



What you need to know about prescribing, the 'drugs bill' and medicines management.

A guide for all NHS managers

December 2008

For circulation to:

- NHS Commissioning teams
- Practice based commissioners
- NHS Finance teams
- NHS Directors
- NHS Non-executive directors
- NHS Governance teams
- Public health teams

Your medicines management / pharmacy team are familiar with this subject. Contact them for more detailed information about your local arrangements.

About the National Prescribing Centre (NPC)

The NPC is an NHS organisation formed in 1996. 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*. The NPC work programme is designed to support the specific needs of commissioners, providers and individuals with an involvement in prescribing, therapeutics and medicines management. In order to improve the flexibility, accessibility and timeliness, it provides key NHS audiences with a range of choices for accessing its outputs. This includes making use of the opportunities provided by electronic learning environments as well as more traditional approaches. Enhanced versions of many of the NPC materials, including this document, are available through the NPC websites, www.npc.co.uk and www.npci.org.uk.

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Foreword

Medicines are an essential component of health services and are the most common clinical intervention provided within the NHS. They cost the NHS around £11 billion a year. This means that, second to staff costs, medicines are the biggest single budget expenditure in the NHS. Consequently, there is a high level of public and media interest in both the availability and safety of medicines.

Medicines, when used effectively, make an enormous contribution to patient's health and well being. There are, however, risks associated with medicines usage which NHS organisations need to be aware of and manage. Clinically, poor medicines management can lead to hospital readmissions because of treatment failures. Whilst financially, poor medicines management can lead to pressure on the 'drugs bill.' It is in the interest of both patients and NHS organisations to ensure good medicines governance.

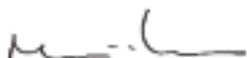
There are a wide range of factors which influence how patients can access medicines, what medicines are prescribed and whether patients ultimately take them. These factors range from legal frameworks and standards, through to attitudes and preferences of prescribers and patients.

To make effective decisions about the commissioning and design of high quality, safe services, manage the 'drugs bill' and ensure governance around medicines, NHS managers and commissioners need a basic understanding of the range and complexity of the issues surrounding the use of medicines

This document is intended to be a readily accessible quick reference guide which will enable all NHS managers to gain an understanding of the fundamentals of medicines usage. In addition it highlights areas in which they may wish to take action, working with colleagues involved in prescribing and medicines management, within their own and partner organisations. I know it will be useful to you in developing and delivering services involving the use of medicines.

Michael Dixon

Chair, NHS Alliance



Executive summary

Medicines are used in almost all NHS services and the NHS spends around £11 billion a year (18% of its total budget) on them. This is the largest single expenditure in the NHS after staff costs. All managers working in the NHS, whether in commissioning, governance or finance teams, at director or non-executive director level need to have an understanding of medicines.

This is a high level guide, which will give you a basic understanding of how medicines are managed and regulated throughout the NHS to ensure safe, effective and cost-effective usage. This is a complex area; your organisations should have specialist medicines management teams who are experts and can advise you on how the principles outlined in this guide apply to your health economy. This guide will not replace their expert input. In some instances, medicines management / pharmacy teams may need support from you to resolve some of the wider issues around medicines usage.

- **Section 1** begins by outlining some basic facts about medicines, it underpins what follows in the guide and includes cross links to later sections. Skimming this section will give you a basic understanding of the legal frameworks and systems that govern how medicines are marketed, priced and supplied to patients. As well as how prescribers make decisions and what influences them.
- **Section 2** looks at expenditure on medicines and typical financial flows in the NHS. It is split into primary and secondary care and describes, for example, pricing, payment mechanisms and high cost drug exclusions.
- **Section 3** considers how medicines need to be intrinsically linked into commissioning and contracting processes and service re-designs.
- **Section 4** outlines local activities for managing medicines in individual organisations and across healthcare economies. It focuses particularly on the managed entry of medicines, and the importance of having a health economy wide approach. In addition it discusses briefly the sort of local support activities likely to be underpinning safe, legal, effective and cost-effective medicines usage in your organisation.
- **Section 5** talks about the importance of medicines governance and safety being embedded in all organisations, and describes the national organisations who contribute to that. It highlights what the regulator will be looking for from your organisations and the guidance NHS organisations are generally expected to follow.

We expect that readers of this document will want to:

- Review the key messages at the beginning of each section and the ‘What this means for you’ boxes. Where they have implications for your organisations, work with your medicines management teams, to take actions necessary for your organisation to use medicines safely and effectively
- Retain a copy (or bookmark the web page) to refer to as issues with medicines arise
- Ensure that your medicines management teams are clearly linked into commissioning and prioritisation processes, clinical governance and risk management processes
- Refer to the signposted resources which review some key issues in more detail

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Introduction

Medicines are the most common clinical intervention. In recent years, the focus on preventative health and the early use of medicines, the wider availability of specialist medicines for previously untreatable conditions and an ageing population have all led to increases in medicines usage.

Moreover, medicines are intrinsically linked with many of the overall policy objectives of the NHS. It would be unthinkable to manage long-term conditions, reduce inequalities in the treatment of cardiovascular disease and help smokers to quit without using medicines to some extent. Equally, re-designing services to be more personalised and easier to access for many patients will have medicines (getting them, taking them) as a key component.

Medicines can improve both the length and the quality of peoples' lives. However, all medicines have inherent risks associated with them, whether from unwanted effects, inappropriate or incorrect usage, or unsafe systems.

Expenditure on medicines also represents a significant area of financial risk for organisations to plan for and manage. PCTs are responsible for commissioning medicines in both primary and secondary care. Managing the entry of medicines needs to be considered in much the same way as the commissioning of other services.

Managing the clinical and financial risks associated with medicines usage is complex. National policy and the needs of a local health economy must both be balanced against the clinical needs and preferences of individual patients. Alongside this is a legal framework which determines how medicines must be managed (from procurement through to disposal) which impacts on service design and governance. Commissioners and providers of services to patients must work together to ensure that, across the health economy, risks are minimised and that patients obtain the maximum benefit from their medicines.

To do this effectively it is crucial that managers and directors in NHS organisations have a basic understanding of the ways in which medicines can, and in some cases must, be managed.

This guide is a quick reference document for all NHS managers and directors which outlines the main issues and common pitfalls around medicines usage in the NHS. Where more detailed information resources are available they are signposted. Medicines management / pharmacy teams in PCTs and NHS trusts will be able to give managers more detailed information and advice where necessary.

Audience for the document

- Executive and non-executive directors of all NHS trusts and PCTs
- PCT and practice based commissioners
- Finance teams in NHS trusts and PCTs
- Governance and public health teams

Section 1: Some key facts about medicines

This short section will outline the legal frameworks and concepts which underpin medicines usage. Skimming this section before reading the rest of the document will help to ensure that you have a good grip on some of the basic facts that underpin medicines usage. It will also give links into the rest of the document which looks at these areas in more depth.

1.1 How do medicines get into the UK market?

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

When medicines receive their marketing authorisation they are considered acceptably safe (although some rare side-effects will only emerge once the medicine is in wide use), more effective than a placebo, and that a reliable product can be consistently manufactured.

What is still to be established, is how effective the medicine is compared to accepted treatments, and whether the medicine represents good value compared to other treatments already in use (**see section 1.4**).

Medicines are licensed in one of three categories, Prescription Only Medicine (POM), Pharmacy medicine (P) or General Sales List (GSL). This category impacts on how the medicine can be obtained by patients (**see section 1.3**) and may change over time.

In addition some POM medicines are designated controlled drugs (CDs) and require organisations to have specific governance arrangements in place to ensure their safe usage and handling (the Healthcare Commission provide external scrutiny on these arrangements – **see section 5.3**).

For more information about medicines safety and regulation **see Quick fact sheet 1**.

1.2 How are medicines priced?

A **branded** medicine is a drug marketed under a brand name. A pharmaceutical company creating a new medicine usually markets it under a brand name, normally initially under the protection of a patent, which prevents other manufacturers making it. A **generic** version of a drug is pharmaceutically equivalent to the branded version, containing the same active ingredient(s) at the same strength, but may only be produced after the branded drug's patent has expired. To recover research and development costs, brand name drugs are normally much more expensive than generic versions of the same product. The National Audit Office estimates that the NHS could save about £200m a year through greater use of lower cost generic medicines.¹

WHAT THIS MEANS FOR YOU:

Organisations need to have systems in place to recognise the opportunities to maximise savings to the NHS by using generic medicines, particularly as new generic medicines become available. The NHS Better Care, Better Value Indicators (**see section 5.6**) allow PCTs to benchmark their prescribing of some lower cost medicines (often generics) over time and nationally against other organisations.

The NHS spends about £8 billion a year on **branded** medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism which the Department of Health uses to control the prices of these medicines, by regulating the profits that companies can make on these sales. It is a voluntary agreement between the Department of Health and the branded pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry). A new PPRS agreement effective from the 1st January 2009, introduces a flexible pricing scheme. This scheme is intended to ensure that medicines fairly reflect their value to patients and more patients benefit from a wider range of drug treatments at a fair price to the NHS.²

In primary care, *The Drug Tariff*,³ compiled monthly by the Prescription Pricing Division of the NHS Business Services Authority, outlines what will be paid for medicines and appliances supplied (usually by community pharmacists but in some cases by dispensing GP practices, appliance contractors and any GP personally administering) against an NHS prescription.³ VAT is not generally payable on FP10 prescriptions. **See also section 2.2.**

The *Drug Tariff* also outlines which dressings and appliances (dispensed by community pharmacists, dispensing practices and appliance contractors) are allowable on an NHS prescription. Dressings and appliances cost the NHS £504.2 million in 2007. There is also a range of 'borderline substances', generally food or toilet preparations, which, for specified conditions, may be regarded as drugs. Prescribing of borderline substances cost the NHS £307.5 million in 2007.⁴

Over 500 high volume generic medicines fall within the **Category M** scheme of the Drug Tariff. The reimbursement price for Category M medicines is adjusted by the Department of Health to provide a funding stream for the community pharmacy contractual framework. Further information about Category M is available on the DH website on <http://www.dh.gov.uk/em/Healthcare/Medicinespharmacyandindustry/Genericmedicines/index.htm>

In secondary care, NHS trusts procure medicines. Medicines can be purchased via national or regional contracts following competitive tendering. **See also section 2.3.**

WHAT THIS MEANS FOR YOU:

Prices paid by the NHS are determined by a range of different funding mechanisms and can result in different prices being paid in primary and secondary care. To make informed decisions about medicines usage, NHS organisations need to understand the different levers and pressures on medicines costs across sectors (**see also section 2**).

1.3 How are medicines supplied to patients and who can prescribe?

The law has controls in place that govern how patients can obtain medicines.⁵ These controls are linked to the medicines legal category (see also **section 1.1**) which means that:

- **Prescription Only Medicines (POMs)** can only be supplied or sold in accordance with an 'appropriate' practitioner's (e.g. a doctor or non-medical prescriber) prescription (see later). In addition, in general, POMs can only be sold or supplied to patients from registered pharmacy premises by or under the supervision of a pharmacist.
- **Pharmacy medicines (P)** do not require a prescription. They can be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist.
- **General Sales List (GSL)** medicines do not require a prescription and can be sold from a wider range of premises, such as supermarkets.
- There are some exemptions from these restrictions, see www.mhra.gov.uk

In addition, POMs must be appropriately labelled and a patient information leaflet included with every supply. This means that medicines given to patients by any NHS service (for example, out-of-hours, ambulance services, walk-in centres) must be in appropriately labelled packs with a patient information leaflet.

WHAT THIS MEANS FOR YOU:

The law restricts who can sell or supply medicines to patients. It also determines what information must be supplied to patients with medicines. All services must take account of the law relating to this, organisations reviewed by the Healthcare Commission will have these arrangements scrutinised. For more information, seek advice from your medicines management / pharmacy team.

Only certain healthcare professionals are legally allowed to prescribe (**see box 1**). Doctors currently account for 98.8% of NHS prescribing in primary care. However, qualified non-medical prescribers, in particular nurse and pharmacist prescribers, are becoming more common. As services develop, in part to improve access for patients, the proportion of prescribing by these groups is likely to increase.

In some circumstances, patients can obtain supplies of medicines using a patient group direction (PGD). PGDs are used in NHS services like walk-in centres and out-of-hours services, however, they are not suitable in all situations and there are constraints on their usage. The NHS has a PGD website to help services decide whether PGDs are appropriate and help with their implementation (www.portal.nelm.nhs.uk/PGD/default.aspx).

The Department of Health briefing document *Medicines matters*⁶ outlines in detail all the options that providers (and commissioners) have for structuring their services so that patients are able to legally and safely access their medicines.

Box 1: Who can prescribe?

Doctors and dentists can prescribe once they are professionally qualified.

Non-medical prescribers are healthcare professionals who undertake additional post-registration training to enable them to prescribe within their area of competence. There are two types of non-medical prescribers. Independent prescribers (can be pharmacists and nurses, and from late 2008 optometrists) and supplementary prescribers (can be nurses, pharmacists, optometrists, physiotherapists, chiropodists / podiatrists and radiographers). Supplementary prescribers work in partnership with a doctor (or dentist), within an agreed patient-specific Clinical Management Plan.

District Nurses and Specialist Community Public Health Nurses (including Health Visitors) can train to prescribe from the Nurse Prescribers' Formulary for Community Practitioners (NPF).

WHAT THIS MEANS FOR YOU:

Most prescribing is done by doctors. However, for some services, there may be other options that can give patients safe and appropriate access to medicines. These options have specific legal requirements, and safety and governance systems need to be in place. To determine which option is right for a given service, commissioners and providers need to seek advice from medicines management / pharmacy teams. **See also section 3.**

1.4 What is good prescribing?

'First do no harm' remains a cornerstone of clinical practice. Generally, prescribers seek to maximise the effectiveness of treatment, minimise the risks associated with it, minimise cost and respect the patient's choices.⁷ Each prescribing decision is a balance between all these elements.

At the same time, prescribers must keep up-to-date with practice in their fields. As evidence changes and new medicines are launched, prescribers need to know about new developments and decide what the implications are for their prescribing practice (**see also section 4.3**).

To maximise the effectiveness of treatment, prescribers need to consider a range of factors for individual patients and for their population as a whole. These factors include an assessment of the prevalence and severity of the condition, the outcome of intervention / no-intervention, likelihood of benefit and evidence of effectiveness. For the population, this may mean targeting previously untreated patients to receive a medicine which, in the longer term, will improve their health outcomes. For example, the increase in statin prescribing (and therefore expenditure) in line with guidance from the National Institute for Health and Clinical Excellence (NICE).

The scope to make a cost-effective prescribing decision arises because there are generally a range of medicines available to treat a given condition. So, the prescriber will have several options to choose from. Where there is no clinical or individual patient reason that points to the use of one medicine above another, the one with the lower acquisition cost is likely to be the most cost-effective choice and represent best value for money for the NHS. **See section 1.2.**

Supporting prescribers to make effective, safe and cost-effective choices is a key function of local medicines management / pharmacy teams. The role of these teams is briefly outlined in **section 4**.

1.5 What influences a prescriber?

Influencing prescriber behaviour is a key factor in ensuring that patients get the medicines that they need (effective, safe, right for the individual patient) and that the NHS gets best value for money. The influences on prescriber behaviour are complex. Prescribers make decisions based on patterns, often repeat decisions, based on habits. These habits are established by early training, own experience, reading and personal interactions with trusted colleagues. These internalised cognitive mechanisms can be difficult to influence.

Some approaches that NHS organisations can use to influence prescriber behaviour have been identified.^{1,8} Examples are listed below and, unless otherwise indicated, they are discussed in **section 4** of the document.

- Communication from trusted sources (for example, summary journals) and local opinion leaders (for example, PCT / PBC pharmaceutical advisers and secondary care colleagues)
- Audits of prescribing practice
- Provision of tailored comparative (benchmarking) information to GP practices
- Provision of practical clinical support, such as pharmacist or pharmacy technician time to GP practices
- A coordinated approach to prescribing across the primary and secondary care sectors (for example, area prescribing committees)
- Local formularies (in both primary and secondary care) and guidelines (local and national)
- Financial incentives (**see section 3.1**)
- Involvement and education of patients (**see section 1.6**)

1.6 Why don't patients take their medicines?

Encouraging patients to get the most from their medicines is essential. Since the decision about whether to take a medicine or not ultimately lies with the patient it is crucial that prescribers and patients make 'shared decisions' about medicines. This fits with the model of good prescribing which respects the patient's choice (**see section 1.4**).

Informed patients, who share decision-making with their prescribers about medicines, are more likely to take their medicines correctly. This may reduce the need for, for example, follow-up care or hospital admission due to medicine related treatment failures as well as avoiding medicines wastage (**see section 1.7**).

In 2009, NICE (**section 5.1**) will publish a guideline on encouraging shared decision-making around medicines. More information and resources to support concordance can be found on the Medicines Partnership website.⁹

1.7 How are medicines wasted?

Medicines are wasted when they have been dispensed to a patient, but are not taken. It is estimated that about £100 million of medicines are returned unused. When those medicines unused but not returned are taken into account this is almost certainly an underestimate.¹

There are a range of actions that PCTs and NHS trusts can take or facilitate which will help reduce medicines wastage. For example, identifying where waste is coming from, encouraging shared decision-making with patients, better use of 'patients own drugs' across care interfaces, improving processes for obtaining repeat medicines.¹⁰ For more information, seek advice from medicines management / pharmacy teams.

1.8 What is the role of the pharmaceutical industry?

Developing a new medicine takes on average 10 to 12 years and can cost a pharmaceutical company around £550 million.¹¹ In order to ensure a return on the research and development costs associated with a new medicine, the pharmaceutical industry actively market and promote their products. Industry promotion is a potent influence in determining which medicines are prescribed (**see also section 1.5**).¹ It is therefore important that organisations, and practitioners, are protected from undue influence. The pharmaceutical industry, through the ABPI, has its own code of conduct. In addition, all NHS organisations should have a code of practice governing interactions with the pharmaceutical industry.¹²

There may be a number of occasions where the interests of pharmaceutical companies are in line with the objectives of an NHS organisation, and this can provide a useful resource to help implement NHS policies. Where this is the case, joint working can be considered. The Department of Health and the ABPI have published a resource document for organisations seeking to work in partnership.¹³

Section 2: Paying for medicines in the NHS

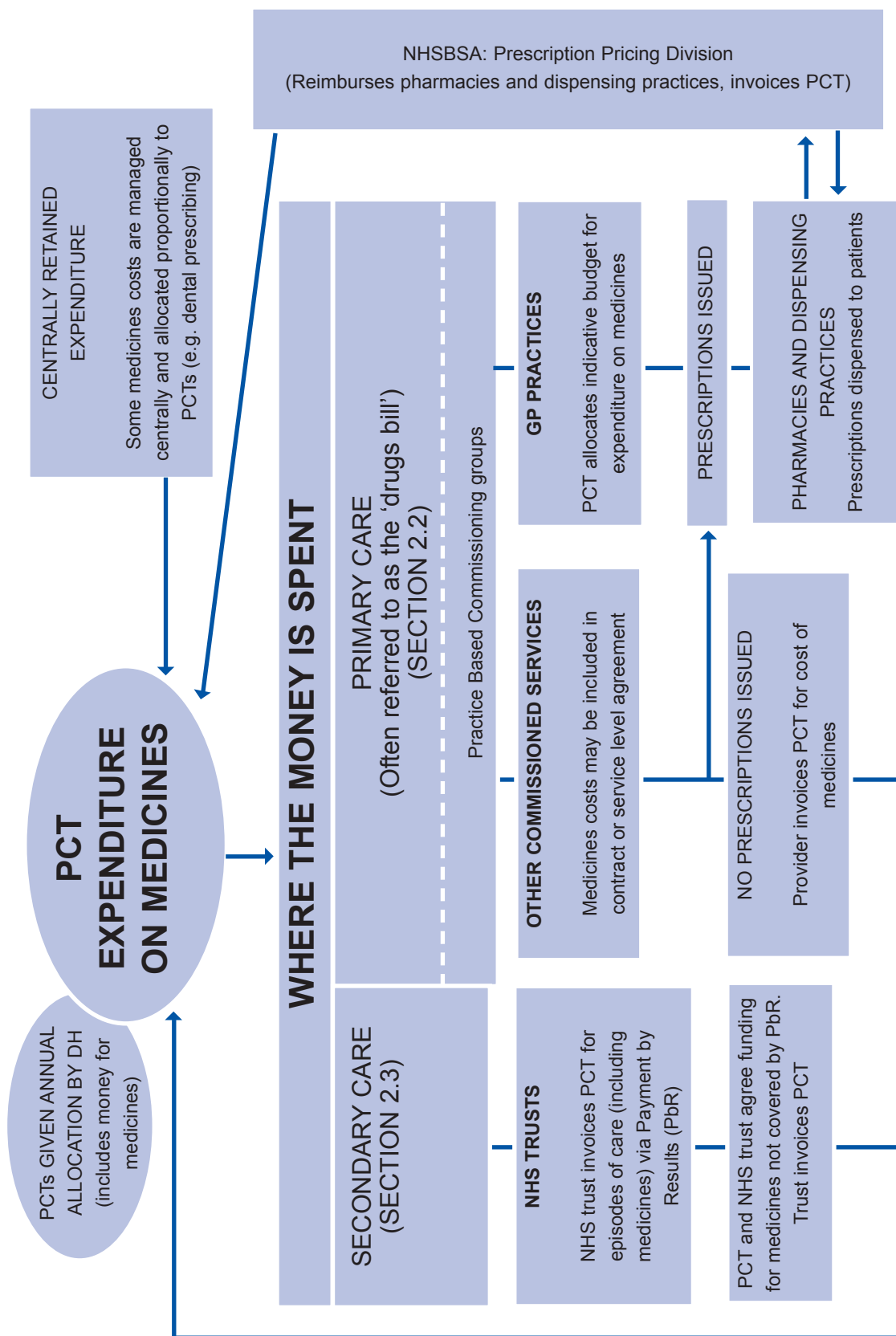
Key messages in this section

- The National Audit Office estimates that, in primary care, the NHS could save about £200m a year through better use of low cost generic medicines.
- The NHS Better Care, Better Value Indicators (**see section 5.6**) allow PCTs to benchmark their prescribing of some lower cost medicines (often generics) over time and nationally against other organisations.
- Medicines management / pharmacy teams have access to a wide range of information resources held nationally to help manage the primary care 'drugs bill' — **see Quick fact sheet 2**.
- Secondary care expenditure accounts for approximately 20% of the total national drugs bill. It is growing at a faster rate than, and directly impacts on, what is prescribed in primary care.
- In secondary care, most medicines (by volume) are covered by the Payment by Results (PbR) tariff. However, up to 60% of expenditure on medicines is outside or excluded from PbR.
- PCTs and NHS trusts need explicit mechanisms and agreements for funding high-cost, non-tariff medicines. If this area is not actively managed expenditure on these medicines may creep up in an unplanned way. This is a complex area, seek advice from your medicines management / pharmacy team and read additional resources provided by the NPC.

This section will look at the structures and processes in place to help manage expenditure on medicines in the NHS. It will cover how the NHS plans for expenditure on medicines in primary and secondary care, and the mechanisms used to account for, and monitor, expenditure.

Figure 1 illustrates typical financial flows for medicines in the NHS.

Figure 1: Overview of typical financial flows associated with medicines



2.1 Who gets the money for medicines?

The Department of Health allocates funding to PCTs on the basis of the relative needs of their populations. A weighted capitation formula determines each PCT's target share of available resources, to enable them to commission similar levels of health services for populations in similar need. The money available for medicines is part of this overall allocation (unified allocation). PCTs individually will then calculate how much money is needed to cover prescribing for their population, for example, primary care prescribing, cancer drugs, other drugs excluded from PbR etc.

2.2 Primary care prescribing

When calculating expenditure on prescribing in primary care (commonly known as 'the drugs bill') PCTs need to factor into their planning:

- The prescribing costs associated with meeting the needs of their populations
- The scope to target prescribing more effectively (for example, implementation of guidance from NICE — **section 5.1**)
- Potential efficiency savings (for example, encouraging prescribers to switch to lower cost equivalent medicines (**section 1.2**)¹⁴)

In general, PCTs allocate an indicative budget to each of their GP practices. The budget is to cover prescriptions issued by medical and non-medical prescribers for patients registered with the practice. How budgets are set varies across PCTs. A starting point is generally the current national rate of growth of the drugs bill along with the PCTs historical spend and weighted capitation. To assist in budget setting, PCT heads of medicine management and their teams have access to a wide range of data about prescribing patterns and expenditure at PCT and individual practice level (**see Quick fact sheet 2**).

Prescribing is part of the practice based commissioning (PBC) (**see section 3.2**) devolved budget (which also includes hospital care) and whilst indicative budgets for prescribing and other elements of devolved budgets are set at practice level they can be 'aggregated' at PBC group level. For aggregated budgets, savings occur 'to the PBC group'.

Other service providers. PCTs also need to take account of expenditure on medicines from other service providers in their budget setting process. As well as GP practices, there are other services where medicines are prescribed, supplied or administered. For example, out-of-hours services, walk-in centres, community clinics and hospitals, as well as enhanced services commissioned from community pharmacists and GPs / pharmacists with a special interest (**see section 3.3**).

Budgets managed centrally. The unified allocation given to PCTs covers some "elements of which resources have been retained centrally" for example, dental prescribing. These costs are allocated proportionately across all PCTs.

WHAT THIS MEANS FOR YOU:

PCTs must ensure money is available to cover primary care prescribing by GPs and non-medical prescribers. As services shift from secondary to primary care (potentially using new providers), the impact on budgeting for expenditure and financial flows needs to be considered.

Payment mechanisms

The majority of prescriptions in primary care (known as FP10s) are dispensed by community pharmacists, the others by dispensing GP practices and appliance contractors (**see also section 2.2**). Once prescriptions have been dispensed they are sent to the Prescription Pricing Division of the NHS Business Services Authority (NHSBSA). The NHSBSA reimburses community pharmacies and dispensing practices for the medicines that have been dispensed using a pricing schedule published in the *Drug Tariff* (**see section 1.2**).

All prescriptions are coded, so that the NHSBSA can then invoice PCTs for the cost of the medicines which have been prescribed by their practices. The data collated by the Prescription Pricing Division can be used to view and analyse prescribing data and expenditure (**see Quick fact sheet 2 and section 3**).

Medicines supplied to patients by mechanisms other than FP10 prescriptions require direct reimbursement arrangements between the PCT and the provider.

2.3 Secondary care prescribing

PCTs commission care provided within secondary care. Expenditure on medicines is part of this commissioned activity. Most medicines (by volume) used in secondary care are included in the PbR tariff. The tariff sets the price that PCTs pay NHS trusts (or any other providers) for a given episode of care, and includes the medicines used.

There are a small number of medicines which are not covered by the PbR tariff. There are no national data available on exactly how much expenditure is outside tariff arrangements but informal estimates suggest that it may be up to 60% of expenditure in larger specialist Trusts and 30-40% in smaller Trusts. Typically these high-cost medicines are:

- Specialist medicines explicitly excluded from tariff (i.e. high-cost low-volume)

- Used to treat conditions not yet included in the PbR tariff
- Recently launched medicines (**see also section 4.1**)

The Department of Health allocates an annual inflationary uplift to all PbR and non-PbR activity which includes a percentage for medicines. There is also an uplift allocated for new recommendations from NICE (**see section 5.1**) in that year. PCTs (and NHS trusts) then need to target the uplift locally. For all non-PbR activity, the uplift is the starting point for local negotiations around expenditure on high cost medicines. It is expected that the NICE uplift will be targeted appropriately across both PbR and non-PbR activity (e.g. chemotherapy). The majority of expenditure on medicines in secondary care should be covered within the annual uplift, however in some circumstances there is provision for the PCT and NHS trust to agree 'pass-through' payments.

This is a complex area. Detailed explanations are outside of the scope of this guide. For more information, the National Prescribing Centre is producing additional resources in this area (**see box 2**). You can also seek advice from your medicines management / pharmacy team.

In addition, **specialised commissioning teams** (see also **section 3.1**) based across Strategic Health Authority areas commission specialised services (high-cost, low-volume interventions and treatments) on behalf of their PCTs. The cost of medicines associated with specialised services comes from the PCT's budget.

What the additional resources produced by the National Prescribing Centre will cover:

- An explanation of how 'Payment by Results' (PbR) works
- Suggestions for how medicines not covered by PbR can be managed by PCTs and their providers
- A description of the individual funding request process
- Signposting to further resources and examples of practice within the NHS

(Available on NPC website at www.npc.co.uk)

WHAT THIS MEANS FOR YOU:

Funding arrangements for some secondary care medicines can be complex and often attract significant public and media attention. PCTs and NHS trusts need to invest time and resources to ensure that there is clarity around how medicines are funded to provide equity for commissioners, providers and patients. It is important to be aware of how your organisation manages these medicines. **See also section 3** and additional resources produced by the National Prescribing Centre.

Procuring medicines in secondary care

Medicines in secondary care can be purchased centrally via NHS Purchasing and Supply Agency (PASA) contracts, as well as locally by individual NHS trusts. Unlike community pharmacies, NHS trusts must pay VAT on the purchase price of medicines which is passed onto the commissioner.

Most **generic** medicines are purchased on national contracts and **branded** medicines on regional contracts. Where offers are made, contracts are awarded to the most 'economically advantageous offer' (not necessarily the cheapest). Where there is little therapeutic competition, it is not always possible to obtain any discounts and hospitals pay the hospital list price (which usually corresponds to the *Drug Tariff* price — **see section 1.2**). Contract prices paid will vary for different regions but can be obtained by PCTs via local contacts. More information about PASA can be found at www.pasa.nhs.uk/PASAweb

Central contracting for some medicines is also possible for PCTs although this would necessitate changing the route of supply (i.e. from community pharmacies to directly funded PCT suppliers). This model is used in some areas for enteral feed or dressing supplies.

Some manufacturers offer reduced prices via patient access (or risk share) schemes. In these schemes a rebate on price is paid to users if the medicine is not effective. Their usage is complex and time consuming but may allow patients greater access to medicines.¹⁵

Homecare service providers

Recently there has been a large growth in supply and administration of medicines to patients in their own homes by commercial Homecare Service Providers. It is estimated that 100,000 plus patients are now receiving their medicines via the homecare route. Prescriptions taken from secondary care are dispensed (in 'primary care') and then delivered to the patient's home. Homecare providers can also offer various levels of support to the patient (e.g. intravenous administration of medicines, training, nursing care). These arrangements effectively mean that VAT is not payable on medicines (normally secondary care pay VAT).

Management of homecare arrangements falls between primary and secondary care and is complex and difficult to measure accurately. Although it is currently not possible to measure the figure accurately, the value of medicines being supplied by this route annually is estimated to be in excess of £400 million, and these figures are expected to increase substantially as clinical services move away from hospitals to the community. More information can be obtained from the PASA website.¹⁶

Section 3: Medicines in commissioning and contracting

Key messages in this section

- Medicines are integral to the successful delivery of most services. Commissioners need to consider medicines in service re-designs, and as commissioning arrangements change and practice based commissioning further develops.
- All commissioners need processes, and relevant expertise, to ensure medicines safety and governance in the services they commission. PBC consortia need to determine what support they require and how to obtain it (**see also section 4**).
- There are a range of specific issues around medicines usage (**see section 1**) which, if not considered, could lead to delays in services or, in more severe cases, Healthcare Commission (**section 5.3**) investigations. (**See <http://www.healthcarecommission.org.uk/nationalfindings/publications/investigationreports.cfm>**).
- Commissioners and medicines management teams can identify issues relevant to their organisations using '*Medicines in Commissioning: A toolkit to help ensure safe and accessible services for patients*' developed by East and South East England specialist pharmacy services. (**See <http://www.nelm.nhs.uk/en/NeLM-Area/Community-Areas/Primary--Community-Care/Support-Information/Medicines-in-Commissioning-Toolkit/>**).
- Current provider contracts offer a range of opportunities, in primary and secondary care, to influence both what is prescribed and the quality processes that providers use to support and improve medicines usage. For more information seek advice from your medicines management / pharmacy team.

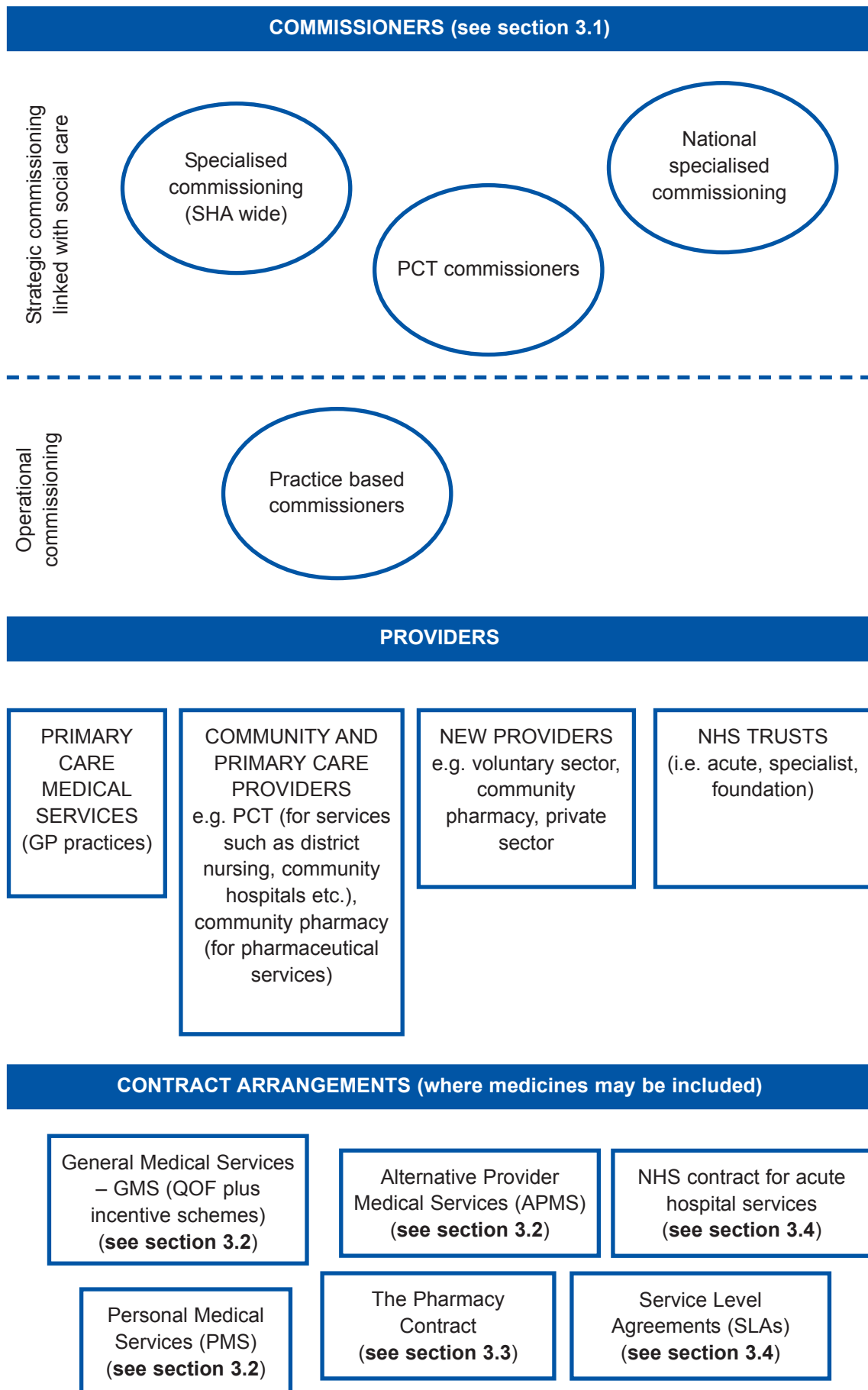
The NHS uses a range of ways to commission and contract for NHS services from a range of different providers (**see figure 2** for an illustration of this). With the move to provide more patient-centred services closer to home, it is likely that commissioners will be contracting with a wider range of providers. Some of these providers are the 'traditional' providers of services others are new / emerging providers.

Traditional providers include, GPs, community pharmacy (for pharmaceutical services), the PCT (now separated into a provider arm) who have provided services such as, district nurses, community hospitals, intermediate care, end-of-life care, specialist services and practitioners (e.g. TB clinics), community nurses, etc. It is likely that there will be competition for many of these traditional services from, for example, the voluntary sector (e.g. sexual health services), the private sector, other GP provider groups, acute Trust outreach services and social care providers.

In addition, the shift in care closer to home is likely to lead to the development of a new range of commissioned services available in a primary care setting. For example, moving some secondary care services to more local service providers (GP provider groups) or developing new clinical services in convenient locations (community pharmacies).

Commissioners have the opportunity to influence which medicines are prescribed, as well as the processes that need to be in place to support their safe and effective usage. This section will describe the main arrangements and highlight how commissioners and service providers can use them.

Figure 2: Overview of potential commissioning arrangements



3.1 Commissioners

World Class Commissioning envisages that, through more effective commissioning, the NHS will secure better health, care and value for NHS patients.¹⁷ With practice based and PCT commissioners, the overall vision of commissioning is the local commissioning of frontline services for patients by practice based commissioners (*operational commissioning*). With PCT commissioners managing *strategic commissioning*, this involves, for example, overseeing PBC, holding PBC groups to account for their commissioning, and helping PBC groups by contracting with providers and performance managing against those contracts.

Clearly prescribing and medicines management issues are important to both PCT and practice based commissioners. Effective medicines management will help deliver a range of commissioning priorities, for example, improving patient safety, maximising public health benefits, budgetary control, patient care pathway design, reducing emergency readmissions. In addition, one of the aims of PBC is to encourage GPs to get greater value for money from their prescribing by entitling them to reinvest a proportion of any efficiency savings they make into the commissioning of new services for patients.

PCTs have separated commissioning and provider functions. Over time, this will have an impact on how prescribing and medicines management support is provided in primary care. Current provision is largely via PCT employed medicines management teams. However, it is likely that a number of models of delivery will emerge as PBCs progress and develop. For example, PCTs reconfiguring their prescribing support around PBC groupings, and PBC groups appointing their own pharmaceutical advisers.

WHAT THIS MEANS FOR YOU:

Early consideration of medicines (safety, governance, access, etc.) is important when commissioning, re-designing or providing services.¹⁸ Be aware of how your organisation ensures this. There are different ways to ensure expert input is being obtained. For example, some commissioning teams are recruiting pharmacists as core team members, whilst others are ensuring all new service developments are reviewed by, for example, an area prescribing committee (**see section 3.2**).

There are separate commissioning arrangements for specialised services i.e. those with low patient numbers but which need a critical mass of patients to make treatment centres cost-effective. Very often specialised services are associated with the use of high-cost medicines. They are either commissioned regionally, by the 10 Specialised Commissioning Groups (SCGs), which sit with SHAs, or nationally by the National Commissioning Group (NCG).¹⁹

WHAT THIS MEANS FOR YOU:

Decisions made by specialised commissioning groups cover multiple primary care organisations. Specialised commissioning decisions will involve medicines which are part of the PCTs overall budget (see section 2.2). Local processes should be in place for managing the financial, clinical and safety implications of specialised commissioning decisions.

3.2 Primary care contracts

There are a range of different contracts for primary care medical services. Most primary care medical services are provided by GP practices using two main contracts, the General Medical Services (GMS) contract and Personalised Medical Services (PMS) contract. Primary care medical services provided by other providers generally use an Alternative Provider Medical Services (APMS) contract, although GP practices offering services outside their main contract can also use APMS contracts. Providers can hold a variety of contract types with a variety of commissioners, for example, a GP practice may have a GMS contract with one PCT and an APMS contract with a second PCT.

These contracts are discussed briefly in box 3 and more detailed information on all these contracting arrangements can be found on the Department of Health website.²⁰

Box 3: Common contracts for primary care services

General Medical Services (GMS)

The main contract under which GP practices work is the GMS. It is negotiated centrally (between the Government, the British Medical Association and the NHS Employers [via the NHS Confederation]) and covers the pay arrangements between the PCT and a GP practice. The contract covers essential services (which all GMS practices must provide) and additional and enhanced services. GMS is not re-negotiable locally.

Personalised Medical Services (PMS)

PMS is the other main GP contract. Similar to the base GMS contract in that it provides a sum of money to provide a range of services but these are not necessarily based around minimum essential services. Agreements are locally negotiated and have the ability to introduce local flexibilities, for example, quality indicators around medicines usage, not available under the GMS contract.

Alternative Provider Medical Services (APMS)

APMS contracts broaden the range of potential providers from whom PCTs can commission services. It also opens up the provision of services to providers other than GP practices. Like PMS, APMS offers more flexibility, for example, to include quality indicators relating to medicines.

Quality and Outcomes Framework (QOF)

Introduced in 2004, QOF is a system to reward practices for providing good quality care to their patients, and to help fund work to further improve the quality of healthcare delivered.²¹ QOF can be accessed by both GMS and PMS practices, although for PMS practices it can be tailored locally. The philosophy underpinning the QOF is that incentives are an effective way of resourcing work, driving up standards and recognising practices' achievements. Between a third and a half of a GP's income comes from achieving QOF.²² Whilst participation in QOF is technically voluntary it is taken up by almost all GPs. It has a range of 'indicators' which, if practices fulfil, earns them points (which vary per indicator) the points translate into additional income.

There are a range of 'clinical domains' in QOF mostly around long-term conditions. Many domains have implications for prescribing as they drive up use of some medicines. In addition there are 'medicines management' indicators. Two of these reward practices for meeting with a prescribing adviser and agreeing up to three actions relating to prescribing in line with local priorities. The three actions can vary from practice to practice. Some examples include: a self audit on how the practice is implementing guidance from NICE (**see section 5.1**); developing repeat prescribing systems to improve access to medicines. QOF clinical domains do not cover all conditions. It is important to ensure that opportunities to improve prescribing in these areas are not missed.

Incentives

PCTs can also choose to use incentive schemes to target local prescribing priorities.²³ For example, the incentive schemes might reward practices for more efficient prescribing, like switching from high-cost to lower cost medicines (using Better Care, Better Value indicators: **see section 5.6**) or for addressing a safety issue in a specific patient group (in line with National Patient Safety Agency guidance (NPSA): **see section 5.2**).

As highlighted in **section 2.2**, for PBC consortia, prescribing is part of devolved budget arrangements. So, there is an additional incentive to maximise cost-effective prescribing in order to reinvest savings in the local PBC economy.

As well as contracting for primary care medical services, some dispensing practices, working in rural locations, are contracted to cover the dispensing element of the pharmacy contract (**see section 3.3**). Since 2006, dispensing practices have an additional incentive scheme (Dispensing Quality Payments Scheme) which rewards them for providing high quality services to their dispensing patients. Practices which sign up to the scheme and achieve all the quality requirements receive a payment for each dispensing patient.

WHAT THIS MEANS FOR YOU:

The Quality and Outcomes Framework (QOF) and incentive schemes provide PCTs with a way of rewarding practices for improving their prescribing and medicines management. The schemes can be used to optimise a PCT's local health priorities, as well as helping to implement national guidance. PMS and APMS contracts have local flexibility and offer additional opportunities to use quality indicators to influence prescribing and medicines management. Whatever indicators are included in contracting arrangements, they need to be effectively monitored and evaluated.

3.3 Community pharmacy contractual framework

Most patients live close to a community pharmacy and, although not traditionally seen as provider of primary care clinical services, this role is increasing. The recent pharmacy White Paper highlights how community pharmacy can be used to meet many key policy objectives, by allowing convenient access to services close to the patient's home, in particular in hard to reach deprived communities.¹⁸ It envisages community pharmacies as 'healthy living' centres promoting health and well-being (for example, screening for vascular disease), supporting people with long-term conditions and a first port of call for people with minor ailments.

The NHS has regulations for awarding contracts for community pharmacy services. PCTs are responsible for securing NHS pharmaceutical services in their area. In contrast with other primary care contractors PCTs do not have individual contracts with community pharmacists. Generally community pharmacists provide services under a 2005 contractual framework for community pharmacy agreed between the Department of Health and the Pharmaceutical Services Negotiating Committee, and NHS Employers and operated through the PCT.

Under their contractual framework community pharmacies must provide a range of essential services, for example, dispensing prescription medicines, giving advice and selling non-prescription medicines. Since 2005, they can also provide advanced services (for example, Medicines Use Reviews). The funding for advanced services is linked to the payment schedule the NHS uses for generic medicines. The contractual framework also makes provision for commissioners to negotiate 'enhanced and local services'.

For more information contact your medicines management / pharmacy team or for details of the contractual framework see the Pharmaceutical Services Negotiating Committee website (www.psnc.org.uk).

WHAT THIS MEANS FOR YOU:

Community pharmacies, as well as providing pharmaceutical services, will increasingly become an alternative provider of some primary care medical services traditionally associated with, for example, GP practices. For more information, seek advice from your medicines management / pharmacy team.

3.4 Contracting with NHS trusts

There is a standard NHS contract for acute hospital services which covers agreements between PCTs and providers for the delivery of acute hospital-based care. The contract applies to agreements for 2007-08 for NHS trusts, foundation trusts and new agreements between PCTs and independent sector providers. There are two versions of the contract, a legally-binding one for foundation trusts, and an abridged service level agreement version for NHS trusts. Quality indicators around prescribing may be included within these contracts. For example, adherence to formulary, purchasing audits, outpatient prescribing, standards around the handling of medicines. There is also potential to include agreements on the management of high-cost drugs and entry of new medicines within contracts and service level agreements (**see section 4**).

WHAT THIS MEANS FOR YOU:

PCTs and NHS trusts have the potential to include specific quality indicators linked to local medicines management priorities in service level agreements and contracts.

Section 4: Local activities to manage medicines effectively

Key messages in this section

- There are a range of local medicines management activities that can help ensure safe, high quality, effective services. Many of these activities will be happening in your organisations. Managers and medicines management teams should ensure that they meet the needs of your organisation, and contribute to local and NHS priorities.*
- New medicines need to be actively managed into local health communities to ensure safe and equitable access for patients, as well as managing financial risk. There should be processes and systems to help your organisations do this, in partnership with other relevant stakeholders.
- Health economy (area) prescribing committees (sometimes referred to as APCs) help to manage the use of medicines across care interfaces. These groups can have wide ranging remits and can be an effective way of managing medicines across a health community. There should be a link between clinical decisions made by the group and decisions about affordability and prioritisation.
- Commissioners and finance teams should be aware of how their APC (or equivalent) works, the membership of the group and how they are linked into decision-making. For more information, review the NPC's fitness for purpose guide for APCs, *Managing medicines across a health community: making APCs fit for purpose, 2007* and contact your medicines management / pharmacy team.

*To help review existing services, and plan for future developments, you and your medicines management / pharmacy team could use the National Prescribing Centre's guide to medicines management — *Moving towards personalising medicines management, 2008*.²⁵

This section briefly highlights some key local activities which will be happening to some extent in your organisation. Your medicines management / pharmacy teams will be able to give you a full picture of local activities.

4.1 Managed entry of medicines

New medicines are launched on a regular basis. For planning and risk management purposes, it is important to understand early on the potential impact that a medicine may have on the health of the local population, funding implications and service design.

PCTs and NHS trusts should all have processes to help actively manage new medicines. Managers need to be familiar with how these systems work and what they can and can't deliver. Medicines management / pharmacy teams can advise on local arrangements, however, some of the key issues are listed here:

- Where a new medicine has been appraised positively by a NICE (**see section 5.1**) technology appraisal, NHS organisations must make funding available within three months (unless otherwise notified by the Department of Health). If it is **included** in the PbR tariff there is a NICE uplift to cover in year funding. If it is **not included in, or excluded from**, the PbR tariff, commissioners and providers should have local procedures in place which agree funding of the medicines (**see section 2.3**)
- Most significant medicines will be referred to NICE (**see section 5.1**) for appraisal. NICE is currently developing systems to appraise many new medicines and all new cancer drugs at launch. However, in some cases there will be an interim period before NICE guidance is issued. Blanket funding bans by NHS organisations are not acceptable pending NICE guidance. Trusts need to have processes in place for managing the entry of new medicines prior to NICE guidance. *High quality care for all, the NHS Next Stage Review final report*, outlines, through the NHS Constitution, the right of NHS patients to expect rational local decisions based on a proper consideration of the evidence on funding of new drugs and treatments which have not been (or will not be) reviewed by NICE²⁴
- There are a wide range of resources nationally to help plan for the introduction of new medicines, including horizon scanning documents and groups, pre-launch reviews of non NICE medicines and costing tools. **See also Quick fact sheet 3**
- As well as the cost of medicines it is important to take into account the service implications of new medicines, for example, a medicine may be more expensive but could reduce the costs associated with a service overall. Alternatively, a new medicine may have a high risk profile that requires ongoing monitoring, and so services need to be re-designed to accommodate this

WHAT THIS MEANS FOR YOU:

Mechanisms should be in place to ensure managed entry of medicines. This can help ensure consistent and transparent decisions about medicines as they become available, in line with the draft NHS Constitution, as well as ensuring that financial, clinical and safety risks are managed. In many cases, managed entry will need collaboration between primary and secondary care organisations. Health economy wide prescribing and medicines management committees (or equivalents) can be an effective way of facilitating this (**see next section**).

4.2 Health economy prescribing and medicines management committees (APCs)

Clearly, all individual organisations need to manage their governance and risk around medicines (for example, using a medicines management committee). However, ensuring that medicines are well managed across a health community, in terms of entry of new medicines and interventions, safe and effective choices, and equitable access for patients, is likely to require the input of a wide range of stakeholder organisations. Traditionally the clinical and financial risks and benefits associated with medicines have been managed using a range of collaborative, area wide approaches.

The collaborative approach often involves a committee with appropriate stakeholder membership, working with delegated authority from their organisations (PCT / NHS trust etc.) to agreed terms of reference. For shorthand these committees can be referred to as Area Prescribing and Medicines Management Committees (APCs) although different health economies will have different names for them.

Many were established to manage more effectively the entry of new drugs into the NHS. Now, however, the functions and forms of many APCs go far beyond this original remit. In particular, they can be used as forum to resolve issues around medicines safety and usage across the care interfaces, for example from primary to secondary care.

The NPC has published a fitness for purpose framework for APCs (or equivalents) which proposes that APCs review their scope and functions along with the structures and processes that are in place to support their activities.²⁵

WHAT THIS MEANS FOR YOU:

Health economy (area) prescribing committees (sometimes referred to as APCs) can have wide ranging remits and, if functioning well, can be a very effective way of managing medicines across a health community. Be aware of your APC and how you link into it, for example, how do clinical decisions made by your APC link to decisions about affordability and prioritisation.

4.3 Practical support for GP practices and PBC consortia

There are a wide range of practical support activities that can be delivered at practice or PBC level by medicines management teams. Some examples of these include:

- Providing information for prescribers around therapies, for example, evidence-based summaries of data or reviews of new medicines
- Facilitating audits of prescribing practice e.g. against NICE guidance or to identify unmet pharmaceutical need
- Reviewing processes and prescribing to help ensure that it is safe and appropriate
- Clinical support within the practice using practice based pharmacists and pharmacy technicians, for example, undertaking clinical medication reviews for target patient groups
- Discussing options for more cost-effective prescribing (**see section 1.4**)
- Supporting medicines management activities in the QOF (**see section 3.2**)
- Provision of pharmaceutical and prescribing advice to all members of the practice team

WHAT THIS MEANS FOR YOU:

The NPC's guide, *Moving towards personalising medicines management*,²⁶ describes a range of medicines management activities. The guide can be used, with your medicines management teams, to identify where there may be gaps in provision or the potential to develop new activities.

4.4 Managing and monitoring medicines usage and expenditure

There are a wide range of activities that can help to monitor medicines usage and to manage expenditure. In primary care, much of the data necessary to facilitate this is held on national databases and is accessible by medicines management teams.

Some examples of what medicines management teams use this information for:

- To monitor usage to identify potential under prescribing
- To monitor usage as part of a practice audit
- To benchmark GP practices in a PCT against others on progress toward priorities
- To benchmark PCTs against others on the same (or different) targets
- To help to set prescribing budgets
- To monitor expenditure to identify early where budgets may be overspent
- To identify areas for discussion with practices

Section 5: Medicines safety and governance

Key messages in this section

- Medicines safety and governance should be integral to all services using medicines. It is something that both the regulator (the Healthcare Commission) and performance management organisations (e.g. SHAs and PCTs) will want to ensure.
- The Corporate Manslaughter and Corporate Homicide Act 2007, states that Trusts need to have a culture of safety firmly in place.
- Safe practices should be embedded in patient care, along with clear lines of accountability. That means having appropriate up-to-date medicines policies and procedures in place and trained staff, whether a provider organisation or a commissioner.
- National organisations like the NPSA and NICE regularly issue guidance about medicines usage. NHS organisations are generally expected to act on their recommendations.
- In the UK, responsibility for medicines regulation lies with the Medicines and Healthcare products Regulatory Agency (MHRA) an executive agency of the Department of Health.

This section provides an overview of the national organisations producing guidance for, or regulating, NHS organisations.

5.1 National Institute for Health and Clinical Excellence (NICE)

NICE provides national guidance on the promotion of good health and the prevention and treatment of ill health. It is expected that NHS organisations will follow NICE guidance. The draft NHS Constitution reflects this, by stating that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if the patient's doctor says they are clinically appropriate. Operating frameworks and standards around medicines management frequently refer to NICE. It is likely that any new providers of services to NHS patients will need to ensure that NICE guidance is followed.

For more information about the work of NICE see www.nice.org.uk

For a summary of resources that NICE produce to help with prescribing and medicines management activities see **Quick fact sheet 3**.

WHAT THIS MEANS FOR YOU:

PCTs have a statutory duty to provide funding and resources for medicines and treatments recommended by NICE's technology appraisal guidance. So, when NICE recommends a technology, the NHS must ensure it is available to those people it could help, normally within three months of the guidance being issued.

5.2 National Patient Safety Agency (NPSA)

The NPSA regularly issues alerts and directives, many of them relating specifically to medicines. Some NPSA guidance has a required implementation date. Organisations must signal their implementation status via the Department of Health Safety Alert Broadcast System (SABS), ranging from 'no action required', through 'action ongoing' to 'action complete'.

The NPSA also maintains a database of reported patient safety incidents.

It is the responsibility of commissioning organisations to ensure that NPSA alerts are implemented by the providers that they commission services from. Commissioning contracts should be developed which make provision for this and allow the commissioning organisation to monitor ongoing adherence to NPSA guidance. The pharmacy White Paper recently recommended that chief pharmacists of provider organisations, PCTs and other commissioners should have the lead role in ensuring that safe medication practices are embedded in patient care. This includes working with other senior health professionals and senior managers to ensure that organisations respond to the NPSA and other alerts efficiently and in good time, thereby reducing risk to patients.

The recent Corporate Manslaughter and Corporate Homicide Act 2007, made it clear that in the event of an unexpected death, a Trust will need to be able to demonstrate that a culture of safety is firmly in place in the organisation. An organisation will be guilty if the way it manages or organises its activities causes a person's death and amounts to a gross breach of the duty of care owed to that person.

For more information about the work of the NPSA see www.npsa.nhs.uk

WHAT THIS MEANS FOR YOU:

Organisations need to ensure that there is a process in place to ensure implementation, and monitor adherence to, NPSA safety alerts. Performance monitoring organisations, for example, the Healthcare Commission (**see later**) will be assessing commissioning organisations on how well they implement and monitor NPSA alerts.

5.3 Healthcare Commission (soon to be the Care Quality Commission)

The Healthcare Commission inspects the quality and value for money of healthcare and public health. The Commission's principal means of assessing the NHS in England is by the Annual Health Check (AHC). The AHC is directed by the Department of Health's Standards for Better Health but it also scores NHS trusts on many aspects of their performance, including the quality of the services they provide to patients and the public, and how well they manage their finances and other resources. These scores are based on a range of information gathered throughout the year. This includes information collected through various service reviews and inspections, as well as the data collected by other organisations, such as the Commission for Social Care Inspection, the Mental Health Act Commission, the Audit Commission and Monitor (the regulator for NHS Foundation Trust). Also as part of its AHC, the Healthcare Commission follows up on the way Trusts are implementing guidance from NICE and the NPSA.

The Healthcare Commission was given additional responsibility to provide external scrutiny of the new arrangements for controlled drugs governance (in England) following the government response to the Shipman Fourth report (**see also section 1.1**). This responsibility includes ensuring that local governance arrangements, intelligence networks and provisions for incident panels are satisfactory as set out in regulation.

Private and voluntary sector providers of healthcare are also regulated by the Healthcare Commission.

In 2008, the Healthcare Commission will be merged with the Commission for Social Care Inspection to form one organisation, the Care Quality Commission. For more information about the work of the Healthcare Commission see www.healthcarecommission.org.uk

WHAT THIS MEANS FOR YOU:

As part of its Annual Health Check, the Healthcare Commission (soon to be the Care Quality Commission) will want to see that your organisation keeps patients, staff and visitors safe by having systems to ensure that medicines are handled safely and securely (core standard C4d). This includes arrangements for controlled drugs. Commissioners of services need to be assured that their contractor services and their commissioned services are meeting the relevant aspects of these standards. This includes services commissioned from private and voluntary sector organisations.

5.4 National Prescribing Centre (NPC)

The NPC was established in 1996. Directly funded by the Department of Health and, for publications, by NICE, the NPC aims to promote and support high quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery. Its work programmes range from information on the clinical effectiveness of medicines to good practice guidance (for example on controlled drugs), through to systems and processes for managing medicines in small and large organisations.

For more information about the work of the NPC see www.npc.co.uk or www.npc.nhs.uk. There is a large and expanding e-Learning resource at www.npci.org.uk

5.5 National clinical guidance

National Service Frameworks (NSFs) are Department of Health guidance that defines evidence-based standards and good practice in a clinical area or for a patient group. Examples include mental health, coronary heart disease, long-term conditions and older people. In 2004, the Department of Health published a specific resource document to help the development of medicines management services to support the NSFs which included an outline of what a good medicines management programme would look like.²⁷ NSFs with significant implications for medicines management are the NSF for older people and the NSF for long-term conditions.

WHAT THIS MEANS FOR YOU:

NSFs can lead to additional expenditure on medicines as more patients are treated. For instance, national expenditure on statins is increasing by around 30% year on year in line with recommendations made in the coronary heart disease NSF.

5.6 Better Care Better Value (BCBV) Indicators

BCBV Indicators, published by the NHS Institute for Innovation and Improvements are intended to help NHS organisations make effective use of public money in the delivery of high quality healthcare.

The indicators cover four areas, one of which includes prescribing in primary care. The prescribing indicators challenge PCTs to review prescribing of high-cost medicines compared to equivalent lower cost products and implement changes where this is considered appropriate. The proportion of lower cost prescriptions for some commonly used medicines varies significantly between PCTs. The indicator describes the productivity opportunity that could be gained by using less costly products at the same level as the top 25% of all PCTs. Organisations are able to benchmark their own performance over time and nationally against other organisations.

It is estimated that the NHS saved £60 million the first year the statin indicator was available²⁸ and 25% of PCTs now have at least a 77% rate of lower cost statin prescribing.²⁹

For more information about BCBV indicators see www.productivity.nhs.uk

5.7 Medicines regulation

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health. The MHRA's role is to ensure that medicines and medical devices work, and that they are acceptably safe. For more information about the work of the MHRA, and its independent advisory committees such as the Commission on Human Medicines, see www.mhra.gov.uk. See also Quick fact sheet 1.

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Appendix 1

Quick fact sheets

1. Medicines safety and regulation
2. Information on usage of, and expenditure on, medicines
3. NICE resources to help with implementation

Quick fact sheet 1: Medicines safety and regulation

Medicines are licensed for use in the UK by the UK Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Responsibility for national medicines regulation lies with the MHRA – an executive agency of the Department of Health. The EMA co-ordinates and provides regulatory support to member states of the EU and the European medicines advisory committees. The EMA is also responsible for medicines that are authorised through a centralised European Procedure.

Licensing medicines

Medicines must meet safety, quality and efficacy criteria before they can be marketed in the UK. Companies wanting to market a medicine must apply for a 'marketing authorisation' and submit data which show that the medicine meets appropriate safety, quality and efficacy standards. The MHRA will then assess the medicine's benefits against its potential risks.

A marketing authorisation specifies what the medicine can be used for within the terms of its licence. All medicines have a summary of product characteristics and a patient information leaflet which give details of what the medicine can be used for, how it is to be used, possible side-effects, etc.

How safe does a medicine have to be?

No medicine is a hundred per cent safe and all medicines can have side-effects. In assessing safety, the MHRA asks: do the benefits of a medicine outweigh the risks to patients and the public? Such assessment must consider the balance of benefits and risks according to the type of medicine. For example, the side-effects profile of a medicine that is used to treat a life-threatening illness will differ from that of a medicine for a common minor ailment. Although it is often not possible to predict which individuals may be at risk of side-effects, patients and healthcare professionals have to weigh up the pros and cons of each medicine when deciding a course of treatment. Information about the safety of medicines is published regularly on the MHRA's website (www.mhra.gov.uk) and in its monthly bulletin for healthcare professionals called Drug Safety Update (see www.mhra.gov.uk/mhra/drugsafetyupdate).

Safe use in practice

Although a medicine may be considered acceptably safe by the licensing process, this does not necessarily mean that the way it is used in clinical practice is safe. This aspect is not considered as part of the licensing process.

How safety issues are monitored

The MHRA monitors all suspected adverse drug reactions (ADRs) through the Yellow Card Scheme, and a wide variety of additional data sources, and will take action where there are safety concerns. ADR reporting is the professional responsibility of all healthcare professionals. Patients can also report ADRs via the internet and using leaflet reporting cards (www.yellowcard.gov.uk).

To monitor new medicines a black triangle accompanies them in prescribing manuals and product information. This is to prompt healthcare professionals and patients / public to report any suspected side-effects to the MHRA via the Yellow Card Scheme. This gives a broader picture of how the new medicine is performing in the general population.

The NPSA also maintains a database (the National Reporting and Learning system – NRLS) of reported patient safety incidents. All NHS trusts are linked electronically to this system, although individual practitioners and patients are also encouraged to report patient safety incidents to the NPSA. This system is used to report errors made in the use of medicines rather than side-effects etc., which should be reported through the Yellow Card Scheme.

Quick fact sheet 2: Information on usage of, and expenditure on, medicines

Prescription Pricing Division (PPD) of the NHS Business Services Authority

The PPD collates primary care prescribing data, which is made available to the NHS through two main electronic systems; which require a valid user identifier and password, and a connection to the NHS net. www.ppa.nhs.uk

Electronic Prescribing Analysis and Cost (ePACT.net). This online system allows authorised users, including general practitioners, primary care trusts and other NHS stakeholders, to view and analyse prescribing volumes, trends and costs. It allows real time on-line analysis of the previous 60 months' prescribing data. Information is available at prescriber, practice and PCT level for PCT users.

Prescribing Toolkit. The Prescribing Toolkit contains prescribing indicators and a range of prescribing comparators and related data sets, designed to assist in performance management and financial monitoring and allocation. New data sets are provided on a quarterly basis and are available for the previous 36 months. The Toolkit allows comparison between prescribing organisations – to help identify outliers and areas for improvement. The Toolkit is useful for an overview and comparison of prescribing, but ePACT.net should be used for further analysis, particularly at practice level.

Prescribing Support Unit (PSU)

The PSU is part of the Information Centre for Health and Social Care, which collects, analyses and publishes a wide range of information about health and social care. The PSU deals with data and information relating to prescribing, community pharmacy services and primary care, including the general practice Quality Outcomes Framework (QOF). A range of regular reports and bulletins on national trends and policy are published. These also include prescribing measures, expenditure, allocation and non-medical prescribers. www.ic.nhs.uk/psu

The Unit hosts and manages the national prescribing information database, the Prescription Cost Analysis (PCA), which covers all prescriptions dispensed in the community in England. This is used for answering parliamentary questions and requests from the public and private sector about all aspects of the primary care drugs bill. The data used to populate this database is provided by the Prescription Pricing Division (PPD) of the NHS Business Services Authority.

NHS Institute for Improvement and Innovation: Better Care, Better Value Indicators

The Better Care, Better Value Indicators (formerly called the Productivity Metrics) are designed to help local NHS organisations make the most effective use of public money, to deliver quality healthcare. These indicators can be used locally to:

- Help inform planning
- Show potential efficiency savings in different aspects of care at PCT and SHA level

Prescribing indicators, provided by the PSU, are included. www.productivity.nhs.uk

Quick fact sheet 3: NICE resources to help with implementation

NICE provides national guidance on the promotion of good health and the prevention and treatment of ill health.

The guide *How to put NICE guidance into practice* ([www.nice.org.uk/using Guidance](http://www.nice.org.uk/using-Guidance)) is the cornerstone of NICE's implementation support programme. It provides an implementation model to help NHS organisations comply with the Department of Health's 'Standards for better health' and meet the expectations of the Healthcare Commission.

There are a range of tools available on the NICE website that may be of use in prescribing and medicines management activities.

- Costing tools for all technology appraisals, public health guidance and clinical guidelines (see www.nice.org.uk/costingtools)
- Implementation advice (for all public health guidance, clinical guidelines and selected technology appraisals) (see www.nice.org.uk/implementationadvice)
- Audit criteria help organisations plan clinical audit projects based on the key priorities of the guidance (see www.nice.org.uk/auditcriteria)
- Slide sets (for all public health guidance, clinical guidelines and technology appraisals) covering key messages in the guidance (see www.nice.org.uk/slidesets)
- Forward planner (see www.nice.org.uk/ForwardPlanner)
- Commissioning guides, to support NHS commissioners in England (see www.nice.org.uk/commissioningguides)
- Shared learning database (see www.nice.org.uk/sharedlearning)
- ERNIE (evaluation and review of NICE implementation evidence) database, which provides a bank of guidance-specific implementation uptake reports produced by NICE and references to external studies looking at how NICE guidance is being implemented (see www.nice.org.uk/ernie)
- Implementation Consultants who are out in the field who meet regularly with NHS organisations (see www.nice.org.uk/page.aspx?o=350123).

Appendix 2

Acknowledgements

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