Review of NHS pharmaceutical contractual arrangements

Report by Anne Galbraith

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Foreword by Anne Galbraith

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29 March 2007

Dear Lord Hunt

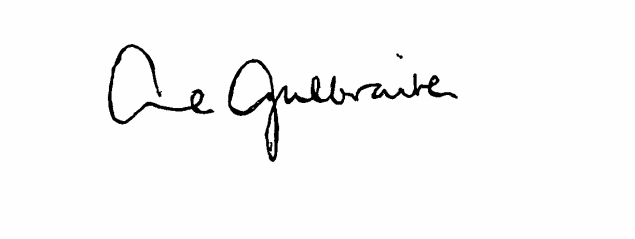
Review of NHS pharmaceutical contractual arrangements

I am pleased to enclose my report reviewing NHS pharmaceutical contractual arrangements. This review was commissioned by Andy Burnham MP on 11 January this year. I am most grateful to Chris Town and Sue Ashwell for their assistance to me throughout the review. They have been an invaluable and expert source of advice and support.

I would also like to thank the many individuals and organisations who gave so willingly of their time and energy to provide me with their insights into the operation of the current arrangements and their ideas on how this can be improved and reformed. I hope they find this report reflects the many diverse views fairly and representatively.

Pharmaceutical services are essential. My aim has been to consider pragmatic ways in which patients and consumers might derive yet greater benefit from these services. I trust you will find my proposals fulfil that aim and provide a helpful platform from which the Department can take forward its planned consultation.

Yours sincerely



Anne Galbraith
Chair of the Review on NHS pharmaceutical contractual arrangements

Executive Summary

Introduction

- On 11 January 2007, Andy Burnham MP, the Minister of State for Delivery and Reform, commissioned me to review NHS pharmaceutical contractual arrangements.

- The purpose was to review current arrangements, taking account of competition and consumer choice concerns and the principles of better regulation, and consider the extent to which these arrangements reflected wider developments in health service commissioning and contributed to the aims of the White Paper *Our health, our care, our say*.

- The findings from this review were to inform formal consultation on how best arrangements should be developed or reformed.

- **Chapter 1** sets out the terms of reference and methodology for the review together with background information I considered relevant to the current and future provision of pharmaceutical services. More information on these is included in Annexes A – E to my report.

- Following an initial briefing for interested parties in January, I appointed Chris Town and Sue Ashwell to assist me. I held five Inquiry Sessions with 23 organisations from patients, consumers, the NHS, contractors and the Office of Fair Trading between 1 February and 7 March. Synopses of these discussions together with additional papers received are included at Annex F.

- **Chapter 2** sets out the context for our discussions and looks at the available resources and health challenges now.

- England's population is rising and ageing: the population is set to grow from 49.4m in 2001 to 54.6m in 2021 and life expectancy continues to increase.

- The public health challenge and problems associated with an ageing population also look set to increase with rising incidence of chronic long-term conditions, including obesity.

- 50% of people do not take their prescribed medicines as intended. Patients and carers continue to need to be more involved in decisions about treatment and receive more information about the benefits and risks.

- There is potential for pharmaceutical contractors to widen their contribution to healthcare. Pharmacy contractors provided nearly 17,000 local enhanced services under the new contractual framework in 2005/06 and had completed half a million Medicines Use Reviews (MURs) by the end of 2006.

- **Chapter 3** explores how this contribution might be tapped, building on our discussions at the Inquiry Sessions.

- Patients think highly of pharmaceutical services – patients value convenient, accessible services, which are local to them.

- For both patients and consumers, the key Primary Care Trust (PCT) role should be to assess needs and stimulate provision by being more proactive, encouraging pharmacies to start thinking about their considerable potential.

- For the NHS, there is a lack of influence for PCTs in terms of clinical services decided at a national level, e.g. MURs are provider-led and PCTs are unable to predict their spend on these, nor can they manage the quality and effectiveness of these through existing contractual arrangements.

- Contractors are keen for more services being funded as part of nationally agreed and set advanced or essential services. Pharmacy has invested significantly in new service provision but has yet to see the fruits of this in secure local funding of enhanced services such as minor ailment schemes.

- The Office of Fair Trading's view is that market deregulation with contestability for enhanced services would drive up standards.

- **Chapter 4** discusses what the pharmaceutical service of the future might look like.

- There are fundamental principles to underpin the contractual model of the future, e.g. adopting models of practice which enhance the patient experience and support their wellbeing, promoting safe use of medicines.

- The attributes of a good pharmaceutical service support and enable patient involvement in managing their medicines, and are personal, accessible, knowledgeable and professional.

- We consider there is potential to develop what we term a "pharmaceutical care management" service with a more clinical focus, integrated with other services, quality-proofed and underpinned by appropriate standards. PCTs may need to be able to offer incentives to develop best practice focussed on the health needs of the population.

- **Chapter 5** explores areas which we think could be addressed now, without the need for changing the existing primary legislation.

- PCTs need a platform from which they can properly plan and manage the provision of pharmaceutical services. Pharmaceutical Needs Assessments (PNAs) should have a consistent structure across all PCTs and have national comparability in breadth and depth.

- There should be clearer links between local health needs and the provision of more clinical services through PNAs.

- Consistent accreditation arrangements for advanced and local enhanced services and the development of common standards for accreditation and training are advisable.

- The Department has existing powers to include providers on pharmaceutical lists for a fixed period and should consult on introducing such measures.

- More integrated professional working with closer co-operation amongst professionals is desirable, e.g. developing a performance management indicator for repeat dispensing services and how the provision of the Medicines Use Review service can best reflect local priorities. For example, through PNAs, PCTs could identify key priority areas/patient groups for the provision of MUR services.

- Otherwise, the Department should only proceed to transfer services to nationally agreed tiers where there is clear proven need and advantages.

- Quality is difficult to measure and patients do not necessarily recognise a quality service. There is a need for more and wider information about what patients can expect of a modern pharmaceutical service.

- Improving patient awareness and understanding of pharmaceutical services and encouraging the recognition by patients/consumers of pharmacy as part of the "NHS family" is desirable.

- In rural areas, we consider the Department should explore, with the General Practitioners' Committee (GPC) of the British Medical Association and Pharmaceutical Services Negotiating Committee (PSNC), instituting a single regulatory test.

- Enabling General Practitioners who provide dispensing services to sell a wider range of over the counter medicines – both General Sales List and Pharmacy-only medicines - to their NHS patients, would improve access where there is no convenient pharmacy.

- **Chapter 6** explores areas which could be addressed in the future assuming certain changes to the current primary legislation

- We consider PCTs' commissioning roles should be strengthened, to stimulate competition and ensure future contractual arrangements are founded on the services to be provided and their quality, not on simple market entry.

- We received two similar proposals for a PCT-based Pharmacy Access [Planning] Framework from the PSNC and Lloydspharmacy which would develop the current control of entry system.

- We consider there should be a single contractual framework in the future grounded on a more evidence-based assessment of the pharmaceutical health needs we discuss in Chapter 5. This would set out the requirements for all potential providers to meet but should be sufficiently flexible to allow PCTs to contract for a minimum service to ensure prompt access to medicines and to the supply of appliances.

- Whilst we do not consider further moves to nationalised contracting arrangements or simple deregulation would meet these principles, we identify two possible options: devolving contracting responsibilities wholly to PCTs with certain minimum requirements kept at national level, such as standards, or introducing the concept of "any willing provider" for the provision of essential services (as is currently being considered for the provision of services in the acute sector) with more contestability for local enhanced clinical services.

- With this in place, we feel that control of entry will fall away.

- PCTs should be able to terminate contractual rights for under-performing or poorly performing providers. This will help address the limited means at present by which PCTs can open provision up to competition or remove such provision where no longer needed or providers fail to meet local needs.

- Pursuing this would require a step change in the capacity and capability of PCTs as commissioners of pharmaceutical services.

- We believe the Department should consider introducing new legislation to achieve this.

- We consider existing quality requirements should be developed further. The current clinical governance framework provides a sound basis, but needs to be built on to deliver more clearly defined quality outcomes.

- We have identified barriers to change including cultural barriers and the need to shift to a collaborative framework for patient-focussed services.

- **Chapter 7** sets out our thoughts on funding implications arising from our findings.

- There are a number of factors which will influence funding for pharmaceutical services in the future including shifting money from the acute sector to primary care and engendering contractor confidence.

- We consider that with the technological and professional changes taking place, there should be less emphasis and less value on the purely dispensing element of NHS pharmaceutical services. Whilst this will always remain important, the pharmaceutical service of the future has the potential to be radically different to that of even today.

- Instead, funding should focus on the provision of clinical care services and initiatives which support health. So a lower proportion of the overall pharmaceutical budget would be spent on dispensing activity and a higher proportion on clinical activity. Funding "floors" to support this greater clinical activity may be appropriate.

- There are other factors to take into account, including the question of fixed costs for PCTs where new contractors open, and any "cross-border" impact from new funding arrangements.

- We consider the Department should explore and consult on the finance implications arising from our recommendations in Chapter 6, and in particular on transferring commissioning responsibilities to PCTs and the measures available to promote quality and engender contractor confidence from such a shift.

Chapter 8 sets out our conclusions from this review.

- Services of the future should be based on certain key principles. These are:

    - empowering PCTs to commission to meet local needs for more personalised services;
    - transparently contestable and equitable;
    - aim to maximise quality and to focus on outcomes as well as outputs; and
    - enhance and reward the clinical focus and professional delivery.

- We consider that standing still is not an option. Nor do we consider further moves to nationalised contracting arrangements or simple deregulation would meet these principles. We have identified in Chapter 6 two possible options for devolving future contractual arrangements wholly to PCTs.

- ☐ We believe these offer practical proposals for developing pharmaceutical service provision with certain minimum requirements kept at national level, such as standards to meet the key principles and promote pharmacy as a key partner in the delivery of patient-centred healthcare services.

Chapter 1: Introduction

1. On 11 January, the Minister of State for Delivery and Reform (Andy Burnham MP) announced publication of the Department's report reviewing the reforms it had introduced in 2005 to the "control of entry" regulatory system for NHS pharmaceutical contractors in England.[1]

2. In the light of that report, he considered it was open to further debate whether the "control of entry" system remained a suitable vehicle to enable NHS primary care trusts (PCTs) to meet their new roles and responsibilities for commissioning a patient-led NHS and pointed to shortcomings in the regulatory system.

3. He therefore announced a review of action needed to allow PCTs more powers to commission pharmaceutical services and appointed me to chair and lead those discussions.

Terms of reference

4. The terms of reference for my review were

> "To examine:
>
> current contractual arrangements for the provision of NHS pharmaceutical services in England, taking account of the existing "control of entry" system and review of progress, competition and consumer choice concerns and the principles of better regulation;
>
> consider the extent to which these arrangements reflect wider developments in health service commissioning and contribute to the aims of the White Paper *Our health, our care, our say;* in particular, securing high quality services which offer greater access and choice, supporting independence, well-being and improving health and providing effective help to those with high levels of need;
>
> inform formal consultation on how best these arrangements should be developed or reformed in order to maximise this contribution and ensure value for money for the NHS and the broader community; and
>
> to report by March 2007."

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1 http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/Browsable/DH_064405

Background to this review

Provision of pharmaceutical services

5. A number of developments have taken place in recent years affecting the provision of pharmaceutical services. I considered the following significant:

- A new contractual framework for community pharmacy;
- Local Pharmaceutical Services (LPS);
- Reforms to the control of entry system;
- The Department's review of progress made with the control of entry reforms; and
- The Department's review of Part IX of the Drug Tariff.

6. Further information on these from briefing material prepared by the Department is set out in Annex A.

Contractual arrangements for other primary care providers

7. Similarly, contractual arrangements for other providers of primary healthcare services (GP medical services, dentists and opticians) have also changed or are in the process of changing.

8. The Department produced briefing papers for my review explaining these in more detail. Details are in Annex B.

Wider policy context

9. At the same time, pharmaceutical services are not divorced from the rest of NHS and wider policy work currently progressing. I considered there were a number of initiatives which were significant to my review - in particular:

- reform of the public sector and the recent Policy Review[2] published on 19 March
- the White Paper *Our health, our care, our say* ;
- the development of Practice Based Commissioning and the Department's current consultation on commissioning for health and well-being[3] as part of the development of commissioning roles, giving more local autonomy and accountability; and

[2] *Building on progress: Public services* published by Prime Minister's Strategy Unit
[3] http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_072622

- system reform and the Department's consultation on opening up secondary care to more competition.

10. Further information about these initiatives prepared by the Department is at Annex C.

Methodology for the review

11. Following the launch of my review, I held a briefing session on 18 January to which a number of key stakeholders were invited, including representatives of patients and consumers, the NHS, contractors and their representative organisations and the press.

12. I put forward a number of key questions at this session which I thought it would be helpful to ask stakeholders to address. These are set out at Annex D. These proved particularly useful in the early sessions helping focus everyone's attention.

13. To assist me, I appointed Chris Town, former Chief Executive of Greater Peterborough PCT and chair of the joint negotiations on the new pharmacy contractual framework, and Sue Ashwell, Chief Pharmacist and Assistant Director of Commissioning for Cambridgeshire PCT. However, the final report is my responsibility.

14. I held five Inquiry Sessions between 1 February and 7 March. In all, 23 organisations attended. Details of those presenting evidence together with synopses of our discussions are at Annex F to my report. This also includes supplementary papers we received from them and from other organisations.

Chapter 2: The context for our discussions

In this chapter, we discuss:

- ✓ **England's population is rising and ageing – the population is set to grow from 49.4m in 2001 to 54.6m in 2021 and life expectancy continues to increase.**
- ✓ **The public health challenge and problems associated with an ageing population look set to increase with rising incidence of chronic long-term conditions, including obesity.**
- ✓ **50% of people do not take their prescribed medicines as intended. Patients and carers continue to need to be more involved in decisions about treatment and receive more information about the benefits and risks.**
- ✓ **There is potential for pharmaceutical contractors to widen their contribution to healthcare. Pharmacy contractors provided nearly 17,000 local enhanced services under the new contractual framework in 2005/06 and had completed half a million Medicines Use Reviews by the end of 2006.**

The opportunity now

1. We believe there is increasing focus on the potential for pharmaceutical contractors to widen their contribution to healthcare. That focus was most recently highlighted in the Government's Policy Review paper "*Building on Progress: Public Services*" published on 19th March with its emphasis on delivering public services in future which are both personalised and equitable. There are some considerable challenges ahead – and we believe – some considerable opportunities.

The resources now

2. As at 31 March 2006, we learnt there were 9,872 community pharmacies and 139 appliance contractors providing pharmaceutical services in England. They dispense around 700 million items a year. This equates to an average of just under 66 contractors for each of the 152 PCTs. However, distribution is not even and we were told there are no "optimal" targets as to the numbers of contractors per PCT. We understand the Department expects the number of pharmacies to increase in the immediate future as a result of the reforms to the regulatory system introduced in 2005, in particular in the categories exempt from the control of entry restrictions.

3. Pharmacy contractors provided, for example, nearly 17,000 local enhanced services under the new contractual framework in 2005/06 and had undertaken over half a million Medicines Use Reviews by the end of 2006.

4. In addition, about one in eight GP practices offer dispensing (but not full pharmaceutical services). There were 4,299 dispensing doctors providing services from 1,137 general practices as at 30 September 2005 – chiefly in semi-rural and rural areas. There are some 32,500 GPs in all providing services from some 8,500 general practices.

5. As at 31 March 2006, the 139 appliance contractors providing services in England dispensed around 3 million items annually.

6. These three groups of contractor dispensed 720 million prescription items in England in 2005. This compares with 473 million 10 years ago – a 52% rise or an average 4.3% rise year on year. Of these 720 million, over 90% were dispensed by pharmacies and appliance contractors and just under 7% by dispensing doctors. The remainder were items personally administered to patients by GPs or their staff (e.g. vaccines).

7. The costs for PCTs of these continue to rise. In 1995, Primary Care Trusts spent £3.7 billion on medicines and appliances in the community. By 2005, this had risen to £7.9 billion[4]. This is estimated to account for over 10% of a typical PCT's total NHS budget today. These costs are predicted to rise as more medicines come on stream and as more healthcare is delivered in the community to support an increasing number of people living independently with long-term medication conditions.

The health challenge now

8. We know that England's population is rising – and ageing. The population is expected to grow from 49.4 million in 2001 to 54.6 million in 2021. Average life expectancy has increased pretty consistently and is expected to rise further.

[4] This is the Net Ingredient Cost (NIC) which is the total cost of medicines supplied less any discount contractors achieve.

Table 1 – Average life expectancy[5]

Year	Male	Female	Average*
1901	45.0	48.8	46.9
1951	65.7	70.7	68.1
2001	76.0	80.6	78.2
2021 (projection)	80.4	84.0	82.2

* assumes a ratio of 105 male births to 100 female births.

9. We were advised that an ageing population will require more medication. 4 in 5 people over the age of 75 take at least one prescribed medicine, and 36% take four or more[6].

10. In 2001, the National Service Framework for Older People reported some medicines are under-used in older people (as well as in others). For example, anti-thrombosis treatments to prevent stroke, preventive treatment for asthma, and antidepressants are not always prescribed for patients that would benefit. Critically, even where prescribed to meet a clear health need, as many as 50% of older people may not be taking their medicines as intended by their doctor.

11. Patients and carers continue to need to be more involved in decisions about treatment and to receive more information about the benefits and risks of treatment. Demand for proper support to help patients in managing their medication regimes remains therefore both necessary and growing.

12. The public health challenge and associated problems looks set to increase. The incidence of chronic long-term conditions is set to increase too. Whilst smoking is on the decline it is still the single greatest cause of illness and premature death, killing an estimated 86,500 people a year, with some ex-smokers suffering the health consequences many years later. Between 15,000 and 22,000 deaths are related to alcohol abuse, a problem which also accounts for 150,000 hospital admissions a year.

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[5] Data sources: the 1901 and 1951 figures have been calculated from an unpublished database of estimated mortality rates for England & Wales. The 2001 figures are from the 2000-2002 Interim Life Tables (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=14459&Pos=&ColRank=1&Rank=422). The 2021 figures are from the period life expectancy tables based on the 2004-based principal population projections which can be found at the Government Actuary's Department (GAD) website (http://www.gad.gov.uk/Life_Tables/eoltable.htm). Official national life expectancy data is always published for males and females separately. The combined figures shown here are just weighted averages.

[6] Health Survey for England 1998, Volume 1: Findings

Sexually transmitted infections continue to rise, affecting both health, e.g. HIV, and fertility, e.g. chlamydia. Obesity is perhaps the biggest single risk factor for longer-term health problems. The 2004 Health Survey for England showed constant rises amongst both men and women to almost 24% of the population in 2004. Type II Diabetes - which can require constant medication to keep in check - is expected to increase 54% by 2030 and hypertension by 28% - both related to obesity[7].

13. We learnt there are unintended consequences and problems for people with complex medication needs. Alliance Boots put some salient points to us:

- "70% of people who go to the A&E department did not need to go there if their GP was available. Because A&E departments have tough targets, such as the four-hour target, sometimes in order to meet that target, if they are running behind, they will admit someone. If they admit someone into the ward it costs £2,500, which is money wasted. [8]
- A staggering 50% of people do not take their prescribed medicines as intended. Part of it may be that they get side effects, or part may be that they get confused and they give up on it. For example, only 28% of diabetics have good glycaemic control. 72% of diabetics do not have good glycaemic control. 25% of people give up on statins after a year. They will have been prescribed statins to prevent more serious problems, such as coronary heart disease (CHD), but they give up the medication after a while because there are no symptoms so they think it has gone away.
- 40,000 strokes each year could be avoided if people adhered to their medication as prescribed and complied with it properly. 100,000 heart attacks can be avoided.
- 11% of hospital admissions are generally because people have not taken their medication correctly."[9]

"If you add all that up, it indicates that there is a huge amount of preventable ill health, wasted medicines, a huge cost to the NHS, not to mention the waste of time for the A&E departments and GPs. It is an issue that is getting worse, and this begs the question about what we can do about it."
From discussions with Alliance Boots

[7] *Our health, our care, our say* pp 32-33.
[8] *Our health, our care, our say* direction paper - http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453
[9] Dr G Lomax, healthinformation.org.uk

14. The Independent Pharmacy Federation (IPF) and others backed this up. The RPSGB reported that medication errors cost the NHS £500 million per year[10] and that:

> "Research shows that about 6.5% of admissions to hospital are related to an adverse drug reaction (ADR) and an estimated cost of £466 million per year[11]. Most of these are avoidable reactions. Community pharmacists have the skills and knowledge to be able to detect ADRs[12] but they do not have access to sufficient patient information to be able to systematically use their knowledge and skills. The sharing of appropriate information about the patient and the targeting of pharmacists' skills could significantly reduce the impact of ADRs on hospital admissions and reduce associated morbidity"
> *From Royal Pharmaceutical Society of Great Britain response to the Review*

15. The IPF also reported over 400,000 older people attend A&E departments each year and 30% of people over the age of 65 have a fall in any one year.

16. We were also aware of a study of 2,636 adult patients attending St Thomas' Hospital A&E department, nearly three-quarters of whom presented between 8 am and 8 pm. An A&E visit now costs around £90 per visit. The report[13] found that 8% of those people could have been managed by a pharmacist for symptoms such as breathing difficulties, stomach problems and pain.

[10] National Prescribing Centre Bk1 2002:9
[11] Pirmohamed M et al Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ 2004;329:15-19
[12] Paulino EI et al. Drug related problems identified by European community pharmacists in patients discharged from hospital. Pharm World Sci. 2004 Dec;26(6):353-60.
[13] Bednall R et al: Identification of patients attending Accident and Emergency who may be suitable for treatment by a pharmacist *Family Practice* 2003; **20**: 54 - 57

Chapter 3: Tapping into the potential

In this chapter, we discuss:

- ✓ **Patients think highly of pharmaceutical services – patients value convenient, accessible services, which are local to them.**
- ✓ **For both patients and consumers, the key PCT role should be to assess needs and stimulate provision by being more proactive, encouraging pharmacies to start thinking about their considerable potential.**
- ✓ **For the NHS, there is a lack of influence for PCTs in terms of clinical services decided at a national level, e.g. MURs are provider-led and PCTs are unable to predict their spend on these, nor can they manage the quality and effectiveness of these through existing contractual arrangements.**
- ✓ **Contractors are keen on more services being funded as part of nationally agreed and set advanced or essential services. Pharmacy has invested significantly in new service provision but has yet to see the fruits of this in secure local funding of enhanced services such as minor ailment schemes.**
- ✓ **The Office of Fair Trading's view is that full market deregulation with contestability for enhanced services would drive up standards.**

1. In the light of this evidence, we explored in our discussions with stakeholders just how far the potential for pharmaceutical services may be developed and how it could be tapped. We wanted to test how services might develop to meet the health problems of today and tomorrow. We found a rich seam.

Patients and consumers

2. As identified in the key questions (Annex D) we think there are some subtle differences between the needs and expectations of patients and consumers.

Patients

3. Patients can be termed "reluctant" consumers of health services. However, we know from the Department's own review of control of entry how highly patients think of pharmaceutical services. For example, the report included responses to the consultation in 2005 preceding the White Paper, *Our health, our care, our say*. People expressed

considerable satisfaction with pharmacy services, saying they were "accessible, friendly and expert"[14].

4. That view was reinforced not only by the patient organisations we met but also by others over the course of the review. Patients value convenient, accessible services, which are local to them. Local in the sense of local to their home, local to their doctors and clinics, and local to where they go shopping or travel. We also noted that both patient organisations and professionals considered there was a place for more specialist services – i.e. people would be prepared to go further to a particular provider if they were being offered a particular service they valued. Access to services for the housebound and the less mobile is also important. As the ageing population increases, so could the need for home delivery services.

5. We heard that view being reflected in opinion research Lloydspharmacy has carried out with customers and staff on their perceptions of the Medicines Use Reviews (MUR) service which they call a "prescription MOT". Of 400 customers, 95% were reported as very satisfied or satisfied with the service. Of 580 pharmacists, 89% agreed the service is helping customers with their medicines.

6. Where change has taken place - particularly in the opening of new 100-hour pharmacies - we noted that patients enjoyed better access. However, this was not a universal experience. We also noted certain problems - that not everyone has seen as significant or beneficial a change as others, that information is not as readily available as it should be as to what services are offered and when. In addition, patients remain concerned about the longer-term impact some of the exemptions may have on being able to continue to use the outlets they wish to do.

> "The 100-hour pharmacy rule allows larger pharmacies to come in and may have a severe impact on existing services, which patients may prefer."
> *From Synopsis of discussions with the Patients' Association and the Long-Term Medical Conditions Alliance*

7. We explored how patients would know a good quality service when they met it. We found from the evidence that the answers are not clear-cut. However, a common theme and essential first step is the need for more and wider information about what patients can expect of a modern pharmaceutical service.

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[14] *Your Health, Your Care, Your Say Research Report*, Opinion Leader Research, London, January 2006, page 47

8. We also noted that in the views of the Patients' Association, pharmacies should not be there as of right. PCTs should have appropriate powers to remove inadequate or poor service provision and replace with better services.

> "Changes in population, not just in rural areas, have led to some gaps in provision of pharmaceutical needs whereas in other areas there is over-provision, which has its own problems. For example, a better service may be provided from one pharmacy rather than two small ones where neither separately provides all the functions."
> *From Synopsis of discussions with the Patients' Association and the Long-Term Medical Conditions Alliance*

9. To do this, pharmacies need to have appropriate national standards against which service provision and the clinical care provided can objectively be judged. In this way, people can be helped to make their own judgements about what to expect of the "best" services when they go into any pharmacy.

10. We believe there are particular matters affecting patients who live in areas that are more rural. The rules governing whether or not a doctor is able to dispense to their patients where there is no convenient pharmacy are rather artificially drawn. If a pharmacy does open nearby, some – but not necessarily all - of the doctors' patients then move over to the new pharmacy service[15]. We understand why this should be – so that a pharmacy may be assured some level of business.

Consumers and the public

11. We met representatives from *Which?* and heard similar concerns. They called for far clearer procurement routes by which pharmaceutical services are awarded. A key PCT role should be to assess needs and to stimulate provision by being far more proactive than they have been up to now – by contracting and tendering for such services. This would stimulate the market and encourage pharmacies to start thinking about their considerable potential.

12. *Which?* felt that there should be more proactive encouragement for people to go to pharmacies to receive their treatments provided this was not used to encourage consumers to acquire greater quantities of medicines, which were not suitable, or when other alternative routes might be more appropriate. When consumers go to a doctor or dentist,

[15] The current rule, generally, is that dispensing patients who live in rural areas within 1.6km of a new pharmacy will transfer over to that pharmacy, even if the pharmacy and dispensing practice are close together. Those who live further away will not.

they expect a clinical service because of the clinical environment. If pharmacy is to "up its game" as a more clinical service provider, a clearer focus on the appropriate clinical environment is needed. The introduction of private consultation areas for MURs is a step in the right direction. We believe that future pharmaceutical service provision and payment structures should make more of the pharmacist's clinical contribution to the care of the patient.

13. *Which?* reminded us of their survey of out-of-hours provision and that just 3% of consumers would turn first to a pharmacy if they or a member of their family needed healthcare or treatment outside normal GP hours. Whilst those who did use a pharmacy expressed satisfaction with the service, only 1 in 10 who had sought out-of-hours care in the past year had consulted a pharmacy[16]. There is, however, the potential for pharmacists and pharmacy support staff to play a bigger role in how people actually use medicines and in being helped to take care of themselves.

NHS organisations

14. We met the NHS Confederation/NHS Employers and the PCT Network and individual SHA/PCT officers who have responsibility for pharmacy. We were advised of certain strengths apparent in the new contractual framework and other areas which could be improved. Strengths included cost-effectiveness, better access, longer opening times, truly "independent" contractor status (e.g. outside NHS pensions scheme), and the "added value" of extra services that pharmacy provides which are not restricted by a "fee per service" arrangement. The NHS was keen not to lose these for the sake of addressing apparent shortcomings.

> "Strengths included: pharmacists being independent contractors – there is no "grey" area – and whilst substantial, NHS payments are not their only income stream. There are added benefits from supplying OTC medicines; . . . no "fee for service" restrictions – there is added value and merit in *ex gratia* activities which a "fee per service" system would remove. Pharmacy is cost-effective . . . the public health element and "read across" to other contracts; . . . open access (longer opening times, no appointments, ability to access advice, no registration requirements)" *From Synopsis of discussions with NHS Confederation/NHS Employers/the PCT Network*

[16] *"Which Way? Negotiating the out-of-hours maze"* Which? 2006.

15. The apparent shortcomings included differences in and the bureaucracy of primary care contracting arrangements, the importance of maintaining shared "values", the proliferation in some areas of 100-hour pharmacies and the absence of PCT powers to influence and control generally.

> "If PCTs are to strengthen pharmacy commissioning, the exemptions, and especially 100-hour pharmacies, should be removed. Whilst sensible individually, their cumulative effect is to hamper or cut across PCT commissioning and service development plans. Nonetheless, 100-hour pharmacies can improve access for example in rural areas or out-of-hours. Where needed, they should form part of those plans. If not, they should not receive the same professional allowances. This would help improve business confidence."
> *From Synopsis of discussions with PCT-SHA representatives*

16. Lack of influence was acutely felt for the NHS in terms of clinical services decided at a national level over which PCTs had insufficient or even no control.

> "Greater PCT influence and control is required for MURs to ensure provision matches local health needs and dovetails with not duplicates GP action . . . This would be a suitable case for joint commissioning to operate. This throws up some of the pros and cons of having a national contracting framework as opposed to local."
> *From Synopsis of discussions with PCT-SHA representatives*

17. Other barriers identified included the absence of efficient levers in the regulations to govern market entry and exit, the unlimited duration of "contracts" and that these were premises/location-focussed rather than service-based. Payment systems remained heavily weighted to the volume of activity rather than its quality and outcomes. The NHS generally felt a national role should be to set service standards, with the powers and actions left to individual contractor negotiations, with local accreditation. A pharmacy Quality and Outcomes Framework (QOF) could be helpful in this respect. We discuss this further in Chapter 6.

Contractors

18. We met representatives from pharmacy, dispensing doctor and appliance contractor organisations as well as individual contractors and professional organisations. Pharmacy felt that the new framework had created a significant shift to a more clinical model but there was more that could be done to move in that direction.

19. In general, pharmacy had invested significantly in new service provision but had yet to see the fruits of that in terms of a more secure basis for local funding of enhanced services. As one contractor puts it, the barrier to this is:

> "Reluctance at PCT level to commit funds to innovative pharmacy development"
> *From the Synopsis of discussions with the Independent Pharmacy Federation*

20. PCT financial difficulties combined with local control of a significant part of resources through practice based commissioning was seen to be a longer-term challenge for community pharmacy. Hence, pharmacy contractors were keen on more services being funded as part of the nationally agreed tiers of either advanced or essential services. We learnt of broadly comparable plans which two organisations developed to improve PCT planning processes. We examine these in more detail in Chapter 6.

21. Much could be done to improve the operating environment in which contractors provide services – for example, PCTs should be more consistent and efficient in determining where to site new provision and in setting and applying quality standards – for example in accrediting premises. Two particular issues were: (1) national standards for consultation areas are differently interpreted by PCTs and (2) numerous service specifications for the same local enhanced services.

22. We met the General Practitioners' Committee (GPC) of the British Medical Association and the Dispensing Doctors' Association as well as the Small Practices Association. Doctors provide dispensing services usually in more rural areas to patients. We heard that these are often needed to maintain patient access to urgently needed medicines readily and promptly where a pharmacy would otherwise not be viable in the current payment system. Whilst the range of services can be more limited than those from a pharmacy, some services (e.g. medication reviews) are available to patients by virtue of the medical contracts held. However, we noted that there are significant differences in terms of what is expected of a pharmacy as "essential services" in an NHS pharmaceutical contract (whether it is in a rural or non-rural area) and what is required of a dispensing doctor. For their part, doctors were particularly keen to be able to sell over-the-counter medicines to their patients who may not have a convenient alternative source of supply locally. Those doctors we spoke to agreed that it would be helpful if each practice had a pharmacist to work with them; we appreciate that is not a

simple change. These doctors were also concerned with the proliferation of 100-hour pharmacies. We discuss these in more detail below.

23. We met the British Healthcare Trades Association to hear about the concerns of appliance contractors, which dispense stoma and urology appliances and provide a number of related services, such as the customisation of appliances where necessary and home delivery of items. These providers are active in what could be deemed a niche market. Whilst patient numbers are fewer, the appliances they provide are critical to quality of life.

24. The main problem is that the current system, even after reform, effectively freezes them out of the market. It is extremely difficult for a contractor who only supplies appliances to be able to gain market entry under the current legislative framework because of the nature of their business. Such contractors do not necessarily provide services to the local neighbourhood. They are more likely to provide them to a much wider catchment area and often nationwide, rather like internet-based pharmacy operations.

Office of Fair Trading

25. We were able to discuss with the Office of Fair Trading (OFT) their views to allow full market deregulation in order to drive up standards. The OFT also considered there were adequate measures to ensure safeguards in place where these were needed – such as the Essential Small Pharmacy scheme. We also noted that the OFT favoured a fee per item of service or prescription. Whilst a specialist market, the OFT considered that competition will deliver quality improvements. Competition could be introduced via a free market for dispensing and via contestability for enhanced services rather than via a "big bang" approach and developed from there. Some drawbacks are that quality is difficult to measure and patients do not recognise it – or may not be aware if they are not receiving a quality service.

> "Patients will not necessarily recognise a "good" quality service. They can only see the things they understand, their interactions directly with the pharmacist and the advice given. However, there is scope for educating consumers to recognise some aspects of good pharmacy services from bad pharmacy services."
> *From Synopsis of discussions with the Office of Fair Trading*

26. So there can be trade-offs between the convenience a patient wants, and the quality service a PCT will commission. An example of this is repeat dispensing arrangements. Here the quantity issued is only one month at a

time whereas a patient might wish to receive medication for a longer period. However, the pharmacist issuing the repeat amount can review compliance and concordance on a monthly basis and help identify any potential side effects or problems that the patient may report. The pharmacist can then work in partnership with the prescriber to help the patient get treatment tailored to their particular needs.

27. Although the OFT recognises that a tension can arise between the convenience a patient wants and what may, in the long-run, be in their own interests, their opinion is that it may be possible to introduce regulations to address these specific difficulties while allowing all pharmacies with qualified staff to enter the market. They believe that, in this way, it would be possible to protect patient needs while encouraging pharmacists to provide services of as high a quality as possible.

Chapter 4: What might the pharmaceutical service of the future look like?

In this chapter, we discuss:

- ✓ **There are fundamental principles to underpin the contractual model of the future, e.g. adopting models of practice which enhance the patient experience and support their wellbeing, promoting safe use of medicines.**
- ✓ **The attributes of a good pharmaceutical service support and enable patient involvement in managing their medicines, and are personal, accessible, knowledgeable and professional.**
- ✓ **We consider there is a potential to develop a "pharmaceutical care management" service with a more clinical focus, integrated with other services, quality-proofed and underpinned by appropriate standards. PCTs may need to be able to offer incentives for best practice focussed on the health needs of the population.**

1. In these discussions, we asked ourselves what the pharmaceutical service of the future might look like and what it might offer patients and consumers. These reflect both elements available now and elements that might be developed in the future.

2. As a backdrop, we believe there are some fundamental principles to underpin the contractual model of the future. It should continue to:

   - adopt models of practice which enhance the patient experience and support their wellbeing;
   - promote safe use of medicines;
   - maintain and improve, where appropriate, accessible services which provide value for money for the NHS;
   - ensure convenient opening times which suit the need for different services at different times of the day;
   - reflect the increased emphasis on supporting people's independence and well-being, and self-care;
   - provide a mix of both informal services (such as ad hoc advice) and clinical services (such as medication reviews) which can be tailored to match differing patient requirements
   - reflect the changes in modern technologies (for example, the use of robotic dispensing, internet-ordering etc);
   - support staff training and accreditation as part of a professional service;

- take more account of the principles of Skills for Health, the changed training of pharmacy and medical graduates who have entered the profession over the last 10 to 15 years and those coming on-stream now and of the registration of pharmacy technicians.

3. Mandatory continuing professional development and future arrangements for professional regulation mean that we should be confident of a system for pharmaceutical services that demands that those delivering them are judged against standards of clinical knowledge and competence that today's graduates take as a minimum, including good communication skills with patients and with other professions.

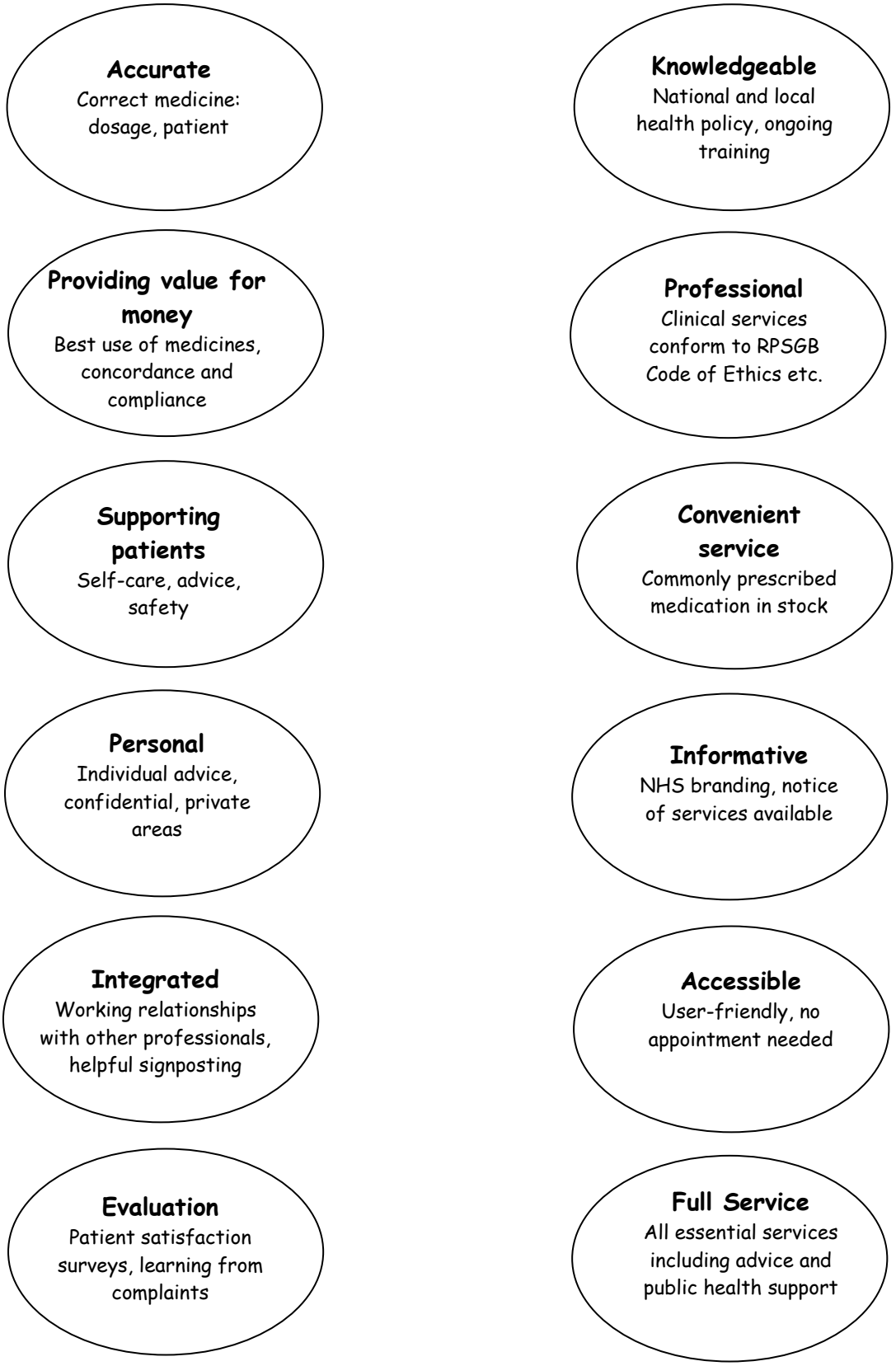
4. We also noted the consultation the Department is currently undertaking on proposed changes to the rules governing medicines supply in pharmacies in future and which will help pharmacists to focus more on clinical, cognitive services within the pharmacy or elsewhere. In brief, these changes will mean that a pharmacist is no longer tied to the dispensary and can be absent from the pharmacy on occasions provided appropriate systems and controls are in place, including appropriately trained and competent pharmacy staff. The changes will also facilitate the use of modern technology, in maximising the effective use of the pharmacy workforce.

5. This model may not attract all. There will be those who wish to continue working principally in the supply of medicines. We think they should be able to do so provided this is meeting a proven need within an expanded contractual framework. PCTs could have an important function too in supporting professionals who wish to re-train or acquire new clinical skills.

6. As a starting point, we think that getting the medicines right for the patient, as well as putting the medicines in the right box, is key. It is important that patients are assured of timely access to medicines and appliances, and consistent standards and attributes when they need a dispensing service. The supply process can also offer an opportunity to talk to the patient or carer about how to get the best from the medicine or appliance.

7. We noted and welcomed that many of these attributes were endorsed in a paper from the Dispensing Doctors' Association about dispensing services. Such attributes are all-important and provide a sound basis from which effective pharmaceutical services can develop.

Attributes of a good pharmaceutical service



These are standards generally accepted as indicative of good professional practice in pharmacy as set out in the Royal Pharmaceutical Society's Code of Ethics and Standards[17]. An important "given" is that the service of the future can and must include a quality supply function. However, we accept that supply and more clinical services may not be provided by the same person or at the same time or place in the future. In these situations, good professional practice requires effective communication to ensure services are joined up.

8. We noted in this respect that appliance contractors, whilst seeking to raise service quality, do not have a common Code of Practice to which all subscribe.

9. We also believe there are new horizons to which pharmaceutical services should look. These go well beyond the provision of essential and what we call "baseline" clinical services (such as MURs) as determined at a national level. We have in mind a service which has a much greater clinical focus, is integrated with other NHS services for patients and carers and quality-proofed as a pharmaceutical service. We believe this to be in line with the ambitions set out in the Policy Review paper we noted in Chapter 2.

10. By way of example, the Independent Pharmacy Federation proposed new elements within the contractual framework for "cognitive services" which go further than the current advanced service of MURs and many of the current levels of local enhanced services. We think this comprises many of the features of what we term the "pharmaceutical care management" service of the future.

Example – the Independent Pharmacy Federation

The New Cognitive Services Contract Elements

This would include:

- a Medicines Management Service;
- agreed assessment criteria and funding mechanisms for a pharmaceutical service for patients identified under the Disability Discrimination Act; and
- an improved mechanism for collaboration between Health and Social Care services.

[17] Published annually by the Royal Pharmaceutical Society and available on their website at www.rpsgb.org.

The medicines management service would comprise a patient/pharmacist interface for

i) Full Medication Review aligned with NICE guidance, PCT prescribing policy and linked to GP prescribing advice;
ii) Pharmacological optimisation; reduction of adverse drug reactions; reduction in drug-induced falls in the elderly; reduction in iatrogenic reactions;
iii) Therapeutic optimisation;
iv) Eradication of food/drug interactions;
v) Eradication of OTC/NHS medication interactions;
vi) Brand/generic conversions and vice versa;
vii) Disease monitoring;
viii) Identification of drugs of limited clinical value;
ix) Adjust medication to co-terminus treatments;
x) Engage patients in motivational compliance discussion.

Funding would be derived from various sources such as current prescribing advice schemes; existing MUR funds; reduced hospitalisation via increasing eradication of adverse drug reactions (ADR), drug interactions and iatrogenic reactions and reduced medication errors. Services such as Near Patient Testing would be funded through Practice Based Commissioning (hence Secondary Care). Services such as Monitored Dosage Systems (MDS) to the Elderly would be funded from reduced social care and acute care costs.

11. We saw additional benefits where the service provider acts as a powerful advocate and interpreter of local and national policies for the benefit of patients. By virtue of their position in the community, many contractors are well placed to foster stronger links between health and social care services as envisaged in the IPF paper. This may, in fact, be a "unique" selling feature for the provision of a "pharmaceutical care management" service. It has the built-in advantage of being able to bring together in one place the vast landscape of health, be that expressed in terms of self-care, supporting effective prescribing, helping patients to get the best out of their medicines, the management of complex medication regimes, to support for those with long-term conditions.

12. We recognise that existing contractors will press to have some degree of dedicated funding for a pharmaceutical care management service to give them greater certainty and motivation – as well as a degree of income protection. We make some general points about financial arrangements in Chapter 7.

13. On the other hand, PCTs increasingly will wish to commission such services from the 'best' provider in order to secure the best return for their investment, but using common criteria such as activity, quality and outcomes against which potential providers are assessed and chosen. Indeed, it may be most appropriate for a PCT to contract for the full range of pharmaceutical services from a range of providers and

contractors. That could include local hospitals or providers of other primary care services, as well as pharmaceutical services contractors. We note that some PCTs have begun this process.

14. PCTs may need to incentivise this greater clinical focus and interaction underpinned by appropriate standards. Nevertheless, we see the potential for significant benefits in terms of the added value from improved clinical interaction and value for money for the NHS. Much play has been put on the need to "incentivise" professionals to reconfigure service provision. We are not convinced that such incentives must always be financial. We think that contractual levers can play an equally effective role. For example, we consider it would be possible to devise quality markers for the management of long-term conditions. These might identify the contribution of particular professions to seamless care pathways or could be common across the providers concerned.

15. Developing "pharmaceutical care management services" in primary care is we think key to using wisely the vast sums of money spent on drugs. This function in getting the best outcomes for patients from the medicines they take would, we believe, make a significant contribution to improving the health of the population. It can also be expected to reduce hospital admissions due to reduced adverse drug reactions, side effects or failed therapies.

16. Against the backdrop of a move to this new kind of service, the next two chapters set out some of the major themes emerging from the review and our more detailed findings. We found that despite differences noted earlier, these themes were remarkably common across our discussions.

17. We have already reported a number of strengths within the current framework. This includes excellent accessibility to services with high levels of patient satisfaction. The current provider base is reasonably diverse with a range of providers in competition and no one business having a monopoly. The framework is considered "highly permissive" with untapped potential to develop much further the range and quality of pharmaceutical services provided.

18. Contractors have a loyal patient base with many returning to the same pharmacy repeatedly. This reflects the high public esteem which is reported as second only to GPs and on which contractors can and should build to develop services.

19. At the same time, we believe from the evidence and our discussions there are a number of areas which can be developed, both now and in the future.

Chapter 5: Major themes: areas which could be addressed now

In this chapter, we discuss:

- ✓ **How PCTs need a platform from which they can properly plan and manage the provision of pharmaceutical services. Pharmaceutical Needs Assessments (PNAs) should have a consistent structure across all PCTs and have national comparability in breadth and depth.**
- ✓ **There should be clearer links between local health needs and the provision of more clinical pharmaceutical services through PNAs.**
- ✓ **Consistent accreditation arrangements for advanced and local enhanced services and the development of common standards for accreditation and training are advisable.**
- ✓ **The Department has existing powers to include providers on pharmaceutical lists for a fixed period and should consult on introducing such measures.**
- ✓ **The Department should explore what further steps can be taken to make LPS user-friendly and manageable for PCTs and contractors alike.**
- ✓ **More integrated professional working with closer co-operation amongst professionals is desirable, e.g. developing a performance management indicator for repeat dispensing services and how the provision of the MUR service can best reflect local priorities. For example, through PNAs, PCTs could identify key priority areas/patient groups for the provision of the MUR service.**
- ✓ **Otherwise, the Department should only proceed to transfer services to nationally agreed tiers where there is clear proven need and advantages.**
- ✓ **Quality is difficult to measure and patients do not necessarily recognise a quality service. There is a need for more and wider information about what patients can expect of a modern pharmaceutical service.**
- ✓ **Improving patient awareness and understanding of pharmaceutical services and encouraging the recognition by patients/consumers of pharmacy as part of the "NHS family" is desirable.**
- ✓ **The Department should keep the impact of exempt pharmacies and particularly those that offer 100 hours or more a week under close review and only amend regulations where there is clear and evident need. One area is the current restriction on exempt applications succeeding where there is an LPS service.**
- ✓ **In rural areas, we consider the Department should explore, with the PSNC and GPC of the British Medical Association, instituting a single regulatory test.**
- ✓ **Enabling GPs who provide dispensing services to sell a wider range of over the counter medicines - both General Sales List and Pharmacy-only - to their NHS patients, would improve access where there is no convenient pharmacy.**

Contractual arrangements

Pharmaceutical Needs Assessments

1. The degree to which PCTs have used pharmaceutical needs assessments (PNAs) to assist their planning of service provisions appears mixed. We have heard that this can range from a simple map of the area with the providers denoted to a sophisticated assessment of current and future requirements and the role such services play in the promotion of better public health and prevention of disease.

2. We consider – given what we say later about control of entry – that PCTs need a platform from which they can properly plan the provision of pharmaceutical services. PNAs – however rudimentary or complex – already provide one mechanism. In 2004, the Department commissioned Keele University and Webstar through NHS Primary Care Contracting to provide guidance for PCTs on developing PNAs[18]. The Department also commissioned the University of Manchester[19] in 2006 to evaluate the implementation of PNAs. Out of a response rate of 74% of PCTs, 90% had completed a PNA of which 85% had used one or more resources to assist with the process of undertaking a PNA. Local community pharmacists were engaged in the process in most (92%) of PCTs. The findings do not, however, provide any information about the quality and coverage of the PNAs undertaken, or their rigorousness.

3. If PNAs or their successors are to be truly useful, we consider they must have national comparability in breadth and depth. As put to us by one commentator:

> "PCTs should be mandated to perform a comprehensive 'Pharmaceutical Needs Assessment' for all their localities using data from their public health review. This assessment should be the basic tool a PCT uses when deciding which services to commission locally and for identifying areas where service provision is substantially inadequate, i.e. there is little or no service provision, or partially inadequate, i.e. where there is service but not all the required services are provided."
> *Association of Independent Multiple Pharmacies*

[18] http://www.primarycarecontracting.nhs.uk/189.php

[19] Findings of the study were published in the *Pharmaceutical Journal* (Vol 277), 5 August 2006

4. PNAs will fail, in our view, to make any significant difference unless:

- They have consistency across PCTs. Such consistency may best be achieved through nationally applicable Directions;
- They fully support a PCT's wider assessment of the health and well-being needs of the population for appropriate services from a range of accessible locations ;
- They set out a range of desired health outcomes which contractors are to meet;
- PCTs support PNAs with sufficient capacity and skills at an appropriate level within their organisation and professional structures; and
- They are "live" documents which have been through a thorough process of consultation with patients, consumers and health professionals and are reviewed (and peer reviewed) regularly.

5. We received papers from the PSNC and Lloydspharmacy which reflect many of the points made here. We discuss these further in Chapter 6.

We therefore believe the Department should consider consulting on developing Pharmaceutical Needs Assessments to support this direction and provide a clearer link between overall health needs and the provision of more clinical pharmaceutical services.

Accreditation arrangements for advanced and local enhanced services

6. This is a considerable concern for both contractors and PCTs. Whilst the principle of giving PCTs control is welcome, there is concern as we have already reported, that standards and decisions are inconsistent between PCTs. At its simplest, a pharmacist can be allowed to provide enhanced services in one PCT but has to undertake further accreditation to provide a comparable service in a neighbouring PCT. We also heard of inconsistent PCT decisions regarding the accreditation of premises. The implication from our review is that contractors feel PCTs may be erecting artificial barriers so as not to contract with a provider and therefore avoid financial expense. Contractors with outlets in more than one PCT report differing decisions as to the standards of premises for providing confidential discussions or that training for service provision in one PCT is not recognised in another. This seems to us both unnecessary and burdensome unless the PCT has good reasons for these differences.

> "there should be a set of nationally specified quality standards that are common to all providers for accreditation. The need for separate accreditation for each PCT is a barrier to continuity of service"
> *From Synopsis of discussions with Company Chemists' Association*

We therefore believe the Department should consult with PCTs and contractor organisations on developing common standards for accreditation and training. This should allow for situations where PCTs wish to commission very specific clinical services which justifiably allow for additional requirements over and above what are considered the "usual" norms.

Contractual performance and quality

7. We found a high degree of consensus about the changes the current contractual framework has brought about. For the first time, for example, standards for premises have formed part of the new contractual framework. It has been suggested that standards could now be included as part of essential services.

8. We also found consensus on PCTs being able to manage performance by amending contractual requirements. A major concern is that PCTs have no powers to end contracts other than under LPS schemes. Combined with two facets of the current regulatory system (approval of all minor relocations under 500 metres and exempt applications where contractors wield most of the power) this represents a major hurdle to PCTs in planning the provision of pharmaceutical services to meet the clinical needs they have identified.

> "A PCT's ability to manage local contractual arrangements is greatly hindered by open-ended contracts. There is generally a lack of levers for PCTs to performance-manage community pharmacy and dispensing doctor contracts."
> *NHS Confederation/NHS Employers/the PCT Network response to the Review*

> "We also have concerns about the present 'Pharmacy Contract for Life' arrangement that currently exists. We find it quite odd that there are no time limits on contracts and service quality is variable. Unless someone is very negligent, the contract is kept."
> *ASDA response to the Review*

> "The new pharmacy contractual framework provides service specifications and a basis on which we can start to measure quality and outcomes of performance. Under-performance can be addressed by asking if this person is complying with the contract and the service specification. If they are, then there should not be concerns about its adequacy. If they are not, then the route is to address those concerns. If the concerns cannot be addressed, then the service will be an inadequate service and a PCT would then say that this is an unacceptable level of service provision and the local contract will be removed. Clear decision criteria as to the quality of the service are essential."
> *From Synopsis of discussions with the Pharmaceutical Services Negotiating Committee*

We note that there are already powers[20] in existing legislation for the Department to regulate so that providers are included on the PCT's pharmaceutical list for a fixed period. In other words, the right to provide services is time-limited. The Department should therefore consider consulting on introducing such measures.

Local Pharmaceutical Services

9. Local Pharmaceutical Services are an alternative to the current national framework. However, we noted that the current LPS contracting system is complex to administer and the current take-up rate is disappointing with around 16 contracts nationally, together with some 216 other contracts supporting essential small pharmacies.

> "LPS has been administratively complex and time-consuming to operate "It took nearly two years to write the contracts. For a PCT and a pharmacy, that was horrendous". The new framework means PCTs do not have to go down the LPS route to secure extra services. However, LPS does "give some business certainty"
> *From Synopsis of discussions with the Pharmaceutical Services Negotiating Committee*

10. We think many have been put off LPS by local process and administrative requirements relative to the more familiar national contractual framework and this is a significant deterrent for both PCTs and potential LPS contractors. At the same time, we noted that many PCTs may have considered LPS irrelevant since the new contractual framework was considered adequate for most PCTs and contractors to fulfil current needs. We heard that the Department is producing a standard contractual template and guidance which may encourage more PCTs and contractors to take this route.

[20] Section 129(6)(d) of the NHS Act 2006.

LPS can be particularly helpful in situations less easily covered by national arrangements, for example, in commissioning out-of-hours pharmaceutical services, or services from alternative providers, such as acute trusts.

We welcome the move to produce a standard contractual template and guidance for LPS. We consider the Department should explore what further steps can be taken to make LPS more user-friendly and manageable for PCTs and contractors alike in the light of this.

Integrated professional working and contractual arrangements

11. GPs and pharmaceutical contractors appear to be less engaged with each other through their contracts than perhaps is the ideal. Despite early positive comments from the GPC about the new pharmacy contract, there seems less enthusiasm and opportunity for dovetailing requirements to enable the two contractual frameworks to work in synergy. There are a variety of approaches to this. Some have argued there should be clearer demarcations between what is expected of GPs and pharmacies under their respective contractual arrangements. This would be simple for all to follow and understand.

12. Others have argued that commissioning in future is not going to work like this. Integrated care and seamless patient care pathways are going to demand closer co-operation amongst professionals – not less. We noted and welcome the work of the NPA to develop with the GPC a framework for good communications between GPs and pharmacies. We also heard from Alliance Boots on this. Their regional managers are tasked with meeting PCTs and GPs. Local branch pharmacists have personal objectives to visit local GPs and dispensing technicians have built up good relationships with them as well. We think these are important because commissioners will increasingly wish to focus on "holistic" service provision. Two key factors here are going to be patients meeting different providers who contribute to their care at different times and stages, whilst the care remains personal and individual to the patient, and the commissioner wishing to be assured that the service provided promotes equitable access and outcomes for those patients. We have noted earlier the potential for community pharmacies to act as bridges in developing more integrated health and social care services, through their frequent informal contacts with patients and carers.

> "Aligning primary care contracts around essential, advanced and local enhanced services can remove discord between professions and opens up the possibility of greater partnership."
> *From Synopsis of discussions with Lloydspharmacy and Green Light*

13. We noted in discussions that two of the major elements of the new contractual framework had not yet realised all the benefits that might be expected of them.

14. The first of these is the uptake of repeat dispensing which appears variable and is more successful in some PCTs than in others. This in part, we believe, reflects general experiences in the relationships between GPs and pharmacists. Where there is good communication, GPs appear to have fewer concerns about handing over control of repeat supplies to a pharmacy. Pharmacy contractors should not underestimate how seriously GPs take their role as guardians of a comprehensive record of patient care. Any move to pass "control" of the management of future supplies of medicines to pharmacies may be seen to threaten the integrity of the GP record. To ensure the records of medicines are reliable has to be dealt with through reliable communication, trust between patients and professionals that is part of truly multi-disciplinary care.

15. The second is the operation of MURs. We noted that PCTs pay from their finite resources for the services provided but are concerned they are "frozen out" of the MUR process and have insufficient influence over the extent to which they can manage this aspect of the contractual framework or the way in which they are provided. PCT representatives told us they are concerned these types of service are not being carried out in the spirit in which they were intended and are simply seen as a source of revenue.

> "in principle MURs are excellent when provided correctly but the spirit is being abused. The service from some providers is target-driven and simply used as a source of revenue. This confuses patients, antagonises GPs leaving PCTs in the middle ground. PCTs can find it difficult to access adequate information for governance and monitoring purposes (e.g. because of commercial sensitivity). There is limited ability to focus MURs on specific patient groups which is not helped by professional relationships. There is unnecessary duplication and expense for the PCT where the GP and pharmacy provide the same service, missing out more needy patients. It is difficult to verify and justify the PCT investment." *From Synopsis of discussions with NHS Confederation/NHS Employers/the PCT Network*

16. We have discussed above how we consider PNAs could be developed. Part of this development could be to make more effective use of PNAs than is presently the case to direct the provision of MURs. This would assist both contractors and PCTs. Contractors would know they had to address key priority patient groups for the MUR service. PCTs would have more confidence that MURs are being used to help patients most in need.

Where these are not specified, PCTs and contractors can continue to rely on key health areas such as diabetes, asthma etc as identified by the Department. The provision of an MUR service is also an area where quality indicators could be introduced. One potential measure could be the proportion of MURs undertaken for the PCT's target patient groups.

We consider the Department should explore with PCTs:
(i) developing a performance management indicator which promotes effective inter-disciplinary working in implementing repeat dispensing services; and.
(ii) the extent to which the provision of the MUR service can best reflect local health priorities.

Moving contractual services "up" the tiered structure

17. Leading on from this, as reported earlier, many contractors pressed to move more services (e.g. minor ailments, stop smoking services) to the advanced or essential level.

> "Current arrangements have delivered excellent choice and fantastic access to patients. There must be a range of services that every person in the country can, should and must expect from their community pharmacist. It makes sense for those to be contracted nationally"
> *From Synopsis of discussions with Association of Independent Multiple Pharmacies*

18. Easy access to minor ailment treatments, stop smoking and sexual health services are broadly what we would expect most PCTs to need and to commission. It is proven that pharmacies are as capable as others of providing these. We were not surprised to receive broad endorsement for services to be stratified within a tiered structure as now. We noted that services which are negotiated and agreed at a national level save valuable PCT and business resources and costs.

> "All services where there is a national need should be co-ordinated and negotiated nationally. This would save on PCT and contractor time and effort."
> *Alliance Boots response to the Review*

19. Yet we also noted that PCTs feel "disempowered" in the delivery of the advanced services which their funding pays for because it is by and large the contractor who decides whether or not to provide the service. This limits the PCT's options. That must call into question the overall benefits of such a framework if there is inadequate or reduced ability to influence the direction and nature of the service itself.

This surely detracts from PCTs' responsibilities with regard to commissioning local services depending on the needs and priorities of their population and comparable services already commissioned from other providers.

20. Whether the current three tiers should remain (see Annex A for further information) is, we think, open to further debate. We think there are inherent tensions within the second tier of "advanced" services. As mentioned earlier, pharmacy contractors and representative bodies on the whole want to see more services move into the nationally agreed sphere to include things like stop smoking and minor ailments schemes. However, the NHS commissioners want to see much greater control over what goes on under this badge.

21. That said the NHS was supportive of a national contract for essential services, but with other services determined according to local requirements.

Given the experience with MURs and some teething problems that have arisen for PCTs, we consider the Department should only proceed to transfer services to nationally agreed tiers where there is clear proven need and advantages which compensate for any actual or perceived loss of local control and influence.

Improving patient awareness and understanding

22. We have heard from many sources that there appears to be inadequate understanding amongst patients about the extent to which pharmaceutical services are developing and the benefits that may accrue. We note the Department understandably proceeded cautiously as the new framework came into place so as not to raise unreasonable or premature expectations. However, the framework has now been in place for almost two years and it is time that patients were more aware of what pharmaceutical services may offer. As pointed out to us:

> "There is also a concern that many members of the public still see some of the new services as 'My GP does this for me' roles. It would help if the DoH sponsored an awareness campaign explaining what these new services are and how pharmacists can help, as opposed to going to their GP."
> *ASDA response to the Review*

We note the Department is planning a communication exercise which will provide more information for patients about the range of services available from their pharmacy. The Department should ensure this information is also available to patients in rural and deprived areas where the wide range of services available under the new contractual framework for pharmacies may not be so familiar.

NHS Branding – convincing patients that pharmacy is part of NHS services

23. Closely related to this, is the question of how recognisable a pharmaceutical service is as part of the "NHS family". We thought of pharmacies abroad for example in France and Spain where there is an immediate focus on clinical services and noted that in England, pharmacies are located in a range of settings from clinical to retail. Unlike abroad, many pharmacies are owned by chains for whom an additional NHS corporate "logo" might be thought to conflict with the particular corporate brand. We heard that some people – perhaps those who are not keen to make use of a GP or clinic - appreciate the less formal atmosphere. We also noted the requirement to use the NHS logo on community pharmacy practice leaflets as part of NHS services.

We think that decisions as to "branding" premises are for contractors to take, in line with requirements for use of the NHS logo. We would encourage contractors to consider how better they can manifest their links with the NHS through the services they provide.

Control of entry

24. The current NHS (Pharmaceutical Services) Regulations are complex for PCTs to administer and contractors are concerned about the consistency of PCT decision making. We note the Department has committed to keep the operation of the regulations under review and to amend these where appropriate. One area brought to our attention is the current restriction which means exempt applications fail if there is an LPS scheme providing services to the neighbourhood – originally introduced in 2005 to ensure PCT plans for LPS services were not adversely affected. However, this has had unintended consequences.

> "The LPS Pharmacy restriction on the granting of an exempt pharmacy is questionable, and interpretation is varied. Many LPS contracts have been granted as a 'bolt-on' to the PhS contract and provide a limited benefit which can now be provided by a PCT commissioning an enhanced service."
> *ASDA response to the Review*

25. We further recognise that in announcing this Review, it was made clear there would be no immediate major changes to the current system, but we felt it would be unfair if we did not reflect strongly-held views on the operation of the current system, particularly the impact of 100-hours pharmacies. Whilst we were told they have improved access in various areas, we were also made aware that they create uncertainty for contractors and impede PCTs' commissioning ability. To cite one respondent:

> "Current pharmaceutical regulations in respect of the 'balanced package of measures' exemptions are at odds with this [commissioning] framework, because they eschew the necessary forward planning of local provision. Instead, they cast PCTs in a passive or, at best, reactive role; PCTs consider applications to join the pharmaceutical list at the time of applicants' choosing, not their own. Furthermore, where applications meet exemption criteria, PCTs are powerless to deny them, even if they calculate that the net result may ultimately be detrimental." …
>
> "The current 'balanced package of measures' arrangements make it difficult for PCTs to plan strategically and match local pharmaceutical provision to areas of need, and are therefore out of line with broader NHS reforms. The emerging commissioning framework is more demanding of a managed approach and PCTs are intended to be more capable of delivering it."
> *National Pharmacy Association*

We consider the Department should keep the impact of exempt pharmacies and particularly those that offer 100 hours or more a week under close review. The Department should only amend the regulations where there is clear and evident need for change and such change should endeavour to reduce the complexity and burdens of these regulations and promote consistency. One area to review is the current restriction on exempt applications succeeding where there is an LPS service.

Rural issues

26. We heard diverse views on the question of access to services in more rural areas.

27. We consider the following factors relevant:

- The control of entry system does not apply in the same way to all contractors of pharmaceutical services or all parts of the country;
- There are different legislative hurdles for doctors and chemists to pass to provide services;

- Some but not necessarily all dispensing patients will switch service providers if a pharmacy opens near to a dispensing practice;
- Patients in rural areas may not benefit from the same pharmaceutical services as those in non-rural areas – yet PCTs with rural areas also have non-rural areas and the same PCT has responsibility for its population as a whole;
- These arrangements are not consistent with the PCT having a role to secure equitable access to a full range of services for patients and carers.

28. These factors are particularly relevant we believe in what we term the "market town" scenario – where patients may pass one or more pharmacies on their way to and from their doctor's dispensary. Many of these dispensing practices would have acquired the ability to dispense under what are termed "historic rights". Whilst this avenue is no longer open, those with these rights continue to enjoy them. We are not convinced the need for this should continue in perpetuity.

29. We noted that in Scotland a Local Health Board commissions dispensing from a doctor where no pharmacy is available. If a pharmacy then opens, dispensing ceases. We also heard that the funding arrangements under the new GMS contracts are intended to cover the provision of such medical services. The Dispensing Doctors' Association told us that in rural practices, doctors might not have the opportunity to generate the same level of income, i.e. through Quality Outcome Framework (QOF) payments as their urban counterparts. Therefore, dispensing can be vital to some rural practices.

> "The need for cross subsidisation of medical services by pharmaceutical services remains in rural areas despite the new GMS contract."
> *Joint response of the GPC of the BMA and DDA*

30. We also heard from PCTs that dispensing by doctors is thought to be most cost-efficient where there is 100% dispensing – i.e. in the most rural areas.

31. We recognise the valuable service dispensing doctors provide to those patients who cannot access a pharmacy conveniently. As a rule, however, we do not believe doctors' dispensing should be necessary to subsidise the provision of core medical services. If patient choice is to be fully realised, it seems logical to us that patients should be able to receive full, high quality pharmaceutical services based on what local needs and demands are. We are convinced there are compelling arguments for this to be offered to patients equitably in rural and non-rural areas.

32. Incentives to encourage closer working between GPs and pharmacists in the delivery of clinical services in rural areas is one approach that may merit wider consideration. This might be achieved by having peripatetic pharmacists, particularly in rural areas, to support this practice.

> "There can be particular difficulties in building a professional relationship with larger pharmacies if the pharmacist is constantly changing. The DDA suggested allowing for the concept of peripatetic pharmacists to work a proportion of their time in different practices or areas."
> *From Synopsis of discussions with General Practitioners' Committee of the BMA and the Dispensing Doctors' Association*

33. Alternatively, we are struck by views expressed in the Control of Entry Review report that it would be possible as an interim measure - pending more major structural reform as discussed below – to introduce the same requirements on all contractors who apply to provide dispensing and pharmaceutical services e.g. substituting the "necessary or expedient" test for "prejudice" in GP outline consent applications. In other words, approval to a new dispensing practice would be given only if it were "necessary or expedient for the adequate provision of pharmaceutical services."

We consider the Department should consider this further, in conjunction with the GPC and PSNC.

34. We heard that dispensing doctors would welcome an end to the restrictions that they are unable to sell a wider range of over the counter medicines to their patients.

> "Patients are, at present, not allowed to buy the most cost-effective, simple remedies direct from their doctor, only those drugs deemed to be not prescribable under the NHS. This causes an inequity in service provision for rural patients and an unnecessary increased cost to the NHS. This leads to the ridiculous situation where a patient may buy proprietary Panadol® from their doctor but not the cheaper and equally effective paracetamol for which they would have to make an extra journey to a pharmacy. It is our view that this must change."
> *Joint response of the GPC of the BMA and DDA*

35. This would enable patients to obtain more of the medicines they need where there is no convenient pharmacy service available and may reduce costs where GPs who are dispensing doctors no longer need to write a prescription.

We believe the Department should explore how access to such medicines can be improved to support independence and well-being.

36. We consider these measures would secure more equitable access, greater certainty for patients and contractors and remove a considerable chunk of the regulatory burden within the current regime.

Wider policy concerns

37. We heard concerns that GPs are more embedded in PCT structures and other contractors feel "shut out" from wider policy developments locally such as those that are developing as part of practice based commissioning (PBC). We note the Department is turning its attention to developing a multi-sectoral approach to PBC and has commissioned the NHS Primary Care Contracting team in 2007/08 to support better integration of pharmacy with PBC. We welcome this.

38. Information Technology should support closer joint working and enhance patient care. We heard that the electronic patient record might facilitate this in the fullness of time. In the meantime, there should be optimum utilisation of current IT systems and services to support greater integration of community pharmacists in patient care.

Chapter 6: Major themes: areas which might be addressed in the future

In this chapter, we discuss:

- ✓ **Strengthening PCTs' commissioning roles, stimulating competition and ensuring future contractual arrangements are founded on the services to be provided and their quality and not on simple market entry.**
- ✓ **We received two similar proposals for a PCT-based Pharmacy Access [Planning] Framework from the PSNC and Lloydspharmacy which would develop the current control of entry system.**
- ✓ **We consider there should be a single contractual framework in the future grounded on the more evidence-based assessment of pharmaceutical health needs we discuss in Chapter 5. This would set out the requirements for all potential providers to meet but is sufficiently flexible to allow PCTs to contract for a minimum service to ensure prompt access to medicines and to the supply of appliances.**
- ✓ **Whilst we do not consider further moves to nationalised contracting arrangements or simple deregulation would meet these principles, we identify two possible options: devolving contracting responsibilities wholly to PCTs with certain minimum requirements kept at national level, such as standards, or introducing the concept of "any willing provider" for the provision of essential services (as is currently being considered for the provision of services in the acute sector) with more contestability for local enhanced clinical services.**
- ✓ **With this in place, we feel that control of entry will fall away.**
- ✓ **PCTs should be able to terminate contractual rights for under-performing or poorly performing providers. This will help address the limited means at present by which PCTs can open provision up to competition or remove such provision where no longer needed or providers fail to meet local needs.**
- ✓ **Pursuing this would require a step change in the capacity and capability of PCTs as commissioners of pharmaceutical services.**
- ✓ **We believe the Department should consider introducing new legislation to achieve this.**
- ✓ **We consider existing quality requirements should be developed further. The current clinical governance framework provides a sound basis, but needs to be built on to deliver more clearly defined quality outcomes.**
- ✓ **We have identified barriers to change including cultural barriers and the need to shift to a collaborative framework for patient-focussed services.**

Contractual arrangements

1. We start from the premise that contractual arrangements for the future should be founded on the services to be provided and their quality, not on controls on market entry. We heard that perhaps 85% of a typical pharmacy's business derives from the NHS. It therefore seems illogical to us that there are rather limited means by which a PCT can effectively take action to open provision up to competition or to remove such provision where it is no longer needed or fails to meet local need. Once granted, the current pharmaceutical services contract is for life.

> "PCTs wish to support those who want to apply their professional skills, not those prepared to stand still. So contracts could be time-limited, e.g. reviewed every three years to identify if the need remains the same."
> *From Synopsis of discussions with NHS Confederation/NHS Employers/the PCT Network*

2. We consider there are certain "givens" when it comes to reforming contractual arrangements. Our view is that such arrangements should:

- be seamless, robust and transparent. The commissioning process runs from initiation to contracting, review and termination;
- enable PCTs to explore the market as freely as possible but set this against consistent quality markers; and
- encourage as dynamic a market as possible so that service provision enables changing needs to be met.

> "the CCA would wish to see the principles of patient choice of providers extended to enhanced primary care services as soon as possible, creating the opportunity for pharmacists to become listed as "willing providers"."
> *Company Chemists' Association Ltd follow-up response to the Review*

3. To ensure this works smoothly, it is important that PCTs have both the relevant capacity and capability to undertake an increased commissioning role. In strengthening commissioning functions for pharmaceutical services, we noted the experience of moving GPs and dentists to local contracts.

> "Control of entry should be abandoned and replaced with contracting mechanisms similar to those for general practice and dentistry. Local contracting brings commissioner and provider closer together and ensures better dialogue with PCTs and between health professionals. Too little has changed under current arrangements."
> *From Synopsis of discussions with PCT-SHA representatives*

4. The current system for arrangements agreed at a national level may mean that contractors do not feel accountable to their local PCT in the same way. We believe, this is a significant problem that has to be addressed in any new arrangements. We also heard from the NHS the importance of building trust with contractors and not relying on counting individual items of service as the sole measure of performance. This rather differs from the view put forward by the OFT which considered that a fee per item of service was helpful. The NHS perspective however that this can lead to a loss of "value added" services where every aspect of remuneration is paid and accounted for against performance is, we believe, important.

5. Some contractors considered there was merit in ensuring entry controls to the market remained to engender business confidence. Others recognised there are inherent flaws in the current system and particularly with regard to the way in which the exemptions are now seen to be operating. This has the effect of creating market instability and insecurity. We also noted that this only applies to pharmacies and does not affect dispensing doctors. Further, appliance contractors find it very difficult to enter the market currently.

6. We heard from the OFT about their current work on system reform with the Department which is looking at introducing more competition to the acute sector. More details on system reform are given in Annex C. We note that there are elements within this which found echoes in our discussions on arrangements for pharmaceutical service provision. These include the concept of "any willing provider" and national standards. We also heard the strong view of the OFT that a deregulated market will contribute to raising standards. We noted, however, that once any new pharmacy passes a minimum amount of dispensing activity per month, it automatically receives additional payments from their local PCT. This arrangement would seem to go against the idea of "any willing provider" as it could incur ever increasing expense for the PCT under current arrangements.

7. It is clear to us from the Department's review of the control of entry reforms and our own findings that cautious deregulation has had a considerable impact on some – though not all – PCTs. It is not clear that a simple deregulated market is likely to secure the influence and control over commissioning and service arrangements which PCTs say they need to promote the health of their population. We note the OFT's view that competition is an effective driver for improving quality but the OFT itself recognises that patients and consumers are not sufficiently geared up to recognise a good quality service when they see it.

8. We received two broadly comparable proposals during the review as to how control of entry might be developed. The first was for a "Pharmacy Access Planning Framework" from the PSNC. The key features are for PCTs to devise a map showing current provision and an assessment of current service adequacy. This will then be used to assist business in making applications and to guide PCTs in procuring services from existing or new providers. PCTs are to have a power, where existing contractors do not practise to an acceptable standard, to remove such contractors.

> "The 'Pharmacy Access Planning Framework' would be built with substantial patient involvement so that patient demographics can be taken into account as well as how people use local resources, local transport, the points at which they want to access pharmacy services, and so on. It is quite crucial that a structured template or criteria is built up for establishing the framework. This would set where pharmacies can apply and expect to be considered, and where PCTs may well decline to take an application forward . . . this sort of model is used extensively in other industries, particularly in retail industries.."
> *From Synopsis of discussions with the Pharmaceutical Services Negotiating Committee*

9. The second proposal, devised by Lloydspharmacy, is to develop a Pharmacy Access Framework, which goes rather wider. This comprises three elements, underpinned by a new financial model for community pharmacy:

- an objective, transparent methodology to determine whether and where a pharmaceutical contractor can provide NHS pharmaceutical services
- a standard contractual framework to enable PCTs to more effectively commission pharmacy, GP, dentist and ophthalmology services; and
- incentives to create new models of dispensing which would enable greater pharmacist interaction with patients and public.

We consider both proposals merit further debate and consideration.

10. We noted there are significant differences in NHS contractual requirements and the terms of service for dispensing doctors and chemists. We do not consider these remain justifiable in the longer-term in respect of the range and standards of services to be expected. This is most marked for those living in rural areas.
(We also note the Medicines Act has differing requirements for pharmacies and doctors. These are not at issue here.)

11. At the same time, there must be provision which enables PCTs to contract for a minimum service where this is required to ensure

continued access to certain essential "givens" for any pharmaceutical service. Chief amongst these is ensuring prompt access to medicines. The Department should also consider the need to incorporate specific requirements that promote access for patients to the supply of appliances which are a more specialist area.

We therefore consider the Department should explore moving in the longer term to a single contractual framework which sets out requirements which all potential providers have to meet. This framework should be sufficiently flexible and responsive to meet different needs, including where it is essential to secure a minimum dispensing service.

We note that there may be difficulties for those wishing to enter the market – or to extend their provision – to supply appliances. Specialist commissioning is one approach which has been suggested, where either the SHA or a lead PCT takes responsibility for applications which will have benefits for a number of PCTs – not just the PCT in which the premises are based. This may also be appropriate for those wishing to apply to be solely internet-based or mail-order only contractors.

12. With a focus in future for PCTs on increased commissioning responsibilities, the need to retain the present control of entry system will, we believe, fall away. Its usefulness has been and remains open to question.

> ". . . the control of entry system looks more and more out of kilter with everything else that is happening in healthcare."
> *From Synopsis of discussions with Which?*

13. We agree. Nonetheless, we consider there is a need for an objective basis on which PCTs will reach decisions as to who is to be the pharmaceutical provider or providers in future. We consider the most straightforward approach is to exploit the pharmaceutical needs assessment tool, provided the recommendations we make in Chapter 5 are taken forward. In other words, for PCTs to have a robust tool against which they can assess the need for future providers, they require a more formal evidence-based assessment of pharmaceutical health needs. This is closely linked to the ideas put forward by the PSNC and by Lloydspharmacy. This should be explicitly linked to the PCT's Local Development Plans and other health needs assessments of which it should form a part. This would, we believe, represent a 180-degree shift from the current system which is largely driven and controlled by potential providers of pharmaceutical services.

14. It would also, we consider, bring the commissioning of pharmaceutical services more into line with the principles for more effective commissioning set out in the recent consultation document *Commissioning for health and well-being*, that the Department launched on 6 March 2007 (for more information on this see Annex C). We consider that the principles set out link directly to many of the strengths and opportunities in community pharmacy and pharmaceutical care management highlighted during this review.

15. We are conscious in putting forward this suggestion that we do not make recommendations which "pile further change on top of change". We do not think this will help. Instead, we see this as complementing PCTs' developing role as managed commissioners of quality services through an enhanced PNA which can incorporate elements such as those proposed by the PSNC and Lloydspharmacy in their models. In short, PCTs need a robust planning tool which does not place artificial limits or constrictions on their ability to commission.

16. We consider funding issues associated with this in more detail in Chapter 7. However, our starting point is PCTs will fund and invest for the services required through robust competition.

Stimulating Competition

17. We have made a number of observations and recommendations in Chapter 5 as to action that could be taken now. However, we believe there will be more to be done in future to enhance contestability for the services the PCT has identified its population needs.

18. One simple mechanism would be to deregulate the market entirely. This is a view favoured by the Office of Fair Trading.

> "Without control of entry, it is possible that DH may still want entrants to meet certain minimum objective standards and criteria. This has been possible in other areas of healthcare such as in the provision of elective acute procedures, where private providers are regulated but entry is not controlled . . . fees would not cause a distortion to competition provided they are applied equally."
> *From Synopsis of discussions with the Office of Fair Trading*

19. As we have already noted, from the experience already gained from limited deregulation, we are not convinced that simple deregulation is the best approach. It does not meet the shortcomings already identified. However, it has close links to the concept of "any willing provider" which the Department is considering in respect of acute sector providers.

20. On this basis, we have identified two possible options the Department may wish to explore further in consultation. They are both predicated on the assumption that PCTs have robust PNAs in place and that contracting is devolved to PCTs with certain minimum requirements assured at national level, such as standards.

- First, the provision of pharmaceutical services whatever their scope and nature are subject to an open, transparent and contestable process. PCTs award contracts based on how well applicants meet identified needs and against stated criteria including quality;

- Alternatively, the minimum dispensing services and/or other current essential services are opened up to the concept of "any willing provider" with more advanced clinical services being subject to a contestable process.

21. We think the concept of any willing provider would work best in terms of dispensing or current essential services. There are funding implications under the current payment system which would need to be addressed if this route were pursued. We are not convinced that it would work in terms of commissioning the more sophisticated services we have identified for the future because a PCT will want to plan what, how and when they are to be provided. Tendering for these more clinical services against a robust PNA appears the clearer option here.

22. We consider either option would require a step change in the capacity and capability of PCTs as commissioners of pharmaceutical services.

> "Local commissioning flexibilities can only be best realised where there is capacity within PCTs to analyse current service provision, plan services according to the needs of local patients, commission appropriate services and monitor service provision accordingly."
> *NHS Confederation/NHS Employers/the PCT Network's response to the Review*

23. We have already noted the restricted powers for PCTs to remove poor providers or where there is simply no further need for them to continue to provide services. However, we believe that with a move to greater local commissioning, the Department can consider ensuring there are powers to enable PCTs to take appropriate action. If, after a defined period, a contractor cannot demonstrate that they have reached the new requirements, the PCT should be free to commission alternatives. This would be in addition to the existing power to limit contractual duration.

24. Further, whilst we note the extensive network of existing providers, we do not consider that PCTs should be limited to only securing new service provision from existing contractors. Just because a service can be effectively delivered through a community pharmacy does not mean that in any particular location, that is necessarily the best method, any more than some GP or hospital services should only be commissioned from existing providers.

We believe the Department can consider introducing new legislation which will enable PCTs to wield more influence to address the shortcomings we think are inherent in the current system. We identify two options under which contracting in the future might take place. Changes to legislation should in any case encompass an ability for PCTs to terminate contractual rights for underperforming or poorly performing providers.

Quality markers

25. The new contractual framework initiated a move towards more demonstrable evidence of quality services. This encompassed staff operating within a clinical governance framework which covers risk management, training and continuing professional development and patient feedback and evaluation. We believe this provides a sound basis but needs to be built on to deliver more clearly defined quality outcomes focussed on the benefits patients receive from their pharmaceutical service.

26. Our attention was drawn to a recent Healthcare Commission report[21] on medicines management in acute and specialist Trusts which found that best performance was most strongly correlated with indicators that informed clinical pharmacy time, utilisation of new ways of working and strategic planning. It found that best practice is characterised by optimal use of staff, skill mix, robotics and information technology, and underpinned by efficient systems for the procurement and supply of medicines enabling pharmacists to devote the bulk of their time to direct patient care. These findings may be capable of informing PCTs' approach to commissioning and may have application to any quality pharmaceutical service, including in the community.

27. The contractual model of the future will also require a series of quality indicators and markers against which PCTs may judge not only potential providers but ensure performance and outcomes are of a suitable standard for the reasons given earlier in this chapter.

[21] Healthcare Commission: *The best medicine – the management of medicines in acute and specialist trusts* January 2007

28. We noted the attention Lloydspharmacy gave to this area in their evidence in order to encourage better engagement by contractors and provide incentives for better joint working (e.g. for patients with diabetes or requiring long-term condition management). We were advised that some quality markers would be, as now, service specific, whilst others would be framed in order to reflect the contributions that each professional makes to patient care. Under this proposal, as contractors became familiar with their use, the bar would be raised incrementally as providers achieve relevant QOF ratings. We were advised this would enable PCTs to best influence provision where needed as remuneration would reward provision of services at a level which increases over time.

29. In general, we noted a pharmacy Quality and Outcomes Framework (QOF) could be helpful in measuring outputs and some outcomes. The QOF is part of the development of the new General Medical Services contract. It resources and rewards GPs for how well they care for patients rather than simply how many they treat. Although QOF is not a performance management tool, PCTs can use QOF information to inform discussions with practices about improving quality e.g. for example, through the QOF assessor visit. Developing a pharmacy QOF could promote greater synergy for PCTs across primary care providers. The concept of a pharmacy QOF could be used to address other problems we were told about.

30. If implemented, this could make the incentives for good clinical practice similar to that of GPs, although care would then be needed to avoid the NHS effectively 'paying twice' for the same clinical work carried out potentially by two professions.

We consider the Department should explore and consult on developing quality requirements along the lines set out here.

Rural issues

31. If the recommendations we make above are taken forward, there should be no difference as to the requirements for a potential provider in rural or non-rural areas unless there are exceptional circumstances.

Barriers to change

32. We have discussed in previous chapters a number of barriers we think may exist to achieving change. They are important because contractors of the future will want to invest with confidence.

33. There are clear cultural barriers between GPs, pharmacist contractors and PCTs. We have heard of professions jealously guarding contractual allocations which are seen to be theirs and theirs only. This is not the commissioning way of the future. Instead, funding will have to be contested for and won.

34. However, once won through a process of enhanced contestability, the successful service provider or providers will have to ensure their attention shifts to focus on developing effective collaborative relationships with others to ensure provision meets the needs of patients.

35. This will be the focus of practice-based commissioning for the future. As much as PCTs need to build relationships with pharmaceutical contractors as with any other potential provider, contractors also have a responsibility for building relationships with PCT commissioners and with practice-based commissioners.

36. Whilst nationally there is good awareness of the role of PCTs as commissioners of all primary care services (including primary care and out of hospital care provided by GP practices), this is not yet translated on the ground. Whilst many we met were aware of this shift, we think many contractors need to prepare now for future commissioning arrangements which will expect and require a diversity of providers. This is what is happening in the acute sector and we do not envisage that primary care will be any different.

Chapter 7: Funding implications

In this chapter, we discuss:

- ✓ **There are a number of factors which will influence funding for pharmaceutical services in the future including shifting money from the acute sector to primary care and engendering contractor confidence.**
- ✓ **We consider that with the technological and professional changes taking place, there should be less emphasis and less value on the purely dispensing element of NHS pharmaceutical services. Whilst this will always remain important, the pharmaceutical service of the future has the potential to be radically different to that of even today.**
- ✓ **Instead, funding should focus on the provision of clinical care services and initiatives which support health. So a lower proportion of the overall pharmaceutical budget would be spent on dispensing activity and a higher proportion on clinical activity. Funding "floors" to support this greater clinical activity may be appropriate.**
- ✓ **There are other factors to take into account, including the question of fixed costs for PCTs where new contractors open, and any "cross-border" impact from new funding arrangements.**
- ✓ **We consider the Department should explore and consult on the finance implications arising from our recommendations in Chapter 6, and in particular on transferring commissioning responsibilities to PCTs and the measures available to promote quality and engender contractor confidence from such a shift.**

1. We have explored briefly the potential financial implications arising from our review. We do not claim economic expertise in this area and therefore more detailed examination of the implications of our views will be required. However, the following points seem pertinent to us.

2. First, and importantly, the announcement accompanying the White Paper to shift funding from the acute sector to primary care over the next 10 years should create significant opportunities for all primary care contractors. The future model for a pharmaceutical care management service outlined in Chapter 4 is, we believe, ideally suited to be a candidate for commissioners to consider in this respect.

3. Second, contractors placed a great deal of emphasis on the funding certainty offered by current contractual arrangements. We recognise this has been an important contribution in securing their commitment and investment – as many contractors clearly have done to upgrade their premises and develop staff etc under the new framework. However, this

cannot be viewed as a right to enjoy in perpetuity or without meeting set quality and outcome standards.

4. Third, the current financial flows still depend largely on the prescription business which comes in through the door or via the internet. The importance of that as the basis of a relationship with a patient should not be under-estimated in terms of the opportunities that arise in respect of promoting self-care and supporting people's wellbeing. However, we heard one estimate that £19 in every £20 a pharmacy earns for its NHS services still derives from core dispensing activity which goes to fund the provision of essential services under the new contractual framework.

5. We have already made clear we recognise the importance of maintaining ready access to these services. We have said that with the technological and professional changes taking place, the pharmaceutical service of the future has the potential to be radically different to that of today, just two years after the community pharmacy contractual framework was introduced. We agree the views of NHS Confederation/NHS Employers and the PCT Network here. Financial levers could be enhanced if there was less emphasis and therefore less value on the dispensing element of the service alone. A clear example of this is with internet-only or mail order pharmacies and pharmacies that do not operate a face-to-face service. Such a shift would add value to the range of additional clinical services that other pharmacists are able to offer, thereby encouraging both clinical and skill mix development.

6. We have already commented that opening up the market has impacted on PCT finances. Therefore, to avoid major financial impacts, some redistribution and adjustment of current financial flows seems inevitable. At the very least, we would expect that with a shift to clinical services, funding should follow. That would support a lower proportion of the overall pharmaceutical budget spent on dispensing activity and a higher proportion on enhanced clinical activity, developing the essential services element over time to ensure that patients and consumers can access the same broad range of services from all providers of NHS pharmaceutical services. This would particularly apply if, for example, contractual arrangements moved towards the concept of "any willing provider" in terms of any such provider providing dispensing and/or essential services.

7. We make no judgment as to what that proportion should be. We note however, that current funding (2006/07) for community pharmacy comprises a mix of central allocations (£991 million), money from savings made on PCT drugs budgets through centrally managed price adjustments (£270 million) and retained profits contractors earn on the medicines they dispense (£650 million) –a total of £1,911 million. Central allocations are used primarily to pay for current dispensing and other essential services.

8. We can see good reasons why this should continue to be so. A certain proportion may always be needed to "guarantee" funding for essential services. However, there is surely scope to consider that a proportion of this funding derived from dispensing activity, used as it is to support funding for a wider range of essential services, could switch over time to the provision of the more clinical care services we discuss earlier. With that switch, financial responsibilities should also shift away from the Department towards PCTs. We believe such arrangements could only be viable in any case if power (over the actual spend and the quality, quantity and nature of services provided) accompanies any transfer of risk to PCTs.

9. We consider some shift is desirable to enable pharmaceutical provision to move up the gears. That shift must be towards PCTs as informed and empowered commissioners.

> "The dependence on volume of prescriptions for income detracts from other services that may be commissioned. It does not help develop the skills of the pharmacist or meet patient needs for good healthcare workers easily accessible in the community."
> *From Synopsis of discussions with the Patients' Association and the Long-Term Medical Conditions Alliance*

10. The main obstacle to this shift is the distrust still inherent amongst contractors whether PCTs will buy clinical pharmacy services – for example, if faced with a funding crisis. We noted, however, that for the introduction of the new primary medical services contracts, funding "floors" were introduced for the provision of enhanced services. Such funding – with limited exceptions – is contestable and can be awarded to any suitable provider.

11. We think this model is capable of being used for both enhanced and pharmaceutical care management services, provided that such funding is contestable. This could be especially useful in the early years of new arrangements, whilst they bed down. It would be open to the Department to specify such a floor in consultation with the NHS.

> "The ability to use enhanced services would have more meaningful implementation if there was some baseline floor funding to help PCTs commission them – for example with medicines management. Allied to this, there is a need to ensure appropriate skills are in place where pharmacy services are to be extended."
> *From Synopsis of discussions with the Small Practices' Association, the National Association for Primary Care, the NHS Alliance and the Primary Care Pharmacists' Association*

12. Moreover, pharmaceutical service provision is not limited to these funding sources alone.

> "There are a number of mechanisms which could be considered in order to facilitate change:
>
> - incentives. Pharmacists could be encouraged to tender for and provide local enhanced services traditionally provided by general practice. There may also be opportunities to open up elements of the Quality and Outcomes Framework (QOF) to community pharmacy ……
>
> - a change in the funding flows. Community pharmacists should be able to sustain their business from clinical work. Funds should move with the patient as services move from general practice to community pharmacy."
>
> *NHS Confederation/NHS Employers/the PCT Network response to the Review*

13. It would also be advisable to consider the impact of any shift in funding flows on the NHS Business Services Authority and the financial and other management data derived. At present, the funding arrangements between pharmacy contractors and appliance contractors are different. We noted that the review the Department is undertaking of Part IX of the Drug Tariff aims to ensure consistency in both the accessibility and the level of service provided by these groups – as well as fairness and consistency in the remuneration of services rendered by them.

14. Other factors to take into account in any financial shift will include:

- any liability on PCTs to incur fixed costs from new contractors; and
- cross-border flows, where PCTs receiving a large number of incoming prescriptions may find themselves liable to pay for them.

We consider the Department should explore and consult on the finance implications arising from our recommendations in Chapter 6, and in particular on transferring commissioning responsibilities to PCTs and the measures available to promote quality and engender contractor confidence from such a shift.

Chapter 8: Conclusion

1. This review sets out our findings on how pharmaceutical contractual arrangements could be developed in the immediate future and longer term.

2. We consider and suggest areas for reform which can be undertaken using existing legislation and areas for reform which would require changes to existing legislation.

3. We consider, as a consequence, such changes will enhance the ability of contractors to deliver pharmaceutical services which better meet the needs for patients and consumers now and in the future. Services of the future should be based on certain key principles:

   - empowering PCTs to commission to meet local needs
   - be transparently contestable and equitable;
   - aim to maximise quality and to focus on achieving the best outcomes for patients as well as the necessary outputs; and
   - enhance clinical focus and professional delivery.

   > "The more patients use pharmacy, the more they will understand what it can do for them. If we promote, through local commissioning, what pharmacy can do, setting an access route to a particular service, patients will become accustomed to it and feel comfortable with it."
   > *From Synopsis of discussions with Patients' Association/Long-Term Medical Conditions Alliance*

4. From this review, we do not think that standing still is an option. Nor do we think further moves to nationalised contracting arrangements or simple deregulation would meet all these principles. In Chapter 6 we have identified two possible options for future contractual arrangements.

5. Due consideration will need to be given to secure arrangements that benefit patients and maximise both value for money and the public health gain that will be achieved through pharmaceutical care management and more effective use of medicines.

6. Community pharmaceutical services can provide essential skilled and readily accessible capacity to facilitate - for both PCTs and practice based commissioners - significant shifts to out-of-hospital care. The opportunities to secure high quality services which offer greater access and choice, support independence, well being and improving health and providing effective help for those with high levels of need can be

maximised through shifting the leverage available to PCTs to manage pharmaceutical services in this new way.

7. This review has encouraged our belief that community pharmacy can be a key partner in the delivery of patient-centred healthcare services. We think pharmacy has undisputed potential and willingness to widen its contribution to healthcare to the greater benefit of patients and consumers. At present, there are some obstacles in the environment that reduce their participation and contribution. Anything that can be done to unblock these should be done.

Annex A: Background to this review

New contractual framework for community pharmacy

1. The new contractual framework for community pharmacy in England went live from April 2005. This realised an ambition set out in *A Vision for Pharmacy* in the new NHS from July 2003 for the new framework to reflect modern service requirements and to help ensure community pharmacy is an integral part of the NHS. Under the framework, services are divided into three categories:

   - **Essential services** - must be provided by all community pharmacies and include dispensing, repeat dispensing, health promotion, signposting, support for self-care and disposal of unwanted medicines.

   - **Advanced services** - require both the pharmacist and the pharmacy premises to be accredited. The first of these services is the Medicines Use Review (MUR) where pharmacies review a patient's current medication to ensure patients get best use and resolve any problems.

   - **Enhanced services** - services commissioned locally by PCTs and will reflect the needs of the local population. These can include minor ailment treatment schemes, stop smoking services, emergency hormonal contraception and support for drug misusers.

2. The framework is designed to provide PCTs and pharmacies with opportunities to work effectively together to meet the needs of the local population. These can be further enhanced by PCTs enabling pharmacies to collaborate with other health and social care providers to identify common areas of concern and explore how these can effectively be addressed by a multi-disciplinary/multi-agency approach.

Local Pharmaceutical Services

3. Complementing this framework, since 2002, there has been an alternative contractual route for pharmacies to provide services known as Local Pharmaceutical Service (LPS) contracts. These allow Primary Care Trusts to commission community pharmaceutical services tailored to specific local requirements and gives flexibility to include within a single local contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements. This might for example, address the needs of a specific group of patients such as those over 75 years of age, in a defined

geographic area. So benefits of LPS to patients include access to a broader range of care and services that have been designed with their needs in mind and the opportunity to benefit from the pharmacist's expertise and professional skills.

4. There are two ways in which LPS schemes can be initiated:

   (i) a PCT may specify services/location and other details of an LPS scheme it wishes to commission and invite prospective providers to come forward; and
   (ii) a proposal for a scheme may be put forward by a prospective LPS contractor/provider or any other person

Reforms to the "control of entry" system

5. "Control of entry" is a set of rules derived from the NHS Act 2006 which determine whether a pharmaceutical contractor can provide NHS pharmaceutical services in England. The rules are currently set out in the NHS (Pharmaceutical Services) Regulations 2005 – Statutory Instrument 2005/641 introduced from April 2005. This has been subject to several subsequent amendments.

6. In England, this law says that no new contractor can be entered onto a NHS pharmaceutical list unless it is "necessary or expedient" to secure the adequate provision of pharmaceutical services locally. This is the "control of entry" test. If a PCT considers that it is neither necessary nor expedient to grant a new application, then it must refuse. There are rights of appeal.

7. The system was originally introduced in the mid-1980s and has had the effect of restricting new entrants. The Office of Fair Trading (OFT) recommended total deregulation in 2003 to improve competition, reduce prices and improve access to, and the quality of, pharmaceutical services. In England, the Government responded with a package of reforms, moving cautiously in the direction the OFT recommended but not deregulating in full.

8. The reforms include a revised test and four complete exemptions to the test (provided certain criteria are met), as well as streamlining the applications and decision-making process. The four exemptions are:

   - pharmacies open for at least 100 hours per week;
   - in designated out-of-town large shopping centres;
   - in new one-stop primary care centres; and
   - internet-based and wholly mail-order pharmacies.

9. Following a commitment given in 2003, the Department announced a review of the progress of these reforms on 13 June 2006.

Review of progress of reforms to "control of entry" and findings

10. The Department considered how the reforms introduced in April 2005 had affected access to, and the choice of, NHS pharmaceutical services, their impact on consumers and the retail pharmacy market and the extent to which the operation of the new regulatory system was proportionate to the aims and objectives of the reforms

11. The report[22] found that:

1. Whilst still early days, the reforms had had a modest impact, with more than twice as many pharmacies opening in 2005/06 than in any year in the period 1992/93 - 2004/05, and many contractors making use of the new freedoms introduced. Deprived areas were neither significantly worse nor better off, though slightly more pharmacies closed in these areas during 2005/06. PCTs with greater social deprivation attracted more applications using the new exemptions than would have been expected by chance.

2. More pharmacies were now located nearer GP surgeries compared to 2003. There was no noticeable impact so far on the prices of over-the-counter medicines nor on the pharmacy workforce, nor any significant impact on overall network.

3. Patients reported better hours, access and quality services. However, this was not uniform with little change seen in rural areas. The NHS found the regulations difficult to administer and exempt applications, such as for 100 hours per week pharmacies, in particular hampered their efforts to plan strategically and commission more clinical services. Innovatory practice was attributed more to the new contractual framework than these reforms. Business reaction was mixed. Some reforms were welcome, particularly some quicker procedures for administrative decisions, but many were concerned the exemptions could lead to long-term reduction in choice and none reported business certainty had improved.

22

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/Browsable/DH_064405

12. The Department concluded that the reforms had had a modest but uneven impact on promoting more choice and competition, though access had improved where new 100-hour pharmacies opened.

Review of the arrangements under Part IX of the Drug Tariff for the provision of items - and related services - to Primary Care

13. The Department has been reviewing the arrangements for the provision of dressings, incontinence appliances, stoma appliances, chemical reagents and other appliances listed in part IX of the Drug Tariff since October 2005. The arrangements for the payments of these items and services had remained largely unchanged for 20 years and there was insufficient transparency between the price of an item and the cost to the NHS.

14. The aim of the exercise therefore has been to maintain – and where appropriate – improve the current quality of patient care, to ensure efficiency in procurement and that remuneration arrangements were fair and equitable and represented value-for-money for the NHS and taxpayers.

15. Changes in respect of chemical reagents (blood glucose-testing strips) and dressings took effect on 1 October 2006. Two consultations on the arrangements for stoma and incontinence appliances, and related services closed on 2 April 2007.

- **Consultation 1** sought views on proposed adjustments to the reimbursement levels for some stoma and continence care items.

- **Consultation 2** sought views on proposed remuneration levels for service that contractors provide in relation to the dispensing of stoma and continence care items.

16. Given the proposals set out in the consultations listed in above, the Department has also consulted on amendments to the terms of service for both pharmacy contractors and dispensing appliance contractors, prior to introducing changes expected later this year. This consultation also closed on 2 April. The terms of service for dispensing doctors were not affected.

Annex B: Contractual arrangements for other primary healthcare providers

Primary Medical services

1. Since April 2004, three contracting routes have been available to enable PCTs to commission or provide primary medical services for their populations.

General Medical Services

2. The most common route is General Medical Services (GMS) which is underpinned by a nationally agreed contract. Services are divided – like pharmaceutical services - into three categories:

- **Essential** services - Every GMS practice is required to provide essential services to their registered patients and temporary residents. This can apply similarly to Personal Medical Services (PMS) agreements and Alternative Provider Medical Services (APMS).

- **Additional** services - All GMS and PMS practices have a preferential right to provide additional services. Practices can, however, temporarily or permanently, opt out of providing additional services in accordance with fixed rules. Where opt-outs occur, the PCT is required to commission the services from a different provider, or provide the services itself as a PCT Medical Services (PCTMS) provider

- **Enhanced** Services are essential or additional services delivered to a higher specified standard, or services not provided through essential or additional services. PCTs are able to contract for whatever enhanced services they consider appropriate to meet local health needs. There are National Enhanced Services (NES), whereby PCTs are directed to offer contractors the opportunity to provide such services under nationally set requirements and Local Enhanced Service (LES) - developed locally to meet local need.

Personal Medical Services

3. Personal Medical Services (PMS) became a permanent contracting option for PCTs from 1 April 2004. Roughly, 40% of personal medical services are currently provided through PMS agreements. PMS is underpinned by national regulations.

4. PMS practices are able to deliver a broadly similar range of services to GMS practices. PMS Regulations allow 'core' essential provision plus the ability to contract for additional enhanced services, and allow opt-out from provision of Out of Hours services.

Alternative Provider Medical Services

5. PCTs are able to contract for primary medical services from providers other than under GMS and PMS. Such providers may include commercial providers; not-for-profit organisations; voluntary and community sector organisations; NHS Trusts; NHS Foundation Trusts; GMS or PMS practices under a separate Alternative Provider Medical Services (APMS) contract.

6. As with the other contracting routes, APMS can be used for the full range of primary medical services or for some of those services. So far, APMS has mainly been used for Out-of-Hours provision. However, more PCTs are now exploring use of APMS as a vehicle to provide full primary medical services or specific services for specific populations (e.g. sexual health services).

Dental services

7. From 1 April 2006 every PCT has:

   - a duty to secure or to provide primary dental services to the extent that it considers necessary to meet all reasonable requirements;

   - financial resources for primary dental services directly allocated to them to commission primary dental services from dental practices, dental corporate bodies or to provide the service itself;

   - the power to commission suitable 'high street' specialised dental services more cost effectively to help reduce outpatient waiting times for consultant led services; and

   - resources which remain with the PCT if a provider ceases to provide primary dental services, or reduces NHS commitment so the PCT can commission services from an alternative provider.

8. From 1 April 2006, regulations provide for two types of contract: general dental services (GDS) contracts and personal dental services (PDS) agreements.

9. Under a GDS Contract, the contractor is required to provide a full range of dental services known as 'mandatory services'. In addition, a GDS contract can include, with the agreement of the PCT, other 'additional services' such as sedation and orthodontics.

10. Practices limited to orthodontics provide orthodontic services under a PDS agreement. However, in a similar manner to GDS contracts, the services to be provided under a PDS agreement can also include mandatory services. In other material respects, the terms of contracts are similar under both the GDS contracts and the PDS agreements.

11. Remuneration under both the new contracts is not be on an item of service basis as under previous arrangements. This enables dentists to spend more time with their patients and adopt a more preventive approach to patient care than was possible under item of service payments.

12. There is a contractual requirement to provide a number of units of dental activity in each financial year and a similar requirement in relation to orthodontic activity where the contracts include orthodontic treatment. The number of units to be provided is linked to the annual value of the contract for both GDS contracts and PDS agreements.

Ophthalmic services

13. General Ophthalmic Services encompass NHS sight tests carried out by optometrists and ophthalmic medical practitioners.

14. The optometrist, ophthalmic medical practitioner or optical company apply for inclusion in the ophthalmic list of a Primary Care Trust to provide services, which are governed by statutory instrument, to members of the public who are eligible.

15. Patients who have received a NHS sight test, and who need glasses or contact lenses to correct their eyesight, receive a prescription showing the required strength and type of glasses or contact lenses.

16. Eligible patients also receive an NHS optical voucher, which they can use to meet (in whole or in part) the cost of these glasses or contact lenses. The General Ophthalmic Services budget is a national, demand led budget. Those who provide NHS sight tests currently receive a fee of £18.85 per test. This rate is negotiated with representatives of optometrists and ophthalmic medical practitioners. Optical vouchers currently range from £33.70 - £185.90 depending upon the patients prescription and is reviewed annually.

17. In August 2005, the Department of Health announced a review of the current system of General Ophthalmic Services (GOS). The review was conducted by the Department of Health and the primary focus of the review has been to examine how to support PCTs in commissioning a wider range of community based eye care services, where this is likely to improve patient experience and provide a cost-effective way of increasing capacity and choice. The main outcome of the review, which was launched on 17 January 2007, is a commissioning toolkit. The toolkit provides PCTs with practical advice on commissioning community-based eye care services. The toolkit sets out examples of pathways that make greater use of community-based services, e.g. for glaucoma patients. It explains how PCTs and practice-based commissioners can use the different stages of the commissioning cycle to test the potential benefits of applying new pathways and the factors to take into account in implementing such schemes.

18. To support PCTs in commissioning community-based eye care services, the Government introduced new legislation, in the Health Act 2006, which will allow the introduction of a more flexible, integrated framework for commissioning primary ophthalmic services. Its structure closely follows contractual requirements for doctors and pharmacies. It covers:

    - **essential** services, which all PCTs must commission and which any eligible person may contract to provide, i.e. the provision of NHS sight tests, which is specified on the face of the Act

    - **additional** services, covering any other services that all PCTs must commission and which are prescribed in regulations.

    - **enhanced** services, which PCTs may choose to commission.

19. Draft regulations to introduce this framework will be subject to wide-ranging consultation with stakeholders. The powers in the Health Act also allow PCTs to contract directly with dispensing opticians who own practices (and lay owned practices) that provide a sight testing service, rather than just optometrists, ophthalmic medical practitioners and companies on the General Optical Council's register as is currently the case.

Annex C: Wider policy initiatives

Reform of the public sector

1. The Government's vision is of excellence in public services, with services designed around the needs of users, delivered to uniformly high standards across the country, where staff work flexibly and are rewarded well.

2. To focus on the most challenging areas of service delivery: health, education, crime and asylum and transport, the Prime Minister set up a Delivery Unit in June 2001 under the leadership of Professor Michael Barber to bring about real and perceptible improvements in these priority areas. Working in partnership with Departments and the Treasury, the Delivery Unit focuses on problems and blockages to delivery and developing solutions.

Public sector reform and its underlying principles

3. The Office of Public Sector reform under the leadership of Dr Wendy Thomson is concentrating on ensuring that the wider public sector has the capacity, the structures, skills and the right incentives to be able to produce better services.

4. The government's reform programme is underpinned by the Prime Minister's four principles of public sector reform. These are:

   - a national framework of standards and accountability;
   - devolve more local power to the frontline to deliver those high standards;
   - more flexible working to keep pace with constant change and better rewards and incentives; and
   - more choice for customers and the ability, if provision is poor, to have an alternative provider.

5. These were most recently elaborated in the Public Sector reform paper *Building on Progress: Public Services* published on 19 March 2007.

The White Paper Our health, our care, our say

6. *Our health, our care, our say*: a new direction for community services was published on Monday 30 January 2006.

7. It set out a new strategic direction for improving the health and well-being of the population, and focuses on a strategic shift to locate more services in local communities closer to people's homes. The proposals build on the improvements already made to health and social care and reinforce the existing programme of NHS reform.

8. Key principles of the White Paper included:

- putting people more in control – for example, by piloting a new "life check" to help people in deprived areas assess and tackle their lifestyle risks;
- improving access to primary care – for example, through new incentives to GP practices to offer responsive opening times;
- improving access to community services – for example, by piloting individual budgets that bring together several income streams and put people more in control of their care packages;
- focusing support on the whole needs of individuals, especially those with long-term conditions and greatest need – for example, through integrated care plans; and
- shifting care closer to where people live - for example, through a new generation of community hospitals with strong ties to social care, and a shift in spending away from hospitals to more local settings. Over the next ten years, the Department wishes to see a shift of NHS resources from secondary to primary care - equating to more than £2.5 billion annually.

Practice Based Commissioning

9. At its simplest, practice based commissioning (PBC) is about practices taking on delegated indicative budgets to become more involved in commissioning decisions. PBC is designed to facilitate clinical engagement, improve access, extend choice for patients and help and restore financial balance.

10. PBC places primary care professionals including GPs, nurses and practice teams, working alongside secondary care clinicians and other frontline health professionals, at the heart of decision making to commission services for their local population. It enables them to redesign services that better meet the needs of their patients and more freedom to develop innovative, high quality services within a framework of

accountability and support that will ensure the best and fairest use of public resources.

11. PBC is expected to lead to local innovation resulting in flexible high quality services for patients. It means that patients can benefit from a greater variety of services from a larger number of providers in settings that are closer to home or more convenient for them as set out in the White Paper.

12. From April 2005, practices have been able to receive an "indicative budget" from primary care trusts (PCTs) that they can use to improve the delivery of services.

13. The Department has issued a series of guidance documents on PBC. Most recent guidance confirmed the direction of travel remains unchanged but it[23] clarifies a number of challenges, including:

- clarification and strengthening of governance and accountability arrangements to avoid potential conflicts of interest between the commissioner and provider roles within PBC;
- a methodology for setting indicative practice budgets for 2007/08, including new guidance on the pace of change and the use of resources freed up;
- clarification of the procurement rules for services commissioned through practice based commissioning and the need for tendering, along with the scope for local tariff flexibility.

Commissioning for health and well-being

14. On 6 March 2007, the Department launched its consultation on developing a commissioning framework for health and well-being. This means involving the local community to provide services that meet their needs, beyond just treating them when they are ill, but also keeping them healthy and independent. This framework builds on the White Paper *Our health, our care, our say*, and has a particular focus on partnership. It is for everyone who can contribute to promoting physical and mental health and well-being, including the business community, government regional

[23] Practice-based Commissioning guidance can be found on: http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/Commissioning/PracticeBasedCommissioning/PracticeBasedCommissioningArticle/fs/en?CONTENT_ID=4127126&chk=YwJOY9

offices and the third sector. It aims to help commissioners by showing how they can provide personalised services, promote health and well-being, proactively prevent ill health, and work in partnership to reduce health inequalities by focusing on outcomes for children and adults.

15. The consultation identifies eight steps to more effective commissioning.

1. Putting people at the centre of commissioning
This involves giving people greater choice and control over services and treatments (including self-care), and access to good information and advice to support these choices. Mechanisms will be developed to help the public get involved in shaping these services, with advocacy to support groups who find it hard to express views.

2. Understanding the needs of populations and individuals
Joint strategic needs assessment by councils, PCTs and practice based commissioners will help them to better understand the needs of individuals, by using recognised assessment and care planning processes appropriately, and mitigating risks to the health and well-being of individuals.

3. Sharing and using information more effectively
In order to make effective decisions for individuals and groups, we need to use and share information in an effective way. This includes clarifying what information can be shared under what circumstances, joining up the IT systems of front-line practitioners and encouraging individuals and communities to be co-producers of information.

4. Assuring high quality providers for all services
Commissioners should develop effective, strong partnerships with providers and engage them in needs assessments. Procurement should be transparent and fair. Commissioning will be focused on outcomes, leading to more innovative provision, tailored to the needs of individuals and supplied by a wider range of providers.

5. Recognising the interdependence between work, health and well-being
Commissioners can facilitate collaborative approaches with businesses to improve advice and support for individuals. Additionally, all providers of NHS care will be incentivised to support and promote the health and well-being of their employees.

6. Developing incentives for commissioning for health and well-being
Bringing together local partners using Local Area Agreements will help to promote health, well-being and independence, by using contracts, pooling budgets and using the flexibilities of direct payments and practice based commissioning.

7. Making it happen – local accountability
The Department of Health and the Department for Communities and Local Government will develop a single health and social care vision and outcomes framework, including a set of outcomes metrics aligned with the framework.

8. Making it happen – capability and leadership
The Department of Health and other national stakeholders will provide support to all local commissioners to address their capability gaps, where these national organisations can add real value. This support will be tailored to different types of commissioners – PCTs, practice based commissioners and local authorities.

System reform

16. On 27 November 2006, the Department published two consultation documents:

    - *The future regulation of health and adult social care in England*; and
    - *Code of Practice for Promotion of NHS services,* which covers promotional activity directed at both the public and commissioners.

17. The future regulation of health and adult social care in England took forward a commitment to provide a clear and refocused approach to regulation and a framework for management of the health and adult social care systems in a reformed NHS.

18. It supports the shift in all public services from top-down, target-driven performance management to a more bottom-up, self-improving system built around the individual needs of service users and influenced by effective engagement with the public. Increasingly, improvement is to be driven by the choices made by service users and healthy competition between different service providers.

19. It describes how independent regulation is to support these changes in future, in line with the principles of better regulation. The overall aim is to give people the best and safest care possible, with the best possible value for public money. Effective management of the system backed by

regulation to ensure NHS providers meet accepted safety, quality and governance standards will give patients and service users confidence that whichever provider they choose, whether public, private or third sector, they can be assured of a safe and high quality service.

20. Inspection bodies will be merged to enable a more flexible response to an evolving adult health and social care system.

21. The document set out seven regulatory functions needed to manage the reformed NHS and adult social care systems:

    - Safety and quality assurance
    - Promoting choice and competition
    - Commissioner assurance
    - Information and performance assessment of providers
    - Price-setting and allocations
    - Stewardship of public assets
    - Support, intervention and administration of failure.

22. It also sought views on the implications of the proposals for the regulation of other types of NHS service, such as primary medical care.

23. The Code of Practice for Promotion of NHS services describes how a self-regulatory approach to promotional activity will support these changes, ensuring that information is accurate and reliable.

24. Consultation on these documents ended on 28 February 2007 and the Department intends to publish a summary of responses in due course.

Annex D: Key questions

To support the review, Anne Galbraith has identified certain key questions to discuss with stakeholders in forthcoming meetings.

Pharmaceutical contractual arrangements are not covered by contracts as such in the accepted sense. Rather, the Schedules to the NHS (Pharmaceutical Services) Regulations 2005 as amended set out the main agreed contractual terms of service with which all contractors must comply to provide services. These terms and conditions vary between pharmacies, dispensing doctors and appliance contractors. Schedule 1 contains the requirements for community pharmacies, Schedule 2 for dispensing doctors and Schedule 3 for appliance contractors.

- **What are the strengths and weaknesses of current contractual arrangements for patients and consumers, the NHS and business?**
- **What barriers are there to developing and improving these?**
- **Are there particular legal, operational or financial factors?**
- **What contractual options are there?**
- **Where does the balance between terms and conditions decided centrally (and applied nationally) and local contractual arrangements lie?**

Pharmaceutical contractual arrangements contain certain minimum elements, criteria and standards which are applied nationally to all contractors and others which are determined locally. All arrangements involve a degree of compromise between the parties. In reforming them, which elements and criteria should be retained, improved or removed? What needs to change to the current framework and operational system? What minimum safeguards should underpin such arrangements?

- **How should contractual arrangements develop to improve access for patients to community-based services and best meet their differing needs?**
- **How should arrangements develop to improve consumer choice?**
- **Will such developments impact differently on patients and consumers?**

Patients and consumers have different requirements and expectations of pharmaceutical services. Which factors are common and which different?

- **How can arrangements develop to maximise value for money for the NHS?**
- **How could service contestability and competition be improved?**

The NHS makes a significant investment in pharmaceutical services. Current contractual arrangements are largely determined centrally and contractual terms set out in Regulations rather than a formal contract. This can be inflexible and insensitive to local needs. Yet, once granted, a contractor enjoys a continuing right to provide services, provided national terms and conditions are met. How should this develop?

- **How can business and contractor confidence and certainty be improved?**
- **What contractual and financial arrangements will best support your commitment and investment for patients and the NHS?**

The control of entry review report found that current arrangements had not improved certainty for business. What steps are needed to address this?

- **How can pharmaceutical arrangements best mesh with wider NHS developments such as practice-based commissioning?**
- **How can we best ensure such arrangements are fair, equal and equitable to all?**
- **How can any new arrangement best reward high-quality service provision?**
- **Are there particular factors to consider for transitional arrangements?**

The NHS is undergoing a seismic shift to provide personalised services closer to home in line with the White Paper commitment and ambitions. An important part of this is to tailor future service provision to meet individual needs and preferences. Practice-based commissioning is key to this. Yet national contractual arrangements may be out of line with PCTs' new commissioning roles and responsibilities and can be a blunt tool which hinders rather than supports this direction. What needs to change to ensure we can devise arrangements to help pharmaceutical commissioning fit best with this direction and to promote equal and equitable access for patients and consumers? Payment systems are also often geared to numbers and outputs. Whilst this has already changed under new contractual arrangements, what more can we consider doing which further shifts payment from outputs to outcomes – i.e. maintained and improved health outcomes – and rewards quality?

With any change, we also need to consider what special provisions need to be considered to ensure a smooth handover to any new system.

If there was just one thing you could keep, what would that be?
If there was just one thing you could change, what would that be?

Annex E: Glossary of Terms

ADR	Adverse Drug Reaction
AIMp	Association of Independent Multiple Pharmacies
APMS	Alternative Provider Medical Services
APPG	All Party Pharmacy Group
BMA	British Medical Association
BMJ	*British Medical Journal*
CCA	The Company Chemists' Association Ltd.
CHD	Coronary Heart Disease
COPD	Chronic Obstructive Pulmonary Disease
CPD	Continuing Professional Development
CPPI	Commission for Patient and Public Involvement
DAC	Dispensing Appliance Contractor
DD	Dispensing Doctor
DDA	The Dispensing Doctors' Association Ltd *or* Disability Discrimination Act
DH	Department of Health
EHC	Emergency Hormonal Contraception
ESP	Essential Small Pharmacy
GMS	General Medical Services
GPC	General Practitioners' Committee *or* General Pharmaceutical Council
GSL	General Sales List (a category of medicine)
IPF	Independent Pharmacy Federation
LES	Local Enhanced Services
LIFT	Local Improvement Finance Trust
LMC	Local Medical Committee
LMCA	Long-term Medical Conditions Alliance
LPC	Local Pharmaceutical Committee
LPS	Local Pharmaceutical Services (contract)
LRC	Local Representative Committee
MDS	Monitored Dosage System
MPIG	Minimum Practice Income Guarantee *or* Medicines, Pharmacy & Industry Group (DH)
MUR	Medicines Use Review (a medicines use "MOT")

NHS	National Health Service
NHSC	NHS Confederation
NHSE	NHS Employers
NICE	National Institute for Clinical Excellence
NPA	National Pharmacy Association
OFT	Office of Fair Trading
OTC	Over the Counter (medicines)
'P'	Pharmacy-only (a category of medicine)
PBC	Practice Based Commissioning
PCT	Primary Care Trust
PCTMS	Primary Care Trust Medical Services
PEC	Professional Executive Committee
PGD	Patient Group Direction
PhS	Pharmaceutical Services
PJ	*Pharmaceutical Journal*
PMR	Patient Medication Record
PMS	Personal Medical Services *or* Primary Medical Services
PNA	Pharmaceutical Needs Assessment
POM	Prescription-only medicine (a category of medicine)
PPRS	Pharmaceutical Price Regulation Scheme
PSNC	Pharmaceutical Services Negotiating Committee
QOF	Quality and Outcomes Framework
RD	Repeat Dispensing
RPSGB	Royal Pharmaceutical Society of Great Britain
SFE	Statement of Financial Entitlements
SPA	Small Practices Association