6</td>
<td>2,108,379</td>
<td>27.6</td>
<td>148</td>
<td>43.1</td>
</tr>
<tr>
<td>&gt;0.5</td>
<td>2,902,746</td>
<td>37.9</td>
<td>183</td>
<td>53.4</td>
</tr>
<tr>
<td>&gt;0.4</td>
<td>4,306,886</td>
<td>56.3</td>
<td>215</td>
<td>62.7</td>
</tr>
<tr>
<td>&gt;0.3</td>
<td>4,790,799</td>
<td>62.6</td>
<td>238</td>
<td>69.4</td>
</tr>
<tr>
<td>&gt;0.2</td>
<td>6,325,941</td>
<td>82.7</td>
<td>268</td>
<td>78.1</td>
</tr>
<tr>
<td>&gt;0.1</td>
<td>7,120,672</td>
<td>93.1</td>
<td>287</td>
<td>83.7</td>
</tr>
<tr>
<td>&gt;0</td>
<td>7,651,726</td>
<td>100.0</td>
<td>343</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.1(b) Value and share of sales by concentration of markets: Scotland, 2005

<table>
<thead>
<tr>
<th>C1</th>
<th>NIC (£, 000s)</th>
<th>NIC Share per cent</th>
<th>Number of Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;0.4</td>
<td>269,558</td>
<td>60.3</td>
<td>217</td>
</tr>
</tbody>
</table>

Table 4.1(c) Value and share of sales by concentration of markets: Northern Ireland, 2005

<table>
<thead>
<tr>
<th>C1</th>
<th>NIC (£, 000s)</th>
<th>NIC Share per cent</th>
<th>Number of Markets</th>
<th>per cent of Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;0.4</td>
<td>106,655</td>
<td>61.0</td>
<td>235</td>
<td>85.5</td>
</tr>
</tbody>
</table>

NIC is 'Net Ingredient Cost', a term for the NHS reimbursement price for drugs (the PPRS list price for brands, the Drug Tariff basic price for generics) before fees and allowances paid to pharmacies. Note that Welsh data are not susceptible to this analysis.

The C1 is the 'one-firm' concentration ratio: the value (NIC) share of a BNF Paragraph held by the top manufacturer. The tables show the number of Paragraphs for which the C1 measure of concentration exceeds decreasing levels. Competition authorities often consider markets where the leading firm has a share of 40 per cent or more of sales to be highly concentrated and, in a formal Competition Act 1998 investigation, a firm is
unlikely to be considered dominant if it has a share below 40 per cent of the relevant market.\textsuperscript{34} For reasons of space, only this summary result is presented for Scotland and Northern Ireland. The tables show that across the UK between 67 and 86 per cent of ‘markets’ as defined above feature a firm with a market share of greater than 40 per cent. These markets account for between 47 and 65 per cent of NHS expenditure on prescription medicines. These numbers have increased slightly since 2000 (data not shown).

4.44 Note that these tables only show the share of total drug expenditure accounted for by manufacturers of branded drugs. This is because in UK community prescribing data the individual manufacturers of generic drugs are not recorded (there can be many making any given chemical). Therefore when the C1 position in a market is held by a ‘generic manufacturer’ (as it is coded in the data) it is impossible to tell if that means one or several firms. Following the practice of the Department of Health\textsuperscript{35}, in this case we assume there are many generic manufacturers and take the C1 firm to be the largest brand manufacturer. This potentially underestimates concentrations in some markets.

Dynamic analysis

4.45 In an industry characterised by large sunk-cost investments in R&D and patent protected innovations it is natural for markets to be concentrated in the short run. The specialised nature, costs and uncertainty of the process of developing a new chemical entity constitute a high barrier to entry to most markets for branded drugs so that the average number of new product launches per year is typically low.\textsuperscript{36} However, given the innovative nature of the industry, one would expect market shares to change over time, as new drugs enter markets, taking the place of older products. This section presents a brief account of these dynamic effects.

Introduction to analysis

4.46 Competition between drugs that treat the same condition can take place in two principal dimensions:\textsuperscript{37}

- quality (in the therapeutic sense)\textsuperscript{38} – when new drugs vie to offer, for example, improved clinical efficacy, fewer side-effects, a more favourable trade-off between

\textsuperscript{34} Again, since this analysis is provided for illustrative purposes, no inferences can be drawn from it about how the OFT or another competition authority might define the market or assess dominance in any particular case in the future. Such an assessment would need to reflect the individual hypotheses relevant to the case.

\textsuperscript{35} DH/ABPI (2002), ‘PPRS: The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS’.

\textsuperscript{36} Barriers to entry are clearly much lower for generics manufacturers. Competition between off-patent brands and generics is explored later in this annexe.

\textsuperscript{37} It is also true that branded drugs can compete on time to market, particularly when research begins on two relatively similar technologies following the same breakthrough in basic science. But it is virtually impossible to assess competition on time to market using publicly available data since decisions made during the development process are usually covered by commercial confidentiality.

\textsuperscript{38} Quality of manufacture is strictly regulated by the MHRA and not a dimension of competition.
safety and efficacy, or benefits to patient sub-groups not adequately treated by older alternatives

• price – in particular between drugs offering relatively similar therapeutic benefits.

4.47 We focus in this section on prices, while competition on therapeutic efficacy is the subject of Annexe M of this report. Assessing the relative therapeutic benefits of drugs requires analysis of their pharmacology and the clinical practices in which they are used. The involved nature of such material merits being considered separately. Given its overriding importance in assessing the effectiveness of competition in pharmaceuticals, however, we refer to some high level conclusions of that analysis at the end of this chapter.

DH / ABPI study

4.48 The analysis presented here is similar to that of a joint exercise by DH and the ABPI, DH/ABPI (2002), which sought to explore the workings of competition between branded drugs under the PPRS focusing mainly on the dimension of price. The OFT has updated some of the analysis in that study using data running to the end of 2005 (compared to the end of 2001 in the report).

4.49 DH/ABPI (2002) presents various summary analyses of dynamic competition between on-patent branded drugs. The study focuses mainly on primary care in England, using Prescription Cost Analysis (PCA) data from the Prescription Pricing Division in England and proprietary data sets from IMS Health. Most of the analysis comments on time series of NHS list prices and prescribing volumes for on-patent brands in ATC 2 or 3 categories (usually BNF Paragraphs or Sub Paragraphs but sometimes BNF Sections). Summary accounts of how prescribing volumes respond to price changes and new launches are provided and the evolution of market shares is shown.

4.50 DH/ABPI (2002) encounters difficulties explaining movements in prices and quantities in terms of a model of NHS (mainly GPs’) demand for drugs. The study commissioned an exercise that attempted to model demand relationships in a number of major expenditure areas – for example, proton pump inhibitors, antidepressants and asthma inhalers – using econometric techniques. The objective was to relate the quantities of drugs prescribed by GPs to own prices, the prices of substitutable brands in the same class and, in different models, other factors relevant to GP demand such as aggregate...
prescribing levels of a drug (to proxy for perceptions of quality).\textsuperscript{41} However, it proved impossible to obtain robust and statistically significant demand functions. Due to a widespread lack of price changes among branded drugs estimations of price sensitivity were unreliable because models had to explain large movements in prescribing – that were driven as much by exogenous factors such as government priority frameworks for major diseases as by prices – to very small movements in prices as an explanatory factor.\textsuperscript{42}

OFT analysis

4.51 Because of difficulties with formal models of demand, DH/ABPI (2002) relies mostly on empirical descriptions of price and quantity movements to describe competition – in particular price sensitivity – in primary care markets for branded drugs. The OFT has updated a number of the analyses in the study, extending the data period to the end of 2005, but we do not present all of them here since they do not change the headline messages.

4.52 To take one example, DH/ABPI (2002) presents in tabular form a summary of the impact of new product launches in eleven major markets (defined at roughly BNF Paragraph level) over the period 1989 to 2001. Measures of how each market responds to launches following that of the first mover include:

- the market share achieved by each launch one and four years\textsuperscript{43} after it appeared, and
- the price discount to the first-mover product (considered the incumbent through the whole period) at which each launch appeared.

4.53 Discounts are calculated relative to the first-mover price observed the quarter before a new launch in two different ways. One calculation is for 'modal strengths', where the price of the most widely prescribed presentation of the new drug appearing at launch is compared to the price of the most widely used presentation of the incumbent. A second discount calculation is made on the basis of the relative price per defined daily

\textsuperscript{41} So-called 'consumption externalities' seem to be important in the demand for pharmaceuticals. One GP’s perception of the efficacy or safety of a drug may be influenced by the extent of prescribing by colleagues, in particular if – as is often asserted – British GPs are relatively risk-averse due to their status as independent contractors to the NHS with unlimited professional liability for their clinical decisions.

\textsuperscript{42} Another issue is that PCA and IMS data sets do not distinguish between initial and repeat prescriptions but it is likely that a GP’s elasticity of demand would be different over the two categories. It is reasonable to expect price sensitivity to be higher for initial prescriptions than repeats.

\textsuperscript{43} Or at the end of the sample, whichever is earlier.
4.54 Discounts calculated on the two bases can be very different, for example when the most commonly used form of a new drug is cheaper but also less potent than the modal strength of the incumbent, meaning that it tends to be prescribed in higher quantities at a higher average cost per patient to maintain treatment. We have replicated and extended this analysis and, as in DH/ABPI (2002), we found that discounts are variable according to the basis on which they are calculated. We also obtained some different results for discounts, mainly because we used defined daily doses from a different source. The table below shows a sample from our results, for the proton pump inhibitors (for dyspepsia):

Table 4.2 New brand launches: proton pump inhibitors

<table>
<thead>
<tr>
<th>First entry: Losec® (omeprazole), 1989 Q2</th>
<th>Entry</th>
<th>Lag in quarters</th>
<th>Market share after 1 (4) years</th>
<th>Discount to incumbent at entry</th>
<th>Modal strength†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoton® (lansoprazole)</td>
<td>19</td>
<td>6 per cent</td>
<td>38 per DDD</td>
<td>7 per cent (Cap, EC,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Protium® (pantoprazole)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16 per cent (Tab, EC,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pariet® (rabeprazole)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21 per cent (Tab, EC,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nexium® (esomeprazole)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35 per cent (Tab 20mg)</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
(*) Zoton® and Protium® both initially launched in only one presentation. Pariet® and Nexium® initially appeared in two presentations. Losec® was available in an increasing number of presentations through the sample.
†The modal strength of Losec® throughout the sample was: Cap (EC) 20mg.

4.55 The table shows that each new PPI was launched at a discount to the incumbent (Losec, omeprazole), and that discounts are greater on the basis of price per maintenance dose. However, there are important limitations to what can be inferred from the table since it does not show how the prices of all products move as a group – rather than just relative to one reference product – during the periods between

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44 A DDD is the assumed average maintenance dose per day for a drug used in its main indication in adults. It is important to emphasize that DDDs are standardised units of equivalence that may not apply for all patients or indications. They do, however, capture how drugs are used across large populations. Various sources express an opinion on what are the defined daily doses of different drugs, including the World Health Organisation.
45 DH/ABPI (2002) used DDDs defined by the WHO which set out the average doses at which drugs are prescribed to maintain treatment in adults across many different countries. We were referred by officials at the Department of Health to estimates of maintenance doses more relevant specifically to UK clinical practice, Average Daily Quantities (ADQs).
46 PCA data does not quote prices directly. Rather for each drug (presentation) it quotes total NHS reimbursements to pharmacies in pounds and total volumes prescribed in units (tablets, capsules, etc, rather than packs). Prices can be constructed by dividing the former by the latter. This gives an average price per pill paid by the NHS, which can conceal the prices per pack at which drugs are reimbursed in practice (when, for example, a pack of 56 tablets is not always twice the price of a pack of 28). However, for the drugs considered here and below this issue does not arise since all are available in primary care in one pack size only (usually 28 or 30 units).
launches. As will be seen below, prices in this and other markets in fact become quite closely bunched over time with the result that there is little differentiation on cost between many comparable drugs in later years.\(^{47}\)

4.56 The workings of price competition in a market can be more clearly observed if the prices and prescribing volumes of all products are plotted as time series. Below, we present plots of prices and volumes in four major markets:

- the proton pump inhibitors
- the angiotensin II receptor antagonists (for high blood pressure)
- the selective serotonin reuptake inhibitors (SSRIs, a class of antidepressants), and
- the statins (for cholesterol).

4.57 The plots below display the list prices and volumes of the most widely prescribed presentations (modal strengths) of each branded drug in each market (typically the average maintenance dose as recommended by the BNF). As above, PCA data for England is used. Prices are on a per-unit (tablet, capsule) basis rather than per pack and volumes are in thousands of units.

4.58 The four sets of plots show some striking similarities in the workings of price competition in different therapeutic areas:

- typically brands are launched at a discount to the incumbent in a market. Exceptions include the SSRI Seroxat\(^{®}\) (paroxetine) and the statin Lipostat\(^{®}\) (pravastatin). But in both cases a PPRS price cut (in 1994 and 1999 respectively) soon after reduced the price of the new launch to the incumbent level
- prices are closely bunched in each market, particularly in later years. Price differences between the first and subsequent launches consistently erode over time
- the general trajectory of prices in all markets is downwards. This reflects the mechanisms of the PPRS, in particular the price cuts and constraints on increasing the list price. Products affected by the periodic price cuts are clearly shown. Occasionally a price is modulated upwards but most are static or fall together. In the plots shown prices are reduced outside of the obligatory cuts only very rarely.

4.59 Prescribing in all four markets also develops in similar ways. Considering each market as a whole, prescribing growth is rapid and sustained (and would be seen to be larger still if presentations other than the modal strengths of each drug were included). This is

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\(^{47}\) As can be seen in chart 4.3 below, the greatest price difference between any two PPIs is between omeprazole and a variant (enantiomer) of the same chemical, esomeprazole, which are both manufactured by the same company. Esomeprazole was launched shortly before the patent expiry of omeprazole and, whilst cheaper than branded omeprazole, is more expensive than generic omeprazole. Esomeprazole nonetheless seems to have attracted some prescribing away from generic omeprazole. Issues around the therapeutic substitutability between esomeprazole and omeprazole are taken up in Annexe M of this report.
unsurprising since each therapeutic class treats a condition that is widespread in the UK population and, in three cases, where there is a National Service Framework making it an NHS priority. The NSF for Coronary Heart Disease is relevant to the statins and, possibly, also to the A2RAs\(^{48}\) whilst the NSF for Mental Health is relevant to the SSRIs.

4.60 Trends in relative uptake of different products within each market are also similar. In all cases, the first mover retains the highest volume share as competing brands enter until its dispensing volumes drop sharply with the onset of generic competition.\(^{49}\) Typically, the volume share achieved by a product diminishes for later entrants. These facts probably explain the launch price discounts observed in all four markets. However, most new brands also acquire market share quickly, which perhaps explains the observed price bunching since once a chemical has become established GPs are less likely to switch patients for price reasons.

4.61 The graphs show that volumes of an originator brand experience a significant drop when a patent expires, in response to the entry of much cheaper and bioequivalent generic products. Usually, prescribing of the affected chemical continues along the same trend as before patent expiry but dispensing of the brand is substituted by dispensing of generics (made possible because of high prescribing rates by generic name before patent expiry). The entry of generics is not shown on most plots in this analysis of competition between brands (and so as not to obscure the plots with a multiplicity of lines). However, we have shown generic entry in the statins market in the last two figures below, Figures 4.11 and 4.12. When simvastatin and pravastatin lost patent protection in 2003 and 2004 respectively, dispensing of the originator brands was very largely substituted by dispensing of generics.

4.62 However, significantly, Figures 4.11 and 4.12 do not show significant changes in price or volumes of other on-patent statins when simvastatin and pravastatin lost patent protection.\(^{50}\) Given the very low prices at which generics are available, sustained prescribing of high-priced brands that may be therapeutic substitutes for many patients raises potentially very significant concerns about the cost effectiveness of prescribing

\(^{48}\) NSFs do not recommend individual drugs but may recommend classes and do implicitly require the NHS to use technologies that are required to manage the manifestations of the condition covered. In Annexe M of this report, we examine the cases in which the A2RAs may be considered a preferred treatment for high blood pressure, which is a major risk factor in CHD, even though a similar class, ACE inhibitors, are the usual first line.

\(^{49}\) This is shown by the significant drops in volume trends in the plots as patents expire.

\(^{50}\) A partial exception is Lescol, volumes of which fell gradually from 2003. The prices of two other brands fell in 2005 as part of the implementation of the PPRS price cut. However, as noted in Annexe J, these were likely a competitive response, at least in part, to parallel trade.
behaviour.\textsuperscript{51} While volumes of some on-patent statins may have fallen somewhat since this analysis was undertaken, the extent of inefficiency remains significant. These concerns are taken up in the concluding section of this chapter.

4.63 This effect is also visible in the other markets, even without the inclusion of generic series on Figures 4.3 to 4.8 below (and focusing mainly on the PPIs and SSRIs, where generics are now available, rather than the A2RAs which are all still on-patent). The volumes plots for PPIs (Figure 4.4) and SSRIs (Figure 4.8) show that as each branded product loses patent protection (visible from the drop-off in dispensing of each series beyond a point) dispensing of other on-patent brands in the class remains unaffected until they subsequently lose patent protection.

Figures 4.3 Dynamic competition in PPIs: prices

\textsuperscript{51} The graphs show prices per unit and volumes of the most commonly prescribed strengths. The most commonly prescribed strengths may have somewhat different potency but—because the changes in price when a drug goes off patent are so large—this would not alter the conclusions. For example in February 2007, the Drug Tariff shows the price of generic simvastatin 20mg was 7.2p, and 40mg 12.6p, per tablet while the price of Lipitor (branded atorvastatin) 10mg was 64.4p, and 20mg 88p, per tablet. Thus, even comparing generic simvastatin 40mg with Lipitor 10 mg, Lipitor was more than five times the price.
Figures 4.4 Dynamic competition in PPIs: volumes

Figure 4.5 Dynamic competition in A2RAs: prices
Figure 4.6 Dynamic competition in A2RAs: volumes

Angiotensin II Receptor Antagonists (volumes)

Figure 4.7 Dynamic competition in SSRIs: prices

Selective Serotonin Reuptake Inhibitors (prices)
Figure 4.8 Dynamic competition in SSRIs: volumes

Note: Our data sample does not cover the launch of the incumbent, Prozac® (fluoxetine). Prozac® was launched in 1989 Q1. The second two launches occurred at the very beginning of our sample in 1991 Q1: Lustral® (sertraline) and Seroxat® (paroxetine).

Figures 4.9 Dynamic competition in statins: prices
Figure 4.10 Dynamic competition in statins: volumes

![Figure 4.10](image)

Figure 4.11: Dynamic competition in statins – generics added: volumes

![Figure 4.11](image)

Note: This figure and Figure 4.12 below replicate Figures 4.9 and 4.10 above, with generic series added for simvastatin and pravastatin. Series for those chemicals are highlighted in bold.
4.64 Because the four therapeutic classes discussed here are large, it should be noted they may not be representative of all products. Price movements in smaller markets can be more erratic.

Outcomes

4.65 As noted, the above analysis does not take explicit account of perhaps the most important dimension in competition between pharmaceuticals – that relating to the relative clinical efficacy of the products concerned. In principle, the lack of a price or volume response to a major price change in a substitute product might be understandable if the two products have very different effects.

4.66 However, analysis set out in Annexe M suggests that, under current arrangements, the prices of extremely close substitutes have very different prices. Since the products assessed are among the largest selling in the NHS, this has major implications for value for money – we have identified hundreds of millions of pounds of expenditure that could be used more cost effectively – that is, in giving patients access to drugs and other treatments that represent better value for money for the NHS. Changes to the pricing regime could help address this.

4.67 Arguments concerning therapeutic equivalence are even stronger in relation to an originator product and a generic that is bioequivalent to it. Although here, as noted, there is a volume response to generic entry (through the practice of prescribing by chemical name) price disparities between generics and originator products are such
that we estimate that there is still about £65 million a year to be saved across the NHS through the use of more value-reflective prices for off patent brands.\textsuperscript{52}

\textsuperscript{52} DH has already issued a consultation document on the reimbursement of 'standard branded generics' on 20 January 2005, suggesting that a range of branded generic products should be removed from the PPRS and reimbursed at the lesser of either the Drug Tariff price of the comparable true generic or the list price of the standard branded generic. The DH then carried out a further round of consultation on this proposal, which closed on 24 October 2005. The consultation is on hold, pending the outcomes of this study.
5 COMPETITION IN PRIMARY CARE TO SUPPLY PHARMACIES

5.1 NHS contractor pharmacies buy drugs from manufacturers and wholesalers, supply (or 'dispense') them to patients who have a prescription from their GP for a particular drug and are reimbursed for doing so by the NHS. This chapter considers the process of competition to supply pharmacies. It first describes the role of pharmacies in primary care and the mechanics of pharmacy procurement and reimbursement before considering competition under two main scenarios:

- when GPs write a prescription for a brand (or when no generics are available for the pharmacy to dispense), and
- when GPs write a prescription using the chemical name (and generics are available).

The role of pharmacies within primary care

5.2 NHS contractor pharmacies (the vast majority of all UK pharmacies) act as drugs procurement agents for primary care organisations. PCOs apply control of entry regulations to pharmacies wishing to dispense NHS prescriptions, approving requests they believe help secure the adequate provision of local pharmaceutical services.53

5.3 Pharmacies make a financial return on NHS business by earning fees for services – which may be paid by central government or the local PCO – and by making profits from dispensing prescription drugs. Pharmacies’ payments and working conditions are governed by the national Pharmacy contract (see box 5.1).

Box 5.1: The pharmacy contract

The current Pharmacy contract was negotiated in 2003 between the Department of Health and the Pharmaceutical Services Negotiating Committee (PSNC) representing community pharmacy around the UK. Implementation began in April 2005. Some details are different in each of the four countries but the contract can be described as a UK-wide arrangement.

The contract guarantees a level of income to NHS contractor pharmacies in aggregate in each of the four countries. In England, for example, community pharmacies should collectively earn £1.911 billion in revenues on NHS business during 2006/07 from fees and dispensing margins. This is supplementary to whatever they are able to earn from selling non-prescription products.

The contract provides for pharmacies to perform essential, advanced and enhanced services. One essential service is to offer patients advice on taking medicines. Essential and advanced services are set by DH; essential fees are paid by DH and PCOs in combination and advanced services are paid for by PCOs. Pharmacies that wish to provide enhanced services negotiate these with their local PCO, which pays the fees. Pharmacies can also receive payments for other reasons, for example under the Essential Small Pharmacies Scheme.

53 In 2003, the OFT published a market study on UK pharmacies. In its report, the OFT supported the removal of entry and exit restrictions on community pharmacies. The report concluded that increased competition would lead to improvements in quality and lower prices. (Office of Fair Trading (2003), ‘The control of entry regulations and retail pharmacy services in the UK’, OFT Report No. 609, London.)
In England, the contract assumes that pharmacies will make around £500 million of the total revenue settlement in dispensing margin (although the actual total for 2006/07 is about £650 million). Pharmacies make dispensing margin by being reimbursed for drugs issued to NHS prescriptions at, on average, higher rates than they purchase them from manufacturers and wholesalers. Branded suppliers’ net selling prices are not closely regulated by government but manufacturers typically sell to wholesalers at a 12.5 per cent discount to list price and wholesalers sell to pharmacies at an average 10.5 per cent discount. List prices of branded drugs across the UK are subject to PPRS price controls.

The main mechanism for achieving the aggregate £500m margin in England is through altering generics reimbursement rates, which DH does through the Category M pricing mechanism. Reimbursement for a given generic medicine can differ across the four countries of the UK.

Generics prices are not the only tool at governments’ disposal with which to control pharmacies’ profit. There is also the clawback, set separately in each of the four countries, that recovers some of the average profits pharmacists make on dispensing by applying a deduction to their total monthly reimbursement claims.

5.4 As discussed in Chapter 3, the nature of competition to supply pharmacies depends on how GPs have prescribed. The reason is that GPs’ prescribing decisions bind quite closely what pharmacists can dispense. As mentioned above, when GPs prescribe a brand (either on- or off-patent) The National Health Service (Pharmaceutical Services) Regulations 2005 require that pharmacists dispense that brand. But when GPs prescribe generically pharmacists are entitled to deliver to patients any chemically identical branded or generic product that is available.

5.5 As will emerge in more detail below, when pharmacies are obliged to dispense a brand (either because a GP prescribed it or only that brand is available) they are reimbursed at the manufacturer’s list price, which is controlled by PPRS. In such instances, it is suppliers of the branded product that compete to sell to pharmacies. When pharmacies are able to dispense a generic, by contrast, they have more supply options and are reimbursed at Drug Tariff prices.

5.6 The implication is that competition is best analysed in two broad scenarios:

- when GPs write a prescription either for a specific branded product or by chemical name for a chemical that is only available as a brand, and
- when GPs write a prescription by chemical name for a drug that is off-patent.

5.7 The first scenario accounts for about 75 per cent of community expenditure on drugs, while the second - prescriptions written and dispensed generically - accounts for about 25 per cent.

5.8 Before looking more closely at competition in each scenario it is helpful to describe in more detail the mechanics of pharmacy procurement and reimbursement that influence the competitive process. The situation is outlined in the diagram below.
The mechanics of pharmacy procurement and reimbursement

5.9 Pharmacies supply drugs to patients at the NHS flat-rate prescription charge (which is remitted to government), or for free, before being reimbursed each month. Reimbursements are processed and calculated by central agencies in each of the four countries. Pharmacies are reimbursed according to the Drug Tariff which, in England and Wales, states that the payment to pharmacies comprises:

- the total of the reimbursement prices of the drugs, appliances and chemical reagents supplied against prescriptions less clawback (clawback is discussed below)
- the appropriate professional fees (currently 90p for each prescription plus additional fees for liquids, ointments, creams and pastes where more work is required)

54 The Prescription Pricing Authority in England; the Prescribing Services Unit of Health Solutions Wales in Wales; the Practitioner Services division of NHS Services Scotland; and the Family Practitioner service of the Central Services Agency in Northern Ireland.
• the allowance for the cost of drug containers\textsuperscript{55}.

Pharmacies are also reimbursed any exceptional 'out of pocket' expenses they incur in obtaining drugs.

5.10 Under the pharmacy contract, pharmacies in England received total public funding of £1,766 million for 2005/06, a figure which has risen to £1,911 million for 2006/07\textsuperscript{56}. As noted above (see box 5.1), funding comes both from retained margin (that is, the margin between the price at which pharmacies buy drugs and the price at which they are reimbursed), and from professional fees and other payments which depend on the level of service provided.

Reimbursement prices

5.11 The price at which prescriptions are reimbursed depends on whether they are written for a brand or a generic, and on the availability of true generics in the market. There are two scenarios to consider, which we call 'reimbursing as a brand' and 'reimbursing as a generic' respectively:

• **reimbursing as a brand**: For dispensing branded drugs against branded prescriptions (or against generic prescriptions where no true generic is available, for example when the chemical is still on patent\textsuperscript{57}) pharmacies are reimbursed at the manufacturer’s list price less clawback. That is, each relevant line of their reimbursement attracts the list price before the clawback is applied to the whole bill, and

• **reimbursing as a generic**: For dispensing any drug (brand or generic) against a generic prescription where the chemical is off patent and generic supplies are available, pharmacies are reimbursed at a price set down in the Drug Tariff, again less clawback.

5.12 As described elsewhere in this report, the pricing mechanism for controlling the manufacturer’s list price is the PPRS. Drug Tariff prices are set according to a variety of mechanisms, the most important of which is Category M. This is explained further in see Box 5.2.

\textsuperscript{55} The container allowance is currently set at an average rate of 3.24p per prescription for every prescription (except an oxygen prescription) supplied by a pharmacy, whether or not a container is supplied.

\textsuperscript{56} The 2006/07 total represents a five per cent increase in the funding package to £1,855 million (including £17 million for regulatory burden) plus carry forward of a £56 million underspend for 2005/06.

\textsuperscript{57} Or when pharmacies can prove to the reimbursement processing authority that they were forced to dispense a brand due to generics being unavailable.
Box 5.2: Drug tariff prices

The prices of drugs before clawback (often referred to as 'basic prices' or 'Tariff prices') are contained in Part VIII of the Drug Tariff. The Drug Tariff provides comprehensive information about payments to NHS dispensing contractors, including both reimbursements and fee remuneration. Drug Tariff prices are published monthly for England and Wales, Scotland and Northern Ireland.

The reimbursement prices of many generic medicines, in particular those prescribed in the highest volumes, are listed under Category M of the Drug Tariff. Category M prices are based on the volume-weighted average prices charged by generics manufacturers, or if these are not available, by wholesalers. Since April 2005, these are obtained from information provided quarterly by manufacturers and wholesalers (under voluntary schemes known as Category M and Scheme W respectively). It is usually Category M prices that are adjusted to achieve the retained buying profit in the Pharmacy contract. In some cases a margin of more than 100 per cent is applied to the generic manufacturer’s price to achieve the Category M reimbursement price.

There are a number of other reimbursement categories in Part VIII of the Drug Tariff:

- category A was the predecessor to Category M and still applies to some drugs. Category A prices are calculated formulaically using an average of quotes supplied by up to five manufacturers and wholesalers of generics.
- category B applies to drugs whose usage has declined over time, that are often only available from one supplier.
- category C drugs are priced on the basis of the list price charged for a particular brand or by a particular manufacturer. The price shown in Part VIII of the drug Tariff is paid for a generic subscription even if a different supplier’s product is dispensed.
- category E is for rare preparations that are specially ('extemporaneously') made up from time to time.

The terms of Category M require the ex manufacturer price of a new generic product not to exceed the list price of the equivalent originator brand in the same presentation (formulation, for example, tablet or capsule, strength and pack size) at the date of its patent expiry.

5.13 The bulk of generics reimbursement expenditure is accounted for by Category M drugs, where the price is based on quarterly surveys of transaction prices between manufacturers, wholesalers and pharmacies. These arrangements are intended to save the NHS money by aligning reimbursements with market conditions whilst maintaining incentives for individual pharmacies to procure efficiently (since reimbursements are based on average transaction prices which individual pharmacies can beat). As mentioned in the box above, generics prices are also adjusted to help achieve the retained profit margin in the Pharmacy contract.

58 Where a drug price is not stated in the Drug Tariff, the Drug Tariff states its basic price is the manufacturer’s list price. Full catalogues of list prices are quoted in commercial publications, e.g. Chemist and Druggist and the Monthly Index of Medical Specialties (MIMS).
Clawback

5.14 Pharmacies’ total reimbursements are arrived at after applying the clawback, which operates differently around the UK. In England and Wales, it is a sliding-scale deduction applied to pharmacies’ total monthly payments but elsewhere it is subtracted from reimbursements for individual items. The situation is outlined below:

<table>
<thead>
<tr>
<th>Country</th>
<th>Clawback on branded drugs</th>
<th>Clawback on generic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>England and Wales</td>
<td>Between 5.63 per cent and 11.5 per cent of a pharmacy’s total monthly reimbursement depending on size of claim less exempt items. According to the PSNC, nationally the deduction is about 10 per cent of value at list prices. Average clawback (including zero discount products) is 9.2 per cent.</td>
<td></td>
</tr>
<tr>
<td>Scotland</td>
<td>9.97 per cent</td>
<td>13.5 per cent</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>c. 9 per cent</td>
<td>c. 13 per cent</td>
</tr>
</tbody>
</table>

(1) Dispensed to prescriptions for the brand or an on-patent chemical.
(2) Or branded drugs dispensed to prescriptions when generics are available.
Note slightly different clawbacks apply to dispensing doctors.

5.15 The clawback was originally established as a way of recouping some of the savings pharmacies made from purchasing drugs, including parallel imports and generics, at below list price and has been carried over from year to year at a similar percentage level. The sliding-scale system in England and Wales assumes that the bigger pharmacies, making larger reimbursement claims, can obtain better discounts to list prices than small independents. The systems in Scotland and Northern Ireland assume that discounts are greater for generic drugs.

5.16 Due to the clawback, then, an appropriate measure of the cost of primary care drugs to the NHS is list price minus the average clawback.

5.17 However, some drugs tend not to be sold by suppliers at discounts to list price, including a number of medicines for rare conditions, many products with complex or controlled administration and some highly perishable (for example, temperature-sensitive) preparations. Such drugs may be included on a zero discount list, to which clawback does not apply. Since September 2006, however, the only drugs in England and Wales to which clawback does not apply are those in four specific categories\(^5\) and those where the following three conditions are all met: the manufacturer and the two main full line wholesalers (AAH and Unichem) do not offer pharmacy contractors a discount; fewer than 500,000 items per year are dispensed of the product; and average net ingredient cost per item is more than £50.

\(^5\) Schedule 2 or 3 Controlled Drug; HazChem (product covered by the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 - SI 2002/1869 and appropriate for Pharmaceutical Services); Cytotoxic or cytostatic item - a list of cytotoxic products can be found in Section 8.1 of the BNF; Cold-chain storage item (the product must be stored at 2 - 8°C prior to dispensing).
Retained profit margin

5.18 As noted above, under the pharmacy contract pharmacy reimbursement in England includes £500 million retained profit margin, although in 2006/07 the actual retained profit margin is rather more than this (£650 million). In consultation with the PSNC, the DH measures the margin actually obtained by a sample of pharmacies. This covers brands (including parallel imports) and generics and involves auditing all the invoices of the sampled pharmacies for a particular month. The audited margin of the sample of pharmacies is then aggregated to the whole market for England. The PSNC told us that, from next year, margin analysis would be carried out every month. Hitherto, it has been done less frequently.

5.19 The results of the margin analysis and manufacturers’ returns through Category M are used to ensure that pharmacies receive the retained profit margin of £500 million. This is achieved by adjusting the margin when setting prices for Category M drugs.

Competition to supply pharmacies when a drug is reimbursed as a brand

5.20 When a product is reimbursed as a brand, the suppliers competing to sell into the supply chain are the brand manufacturer and parallel importers. The reimbursement price is the manufacturer’s list price less clawback. For most products reimbursed as a brand, the list price is constrained by the PPRS price control (see Annex J). There are some products, accounting for a small proportion of expenditure, that are outside the PPRS, for example homeopathic remedies and health food supplements.

Supply chain

5.21 Manufacturers distribute their products either directly or through wholesalers. There are two types of wholesalers, full-line and short-line:

- the UK’s eleven full-line wholesalers carry the entire 25,000 product lines recognised by the NHS, that is, the whole BNF, non-prescription drugs and various appliances. Full-liners are important to the security of critical supplies to the NHS, and

- there are around 1,300 short-line wholesalers in the UK that carry only a small proportion of the NHS product list. The discounts to list price short-liners receive from manufacturers for providing a distribution service are more variable than those granted to full-liners. Short-line wholesalers have a particular role in distributing parallel imports.

5.22 One major manufacturer (GSK) operates an ‘agency model’, whereby it does not sell to wholesalers as such. It sells drugs directly to pharmacies, using the wholesaling

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60 To have full-line status, a wholesaler must carry, and be able to deliver twice-daily, the full 25,000 lines, adequately handling cold-storage, high-security items, etc. The MHRA has a team of inspectors that check if currently registered full-liners are fit for purpose.
companies as its agents in delivering to pharmacies. Another major manufacturer (Pfizer) has recently announced that, from March 2007, it will start to sell directly to pharmacies through just one company (Unichem). Another manufacturer has issued tender documents for a direct to pharmacy scheme and a number of others are known to be considering such a scheme.

5.23 The PPRS price control constrains manufacturers’ list prices. It does not directly constrain manufacturers’ net prices to wholesalers\(^6\), but we were told by a number of stakeholders that manufacturers, by ‘custom and practice’, offer wholesalers a standard 12.5 per cent discount to list price on branded products. Wholesalers then compete to supply pharmacies on the basis of a number of factors, including discount on list price and quality of service. Wholesalers’ net revenue (the difference between the price at which they purchase from manufacturers and the price they sell at to pharmacies) is not regulated.

5.24 The 1999 PPRS (which applied until the end of 2004) included a statement that, ‘after appropriate consultation, DH will from time to time indicate the level of margin normally allowable in published NHS prices of supplies distributed through wholesalers’. The 2005 PPRS (which applied from January 2005) stated that DH, ‘in consultation with ABPI and others as required, will review the appropriateness of the provisions relating to the distribution margin for supplies distributed through wholesalers as set out in the 1999 PPRS’.

5.25 We have not collected information on prices through the supply chain. However, we understand that, under the traditional model of supply through wholesalers, prices through the supply chain are broadly as follows:

- by traditional custom and practice, manufacturers sell to wholesalers at a 12.5 per cent discount to list price
- wholesalers sell to pharmacies at discounts depending on volume, with wholesalers’ discounts averaging perhaps 10.5 per cent
- pharmacies are reimbursed by the NHS at list price less clawback (which averages 9.24 per cent of list price across all drugs including those on the zero discount list). Assuming pharmacies buy at 10.5 per cent below list price, this implies average pharmacy margin on drugs of around 1.26 per cent (representing the difference between average pharmacy purchase price of around 10.5 per cent below list price and average pharmacy reimbursement at 9.24 per cent below list price).

5.26 As regards the ‘agency model’ involving direct sales to pharmacies:

- GSK stopped discounts on some, but not all, of its products in April 2005, simultaneously reducing the list price of other products. DH then added most of

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\(^{6}\) Manufacturers’ net prices are potentially constrained by the PPRS profit control, but in practice the profit control is not binding (see Annexe H).
these products to its zero discount list (with the consequence that clawback no longer applied to these products). However, in September 2006, many of these products were removed from the zero discount list as they did not meet the new criteria—at the same time, clawback was reduced (from a typical figure of about 10.9 to about 10 per cent according to the PSNC).62 GSK’s stopping of discounts has reduced pharmacy margins and, under the terms of the pharmacy contract, this required DH to take offsetting measures to restore pharmacy revenue (such as a reduction in clawback). However, we understand the adverse effect on NHS costs may have been offset by GSK’s simultaneous reduction in the list price of other products, and

- Pfizer has announced discounts to pharmacies of between 8.5 and 11.5 per cent of list price, implying a pharmacy purchase price not dissimilar to the traditional model, at least in England and Wales63, although the overall impact of Pfizer’s plans remains uncertain.

- Other companies are also considering entering into similar arrangements.

5.27 As noted above, the level of pharmacies’ aggregate retained margin in England is set in the pharmacy contract and does not depend on actual aggregate margins. Each individual pharmacy’s margin will however depend on the actual price at which it purchases from wholesalers or manufacturers and on its individual clawback (which depends on its monthly reimbursement total. Each individual pharmacy therefore has the incentive to purchase at the cheapest price.

**Parallel imports**

5.28 Pharmacies are reimbursed at list price, whether they dispense a brand sourced from domestic suppliers or from parallel importers. Thus, pharmacies have a strong incentive to purchase parallel imports if they are available more cheaply than supplies sourced directly from the manufacturer.

5.29 Parallel traders legally export brands from lower-priced to higher-priced countries in the Union (but to go on to sell them in the UK they must be licensed by the MHRA). When a product is reimbursed as a brand, parallel trade is the only source of price competition to manufacturers. The development of parallel trade in the UK is depicted in the chart below. In 2005, parallel imports supplied about 18 per cent by value of branded drugs prescribed in UK primary care, or about £1.25 billion at list prices (see Figure 5.1).

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5.30 Parallel traders are able to operate because the variance of prices for the same drug around the EU can be high, due to the diversity of regulatory regimes among countries and manufacturers' commercial decisions about how to price in the light of those. UK prices are on average relatively high, making the UK a major destination for parallel trade. But activity can be volatile because opportunities for it shift when governments and manufacturers alter their pricing regulations and strategies, which they quite often do. The chart above shows the drop in parallel trade in the UK that followed the seven per cent price cut imposed by the 2005 PPRS.

5.31 Parallel importers trade mainly in branded products where there are often wide price disparities between European countries. It is also mainly a phenomenon of primary care. Hospitals frequently purchase drugs on multiyear contracts where continuity of supply from a given source is important – but changing relative prices across the EU can make parallel trade on multiyear contracts unviable for UK importers.

5.32 Parallel trade is profitable when the difference between manufacturers’ selling prices in the UK, and in those other EU countries where supplies can be sourced for parallel trade, exceeds the parallel traders’ transactions costs. If there is competition between parallel traders, any potential profits may be shared with UK wholesalers and/or pharmacies.

5.33 We do not have accurate data on margins earned by UK pharmacies on parallel imports but some estimates relating to 1999-2000 and 2002 suggest it might have been about
seven per cent of list price\textsuperscript{64}. Kanavos et al (2004) suggest a total margin on parallel trade in 2002 of between 19 per cent and 24 per cent\textsuperscript{65}. This suggests UK pharmacies’ average margin on parallel trade was less than the gross margin (before costs) of the parallel traders themselves. A more recent study (Enemardk et al, 2006) indicates parallel import prices increased relative to list prices between the beginning of 2002 and 2004, so UK pharmacies’ margin on parallel imports may now be lower than in the past. This was also suggested to us by a number of stakeholders.

**Summary and conclusions on reimbursing as a brand**

5.34 The NHS reimburses pharmacies at manufacturer’s list price (which is constrained by the PPRS price control) less clawback (which depends on the pharmacy’s monthly reimbursement total). Each pharmacy’s reimbursement price is not affected by what it actually pays for the brand, and hence pharmacies are motivated to purchase from the cheapest source of supply. The cheapest source of supply may be direct from the manufacturer or from a wholesaler which may itself source from parallel imports or the manufacturer (except that some manufacturers are, or soon will be, selling directly to pharmacies using wholesaling companies as distributors). Wholesalers are motivated to purchase from the cheapest source.

5.35 However, when a drug is reimbursed as a brand, each manufacturer only faces competition from parallel importers and, as far as we are aware, there is no requirement for manufacturers to sell on terms that enable pharmacies to purchase at less than reimbursement price. Where competition from parallel imports is weak or non-existent, there is potential for manufacturers to exploit this by reducing discounts on list price, causing pharmacies to purchase at above reimbursement price (which on average is list price less clawback of ten per cent). Under the terms of the pharmacy contract, pharmacies in aggregate (although not necessarily each individual pharmacy) would recover the loss through alternative means (for example, increased margins on generics or lower clawback), increasing the aggregate cost of drugs to the NHS\textsuperscript{66}.

5.36 We have not had access to information on pharmacies’ actual margins but the rough estimates above suggest that the average margin on UK sourced supplies might be about 1 to 1.5 per cent of list price. Margins on parallel imported supplies are probably higher than on UK sourced supplies but are likely to have declined from levels in the past. If we assume the average pharmacy margin on parallel imports lies between 1 per cent (a rough lower estimate of the margin on UK sourced supplies) and 7 per cent (the earlier estimate of the margin on parallel imports), and we also assume parallel imports

\textsuperscript{64} See Annexe J (penultimate bullet of paragraph 6.7 of Annexe J).

\textsuperscript{65} The lower figure represents the estimated difference between average pharmacy purchase prices in the UK (after clawback) and the average of the three lowest price EU countries. The higher figure represents the difference between the UK and the lowest price EU country.

\textsuperscript{66} As noted, one manufacturer has already reduced discounts on some of its products although we understand the potential adverse effect on NHS costs has been offset by reductions in list prices on its other products.
account for 18 per cent of total supply, this implies an average pharmacy margin for branded drugs of about 1 to 2.5 per cent of list price.

5.37 As noted, any such estimates must be heavily caveated, largely because of the uncertainty surrounding the margins actually earned on parallel imports. However, even if parallel import margins are much higher than the levels assumed above, the overall pharmacy margin earned on branded drugs is extremely small compared to that earned on dispensing a drug as a generic. As noted in the last chapter, this issue has the potential to impact on competition between brands and generics and is discussed in greater detail below.

**Competition to supply pharmacies when a drug is reimbursed as a generic**

5.38 When GPs write generic prescriptions for an off-patent chemical, a range of suppliers compete to sell to pharmacies. Competing suppliers include the manufacturer of the originator brand, makers of all bioequivalent generics (including branded generics) and parallel importers.

5.39 The supply chain for generics is similar to that for branded drugs, involving manufacturers, wholesalers (short line and/or full line) or direct supply and pharmacies. Competition between generic manufacturers tends to be vigorous, and consequently for most products they have little ability to sell at higher prices in the UK than other EU countries. Hence, parallel imports of generics tend to be unimportant.

5.40 Individual pharmacies' reimbursement prices for generic drugs do not depend on what they individually pay for the drug. Again, therefore, pharmacies are strongly motivated to purchase from the cheapest supplier. We discuss some aspects of competition to supply pharmacies in the following sections. We consider first competition between generic manufacturers through Category M and second competition between branded and generic suppliers.

**Competition between generic manufacturers: Category M**

5.41 Around 90 per cent of generic medicines (by value) are listed under Category M of the Drugs Tariff. Prices for drugs in Category M are set by DH and are based on a calculation that incorporates the volume-weighted average prices charged by generics manufacturers in the UK.67

5.42 The use of average prices among manufacturers aligns the reimbursement of generic drugs with the market conditions in which they are sold. This process maintains the incentives for individual pharmacies to procure generic drugs efficiently, as reimbursement is based on average prices and pharmacies can negotiate with suppliers

67 The average is a volume-weighted average factory-gate price charged by generic manufacturers, which are obtained from quarterly surveys. A stochastic element is added to the calculations each quarter, to avoid gaming.
to secure a better than average price. For these incentives to be effective in practice there needs to be sufficient actual or potential competition in the supply of generics. While there are hundreds of registered generics manufacturers in the UK, currently around 20 are operative on a regular basis in Category M. Most Category M drugs have between one and ten supplying companies, with the majority facing at least some competition in supply. This is shown by table 5.2 below.

Table 5.2: Concentration in suppliers of Category M drugs in 2006

<table>
<thead>
<tr>
<th>Number of suppliers</th>
<th>Per cent of total value/cost of drugs supplied</th>
<th>Value of drugs supplied annually at ex manufacturer prices £M</th>
</tr>
</thead>
<tbody>
<tr>
<td>One to Three</td>
<td>24.4</td>
<td>287.0</td>
</tr>
<tr>
<td>Four to Seven</td>
<td>47.6</td>
<td>559.4</td>
</tr>
<tr>
<td>Eight or more</td>
<td>28.2</td>
<td>331.3</td>
</tr>
<tr>
<td>Total (see note)</td>
<td>100</td>
<td>1,177.7</td>
</tr>
</tbody>
</table>

Note: The totals of figures in this table do not represent complete totals, as DH does not collect information from all 1000 licence holders.
Source: DH – Data from June 2006

5.43 Two caveats need to be borne in mind in interpreting this table. First, as noted above, this table does not include information from all licence holders, and second, that it is not always possible from the data to determine whether suppliers are genuinely independent. Nevertheless, the table is illustrative of the range of suppliers available. For a small number of low use presentations, there are limited numbers of manufacturers – for example simvastatin 80mg, which is not heavily prescribed, has only one manufacturer in the UK and consequently commands a high price relative to two 40mg tablets.

5.44 Category M has led to strong competitive pressure on generics prices, with UK prices held to be among the lowest in Europe. The principles behind Category M are supported by the BGMA, and Category M is considered to be a well managed and efficient form of pricing generics. There was, initially at least, some concern about the volatility of generics prices, although these have now largely been addressed. The one issue that is, in our view, problematic concerns the disparity between the reimbursement regimes that apply to off patent brands and their generic equivalents, resulting in major differences in reimbursement prices and margins earned on brands and generics. Each of these issues is examined in the following sections.

Effect of Category M on generic prices

5.45 Generic prices in the UK are lower than those seen in many other countries and prices in the UK have fallen sharply in recent years, particularly in 2005. The following two

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68 There are two elements of current arrangements which BGMA does not support, however. The first is that branded medicines are not included in the calculation of reimbursement prices under Category M. The second concerns the size of the margin between market and reimbursement prices for generic medicines which can, in the BGMA’s view, produce anomalies in the marketplace. We consider these issues in greater detail in Annexe L.
charts are based on work undertaken by the Canadian Patented Medicine Prices Review Board using IMS Health data for a number of different countries including the UK. Figure 5.3 shows that UK generic prices fell significantly from 2002 to 2005.

Figure 5.3: Average annual rate of price change, generic drugs in the UK, 2002 to 2005

Source: Patented Medicine Prices Review Board (PMPRB), 2006

5.46 As the figure shows, generic drug prices in the UK have been falling for a number of years. There is however a greater rate of decline in 2005, largely explained by the introduction in the UK of Category M in April 2005. This has a large effect given the large proportion of generic drugs in the UK that are part of the Category M arrangements.

5.47 Figure 5.3 shows that the fall in UK generics prices coinciding with the introduction of Category M in 2005 has been substantially greater than in any of the other 11 countries examined in the chart.
Figure 5.4: Average annual rate of price change, generic prescription drugs, by country, 2005

Source: Patented Medicine Prices Review Board (PMPRB), 2006

5.48 The decline in price from the introduction of Category M is indicative of the extent to which Category M has been able to harness competitive pressures to deliver savings for the NHS, and provides some support for the approach to pricing generic drugs compared to those employed in some other countries.

Category M price volatility

5.49 Quarterly Category M prices for some products have been relatively volatile. There are three main sources of the volatility seen in Category M prices. They relate to:

- supply side issues (for example a decision of a manufacturer to sell large quantities of ‘short-dated’ stock rapidly by significantly reducing the price)
- recalibration (DH recalibration of the tariff to maintain the agreed level of purchase profit for community pharmacies)
- teething problems following on from the creation of Category M (for example, we heard that some companies inadvertently submitted inaccurate data at the beginning of the scheme’s operation).

5.50 Significant volatility in prices may be a problem for PCTs, as it potentially makes it more difficult for them to manage their drugs budgets effectively. In some cases if relative prices of therapeutic substitutes change, prescribing advisers may, for example, need to change their advice to GPs on cost effective prescribing.
5.51 However, we note that a number of factors should combine to reduce the recent volatility of generics prices. Recalibration is within DH’s control and we understand that it has undertaken not to recalibrate the Tariff as frequently in the future. The significance of teething problems should also be expected to decline over time, as companies become more familiar with the Category M arrangements, which have now been in place since 1 April 2005.

Differential reimbursement for brands and equivalent generics

5.52 Category M has worked well to ensure that competition between generic manufacturers delivers savings for the NHS.

5.53 Our concern is that the reimbursement regime is very different for on-patent brands, which are currently priced under PPRS. As noted in the last chapter, this has value for money implications for the NHS, since a product with the same active ingredient as a generic can reimbursed at a much higher price – in some cases as much as twenty times higher.

5.54 It also has the potential to undermine competition between brands and generic equivalents. This arises from the very different levels of margin attached to generic and branded reimbursement.

5.55 Under the current arrangements, drugs reimbursed as generics contribute the bulk of the million retained pharmacy margin under the pharmacy contract, and pharmacies’ average margin on generics is considerably higher than on brands. Our rough estimate above that pharmacies’ average margin on brands was around 0.5 to 2.5 per cent would imply a much higher average pharmacy margin on generics of about 28 to 35 per cent. However, we understand that margins on some generics, in particular some Category M drugs, are much higher—sometimes over 50 per cent.

5.56 This can be a source of considerable advantage to branded manufacturers competing with generics, since it allows them to market their products to GPs and PCTs as cheaper than generics and yet still to sell to pharmacies at a much higher price.

5.57 We explore potential options to address these concerns in Annexe L.

Branded and generic competition: brand equalisation

5.58 Generic prescriptions can be filled by either branded or generic versions of the drug prescribed. A number of branded drug manufacturers compete with generics in supplying the pharmacy against a generic prescription. Further, in some cases few or

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69 An average margin on brands of 0.5 to 2.5 per cent contributes about £25 to £140 million to the aggregate retained pharmacy margin, which was £650 million in 2006/07. This leaves drugs reimbursed as generics to contribute the remaining £510 to £625 million, representing 28 to 35 per cent of reimbursement expenditure on drugs reimbursed as generics of about £1800 million (£1977 million from Table 2.1 less clawback on generics of around ten per cent).
no generic alternatives are available. Therefore, in practice a pharmacy may often dispense a branded drug against a generic prescription for an off-patent drug.

5.59 Brands may be more widely dispensed where a brand manufacturer engages in so-called brand equalisation deals with pharmacies. Brand equalisation involves the brand manufacturer offering a pharmacy a single blended price for the supply of the branded drug to be dispensed against both branded and generic prescriptions. The blended price may provide the pharmacy with a greater margin than stocking both branded and generic drugs. This is profitable for manufacturers as long as the lower prices are still above the costs of supply.

5.60 Figure 5.5 provides an indication of the extent of branded drugs being used to supply generic prescriptions.

Figure 5.5: Distribution of percentages of generic prescriptions for which branded drugs are dispensed (for 132 off-patent chemicals)

Source: BGMA from IMS data.

5.61 Figure 5.5 presents analysis undertaken by the British Generic Manufacturers Association (BGMA) for the OFT, evaluating the difference between rates of generic prescribing and dispensing. The BGMA obtained data from IMS on the number of branded and generic prescriptions for off patent drugs, and compared this with data on the number of branded and generic drugs dispensed to meet prescriptions. The analysis therefore assesses the extent to which brands are used to supply generic prescriptions in practice.
5.62 The data include the top 100 off-patent molecules by volume, and also include all products that came off patent in 2004, 2005 and up to September 2006, with a total number of 132 molecules. The data used is monthly data on prescriptions and dispensing for brands and generics for the year from September 2005 to August 2006.

5.63 On average, brands were dispensed against 22 per cent of the generic prescriptions written over the period analysed.

5.64 It would not be correct to assume that all the differences seen in the chart could be explained by brand equalisation deals, as there are several reasons why generic drugs may have difficulty entering markets for off-patent drugs. These include the following:

- **patents expiring at different times**: there have been cases where a patent expires on a the base molecule of a drug, but a separate patent may remain on a novel method of delivery or presentation (presentations include tablets, liquids, sprays etc), or on a particular salt, so that while the base molecule can be reproduced, the exact chemical including the method of delivery cannot. Under certain circumstances, this means that an apparently generic prescription can only be filled by the original brand. This would include circumstances where the normally used INN included reference to, for example, a salt that was still under patent. Given the complex computer systems used in prescribing, these problems, while temporary, can take many months to be resolved so that generic drugs can compete with off-patent brands.

- **different release profiles**: many branded drugs undergo development throughout their active product life, with a common alteration being to the speed with which the drug is released into the body of the patient. The generic will have been developed on the old release profile and, if GPs routinely write apparently generic prescriptions for the modified release version of the medicine, only the brand can be dispensed. The figure shows drugs by their chemical name. However there may be different versions of the drug available, and some may not have generic alternatives present, particularly if some presentations are prescribed rarely. Consequently the share of the brand in dispensing is larger where there are not an equivalent number of generics available.

- **problems from switching between brands and generics**: for some drugs, there can be disagreement over the effects of switching patients between a branded and generic version, or between two different generic drugs. One particular example is anti-epileptics, where some doctors, pharmacists and patients are resistant to switching due to allegations that this leads to an increase in the number of epileptic fits in the patient, and

- **timing of entry of generic drugs**: while many generic drugs are developed so that they can be launched as soon as a drug goes off patent, there are others where generics have entered after a period of months, or others where generic manufacturers consider it not to be worthwhile starting supply of the drug. Where generics enter the market late, it takes time for their share of the market to grow, so again there is typically a larger proportion of the dispensing accounted for by
brands. Some products in the figure above also lost their patent protection during the period considered and, again, this will inevitably show apparently increased use of the brand.

5.65 The data analysed shows that on average, brands are dispensed against 22 per cent of the generic prescriptions written over the period analysed. As indicated above, this 22 per cent includes those drugs where brand equalisation is taking place, as well as those drugs where the other explanations above may be relevant. In addition, it should be noted that the explanations above are not mutually exclusive for any one drug, such that there may be some brand equalisation taking place for a particular drug as well as some of the other reasons being present. The BGMA estimates that brand equalisation alone may account for on average 10 to 15 per cent of the total supply of generic prescriptions.

5.66 A concern that has been raised by BGMA in relation to brand equalisation is that the prices at which brands are sold to pharmacies for dispensing as a generic are not included in Category M returns. The concern is that as a result pharmacies have greater incentives to negotiate deals with the branded manufacturer, as they stand to gain from any discounts secured in their entirety, whereas under Category M deals with generic manufacturers are reflected in part in reimbursement prices. For Category M products where there are many suppliers this should not be a significant issue since, as noted above, pharmacies are strongly incentivised to negotiate effectively. The concern may be more significant where there are few competing generic manufacturers and fewer transactions on which to base the Category M prices, since this implies deals negotiated with the generic manufacturer will be reflected to a greater extent in reimbursement prices.

Conclusion

5.67 This chapter has assessed the nature of competition to supply pharmacies. This will provide a basis for an assessment of the effects of the PPRS and options for reform later on in the report.

5.68 When a drug is reimbursed as a brand (as is the case for reimbursement of in-patent drugs and branded prescriptions), competition is between the branded manufacturer and parallel importers to supply the pharmacy. When a drug is reimbursed as a generic, competition is primarily between generic manufacturers through Category M, but may also come from branded suppliers, for example through brand equalisation deals, and parallel importers. In both cases, pharmacies are strongly incentivised to negotiate competitive prices with suppliers, delivering savings to the NHS providing these are picked up through margin analysis.

5.69 However, differences in the method of calculating reimbursement prices between brands and generics mean that the levels of margin earned on dispensing as a brand (at least, for domestically-sourced supply) are much lower than those earned on dispensing as a generic. This can be a source of considerable advantage to branded manufacturers competing with generics, since it allows them to market their products to GPs and
PCTs as cheaper than generics and yet still to sell to pharmacies at a higher price. This would also increase costs to the NHS.
6 COMPETITION IN THE HOSPITAL SECTOR

Overview of demand-side incentives in the hospital sector

6.1 In England, Wales, Scotland and Northern Ireland the way hospitals buy and use drugs involves fewer agency relationships than in primary care. Hospitals purchase their own drugs, negotiating purchase prices that are often below manufacturer’s list or Drug Tariff prices. Hospitals can also control prescribing with more certainty than primary care organisations. Hospital doctors are employees so adherence to formularies, or guidance put out by internal Drugs and Therapeutics Committees, can be made a contractual term of employment.

6.2 It seems that in general NHS hospitals have sharper incentives to contain drug costs than primary care organisations and GPs. This is mostly due to how hospitals are funded and is especially true in England.

6.3 In England, hospitals compete for business from PCTs in an internal market for healthcare interventions (viewed as ‘outputs’). This system of ‘Payment by Results’ (PBR) is the main source of revenues for most English hospitals. Under PBR, most admitted patient care, outpatient activity and accident and emergency services delivered by hospitals are subject to a National Tariff. The prices hospitals can charge PCTs for individual surgical procedures, drug therapies, specific types of nursing, etc, are fixed by DH. The price of each intervention is set according to the average national cost of delivering it, though regional variations in the costs of inputs such as land and wages do lead to slightly different Tariff prices around the country. Hospitals deliver services to the Tariff under three-year Service-Level Agreements that confer some stability but are subject to annual reviews, where PCTs assess which hospitals are offering the best quality and quantities of care against the fixed prices.

6.4 Hospitals that cannot deliver services at or below Tariff prices run into deficit. But hospitals that obtain inputs to services more cheaply than the Tariff remunerates them can continue to make profits over time because reference costs for interventions are historical national averages into which the outlays of any one trust do not figure strongly. Only a few interventions are excluded from PBR so beating the Tariff is an imperative for English hospitals.

6.5 The commercial pressure that the Tariff applies is likely to be fairly strong since policy in England appears to be that financially failing hospitals will be allowed to fall. At present, although hospitals are required to balance their books annually many do not

70 Though teaching hospitals, and some others delivering specialised services, receive extra revenues from central government.

71 Tariff exclusions include: ambulance services, mental health services, treatment of learning disabilities, chemotherapy, radio therapy and kidney dialysis. Payments for excluded items are negotiated between PCTs and hospitals. There is also a National Specialist Commissioning Advisory Group (NSCAG) that pays hospitals directly, bypassing PCTs, for a very limited range of services, usually for conditions that affect small patient groups.
and are supported financially. But DH has set a target for all hospitals to be converted to Foundation Trust status within the next few years. Foundation Trusts, introduced in 2003, have greater financial and managerial autonomy than other hospitals and in principle can become insolvent, or be merged with more successful trusts, if they fail financially. The government also envisions that private providers could take up some of the slack for failing NHS hospitals.

6.6 Hence, in England, budget constraints bite for hospitals more than for PCTs which, as local healthcare commissioning monopolies, would probably not be allowed to fail.

6.7 Hospitals are not subject to the internal market model elsewhere in the UK. Instead, hospitals negotiate and agree their funding with either their local primary care organisation or central authorities. In Scotland, hospitals are explicitly jointly-funded with Area Health Boards by the Scottish Executive Health Department. In Wales and Northern Ireland, hospitals are still nominally funded by a process of PCOs choosing between them to commission services. But this happens in a less formal way and is not fully feasible in Wales, for example, where there are 22 Local Health Boards but only 14 hospital trusts.

6.8 Despite the differences in their funding, hospitals all around the UK purchase their own inputs and stand to gain directly from doing so, conferring incentives to purchase drugs efficiently. Like pharmacies in primary care, hospitals endeavour to beat a reimbursement system that is based in some way on average costs (for pharmacies, through the Drug Tariff for generics, and through the clawback for both generics and brands). The difference is that when hospitals are successful savings accrue directly to the NHS, whereas savings made by pharmacies need to be recovered through the clawback.

**Procurement arrangements in the hospital sector**

6.9 Because clinician compliance with hospital formularies, while variable, is relatively strong hospitals have a greater potential to exploit buyer power than in primary care. Further, because they realise immediate benefits from purchasing drugs efficiently they have strong incentives to do so. As a result, joint procurement arrangements have sprung up around the UK, between hospitals at local, regional and sometimes national levels.

6.10 In England, the NHS Purchasing and Supplies Agency (PASA) arranges National Framework Agreements for the purchase of generic drugs for hospitals and has begun overseeing 14 regional Pharmacy Service Groups that procure branded drugs. National Framework Agreements are not legally binding contracts but, rather, negotiated templates of terms and conditions serving as the basis for local contracts. They do quote national prices.

6.11 The Pharmacy Service Groups employ variable approaches in comparison. Some concentrate on securing volume discounts for specific branded drugs. Others put out therapeutic tenders to which all suppliers of products relevant to a given clinical
intervention are invited to bid, that is, manufacturers, wholesalers and parallel importers of broadly therapeutically substitutable drugs. Procuring brands is more fraught for groups of hospitals than procuring generics because hospitals can disagree on the clinical merit of competing on-patent products which are necessarily different from one another. By comparison, once a decision has been made to go with a particular off-patent chemical it is relatively easy to focus on cost.

6.12 In Wales, Scotland and Northern Ireland much the same issues are encountered. In Wales, the All-Wales Drugs Contracting Committee (AWDCC) organises centralised tenders for both branded and generic drugs, though Welsh hospitals also make some purchases unilaterally. In Scotland the Scottish Pharmacologistics Group (SPG) and National Procurement Organisation together award national contracts for generic drugs, whilst branded medicines are jointly procured by regional groups of hospitals. In Northern Ireland, the Regional Supplies Service (RSS) contracts on behalf of hospitals for a large number of drugs, both branded and generic.

6.13 The hospital procurement process is depicted in outline overleaf.
6.14 Due to the financial opportunities and pressures they face, and their collective response to those, it seems likely that hospitals should be able to achieve discounts to PPRS or Drug Tariff list prices when procuring drugs.

6.15 Hospitals, through collective bargaining with manufacturers, may be able to exercise their buyer power to obtain discounts. Collective bargaining may also enable them to get volume discounts for large orders and to achieve lower prices through therapeutic tendering.

6.16 As discussed earlier in this annexe, the system for the prescribing and allocation of drugs is more sensitive to price in the hospital sector than in the primary care sector. Since hospitals may be more responsive to the prices of drugs in the quantities that they procure than primary care trusts, manufacturers may have the incentive to offer them a discount to the listed price. Moreover, the markets for some drugs in the hospital sector may be considered strategic in that they may influence prescribing in primary care.

6.17 This section compares the extent of competition in the markets for drugs in the hospital sector with those in the primary care sector by quantifying the size of the discounts that hospitals achieve from BNF list prices. In order to further explain how...
these discounts arise, an exploratory analysis of the source of variation in discounts across drugs is carried out.

**Savings in the hospital sector**

6.18 One estimate of the savings in the hospital sector comparable to primary care was undertaken by the National Audit Office Wales in 2003. Of particular interest in this report was the finding that, ‘The All Wales Drugs Contracting Committee prices were, on average, 50 per cent lower than those obtained in primary care.’

6.19 We have calculated the discount obtained by hospitals on the fifty drugs on which they spent the most in the calendar year 2005. This calculation is then used to estimate the total value of discounts to hospitals. The data used is provided by PASA from their Pharmex database that has recorded all drugs transactions made by over 150 English hospital trusts since 2003.

6.20 Approximately a third (£550 million) of hospital expenditure on brands in England was spent on the fifty most costly drugs (hospital expenditure on all drugs was £1.6 billion in 2005). The total discount obtained by hospitals on this expenditure (below the price listed in the BNF) was about £77 million (or 12.3 per cent). This is only about two per cent higher than the discount typically secured by a pharmacy on its purchases of branded drugs. Indeed, inasmuch as hospitals purchase direct from manufacturers, this figure is broadly comparable to the 12.5 per cent discount at which branded products are typically sold by manufacturers. Assuming the same percentage discount is obtained on the remaining drugs, the total value of discounts to hospitals would be approximately £230 million.

6.21 However, it is not necessarily the case that hospital discounts are proportionally similar for all drugs. The discounts obtained on each drug exhibited considerable variation, spread more or less evenly from a minimum of 0 per cent to a maximum of 50 per cent of the BNF list price. Within the sample of the fifty drugs, there was no evidence to suggest that the size of the discounts (expressed as a fraction of the BNF list price) depends on the total expenditure on that drug. A speculative examination of a selection of less costly drugs reveals hospital discounts of around 35 per cent, significantly higher than for the fifty most costly drugs. The £230 million estimate for the total value of hospital discounts may therefore be an underestimate of the true value. The considerable variation in the discounts obtained is driven by a number of factors, which are examined below.

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72 The report also notes that, ‘Only a minority of primary care medicines are covered by All Wales Drugs Contracting Committee prices: some 500 out of 14,000 items.’ Source: ‘The procurement of primary care medicines’ – Report by the national Audit Office Wales on behalf of the Auditor General for Wales, March 2003.

73 The selection consists of the twenty drugs with the highest hospital expenditure less than £1 million, and the twenty drugs with the highest hospital expenditure less than £100,000.
Variation across drugs

6.22 There are several potential factors that could explain the variation in discounts across different drugs. We have identified a few possible explanations, and have attempted to verify their validity using the PASA data. It should be noted that the size of discounts arising in reality is the product of complex interaction (negotiation) between hospital trusts and pharmaceutical manufacturers. The observable data only allow us to indirectly infer some of the characteristics of the bargaining process, but do not provide the whole story.

6.23 The following possible causes of variation in discounts were identified:

- certain drugs have more therapeutic substitutes than others, affecting hospitals’ ability to negotiate discounts
- only certain drug markets are considered strategic by manufacturers for a variety of reasons.

The closeness of therapeutic substitutes

6.24 In addition, hospitals’ ability to negotiate discounts (for example through therapeutic tendering) may in part be determined by the therapeutic closeness of available substitutes. Therapeutic tendering is one of the main approaches of the 14 Pharmacy Service Groups and, if successful, should result in better discounts than are possible for drugs where no therapeutic alternatives exist and suppliers have more power to hold out for high prices. Even if therapeutic tendering is not used as a negotiating strategy, the existence of close therapeutic substitutes may enable hospitals to achieve greater discounts through strengthening their bargaining positions.

6.25 In order to examine whether the existence of close therapeutic substitutes is an important factor in determining hospital discounts we calculated the discounts obtained for eight drugs with no other drugs in the same BNF Paragraph (using BNF Paragraph as a proxy for substitutability of alternative drugs). The average discount obtained on these drugs was 9.5 per cent (ranging from 3 per cent to 11 per cent). The average is thus lower than for the fifty drugs of highest expenditure, and with a smaller range.

6.26 Then we looked at three on-patent drugs (in various forms and pack sizes) used to treat common conditions of the cardiovascular system. The NHS and most other countries’ health services spend more on cardiovascular drugs than any other broad category of medicines. As a result, each therapeutic area within the cardiovascular system (statins for cholesterol, calcium-channel blockers for hypertension, etc) has attracted several broadly substitutable products with somewhat distinct chemical action. For data as of early 2005, we found that hospitals achieved discounts to PPRS list price ranging from 7 per cent to 37 per cent.

74 The vast majority of drugs do have substitutes in the same Paragraph (48 out of the top 50 by hospital expenditure).
This contrast suggests that the existence or not of therapeutic substitutes is important in whether hospitals are able to negotiate favourable deals on drugs. This suggests that therapeutic tendering for branded medicines may be having a significant effect.

However, it is difficult to attribute this effect entirely to therapeutic tendering. The existence of therapeutic substitutes for certain drugs may in itself enable hospitals to negotiate greater discounts (through the implicit threat of purchasing from the supplier of the alternative drug). In practice, as mentioned above, the approach to negotiating discounts on branded drugs varies across England, with some PSGs using therapeutic tendering and others preferring to select a single brand in advance and strike deals on volume discounts.

Manufacturers' incentives to offer discounts in strategic markets

One aspect of the hospital sector that could be decisive for the size of discounts achievable is the notion that hospital markets can be 'strategic' for drug manufacturers. Hospitals sometimes initiate treatments requiring lengthy follow-on prescribing in primary care – for example, for chronic conditions with complex initial diagnoses – for which GPs may be reluctant to alter patients' prescriptions once determined by consultants. Here, some manufacturers' might perceive gains from offering hospitals lower prices on drugs to secure follow on prescriptions in primary care.\(^{75}\)

There are, however, a number of reasons why specific drugs may not have strategic markets in the hospital sector:

- PCOs may be able to prevent hospitals from purchasing drugs at very low prices that are likely to be widely used and more highly priced in the community. Scottish AHBs have used joint formularies between primary and secondary care for this purpose and the practice is increasingly widespread throughout the UK.
- Specific hospital markets may be intrinsically less strategic than others. Some medicines are 'hospital-only' and so do not generate much follow-on prescribing in the community (for example, drugs that prevent the rejection of organ transplants). Hospitals may be forced purchasers when they need to deliver critical treatments.

During the course of the market study, we have heard commentary from hospital pharmacists and procurement staff in all four countries confirming that hospitals are

\(^{75}\) One example of this was the subject of a decision of The Director General of Fair Trading in 2001 that Napp Pharmaceuticals had abused its dominant position in the market for sustained release morphine tablets and capsules in the UK. Napp was found to have supplied its sustained release morphine product, MST, at excessively low prices to hospitals, the effect of eliminating competition in the community sector, where it was found to have charged at excessively high prices. The matter was taken to the Competition Appeal Tribunal where the Decision of the Director General was substantially upheld – a link to the judgment of the Director General can be found at [www.of.t.gov.uk/Business/Competition+Act/Decisions/Napp+Pharmaceutical+Holdings+Limited.htm](http://www.of.t.gov.uk/Business/Competition+Act/Decisions/Napp+Pharmaceutical+Holdings+Limited.htm) and that of the Competition Appeal Tribunal at [www.catribunal.org.uk/documents/JdgNapp150102.pdf](http://www.catribunal.org.uk/documents/JdgNapp150102.pdf)
less likely to receive discounts on hospital-only treatments than drugs with large markets in primary care. We have also heard that when PCOs maintain joint formularies, and use their leverage as commissioners of hospital business to encourage compliance, hospitals are less likely to enter into low-priced contracts.

6.32 To examine whether hospitals do indeed obtain lower discounts on ‘hospital-only’ drugs, we compared the discounts obtained on ten drugs listed as ‘hospital-only’ in the BNF with those obtained for the fifty drugs on which expenditure is the greatest. The weighted average discount obtained for the hospital-only drugs was 24 per cent, compared to the 12.3 per cent average for the other fifty drugs, suggesting that hospitals may actually be able to obtain higher discounts on ‘hospital-only’ drugs.

6.33 It is therefore conceivable that the strategic element of hospital drug markets is not such an important factor in explaining the size of discounts, meaning that manufacturers are likely to concede discounts of equivalent size in ‘hospital-only’ drug markets. However, a much more likely explanation is that list prices for ‘hospital-only’ drugs are in effect meaningless, as, since these drugs are only sold to hospitals, manufacturers may allow the list price to remain high whilst changing the ‘real’ price through negotiations of discounts with hospitals. A ‘high’ list price could in this sense be used primarily as a marketing exercise. It is also likely that the PPRS encourages manufacturers to set such initial list prices high, since this effectively insulates them from the constraints imposed by PPRS price controls (namely, the requirement to impose price cuts and restrictions on changes to prices over time).

Conclusion

6.34 In the time available for our analysis we were unable to obtain from PASA sufficient data to control simultaneously for all effects relevant to hospital discounts. Notwithstanding this, the results do at least confirm empirically that, by one means or another, hospitals can induce reasonable competition among suppliers when real choices exist. In particular, the closeness of therapeutic substitutes was found to be an important factor in determining the size of discounts, suggesting that hospitals are able to use therapeutic tendering effectively to obtain greater discounts.