Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change

Consultation Document

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Description	The Pharmacy White Paper (Cm 7341) promised to publish, for consultation, fuller information on a number of proposals for structural change. This consultation fulfils that commitment and comprises proposals to reform pharmaceutical services legislation and proposals to revise the current regulatory system pending those reforms.
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Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change

Consultation Document

Prepared by: Medicines, Pharmacy and Industry – Pharmacy Team

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Executive summary

- In July 2007, the Minister of State for Public Health, the Rt Hon Dawn Primarolo, MP announced that the Department of Health would publish a pharmacy White Paper.

- *Pharmacy in England: Building on strengths - delivering the future* was accordingly published on 3 April 2008. It builds on *A Vision for Pharmacy in the new NHS* launched in July 2003 and *Our health, our care, our say: a new direction for community services* published in January 2006.

- The White Paper set out the Government's programme for a 21st century pharmaceutical service and identified practical, achievable ways in which pharmacists and their teams can contribute to improving patient care through delivering personalised pharmaceutical services in the coming years. A series of consultation events were held in May to consider the proposals in more detail and a summary report of those is now available at http://www.dh.gov.uk/en/Publicationsandstatistics/index.htm.

- The White Paper was developed to align closely with the NHS Next Stage Review led by Lord Darzi and the development of a new primary and community care strategy. *High Quality Care for All* - the *NHS Next Stage Review* final report - was published on 30 June 2008 and *Our Vision for primary and community care* was published on 3 July 2008.

- The White Paper also provided the Government's response to the *Review of NHS pharmaceutical contractual arrangements* commissioned in 2007 and conducted by Anne Galbraith. Her report was published alongside the White Paper. In addition, the White Paper took account of recommendations of the All Party Pharmacy Group' report, *The Future of Pharmacy* published in June 2007.

- The pharmacy White Paper stated at paragraphs 1.7 and 1.8: 'As part of the development work to align pharmacy with the primary and community care strategy, the Government intends to publish, for consultation later in 2008, fuller information on a number of proposals for structural change. That consultation will comprise both actions to be taken in the medium term – including any necessary revisions to primary legislation – and actions to reform the current regulatory system pending those revisions'.

- This consultation fulfils that commitment. In compliance with the Cabinet Office Code of Practice on Consultation, it discusses a number of changes and levers which the Department believes are needed to transform delivery and to align pharmaceutical services within the wider reform programme. Where a change in legislation is indicated, this will apply in England.

Content

- Chapter 1 provides background information about pharmacy as part of the vision for delivering *High Quality Care for All* and *Our vision for primary and community care.*

- Chapter 2 proposes changes to the current NHS market entry system called 'control of entry' to one based on PCTs' assessments of local needs to commission services which promotes choice and competition in the delivery of clinical care and ensures high standards, quality and good patient outcomes for the investment made. It also sets out proposals to enable PCTs to take effective action on quality grounds where contractors are not achieving acceptable performance standards.

- Chapter 3 proposes changes to the current arrangements for pharmacies opening at least 100 hours per week. It also proposes introducing 'supplementary lists' for individual pharmacists and discusses compliance with the Safeguarding Vulnerable Groups Act 2006.

- Chapter 4 sets out proposals for possible reform of arrangements where doctors provide dispensing services, mainly in rural areas, together with a single regulatory entry system for pharmacies and dispensing doctors.

- Chapter 5 discusses market entry proposals for dispensing appliance contractors and a system for appliance contractors comparable to pharmacists' supplementary lists.

- Chapter 6 presents proposals for reforming the NHS (Pharmaceutical Services) Regulations 2005 and current legislation relating to Local Pharmaceutical Services.

- Chapter 7 sets out the questions arising from these proposals on which the Department welcomes views.

- A list of those organisations being consulted is at **Annex A**. Background information to the current market entry and contractual arrangements for community pharmaceutical services is at **Annex B**.

- Partial impact assessments are published alongside this consultation document and can be found at www.dh.gov.uk/Consultations together with an Equality Impact Assessment.

- A template for consultation responses is also included and published separately at www.dh.gov.uk/Consultations.

Responding to this consultation

- Responses should be sent no later than **Thursday 20th November 2008** to: PWPCONS@dh.gsi.gov.uk. Alternatively, copies can be sent by post to:

  Gillian Farnfield
  Department of Health
  Medicines Pharmacy and Industry Group
  Area 453D, Skipton House
  80 London Road
  London
  SE1 6LH

National Listening Events

- The Department will host with NHS Primary Care Contracting a series of national listening events to support this consultation. These will begin later in the autumn and details of how to book will be available as soon as possible at www.pcc.nhs.uk.

Contents

Chapter 1: Introduction and policy background

1. *High Quality Care for All*[1] - the *NHS Next Stage Review* final report - was published on 30 June 2008. It set out our vision of an NHS that gives patients and the public more information and choice, works in partnership and has quality of care at its heart – quality defined as clinically effective, personal and safe. The changes that are now being taken forward, locally and nationally, will see the NHS deliver high quality care for all users of services in all aspects, not just some. It will see services delivered closer to home, a much greater focus on helping people stay healthy and a stronger emphasis on the NHS working with local partners. Pharmacy has a key role to play in delivering this vision, particularly as a provider of services which prevent ill-health, promote better health for all and improve access to services within communities.

A Vision for Pharmacy in the New NHS

2. In the last five years, the pace of change for NHS community pharmaceutical services has probably been more rapid than at any other time in the last 60 years. In that same period, community pharmacy has featured more prominently in how to improve services, how its potential can be more widely recognised by the NHS and by other health professionals, and how its ability to respond innovatively and creatively can be better utilised. That is what the Department intended when it launched *A Vision for Pharmacy in the New NHS* in July 2003. That identified and aligned the Department's ambitions for pharmacy clearly and rightfully alongside the wider ambitions for the NHS as a whole.

A new contractual framework for community pharmacy

3. As part of that Vision, a new community pharmacy contractual framework was put in place in April 2005. It comprises three tiers of services – essential, advanced and local enhanced services. Broadly, essential services are those which every pharmacy must provide, including dispensing. Advanced services are those which, subject to accreditation requirements, a pharmacy contractor can choose to provide. At present, there is one advanced service - the Medicines Use Review (MUR) - where a pharmacist discusses with a patient their use of the medicines they are taking and whether there are any problems which the pharmacist can help resolve. Essential and advanced services are determined nationally. Local enhanced services, such as stop smoking schemes, pharmacy support for people with minor ailments and help for substance

[1] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

misusers, are commissioned locally by PCTs direct with contractors. More information on the framework is available at **Annex B**.

Our health, our care, our say

4. The White Paper *Our health, our care, our say* launched in January 2006 set out a new strategic direction for improving the health and well-being of the population. It focused on a strategic shift to locate more services in local communities closer to people's homes.

The pharmacy White Paper, *Pharmacy in England - Building on strengths delivering the future*

5. The pharmacy White Paper *Pharmacy in England: Building on strengths - delivering the future* published on 3 April 2008 built on this and describes the Department's programme for a 21st century pharmaceutical service.

6. It identifies practical, achievable ways in which pharmacists and their teams can improve patient care in the coming years. It sets out a reinvigorated vision of pharmacy's potential to contribute further to a fair, personalised, safe and effective NHS. This vision demonstrates how pharmacy can continue, and expand further, its role in an NHS that focuses as much on prevention as it does on treating sick people, helping to reduce health inequalities, supporting healthy choices, improving quality and promoting well-being for patients and public alike.

7. At the same time, the Department published Anne Galbraith's report *Review of NHS pharmaceutical contractual arrangements*[2]. This made a number of recommendations for reform to which the White Paper responded.

Structural changes

8. The White Paper also identified a number of areas where the Government believes there is a case for changes to the structures underpinning delivery. These were set out primarily in Chapter 8. The White Paper promised that full consultation on these ideas would follow publication of the primary and community care strategy.

National Listening Events

9. In preparation for this consultation, the Department co-hosted, with NHS Employers and NHS Primary Care Contracting, a series of national listening events in May to support the launch of the pharmacy White Paper. Over 630 delegates attended, drawn from the

[2] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083815

NHS, the professions and representative bodies. The events gave delegates the opportunity to consider and to discuss the proposals in more detail, including a number of the key ideas for structural change. The report of those events, which have developed the ideas set out in the White Paper and informed this consultation, is now available at www.dh.gov.uk/en/Publicationsandstatistics/index.htm. Summaries of the feedback are included in this paper.

The NHS Next Stage Review

10. *High Quality Care for All* describes how the NHS will have high quality at the heart of everything it does, with standards driven up through greater transparency, patient choice and innovation. A draft NHS Constitution, itself now subject to consultation, sets out for the first time the purpose, principles and values of the NHS, and the rights and responsibilities of patients, the public and NHS staff.

11. *Our vision for primary and community care*[3] published on 3 July 2008 as part of the Review, describes in more detail how we, locally and nationally, will ensure high-quality care is a consistent part of everyone's experience of primary and community care. It sets out four key themes for achieving this:

- Patient centred services that are personalised and responsive, built on systematically listening to and acting upon patient views;
- Promoting healthy lives and wellbeing with services that support people in staying healthy, improve access to a range of healthy living services and tackle health inequalities;
- Continuous improvement through a programme of professional development for staff with information tools to compare clinical quality, productivity and patient experience and by an independent, transparent process for developing and reviewing indicators of performance focussed on health outcomes and patient experience; and
- Local leadership, including empowering PCTs to develop their commissioning skills in primary care to deliver better health, better care and better value; and ensuring local decisions lead to a greater and more integrated range of community services.

[3] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085937

This consultation

12. Based on the strategic vision set out in *High Quality Care for All* and taking account of feedback from delegates at the national listening events, the Department has reviewed and refined the proposals set out here for structural change. In summary, the following chapters comprise a series of possible reforms and actions which would enable:

- A stronger focus on commissioning for quality that addresses local needs with adequate powers to tackle poor performance;
- Reforming market entry arrangements for pharmacies providing services for at least 100 hours per week and introducing fitness to practise requirements for individual pharmacists which take account of the need to comply with the Safeguarding Vulnerable Groups Act 2006;
- Revisions to the current regulatory criteria for dispensing doctors, a common regulatory route for their applications and the sale of over the counter medicines by dispensing doctors;
- Revisions to market entry for appliance contractors together with a performance regime for individuals who assist appliance contractors in the provision of services; and
- Amendments to the NHS (Pharmaceutical Services) Regulations 2005 and to the provisions governing local pharmaceutical services (LPS) contracts.

13. The White Paper also contained a commitment (paragraph 8.39) to include in this consultation possible future payment mechanisms to support the introduction of new pharmaceutical services. This was to follow further discussions with the NHS and the Pharmaceutical Services Negotiating Committee (PSNC) which represents pharmacy contractors. In the light of these discussions, all parties have agreed it would be premature to proceed with this proposal at this stage. Further discussions need to take place on the shape and scope of these new services and how payment mechanisms can best support both secure income streams and reward quality delivery before proceeding. The Department will come forward with proposals once these discussions are complete. However, at this stage, the Department does not consider these will require changes to the current legislation.

Chapter 2: A stronger focus on commissioning for quality which addresses local needs

Market entry based on Primary Care Trusts' assessments of local pharmaceutical needs – the Pharmaceutical Needs Assessment (PNA)

What is the problem?

1. Chapter 8 of the White Paper[4] identified a number of shortcomings with the current arrangements governing the system which determines whether a pharmacy provides NHS pharmaceutical services. These are inconsistent with the direction of NHS reforms and the desire to give PCTs more responsibility to secure effective commissioning of adequate services which address local priorities.

2. Such shortcomings are reinforced by the broad themes identified in *High Quality Care for All*. This strengthens the case for reform to current arrangements so that they can better meet the challenges for fulfilling this vision. If PCTs, in developing their commissioning skills, are to be held accountable for delivering pharmacy's contribution to health improvement, they in turn must have adequate means by which they are able to determine from whom, when and where quality services are provided. Just as providers need to have a funding system which provides confidence to invest, so PCTs need to have proportionate and adequate powers to commission according to local needs and govern their financial liabilities and commitments.

3. *Our vision for primary and community care* developed this further. It identified a need for PCTs to move from the relatively narrow focus of administering primary care contractual arrangements to applying the full range of commissioning competences. The areas PCTs will be focussing on in future include:

    - working with clinicians, local authorities and the public to understand the needs of local communities and agree how these are reflected in quality specifications for services and the outcomes for which primary care providers are accountable;
    - developing primary care contracts to ensure increasing incentives for investment in prevention and early identification and management of risk;
    - providing clear, published information for the public about the range and quality of primary care services so that individuals increasingly can make choices; and
    - stimulating innovation and choice by developing markets in primary care.

[4] Paragraphs 8.2 – 8.17

4. As part of the World Class Commissioning Programme, the Department is developing a support programme for PCTs which will rapidly enhance their skills in commissioning primary and community care. An initial guide on the commissioning of primary care is being developed and will be published in autumn 2008. This will be followed by a programme of practical guides and masterclasses to support PCT implementation. Over the next year, the range of support and development available to PCTs will be further enhanced to include:

- predictive modelling and other tools to profile the needs of different segments of local communities;
- developing datasets to collect, analyse and publish information on performance against quality criteria; and
- managing contracts more effectively to identify and tackle poor performance.

5. The Galbraith *Review of NHS pharmaceutical contractual arrangements* echoed this programme. It found a need to strengthen PCTs' commissioning roles to stimulate competition and to ensure that future contractual arrangements were founded on the services to be provided and their quality, not simply on market entry. It recommended that PCTs should undertake a more rigorous assessment of local pharmaceutical needs to provide an objective framework for future contractual arrangements and market entry. This should set out the requirements for all potential providers to meet, but be flexible enough to allow PCTs to contract for a minimum service to ensure prompt access to medicines and the supply of appliances where needed, for example in more rural areas.

6. The White Paper endorsed those recommendations, as part of the World Class Commissioning Programme and as part of the longer-term strategic commissioning direction of continuous service improvement through evidence-based commissioning using local needs assessments.

7. It did however identify[5] a number of important transitional milestones for pharmaceutical services to achieve this direction. These are:

- ensuring commissioning meets local needs and links to practice-based commissioning;
- revising arrangements for contracting for services;
- revising payment mechanisms for such services; and
- ensuring high quality and safety in delivering services.

[5] see paragraph 8.16

8. Once these are in place the White Paper went on to say that unnecessary market entry and exit barriers can be removed to be replaced with criteria which place safety, quality and outcomes at the heart of delivery.

9. Revising contracting arrangements – such as introducing new directed services - and the payment mechanisms to support these do not require, in the Department's view, changes to the current legislative structure. Ensuring both commissioning meets local needs and high quality and safety in delivering services, however, do.

What needs to change?

10. For the last 20 years or so, whether or not a pharmacy contractor provides NHS services has been largely determined by the regulatory system known as 'control of entry'. This is set out in section 129 of the NHS Act 2006 and implemented in the 2005 Regulations. Broadly speaking, an application will only succeed if a PCT considers it necessary or expedient[6] to grant it in order to secure adequate provision of NHS pharmaceutical services locally. There are also certain complete exemptions to this test. Over the years, this test has been subject to considerable review by the Courts. Those decisions have established various precedents and criteria as to how PCTs should consider applications.

11. The effect of this, in the Department's view, is to limit what further changes might be introduced under the current legislation. To achieve the first milestone – to ensure commissioning meets local needs – requires in the Department's view a fresh approach.

12. A new legislative basis should aim to achieve a better balance between the needs of PCTs as commissioners and the certainty pharmaceutical services providers want to invest to provide services. Importantly, the legislative regime should not inhibit, and should encourage where possible, stronger relationships between commissioner and contractor as well as stimulating competition and innovation whilst not undermining the collaboration between professionals which helps ensure safe and consistent patient care. It should also provide a more objective basis than the current test for determining whether or not the NHS will agree to commission new providers or existing providers who wish to expand service provision.

Feedback from the national listening events

13. There was general support for the strategic approach to Commissioning for Quality, as set out in Chapter 8 of the White Paper including for robust pharmaceutical needs assessments (PNAs) that are integrated within Joint Strategic Needs Assessments and

[6] See Chapter 6. This consultation proposes changing the current wording in the 2005 Regulations from 'necessary or desirable' to 'necessary or expedient'.

responded to in PCT commissioning plans. There should be a strong evidence base to inform this assessment and pharmacists, other providers of pharmaceutical services and the public must be able to inform the PNA. It was felt that PCTs must take a comprehensive and consistent approach to PNAs, supported by a national template and robust data, and they could be jointly developed across PCT boundaries, as appropriate.

What we propose to do

14. The Department therefore proposes to replace the current market entry test with one determined by reference to local PNAs. Most PCTs already have a PNA as a result of the regulatory reforms introduced in 2005. However, their consistency, breadth and depth are variable. By legislating in this way, PNAs will be woven more closely into PCTs' strategic planning and commissioning processes and implementation programmes. NHS Employers are setting up a short-term working group to review requirements and develop a support programme for PCTs.

15. Once PCTs have reviewed and revised their PNAs where necessary, they will form a more comprehensive and rational basis than the current market entry test. Importantly, they should also help stimulate the market where needs are identified which are not being met currently. Because PCTs are currently required to consider applications in respect of distinct 'neighbourhoods', an issue which has created uncertainty for PCTs and has given rise to action in the Courts, a specific need for this reference within the legislation could be removed. It would be replaced by the overall assessment of needs locally carried out by the PCT. However, this would not prevent PCTs considering commissioning based on their assessment of the needs of discrete localities. This new test would also be applied where a PCT invited applications, or where a replacement pharmacy was needed either because of withdrawal from the market or the right to provide NHS services has been withdrawn, for example due to underperformance (see further below). The legislative framework should also not prevent applications being made to the PCT where a local need is identified which is currently unmet and for which there is a reasonable prospect the need will continue.

16. An important consideration is that this new criterion should not be used simply as an excuse for PCTs to refuse to commission new, or simply to reduce existing, provision without sound and objective grounds. Therefore, the Department considers that in moving to such a system, some safeguards will be needed. At a minimum, it will be necessary for PCTs to demonstrate that they have considered new applications

- objectively against their PNAs;
- fairly and without bias to applicants compared with existing providers; and
- which set out transparently the basis and reasons on which they have reached their decisions.

17. The Department believes that other factors in deciding applications would also be useful for PCTs to help facilitate this new legislative regime. These factors would help promote a better balance between the interests of PCTs and the interests of applicants than is evident in the current system. The PCT would have sufficient control over service provision for which it is responsible whilst the applicant would have a reasonable prospect of success provided it is meeting local needs. This 'balancing' requirement would help promote greater objectivity and transparency as well as reducing the risk of any inadvertent bias in PCT determinations. At the same time, it would also help bolster PCTs' decisions where there was no clear or justifiable need to approve an application.

18. The Department proposes, therefore, that as part of a new legislative structure, to carry forward existing factors introduced in the 2005 Regulations to the current 'control of entry' test. Further information about the way in which these factors work is available in the current February 2007 edition of *Information for PCTs* accompanying those Regulations[7] but in summary these additional factors would be:

- the level of access;
- the choice and diversity of providers or of services;
- innovation in service delivery;
- the services available to specific populations or to meet specific health conditions or disease needs; and
- the overall longer-term impact of approving new applications.

19. Therefore, a revised test would mean that applications would be determined in future under a two-part process. First, a PCT would be obliged to grant an application where it is satisfied that to do so will secure or will help secure the overall adequacy of pharmaceutical service provision in its area judged against the PNA. Second, a PCT would grant the application if it considers that, judged against the PNA, it would secure these improvements in or improved access to the provision of pharmaceutical services for that area when considered against these range of factors. The Department considers it may be beneficial to introduce these new legislative powers in such a way that they can be tested and evaluated before wider introduction. In addition, as suggested at the listening events, neighbouring PCTs will want to be able to consult each other in developing their PNAs and, where they identify joint needs, commission services to address such needs.

20. The Department also believes it will be important, as now, that PCT decisions can be appealed to an independent body which would arbitrate over disputed questions.

[7] www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Communitypharmacy/NHSpharmaceuticalregulations/Controloentry/index.htm

21. Our current thinking is that the basis for an appeal against a PCT decision would be that an appellant could demonstrate that a PCT has failed to take into account the overall factors that are required for PCTs to reach a decision. In view of its experience of operating the current appeals procedures, the Department considers that an appropriate body to undertake this role would be the NHS Litigation Authority.

22. Under the new arrangements, the Department's view, at this stage, is that the need for the current exemptions for pharmacies opening in large out of town shopping centres, in large primary care centres or for at least 100 hours per week would probably disappear. However just as with the current system, it may also be necessary to allow for exceptions to this general rule. For example, the position of market entry arrangements for appliance contractors is discussed in Chapter 5. Equally, there may be other types of contractor who may be likely to lie outside such a new regime – for example, wholly mail order or internet-only pharmacies who may provide services across several PCTs or nationwide or those who provide specialist pharmaceutical healthcare services to people in their homes and who do not wish to run a traditional pharmacy. PCTs may therefore wish to have the power to commission less than the full range of current essential services from a particular provider where, for example, the need for dispensing services is already met but the need for more specialist services is not. The Department would therefore expect, as now, to retain a general power to make any exceptions to this new system as are considered appropriate.

23. The partial Impact Assessment accompanying this proposal indicates it would cause some additional costs to the NHS of just under £100,000. The potential net benefits are estimated at this stage at £320 million.

Questions for consultation

The Department proposes amending legislation to replace the current market entry system based on the 'necessary or expedient' test with one based on a PCT's assessment of local pharmaceutical needs and to introduce specific factors which a PCT would take into account in determining applications.

Do you agree the current market entry system should be changed to one based on pharmaceutical needs assessments (PNAs)?

What safeguards may be appropriate to ensure transparent, fair and unbiased consideration of applications?

Do you agree that specific additional factors, as identified in this Chapter, should also be introduced to help PCTs determine applications?

Should decisions be appealable and, if so, to whom?

Do you agree exceptions to this new system may be necessary and, if so, what might these exceptions be?

If introduced, do you agree such an approach should be piloted and evaluated before introduction?

Adequate powers to tackle poor performance

What is the problem?

24. In *Our vision for primary and community care*, the Department has stated that quality should be the principal means by which contractors should be judged to provide services. High-quality services, which are responsive to patients and achieve good outcomes, will thrive and be better able to re-invest resources to improve the range of services for patients. The pharmacy White Paper stated[8] that the Government wished to ensure there were effective sanctions to address poor performance. It is important that the NHS has adequate powers to take proportionate but sufficient action against the minority of pharmaceutical contractors who may not consistently perform to the same quality levels as are widely achieved and accepted within the profession and expected by patients and the public.

25. This principle applies equally where performance of NHS contractual responsibilities gives grounds for concern – for example, where there are repeated minor safety incidents or risks which individually do not pose a serious or immediate risk to the public or to public health but cumulatively may indicate action is required.

26. There are currently powers under sections 151 and 152 of the NHS Act where the NHS can take action on grounds of a contractor's continuing 'fitness to practise'. Introduced originally to address safety concerns following the case of Dr Harold Shipman, these provisions address performance on the grounds of a contractor's or an individual healthcare professional's fraud, suitability or efficiency. These powers apply to the contractors who are listed as pharmaceutical service providers with their local PCT. The Department is, as part of this consultation, proposing to introduce the same regime for individual pharmacists and others who assist in the provision of pharmaceutical services (for further details see Chapters 3 and 5).

27. The Department therefore wishes to consider whether the NHS currently has sufficient explicit legislative powers to allow a contractor's performance to be reviewed and considered on the basis of the quality of services delivered.

[8] Paragraph 8.41

Feedback from the national listening events

28. Delegates considered that an approach which facilitates quality standards and continuous improvement, and which is applied consistently across pharmacy and other providers, should motivate pharmacists as well as contractors. Payment structures in the longer term should reward successful patient outcomes to support the provision of high quality services – for example, a system along the lines of primary medical services' Quality and Outcomes Framework (QOF). They recognised this would take time to develop. In the meantime, payment mechanisms should support and reward a culture shift that encourages continuous quality improvement, including the development of staff and the collection and use of robust, meaningful, data that demonstrate key patient outcomes. A national performance management toolkit would support a consistent PCT approach. PCTs also need greater flexibility in the use of sanctions - for example, withholding or reducing payments.

What needs to change?

29. Introducing legislative provisions which expressly allow for action directly related to the quality of delivery and performance would not only clarify the law but also provide a legislative basis on which incentives for contractors to improve delivery could be introduced. It would provide PCTs with an explicit power to de-commission services from poorly performing providers or those who do not consistently meet minimum acceptable quality standards. This would provide opportunities for improved competition and new market entry where needed.

30. The Department is currently reviewing the existing legislation concerning a contractor's fitness to practise and whether this will achieve the objectives to introduce adequate sanctions to address poor performance. A further Impact Assessment will be prepared once that review is complete. If those powers are considered sufficient, the Department would not expect to bring forward further legislative proposals but to use existing powers to meet the desired objectives

31. There are also provisions in the current legislation that allow a time limit to be placed on the period for which an applicant is included on a PCT pharmaceutical list. However, there is no equivalent provision for those contractors who are already included on that list. It may be appropriate, as one of the mechanisms to support quality performance, that where there are concerns, there should be an explicit power for strong levers to address poor quality so that PCTs can more effectively manage market exit. This might be achieved by PCTs issuing remedial action notices with the consequence of de-listing if issues are not addressed satisfactorily within a set timescale.

32. A further power that may be appropriate is that where contractors fail to demonstrate they have provided services to the required quality and standards, PCTs would be able to withhold part or all payments due for that service.

What we propose to do

33. *High Quality Care for All* explicitly relates quality to what is clinically effective, personal and safe[9]. To help make quality information more readily available, the Department will require, in legislation, healthcare providers working for or on behalf of the NHS to publish 'Quality Accounts' from April 2010, just as they publish financial accounts. These reports will provide the public with information on the quality of services provided in terms of their safety, experience and outcomes. Over and above this, the Department is considering whether, if necessary, to introduce legislation to ensure that there are clear powers which enable PCTs to take appropriate action where indicated against listed contractors on the grounds of the inadequate quality of their services. This provision would establish a direct link between the quality of services provided with the power to take appropriate action against the contractor where this level of quality is not met, or is not met consistently. The Department expects PCTs would wish to have flexibility in terms of the options for action that are available to them to deal with such situations. Such action could include, but not be limited to, the ability to set a time limit on contractors or to withhold payments for contractors who do not perform to accepted quality and standards.

34. 'Quality' is of course a wide term. In addition to the explicit criteria of safety, outcomes and patient experience in *High Quality Care for All, q*uality might also be defined by reference to contractual terms of service, to governance arrangements, to the standards of premises, qualifications and experience of staff, to training programmes, or minimum service delivery standards. The Department would expect to set out the detail of such a new regime in Regulations.

35. The Department considers it will be important that those affected have the right to appeal a PCT decision just as they already do under the current 'fitness to practise' regime.

36. The partial Impact Assessment accompanying this proposal indicates there would be additional administrative costs for the NHS and for contractors of around £1.2 million per year. The potential net benefits from introducing this proposal are estimated at this stage at £1.6 million.

9 op. cit. Chapter 4

Questions for consultation

The Department proposes introducing legislation to create an explicit power which enables PCTs to take action against listed contractors on the grounds of the inadequate quality of their services.

Do you think we should introduce explicit criteria of quality to govern market exit?

Do you consider existing legislative powers under 'fitness to practise' are adequate or not? If not, what quality criteria might be used?

Do you agree that PCTs should have the ability to issue remedial action notices with the consequence of de-listing if issues are not addressed satisfactorily within a set timescale or to withhold payments for contractors who do not perform to accepted quality and standards?

If introduced, do you agree there should be an independent appeals mechanism?

Are there other factors the Department needs to consider?

Chapter 3: Community pharmacies and pharmacists

Market entry arrangements for community pharmacies open at least 100 hours per week

What is the problem?

1. In 2006, the Department completed a review of the reforms introduced in April 2005 and published its report in January 2007[10]. This showed that despite earlier misgivings within the industry, the 100 hours per week exemption was by far the most popular. In 2005/06, it accounted for over two-thirds of all exempt applications with 58% of these approved. However, an unanticipated outcome was the emergence of several 'copycat' exempt applications relating to the same area or PCT where applicants would 'jockey for position' close to new developments such as large GP surgeries.

2. The Department's conclusion then was that patients and some NHS respondents reported access had improved where 100 hours per week pharmacies opened, for example in under-provided or rural areas, with no evidence of an *overall* adverse impact on the network. However, It did report problems for the NHS and business in relation to pharmacies opening at least 100 hours per week.

3. The White Paper set out[11] the considerable problems reported by the NHS with this exemption. The White Paper summarised these as:

    - a lack of PCT control over where such pharmacies are located;
    - no match between the better access that a 100 hours per week pharmacy delivers to the need for such an improvement locally;
    - clustering of 100 hours per week pharmacies close to each other or around income sources; and
    - unbudgeted additional expenditure, if thresholds for extra allowances payable under the community pharmacy contractual arrangements are reached, at a cost to the PCT of some £25,000 per annum per 100 hours per week pharmacy.

4. These problems were echoed in the Galbraith *Review of NHS pharmaceutical contractual arrangements* which set out:

[10] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063460

[11] Paragraphs 8.57 – 8.66

> '[the] strongly-held views on the operation of the current system, particularly the impact of 100 hours per week 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[12].

5. Data for 2006/07 published by the Information Centre for Health and Social Care (the Information Centre)[13] showed that the 100 hours per week exemption was still by far the most popular. It accounted for over four-fifths of all exempt applications decided, of which over four-fifths were approved.

6. Data from the NHS Business Services Authority indicate that, as at 30 May 2008, there were 10,306 pharmacies open in England. This compares with 10,133 as at 31 March 2007, 9,872 as at 31 March 2006 and 9,736 as at 31 March 2005, immediately before the entry system was reformed, derived from Information Centre data. This represents an overall increase of 570 pharmacies. Informal information from 77 PCTs indicates that there are 166 100 hours per week pharmacies currently open in those PCTs or a little over two per PCT. If replicated across all PCTs, this suggests pharmacies opening at least 100 hours per week represent a significant proportion if not the majority of new entrants to the market since April 2005.

7. Independent contractors and others have argued forcefully they are subject to abnormal competitive pressures from new 100 hours per week pharmacies which affects their business certainty. The concerns of PCTs have remained and such pharmacies hamper their efforts to plan strategically - and to commission further clinical services - because of the costs arising from each new entrant. Therefore, whilst there are undoubted benefits in terms of improved access, the White Paper reported some significant drawbacks.

What needs to change?

8. The Department's view was that the drawbacks identified by both business and the NHS warranted closer scrutiny. In particular, the Department wished to examine what further action might be appropriate which retained the benefits of the exemption from improved access and a more competitive and innovative environment but which also addressed some of the key drawbacks experienced by both the NHS and by business[14].

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[12] op cit. Chapter 5 paragraph 25

[13] www.ic.nhs.uk/statistics-and-data-collections/primary-care/pharmacies/general-pharmaceutical-services-annual-bulletin-2005-06

[14] It remains open to an applicant to apply under the conventional control of entry test and, if successful, then to open to provide services for at least 100 hours per week, although contractually obliged only to be open for 40 hours per week.

Options identified in the White Paper

9. The White Paper identified[15] four options. These would be transitional pending a longer-term move to market entry based on PNAs:

- The **first** option would introduce a distance restriction on new 100 hours per week pharmacies of 1.6 km or 2 km. Both distance restrictions are used in the current Regulations. This would lead to increased contestability for suitable sites and a better spread of 100 hours per week pharmacies across PCTs. It would prevent future clustering.

- The **second** option would impose a requirement on new applicants to justify the need for a new 100 hours per week pharmacy to the PCT. Whilst still treated as an exemption to the main control of entry test, the Regulations would be amended to impose much tighter requirements for this exemption. This would give better PCT control and probably better distribution of such pharmacies but this needs to be linked to robust and up to date assessments of local needs in order to validate PCT decisions.

- The **third** option would allow the exemption to continue but successful applicants would be contracted using Local Pharmaceutical Services (LPS) contract terms. LPS is a means of direct contracting between PCTs and the provider and can be used to broaden service provision beyond traditional pharmacy services into areas such as outreach or training. This would give PCTs more control to avoid the 'fixed' costs they currently incur from surplus provision. The benefits however depend on PCTs having developed more sophisticated commissioning and the necessary skills.

- The **fourth** option, which can be used on its own or in conjunction with the other three, would strengthen the requirements for specific services a 100 hours per week pharmacy provides. For example, applications would be linked closely to the developments outlined in the White Paper on minor ailment schemes or for more services to be available during out of hours periods.

10. At the time of publication, the Government's preferred approach was to combine the first and fourth options - to introduce a new distance limit of 1.6 kms or 2 kms and to improve the service specifications and requirements for a new 100 hours per week pharmacy. The Government's reasons were that the services such pharmacies provide, as well as meeting local needs, would then more closely match what the Government expects from all such pharmacies in the future, including minor ailment schemes, better access to prescription medicines out of hours, including those for palliative care, urgent advice

[15] Paragraphs 8.64 to 8.66

and the supply of emergency hormonal contraception. In this way, the policy on exemptions to market entry would be aligned with the national priorities identified in the *NHS Next Stage Review* Interim Report published in October 2007 and the primary and community care strategy. It would also demonstrate how access to a range of commonly needed out of hours services can be improved. The Government would expect PCTs to negotiate with existing 100 hours per week pharmacies any necessary amendments to their current service provision.

Feedback from the national listening events

11. Delegates considered these four options in more detail. Generally, delegates preferred a stronger contractual relationship for such pharmacies (either Option 2 or 3 in combination with Option 4), subject to satisfactory resolution of perceived drawbacks.

12. Delegates felt that Option 2 (justification by the applicant of the need for a new 100 hours per week pharmacy) had a number of strengths such as the assessment of applications against clear criteria in PCT PNAs. Further clarity, however, was needed on how an appeals system could be accommodated within this option and how applications for standard hour pharmacies would be affected. Delegates considered Option 3 (continuing as exemption but use of LPS contract for successful applicants) would allow PCTs the greatest contractual levers as service specification and pricing would be more directly within PCTs control. Delegates noted this option could carry potential additional administrative burdens associated with LPS commissioning. They felt that Option 4 (strengthening the requirements on these pharmacies to provide specific services) would offer PCTs opportunities to define and monitor service provision, supported by the PNA.

What we propose to do

13. The Department remains of the view that the case for reform of the current arrangements is made. In addition to the strong views expressed at the listening events, there has been significant Parliamentary interest since the White Paper was published and local campaigning, together with calls for a moratorium on further applications pending this consultation. The Department does not consider that, having announced it would consult, it would be appropriate to suspend these provisions at this time.

14. However, having listened carefully to reactions and in particular the calls for NHS commissioners to have more influence and control in contracting for such pharmacies, the Department is persuaded that the current Regulations should be revised, pending longer-term reform. *Our vision for primary and community care* promises a comprehensive support programme on commissioning for PCTs. In particular, this will include managing contracts more effectively and stimulating innovation and choice by

developing markets in primary care. This will help overcome one of the main drawbacks with developing PCTs' commissioning responsibilities and the skills needed.

15. Subject to views as part of this consultation, the Department proposes that 100 hours per week pharmacy applications should in future be exempt from the current control of entry arrangements but subject to locally negotiated LPS contracts as set out in Option 3 above. This is preferred to Option 2, although the partial Impact Assessment indicates the net benefits from that option may be higher than Option 3, on the grounds that Option 2 may put too high a barrier to entry on contractors to prove the worth of their application.

16. The Department also proposes that the services such applicants provide, as well as meeting local needs, more closely match current health priorities. Therefore, the Department expects that many of these new pharmacies will be commissioned to address, subject to the PCT's assessments of local needs, priority areas for services including those set out in Option 4. These might include:

- minor ailment schemes to enable people to obtain medicines promptly;
- access to prescription medicines out of hours, including for palliative care;
- urgent advice; and
- the supply of emergency hormonal contraception.

17. In this way, the liberalising measures which have opened up market entry are more closely aligned with the national priorities set out in the White Paper, in *High Quality Care for All* and in *Our vision for primary and community care.* It will also demonstrate how access to a range of commonly needed out-of-hours services can be improved.

18. The Department also considers there may be a need for such arrangements to have adequate safeguards to ensure a balance between the needs of PCTs and the aspirations of applicants. PCTs will want to be confident this reformed system meets the shortcomings identified in paragraph 3 above and that their additional expenditure is planned and resourced. Equally, applicants will want to be confident there is a reasonable prospect of securing the right to provide services where their application meets pharmaceutical needs to the required standards and some assurance about income streams.

19. The Department has considered what such safeguards might be. For example, they might include a provision that the approval of such applications by means of a LPS contract will not unreasonably be withheld. They might include certain minimum criteria, such as a minimum contractual period. Importantly, LPS contracts enable the parties to negotiate and agree directly the costs of the service to be provided. As exempt applications, but contracted for under LPS, it may be that certain minimum levels of fees and allowances should be payable which do not significantly disadvantage such

contractors compared with others but which, at the same time, allow some flexibility to promote competition and to secure better value for money for the NHS. The Department has no firm proposals at this stage and invites opinions on introducing safeguards that balance the needs of PCTs and potential applicants.

20. For those already providing services for at least 100 hours per week, they would remain under national contractual terms. However, it would be open to PCTs to negotiate with them any extension to their current service provision to reflect the areas outlined above.

21. The partial Impact Assessment accompanying this proposal indicates there would be additional administrative costs for the NHS and for contractors in agreeing new contracts, estimated at £1.5 million each per year. The potential net benefits of introducing this reform together with strengthened service requirements (options 4 and 5 in the Impact Assessment) are estimated at this stage at £18 million.

Questions for consultation

The Department proposes that 100 hours per week pharmacy applications should, pending longer-term reforms in future remain exempt from the current control of entry test but, if approved, be subject to locally negotiated, directly held Local Pharmaceutical Services (LPS) contracts.

Do you agree we should introduce direct LPS contracting arrangements for pharmacies wishing to open 100 hours per week?

Do you agree safeguards are needed and, if so, what might these comprise (for example, these could be expressed in terms of services, prices, standards, quality)?

Is it sensible that such pharmacies are required to provide a minimum specified level of service such as minor ailment schemes or services out of hours or is this best left to local decisions and negotiations? Are there other factors to consider?

Introducing 'supplementary list' requirements for individual pharmacists, taking account of the need to comply with the Safeguarding Vulnerable Groups Act 2006

What is the problem?

22. The Department made a commitment in 2002 to provide increased protection to the public by ensuring that all registered primary care practitioners performing NHS services in the community were listed with PCTs.

23. The NHS (Pharmaceutical Services) Regulations 2005 (SI 2005/641 as amended) provide a framework within which PCTs can take action if a pharmacy contractor's professional conduct, competence or performance gives cause for concern when an applicant applies to be admitted to a PCT's pharmaceutical list or afterwards. Known as 'fitness to practise', they apply to pharmacies and appliance contractors, sole traders, limited liability partnerships and bodies corporate (i.e. companies and their directors/partners and superintendent pharmacists). However, they do not apply to individual pharmacists such as employees, managers or locums. Locum pharmacists are estimated to make up over 36% of the pharmacy workforce of those who provide or assist in the provision of LPS services.

24. The Department previously considered the introduction of NHS fitness to practise procedures for individual community pharmacists in 2005. There are existing powers in the primary legislation contained in sections 149 and 150 of the 2006 Act and known as 'supplementary lists' but these have not yet been commenced. A decision to extend such lists to cover all registered pharmacists was deferred in 2006 to take account of a review of the arrangements for the performers' list system for primary care professionals. That review report will be published in September 2008.

25. Since then there have been significant policy developments which mean it is timely to consider again the benefits of introducing such a system for pharmacists. These include the major programme of reform to professional regulation, the implementation of the Safeguarding Vulnerable Groups Act 2006 and a pilot programme to extend the National Clinical Assessment Service (NCAS) methodology to pharmacy. More information about these is at **Annex C.**

What needs to change

26. In 2007, the Government published its White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*[16] which set out a series of proposals to reform professional regulation.

The forthcoming draft Pharmacy Order

27. The Department will shortly consult on a draft Pharmacy Order to take forward recommendations to establish a General Pharmaceutical Council (GPhC) in Great Britain. The GPhC will be the new regulator for pharmacists, pharmacy technicians and pharmacy premises, taking over the role currently performed by the Royal Pharmaceutical Society of Great Britain whose functions are being split. The purpose is to modernise and strengthen the regulation of healthcare professionals to ensure patient, public and professional confidence and to make protection of patients and the

[16] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

public the first priority. The draft Order is expected to be laid in 2009. Subject to approval, it will set out the key functions of the GPhC including:

- the registration of qualified and competent practitioners;
- setting and securing standards of practice, education and training, continued professional development and conduct;
- operating fitness to practise procedures to deal with registrants where there are concerns about their fitness to practise and to protect the public from registrants who become unfit to practise; and
- registration, regulation and inspection of pharmacy premises and enforcement responsibilities.

NHS fitness to practise measures

28. A key element of *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* was also to enhance the role of the local NHS in tackling concerns about professionals. Patients, the public and professionals need to be confident that when it is necessary to investigate a professional's fitness to practise, this will be done in a fair, honest and open way. This must safeguard patients but also gain the respect of professionals by being consistent, fair and proportionate.

29. Whilst pharmacists must be registered with their regulatory body in order to practise - and can be disciplined for breach of their professional obligations – there are currently no provisions for such individuals to be listed with a local PCT. They therefore lie outside the current NHS framework that applies to other healthcare professionals such as doctors and dentists. As identified above, pharmacists and pharmacy technicians will in due course be regulated by the GPhC. This means that PCTs have no direct legal recourse in respect of an individual pharmacist's performance of NHS services. This creates deficiencies in respect of the NHS having oversight of appropriate clinical and delivery standards and of controlling potential financial or other irregularities connected with the provision of NHS services where the regulatory body does not consider action is appropriate. It can also mean that the only recourse for relatively minor matters is to refer to the professional regulator. That may be neither proportionate nor cost-effective.

30. Without powers comparable to a performer's list, PCTs will continue to be hampered in respect of individual pharmacists in terms of tackling concerns locally – for example, where there are a series of apparently minor or even trivial complaints which cumulatively may indicate a more significant problem. Pharmacy will remain out of step with the way other primary care practitioners are treated. As the public become increasingly aware of the systems which are in place for addressing local concerns, it is reasonable that they will expect a comparable system to be in place for pharmacists. As the role of pharmacy technicians expands, and with the introduction of professional registration requirements for them expected to come into force in early 2009, it may also

be appropriate to extend the same performance regime to them as well by effecting any necessary changes to the current legislation.

The role of the National Clinical Assessment Service (NCAS)

31. A key element to tackling such concerns locally is the role of the National Clinical Assessment Service (NCAS). NCAS was established in 2001 to work with NHS organisations and individual doctors where a doctor's clinical performance may be giving cause for concern. Their remit has since expanded to include dentists in both general practice and salaried dentists and they provide this service across the UK, across the public and private sectors of health. NCAS now handles between 700 and 1000 referrals per annum. From April 2009, a two-year pilot NCAS service will be extended to include pharmacists.

The Safeguarding Vulnerable Groups Act 2006

32. The Safeguarding Vulnerable Groups Act 2006 was introduced in response to a key recommendation of the Bichard Inquiry. It provides the legal framework for a new vetting and barring scheme which will help prevent those who pose a risk of harm to children and/or vulnerable adults from gaining access to them through their work. Barring decisions will be made by the Independent Safeguarding Authority (ISA), a Non Departmental Public Body. The new scheme, to be introduced on a phased roll-out from October 2009, will build on the current arrangements for pre-employment checks for people working with children and/or vulnerable adults in health and social care settings. It will replace the Protection of Children Act (POCA) scheme and the Protection of Vulnerable Adults (POVA) scheme and supplement current arrangements for Criminal Records Bureau (CRB) disclosures.

Effect of the vetting and barring scheme on pharmacy services

33. The role of pharmacists in providing advice, assistance and guidance to adults who are receiving health care will be classed as regulated activity under the Safeguarding Vulnerable Groups Act. This means that, where a pharmacist is to be employed, their prospective employer will need to check that they are ISA-registered before employing them. It also means that, where an individual is barred from working with vulnerable adults, it will be an offence for them to seek employment as a pharmacist or to work as a pharmacist in an employed or a self-employed capacity.

34. Locum pharmacists employed by an agency will be treated as employees of that agency. It will therefore be the responsibility of the agency to check their ISA registration. However, certain self-employed locum staff may fall outside the checking requirements, although it will be an offence for individuals, who are barred, to work or seek work as a locum pharmacist.

35. The role of some other pharmacy or appliance contractor staff in providing advice, assistance, guidance and/or medical treatment will also be classed as regulated activity under the Safeguarding Vulnerable Groups Act. Such roles include, among others, pharmacy technicians and device suppliers who work with vulnerable adults in their own homes. Where such individuals work on an employed basis, they will be subject to checks of ISA registration by their prospective employer. Where an individual is barred from working with vulnerable adults, it will be an offence for them to seek employment or to work in such roles, whether in an employed or self-employed capacity.

What we are proposing

36. Alongside the implementation of the Safeguarding Vulnerable Groups Act, the Department proposes to commence the provisions for supplementary lists through regulations to enable PCTs to exercise the comparable range of powers in respect of individual pharmacists who assist a pharmacy contractor in the provision of services, as they do with those on the 'main' pharmaceutical list and with other primary healthcare professionals. These arrangements would apply to the managers, employees and locums working for a contractor. The Department would welcome views on extending these provisions to registered pharmacy technicians for whom professional registration will come into force in early 2009.

37. The partial Impact Assessment accompanying this proposal indicates there would be additional administrative costs for the NHS and for individual pharmacists. Patients would benefit from increased assurance and reduced errors. The potential net benefits from introducing this proposal are estimated at this stage to be greater than £5.4 million. There would be an increase in the Department's administrative burdens baseline estimated at £0.8 million per year.

Questions for consultation

The Department proposes to introduce regulations to create supplementary lists to enable PCTs to exercise comparable powers in respect of individual pharmacists who assist a pharmacy contractor in the provision of services, as they do with those on the 'main' pharmaceutical list, and invites views on extending these requirements to pharmacy technicians. From April 2009, a two-year pilot NCAS service will be extended to include pharmacists.

The requirements of the Safeguarding Vulnerable Groups Act 2006 will be rolled out from October 2009. Pharmacists and other pharmacy and appliance contractor staff whose roles involve providing advice, assistance, guidance and/or medical treatment will be subject to Criminal Records Bureau checks and Independent Safeguarding Authority registration.

Do you agree the introduction of 'supplementary lists' for individual pharmacists which would cover both employed and self-employed pharmacists? If not, can you suggest ways in which all pharmacists in England can be brought into the systems for tackling concerns about NHS performance locally which apply to other primary healthcare professionals?

Without a 'supplementary list', how might the new NCAS pharmacy service operate for locums?

Should this framework extend to pharmacy technicians?

Independent Safeguarding Authority

Do you agree that, in addition to pharmacists, other people working in community pharmacy such as pharmacy technicians or others who provide advice, assistance, guidance and/or medical treatment need to be ISA-registered?

How might self-employed pharmacists best be brought within the remit of ISA registration? For example, would it be appropriate to require this as part of a self-employed pharmacist's inclusion on a PCT supplementary list?

Chapter 4: Dispensing by doctors

Background

1. It has been a long established general precept – one that all Governments have endorsed since the NHS came into being – that doctors prescribe medicines and pharmacists dispense them. Good practice requires, wherever possible, the separation of the prescribing and supply functions. In this way, patients receive the benefit of both professions' expert advice, intervention and care.

2. It can also be that a community pharmacy is simply not viable in every part of the country, especially in more rural areas. Patients need to receive their NHS-prescribed medicines promptly, efficiently, conveniently and to high quality. That is where the services of dispensing doctors can, and do, play a vital role, ensuring patients receive their medicines from the surgery's dispensary without having possibly a very lengthy journey to their nearest pharmacy. It does mean that, in those circumstances, the prescribing and supply functions are combined.

3. The current rules under which doctors dispense stem largely from Regulation 30 of the National Health Insurance Commissioners Regulations 1912. Today's equivalent is in regulation 60 of the 2005 Regulations. **Annex B** provides further information about market entry arrangements for dispensing doctors.

4. This part of the consultation identifies two linked changes that might be made in respect of dispensing by doctors – revisions to the current regulatory criteria and a common regulatory route for all pharmaceutical applications.

Market Entry: Revisions to the current regulatory criteria

What is the problem?

5. Whilst the fact that a regulation is approaching its century is no reason, in itself, for review, the country's infrastructure, population, health and, above all, the way healthcare is delivered and structured has changed radically in the intervening years. As the White Paper made clear, pharmaceutical services are themselves being transformed. Both medical and pharmaceutical services have developed greatly within the NHS in the last 60 years. Yet there are some persistent problems which merit scrutiny:

   - **The sustainability of some primary medical services (care from a GP)**. Some dispensing doctors have expressed concern that without their dispensing income they would be unable to maintain full medical services. The Department does not

consider that funding arrangements for medical services are such as to usually require a further cross-subsidy from dispensing income. Funding for medical services supports services and GP income in small practices in urban areas which do not have access to dispensing income. Any cross-subsidising arrangements are, ultimately, anti-competitive unless there is sufficient justification to warrant them. Whilst there will be variations within the average to suggest that some GPs will be unable, without their dispensing income, to maintain appropriate patient services whilst sustaining a reasonable level of income from their primary medical service income, the Department believes this should be exceptional rather than normal.

- **Current regulatory arrangements can lead to anomalies** – examples of this include a distance condition that can lead to patients in close proximity to one another being treated differently - a general practice will find that it dispenses to some patients but not all. Alternatively, pharmacies can be in very close proximity to the dispensing GP's premises (or be based in the same premises) and the existing conditions do not consistently relate to the patient's journey. If the practice and the nearest pharmacy are in opposite directions from the patient's home then the patient's journey from home to GP to pharmacy can be considerably more than 1.6 km. This apparent lack of transparency and fairness is difficult to justify objectively.

- **Costs** - the financial analysis in the partial Impact Assessment suggests that the total pharmaceutical costs associated with drugs, medicines etc. dispensed via general practice and, therefore, borne by the NHS, is greater than the usual arrangements whereby a GP prescribes and a pharmacy dispenses. Such additional costs may be justified where a conventional pharmacy would be unviable and the surgery provides a dispensing service.

Feedback from the national listening events

6. Many delegates expressed serious concern about changing the current arrangements, as patients liked the convenience offered by the GP dispensing service, which also offered opportunities to strengthen GP/patient relationships and continuity of care. Delegates were concerned about the capacity of the existing pharmacy network to absorb increased volumes of dispensing if this service were to be withdrawn from GPs altogether. Delegates agreed an equitable system should apply to both GPs and pharmacists. There were benefits in making better use of all available health professional skills to develop and extend service provision – through, for example, pharmacists working with GPs in practices.

Options

7. It is not the Department's intention simply to prevent GPs from dispensing. They can, and do, play a pivotal role in ensuring access to pharmaceutical services in some areas. The Department recognises the importance to patients of the provision of dispensing by GPs and Ministers have acknowledged the value of those services in debates in Parliament. They have made clear that it is not, and never has been, the intention to remove this option. At the same time, the system does contain anomalies and inconsistencies, which should be reviewed in the light of other proposals.

8. In considering the issues raised, the Department has identified four options on which we are seeking views. Further information about these options is available in the partial Impact Assessment published alongside this consultation**.**

- **Option 1** is no change. This has the advantage of maintaining the status quo, does not remove services from patients and does not put any jobs at risk. It does not, however, address the financial issues or the inequities within the current system identified earlier and in particular, whether GP dispensing can be justified when there is a pharmacy in close proximity.

- **Option 2** is that whilst continuing with current arrangements where GP dispensing applies in controlled localities, the existing specific distance criteria would be removed. This would allow PCTs to determine the rural localities where GP dispensing is appropriate on the basis of their PNA. This option could address the current anomalies of a rigid national scheme and empowers local communities to make decisions appropriate to their needs. It aligns with the longer-term strategic direction for commissioning and pharmaceutical services generally, based on PNAs.

- **Option 3** would mean that, instead of the distance between the patient's home and the pharmacy, the determining factor should be a distance between the dispensing surgery and the nearest community pharmacy. Such a distance could be put at less than the current 1.6 km, for example, at 500 m or at 1000 m. This removes the anomaly of a doctor dispensing to some of his/her patients where there is a community pharmacist in close proximity and also removes the question of a practice having dispensing and non-dispensing patients. Such a `cliff edge' effect is less pronounced than under the current arrangements although there may still be such cut-offs where there are nearby practice boundaries.

- **Option 4** is a variation of Option 3. It would mean that a GP would not dispense where there is a pharmacy within 500 m or 1000 m of the GP practice and a second pharmacy within 1500 m. Those who are permitted to dispense may do so to all their registered patients regardless of the distance between their home

and the surgery or pharmacy. This option maintains an element of choice for patients when having their drugs dispensed and has a less pronounced effect on GP dispensing.

9. It is important to stress that the Department has no preferred option at this stage nor has it come to a view as to whether any reform of these particular arrangements is necessary. However, the Department considers there are a number of related implications to be considered as part of this consultation for:

- the treatment of branch surgeries;
- maintaining services; and
- how any move to new arrangements, if a decision were taken on any particular option for reform, might be achieved.

10. The Department has also set out proposals in chapter 3 to reform the general legislation concerning control of entry and makes further proposals below to introduce a single regulatory route for applications from pharmacies and dispensing doctors.

11. The partial Impact Assessment accompanying this proposal indicates significant variations in net benefits between the different options. This is because the costs and benefits are based on a hypothetical scenario, giving rise to uncertainty. Therefore, a range of possible net benefits is given where appropriate.

Questions for consultation

The Department has identified four possible options to reform the current arrangements regarding dispensing by doctors.

Is the Department right in believing that there are inequities and anomalies within the current procedures under which patients can obtain their medicines and appliances directly from their surgery rather than from a community pharmacist?

Have you any personal experience of any such inequities and anomalies? If so, please briefly set them out.

Do you believe that having a local choice between two or more local dispensers when having a prescription dispensed is important to you? Could you quantify how important this is for you on a scale of 1-5 where 1 is exceptionally important and 5 is of no importance?

Is it right for the Department to publish a national set of rules setting out when a doctor can provide dispensing services or should the local NHS, for example your PCT, consulting with others, have more say?

Do you agree that the four options set out in this consultation document relating to dispensing by GPs are appropriate options for consideration? Are there others that should be considered?

If you have a preference between Options 1-4, please indicate which is your preferred option and why.

If there were to be change, what issues do you believe the Department should take into account when implementing any new system?

Are there other factors to take into account – for example, how well do these options or your preferred option link to the proposals below for a common regulatory route for all applications?

A common regulatory route for all applications

What is the problem?

12. Whilst the regulatory system was reformed in April 2005, different regulatory tests apply depending on the type of contractor with which a PCT is dealing. The 'control of entry' system (see **Annex B** for more information) does not apply to applications from dispensing doctors. This differs from pharmacy contractors and appliance contractors who have to meet current 'control of entry' requirements.

13. A doctor who wishes to dispense to their patients need only show that to do so would not prejudice the proper provision of medical, dispensing, pharmaceutical or local pharmaceutical services locally. This is known as the 'prejudice' test and is only applicable in designated rural (known as 'controlled') localities. A PCT determines whether an area is rural in character or not. Where it does, a pharmacy or appliance contractor wishing to set up in such areas also needs to pass the prejudice test as well as meet the control of entry requirements.

14. Therefore, Anne Galbraith found that the control of entry system does not apply equitably to all contractors, and imposes different legislative hurdles simply according to the type of contractor. It also has different impacts on patients in rural areas. As discussed earlier in this chapter, some but not all rural dispensing patients will switch to a new pharmacy if it opens within 1.6 km of where they live. Yet those who live further away can continue to use their dispensing practice and may not benefit to the same extent. Anne considered such arrangements are not consistent with the PCT having a role to secure equitable access to a full range of services for patients and carers.

15. Anne's report made clear that dispensing doctors provide a valuable service to those patients who cannot access a pharmacy conveniently. Patients should be able to receive full, high quality pharmaceutical services based on what local needs and demands are.

What needs to change

16. Anne considered it would be possible to introduce the same requirements on all contractors who apply to provide dispensing and pharmaceutical services. In other words, the 'necessary or expedient' test would be introduced alongside the 'prejudice' test for doctors who wish to provide dispensing services to patients in rural areas. Approval for dispensing to those patients would be given only if the PCT determines it is 'necessary or expedient' for the adequate provision of pharmaceutical services and does not prejudice the provision of medical, dispensing, pharmaceutical or local pharmaceutical services as now.

17. This would align all contractors within a single regulatory regime. It would also remove a series of separate and detailed rules governing applications from doctors to dispense where a PCT has designated an area as rural. The need for these rules to continue is at best questionable given there are now only a small number of applications from dispensing doctors each year. In 2005/06 PCTs decided 31 (1.5%) applications from doctors to dispense out of a total of 2,043 pharmaceutical applications and in 2006/07 this number fell to 13 (<1%) out of a total of 1,690 in 2006/07.

What we propose to do

18. The Department proposes to amend the 2005 Regulations so that an application from a doctor to provide dispensing services would be dealt with under the current reformed 'control of entry' test set out in regulation 12 to the 2005 Regulations.

19. The current Regulations covering the approval by a PCT of outline consent to a doctor to dispense could then be removed. The provisions relating to PCTs' approving the premises from which doctors dispense would remain in place. Where a dispensing practice amalgamated with a non-dispensing practice, a fresh application for authority to dispense for the new amalgamated practice would be required. The provisions in the 2004 NHS (General Medical Services) Regulations 2004 and the NHS (Personal Medical Services) Agreement Directions 2004 which enable a PCT to contract for dispensing services with a GMS or PMS contractor would no longer be needed as they duplicate the 2005 Regulatory provisions.

20. The provisions which enable a PCT to authorise any doctor to dispense on the grounds that a patient has serious difficulty getting to their pharmacy would remain in place. Doctors would continue to be approved to dispense to those patients who live in controlled rural areas.

21. The partial Impact Assessment accompanying this proposal indicates there are some small net benefits of around £100,000 from this proposal with a small reduction on administrative burdens. The costs and benefits have been estimated cautiously.

Questions for consultation

The Department proposes to amend the 2005 Regulations (and associated primary medical legislation) to introduce a single regulatory route to authorise dispensing by doctors for patients in rural areas.

Do you agree:

- *the proposal to align the regulatory route for dispensing doctor applications with those of pharmacies and appliance contractors?*
- *dispensing by doctors should, as now, apply to those patients who live in designated rural areas?*
- *the approval of doctors' dispensing premises should continue?*
- *the 'serious difficulty' rule should be retained to enable a PCT to authorise dispensing for any patient who has serious difficulty getting to a pharmacy?*

Are there other factors which need to be taken into consideration?

The sale of over the counter medicines by dispensing doctors

What is the problem?

22. The retail sale and supply of medicines is largely controlled by the Medicines Act 1968 (in this section referred to as the '1968 Act').

23. There are three categories of medicines available to patients:

(a) those that must be obtained on prescription (POM or prescription only medicines),
(b) those that do not require a prescription to obtain, but which may only be sold in a retail pharmacy (P or pharmacy medicines), and

(c) those on the general sale list (GSL) which may be sold from retail outlets other than a pharmacy (such as small packets of paracetamol available in a corner shop).

24. Section 51 of the 1968 Act specifies GSL medicines as those products that, in the opinion of Ministers, can be sold or supplied other than under the supervision of a pharmacist with reasonable safety. The relevant secondary legislation is the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984 (as amended). Section 52 of the 1968 Act requires a pharmacist to supervise the sale or supply of a P medicine.

25. The rules concerning the sale or supply of prescription only medicines are set out in section 58 of the 1968 Act and in associated secondary legislation. The sale or supply rules in section 52 of the Act also apply to prescription only medicines.

26. P medicines and GSL medicines are together frequently referred to as over the counter (OTC) medicines. GSL medicines can be sold by anyone, subject to certain conditions set out in section 53 of the 1968 Act. In particular, the products must come pre-packaged and the premises must be capable of being closed to the public. P medicines have conditions attached to them. Broadly, they must be sold through a retail pharmacy outlet by or under the supervision of a pharmacist (section 52 of the 1968 Act).

27. The restrictions on the sale of GSL medicines (section 53) and P medicines (section 52) do not apply to doctors in respect of the sale or supply of such medicines to their patients or their carers as set out in section 55 of the Act.

28. In addition to the requirements of the 1968 Act, conditions in their NHS primary medical services contracts prevent GPs from selling OTC medicines to their patients – primarily because of the link between treatment and the profit generated by the sale of such medicines to patients. This means that patients may not be able to access the most cost-effective remedies if there is no convenient or accessible alternative outlet nearby. Instead, a dispensing doctor may prescribe, on the NHS, an equivalent or more expensive medicine on which a patient may have to pay a prescription charge. This is not an efficient use of NHS resources nor does it help provide a clinically and cost effective service that is also convenient for patients.

What needs to change?

29. The Department considers there is a tension between the NHS ‘rules’ that allow a GP to dispense prescription only medicines, but prevent that GP selling GSL or P medicines which might be cheaper, but equally effective alternatives, to their patients. There is also the more general question of ready access to such medicines where there is no conveniently located pharmacy.

30. These issues could be addressed through a relaxation of the NHS 'rules' in respect of the sale of P or GSL medicines by a dispensing GP. However, any relaxation must also consider the restrictions in the Medicines Act regarding the sale of P medicines and the sale of GSL medicines that are available from other outlets such as a corner shop or newsagents as well as pharmacies. It must also consider whether the Medicines Act – and section 55 in particular – may unduly limit the circumstances under which a doctor may be able to sell medicines to their patients.

Feedback from the national listening events

31. Delegates favoured the proposal to change arrangements for selling OTC medicines where a GP practice has consent to dispense medicines. They also recognised that these must take into account the need for suitably trained practice staff in relation to the safe sale of P medicines - equivalent to the procedures in pharmacies.

What we propose

32. The Medicines and Healthcare products Regulatory Agency (MHRA) announced on 24 July 2008 that it is conducting a project to review and consolidate the current medicines legislation. As an initial step, the MHRA plans to conduct an informal review and consultation with industry and external stakeholders starting in the autumn of 2008 to seek input on potential areas for reform. This review may therefore present an opportunity to address the anomalies identified above.

33. In conjunction with any reform to medicines legislation, the Department would propose to relax the NHS rules, as part of any package of wider changes to GP dispensing, to allow dispensing GPs, who so wish, to sell or supply both P medicines and GSL medicines to their patients where there is no convenient alternative. What constitutes a convenient alternative could be set nationally under a simple distance criterion of, say, 500 m, or could be determined locally by the PCT.

34. The Health Act 2006, together with existing powers in the 1968 Act, makes provision for changes in pharmacist supervision of the sale and dispensing of POM and P medicines. Subject to consultation, this includes an intention to enable the pharmacist to authorise suitably trained and registered pharmacy staff to supervise aspects of the sale and supply of medicines - including the sale of P medicines – working to procedures set down by the pharmacist to ensure safe and effective working in the pharmacy. We would propose extending those provisions to dispensing practices who wish to sell P medicines. Similar arrangements will need to be adopted to ensure that suitably qualified practice staff are able to offer advice to patients in relation to the sale of these medicines and where, for example, they need to refer back to the GP. In due course, it may be possible to enable dispensing doctors to sell OTC medicines to their patients

and requirements to underpin the safe sale of these medicines by practice staff using the powers to make regulations under section 132 of the NHS Act 2006.

35. In addition, the Department would propose that, where there is no convenient alternative, dispensing GPs should be able to supply OTC medicines to all rather than just some of their patients. Otherwise, there may be problems in managing the sale of P and GSL medicines in a practice where only some practice patients are sold OTC medicines by practice staff. The NHS 'rules' need to be clear to avoid confusion and uncertainty for patients, those delivering the service and those managing the service.

36. This reform would not override any local relevant planning regulations. In some areas, local planning consents may limit the use of medical premises to specified, non-commercial activities.

37. The partial Impact Assessment accompanying this proposal indicates significant variations in benefits, risks and costs between the different options. The preferred approach set out above would offer improved access to OTC medicines with least risk to the market structure and dynamics, as identified in the Competition Assessment and in the annexes to the Impact Assessment.

Questions for consultation

The Department proposes to allow, where there is no convenient alternative, dispensing doctors to supply over the counter medicines to all of their patients, subject to the MHRA's review and forthcoming informal consultation on the current medicines legislation.

Do you believe that it would be beneficial for patients and consumers if dispensing doctors were able to sell general sale list (GSL) medicines to their patients where there is no convenient alternative?

Do you believe that it would be beneficial for patients and consumers if dispensing doctors were able to sell pharmacy (P) medicines to their patients where there is no convenient alternative?

How might the term 'convenient alternative' best be defined? For example, should a distance limit of, say 500 m, be set, or should this be left to local determination?

If dispensing doctors were to sell P medicines, do you agree there should be safety provisions regarding such supply - for example, similar or equivalent to those that govern the sale and supply of P medicines through pharmacies?

Are there any risks not identified here in permitting a dispensing practice to make a profit from selling medicines to their patients?

Chapter 5: Dispensing Appliance Contractors

Market entry for dispensing appliance contractors

What is the problem?

1. Chapter 8 of the White Paper[17] identified certain problems in terms of market entry arrangements for dispensing appliance contractors (DACs).

2. These contractors - 128 actively providing services in England compared to over 10,000 pharmacies - provide services to people who need appliances, such as stoma and incontinence care aids, trusses, hosiery, surgical stockings and dressings. They do not supply drugs as do pharmacies or dispensing doctors. However, pharmacies and dispensing doctors can also supply appliances.

3. Appliance contractors range from small sole trader businesses to larger companies. They can provide services regionally or nationwide, often using mail order delivery.

4. Anne Galbraith's report identified a recurrent concern regarding market entry arrangements for new contractors. The current 2005 Regulations - even after reform - restrict entry to the extent that a new potential entrant DAC finds it almost impossible to enter without taking over an existing provider. This is because they account for a relatively small but important proportion of all prescription items dispensed (less than half of one per cent) and their services can be offered regionally or nationally. The current regulatory test – based on local 'neighbourhoods' means that the need for a further or new appliance contractor is rarely if ever justified within a PCT as they consider applications with regard to much smaller populations. As such, appliance contractors do not necessarily provide services to that local neighbourhood. They are more likely to provide them to a much wider catchment area and often nationwide, rather like internet-based pharmacy operations.

What needs to change?

5. It may be the case that there is little additional demand for further entrants to the market for the supply of appliances only. The number of items dispensed by DACs, however, has increased in recent years. The Department estimates it rose some 75% between 2002/3 and 2006/7 (from around 2.1 million to 3.6 million items). It is reasonable to

[17] Paragraph 8.75

assume that some increases will continue as the proportion of older people in the population increases.

6. Importantly, the Department wishes to be assured that any new entry system would not increase costs to the NHS with no or insufficient improvements for patients in terms of access, services or quality. It would be important for any new entry system not to create perverse incentives which led to such a result.

7. The Department is currently consulting on proposals which, amongst other things, consider reforms to the current payment system for appliance contractors. That consultation is due to end on 9 September 2008. Under these proposals, the on-cost payment which contractors currently receive would be replaced by a system akin to that in place for community pharmacies. In future, they would be remunerated on a fee basis for providing a range of essential and advanced services. Fees for essential services would be based on the number of items dispensed via a prescription. Contractors would receive an additional payment based on the number of items dispensed. This payment would cover elements of essential service provision which are not directly linked to dispensing prescription items – for example, operating within a framework of clinical governance.

8. The partial Impact Assessment accompanying this consultation estimates that, if implemented, this might have the same effect of increasing the reimbursement for services if new entrants led to an overall reduction in the number of appliances dispensed by each contractor but new contractors met the qualifying levels for payments.

9. In further discussions with their representatives since publication of the White Paper, we have identified four options, two of which were set out in Anne Galbraith's report, on which we are now seeking views:

- **Option 1** would replace the existing regulatory structure with a national scheme where applications are made to a central registering body. This would remove the involvement of the PCT from the process and would require a new body to be set up to deal with such applications or additional functions given to an existing body. This option is favoured by the trade association representing dispensing appliance contractors. However, it is likely that new primary legislation would be required to set up such a national scheme and then Regulations introduced. At this stage, for the reasons set out in the Impact Assessment, the Department does not favour this option.

- **Option 2** would introduce a new exemption to the current market entry arrangements using the existing regulatory structure. This could be similar to the exemptions already in place for pharmacies such as those providing services in

large out of town shopping centres. Specific requirements can be set out in the Regulations such as the types, standards and the quality of services to be provided. It might also require registration with the Independent Safeguarding Authority under the provisions of the Safeguarding Vulnerable Groups Act 2006 discussed in Chapter 3. Such an exemption would also need certain measures to ensure the NHS retains a reasonable and proportionate control over increases in costs through new DAC contractor premises. If the total level of service remuneration differed in the medium to longer term than intended, or there were significant change in demand for stoma and urology products, it would be open to the Department formally to review the operation of the policy sooner than 3 years following implementation.

- **Option 3** would be to remove market entry arrangements for appliance contractors and adopt an 'any willing provider' approach. As with Option 2, this would be subject to suitable minimum requirements regarding their suitability, the standards and quality of services to be provided as suggested by Anne Galbraith. This would be simple to administer but would again require detailed consideration to ensure the NHS retains a reasonable and proportionate control over any projected increases in costs through new DAC contractor premises balanced against the improvements in access, services and quality.

- **Option 4** would be for a lead PCT or for regional NHS bodies to handle applications on behalf of all PCTs in their area using the existing regulatory test. It may be easier to enter the market where a PCT considers applications relating to a wider geographical area. This would, as with Option 1, likely require amendment to the NHS Act 2006 and is not preferred at this stage.

What we are proposing

10. The Department has put forward four options for further consideration within this consultation. At this stage, in legislative terms, **Option 2** is preferred as it would be relatively simple to achieve and could be taken forward within the existing regulatory framework. If proposals discussed earlier are taken forward to link entry to PCTs' assessments of local needs, the need for such an exemption would likely continue under a reformed entry system – see Chapter 2, paragraph 22.

11. However, the partial Impact Assessment accompanying this proposal indicates that this option may create costs of some £7.8 million which the NHS would have to fund unless there were adequate safeguards within the exemption to ensure the NHS retains a reasonable and proportionate control over any increases in costs through new DAC contractor premises.

Questions for consultation

The Department proposes that applications from dispensing appliance contractors should in future be subject to an exemption from the 'necessary or expedient' test.

What are your views on introducing a specific exemption for applications from dispensing appliance contractors?

What specific requirements might be set out in the regulations such as the types, standards and the quality of services to be provided?

What safeguards might be appropriate to ensure the NHS has a reasonable and proportionate control over any increases in costs through new dispensing appliance contractor premises?

Do the potential benefits of relaxed entry restrictions outweigh the potential costs as identified in the Impact Assessment?

A 'performance' regime for individuals who assist appliance contractors in the provision of services

What is the problem?

12. Paragraph 26 in Chapter 2 above sets out the current powers available in relation to a contractor's 'fitness to practise'. Currently only directors of appliance contractor companies make such declarations to a PCT.

13. These powers can also be applied to individual pharmacists. Known as 'supplementary lists' to distinguish them from the 'main' pharmaceutical lists for contractors, the powers are set out in sections 149 and 150 of the NHS Act. Supplementary lists require equivalent fitness to practise declarations from those who assist contractors in providing pharmaceutical services. They can also be applied to those who assist in the provision of LPS contracts which are direct contracts between a PCT and a contractor.

14. These measures have only been applied to health professionals. Appliance contractors are not a recognised health profession and have no recognised professional regulatory body (as does pharmacy, for example, through the Royal Pharmaceutical Society of Great Britain and, in future, the General Pharmaceutical Council). Yet they can provide much-needed specialist and often intimate healthcare services to patients. The British Healthcare Trades Association is currently developing a voluntary registration scheme and training module for those who supply appliances.

What needs to change?

15. Following discussions with representative bodies of appliance contractors, the Department considers it would be helpful to clarify this anomaly. As identified in Chapter 2, not only has thinking on patient safety moved on considerably in recent years, it is questionable whether certain service providers who have direct patient contact should lie entirely outside a fitness to practise and patient safety framework. Indeed, some people who work for appliance contractors may be more likely than pharmacists (if they do not supply appliances) to have such contact on a more regular basis, for example through helping with catheters or customising stoma appliances for patients either in contractors' premises or in the patient's home.

What we propose to do

16. Whilst the Department believes there is a case to answer which would enable the NHS to take action where an individual working for an appliance contractor may be giving cause for concern, the Department does not wish to introduce legislation where there is no need.

17. Following the White Paper, *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*, a series of work streams have been established to implement the proposals. Work on new roles and emerging professions is being taken forward by the Extending Professional Regulation Working Group. They are expected to report later in 2008 on a series of objective measures to assess whether a particular group needs to be regulated. Priority will be given to those groups presenting the greatest potential risk to patient safety. The Department therefore proposes that, as a first step, those working for appliance contractors should be assessed against these objective measures in 2009.

18. If a risk were to be established which could not be addressed by other means, it would be open to the Department to introduce powers within the legislation to make explicit provision to extend the scope of sections 149 and 150 of the NHS Act to those who assist appliance contractors in the provision of services. However, this may be difficult to achieve without reference to a recognised professional qualification (or recognised and accepted professional standards) for those who work for appliance contractors against which such performance could be gauged.

The Safeguarding Vulnerable Groups Act 2006

19. As discussed in Chapter 3, the Safeguarding Vulnerable Groups Act 2006 was introduced in response to a key recommendation of the Bichard Inquiry. It provides the legal framework for a new vetting and barring scheme which will help prevent those who pose a risk of harm to children and/or vulnerable adults from gaining access to them

through their work. Barring decisions will be made by the Independent Safeguarding Authority (ISA), a Non Departmental Public Body. The new scheme, to be introduced on a phased rollout from October 2009, will build on the current arrangements for pre-employment checks for people working with children and/or vulnerable adults in health and social care settings. This will replace the Protection of Children Act (POCA) scheme and the Protection of Vulnerable Adults (POVA) scheme and will supplement current arrangements for Criminal Records Bureau (CRB) disclosures. Further information is at **Annex C**.

20. Just as with pharmacists, those who work for appliance contractors may need to be registered as part of this implementation programme. Where an appliance contractor is to be employed, their prospective employer would need to check that they are ISA registered before employing them. Self-employed individuals working for an appliance contractor may, however, fall outside the checking requirement and the Department welcomes further views on how best they might comply with ISA registration.

Questions for consultation

The Department proposes that dispensing appliance contractors should - in 2009 – be assessed in terms of the need for regulation against objective criteria to be formulated by the Extending Professional Regulation Working Group. Those criteria will be available later in 2008.

Do you agree the Department' should assess in 2009 whether regulation is needed to govern those who provide or assist in the provision of appliances only?

Are there alternative approaches which might be considered?

If a risk were to be established, do you agree the provisions of sections 149 and 150 of the NHS Act should be extended to include those who assist appliance contractors in the provision of services?

Should self-employed appliance contractors be required to register with the Independent Safeguarding Authority and, if so, how?

Should such requirements be subject to specific limitations - for example, applying only to contractors who fit appliances or who do so in patients' homes?

Chapter 6: Other changes to the legislation

Amendments to the NHS (Pharmaceutical Services) Regulations 2005

What is the problem?

1. The Department believes a number of amendments are needed to clarify and improve the working of the 2005 Regulations.

What needs to change?

2. The 2005 Regulations still contain references to Patients' Forums and Community Health Councils. These bodies no longer exist and have been superseded by Local Involvement Networks (LINks) under provisions in the Local Government and Public Involvement in Health Act 2007. The Regulations need to be updated to reflect this.

3. Suitably qualified optometrists will soon be able to prescribe independently of other independent prescribers. If they provide NHS prescriptions, pharmaceutical contractors require the appropriate authority to dispense such prescriptions. This might be achieved by including a definition of such optometrists in the 2005 Regulations and also in the NHS (Local Pharmaceutical Services etc.) Regulations 2006.

4. Provisions in the 2005 Regulations already enable a PCT that is considering taking action against a contractor on their fitness to practise grounds, to continue to come to a decision on that matter if the contractor notifies the PCT that he wishes to withdraw from the PCT list. This prevents those persons from withdrawing to avoid the possibility of an adverse PCT decision. However, this provision does not apply in respect of changes of ownership. An amendment could be made to the 2005 Regulations to enable the PCT to keep the seller of a pharmacy on its pharmaceutical list until it concludes its action and notifies the outcome as appropriate. This would not prevent the sale of the business itself.

5. The wording of the 'control of entry' test in the 2005 Regulations needs to be aligned with that in section 129 of the NHS Act. In 2006, the NHS Act was consolidated and the language used updated to reflect modern terminology. This would involve a change in the Regulations from the words 'necessary or desirable' to 'necessary or expedient'. The Department considers these inter-changeable and such an amendment would not alter the meaning, or application of the test as expressed in Regulation 12.

6. A contractor providing services for 40 hours per week can apply to the PCT to vary the hours at which he is contractually obliged to be open to provide services. However, there is no similar provision for a contractor opening 100 hours per week. An amendment would make provision for such a facility provided the contractor remains open for at least 100 hours per week. Some consequential amendments would also be made to clarify that in circumstances where a contractor gives three months' notice of a proposed change to opening hours, this would apply in respect of changes to the hours where a contractor is not contractually obliged to provide pharmaceutical services and not their core contractual hours.

7. Contractors must not offer inducements to patients to gain business. This is subject to certain exceptions, such as a home delivery service. This requires updating to reflect the wider services within the new contractual framework. For example, such an amendment should not exclude products which are supplied to encourage and promote better health, such as an item of fruit to a person in the course of discussing healthy eating messages, or providing exercise DVDs to persons being advised about adopting a healthy lifestyle.

8. To ensure the Regulations meet up to date standards and requirements for service delivery, and to give effect to the new Code of Practice on the promotion of NHS funded services, the 2005 Regulations could be amended to make clear that no inducement will be offered or given to other NHS personnel or providers of health care services to protect the reputation of the NHS. It will also offer assurance to the public that recommendations or advice about any provider is not improperly influenced by any arrangements between pharmacies and other providers of which the patient may be unaware.

What we propose to do

9. The Department proposes to lay certain amendments to the 2005 Regulations following this consultation to address the matters identified above.

10. At this stage, the Department has not identified a significant impact arising from these proposals. However, this could change. For example, the proposals about notification of changes in opening hours in paragraph 6 are designed to correct a problem with the operation of the current Regulations. If, however, this led to a considerable and regular increase in applications temporarily to change core contractual hours to accommodate specific holiday periods such as Christmas and Easter, then it may be appropriate to consider ways to help PCTs manage any additional administrative burden. For example, it might be appropriate to introduce a charge for such applications or to limit the number of applications to no more than one per year, or a combination of both.

Questions for consultation

The Department proposes to make certain amendments to the 2005 Regulations and associated legislation.

Do you agree the amendments proposed? If not, which do you not agree with?

At this stage, no significant impact has been identified from these proposals. However, if you consider these amendments would have a significant impact for PCTs or for business, please say what this is and how best any such impact might be managed.

Are there other amendments you wish to propose that the Department should consider? If so, please say how they would clarify or improve the working of the regulatory system.

Amendments to the provisions relating to Local Pharmaceutical Services (LPS) contracts

What is the problem?

11. The Department is proposing to make amendments to LPS legislation where a small number of provisions would benefit from updating.

12. The Department believes these amendments would

- better reflect parallel contracts for other primary healthcare providers;
- address specific issues that have been highlighted by parties to LPS contracts as they have developed; and
- more appropriately reflect the policy intentions set out in this consultation.

What needs to change?

13. The Department believes that the legislation may require amendment in two areas.

14. The first is the meaning of the term ‘LPS scheme’. This is set out in Schedule 12, paragraph 1(2)(b) and (c), to the 2006 Act.

15. At present, the legislation restricts a PCT from being an LPS provider and excludes a PCT from being an LPS provider to another PCT. In certain situations, such as emergencies or the absence of any other suitable alternative provider, it may be prudent for a PCT to have the power to act itself as the service provider in order to fulfil its obligations to its population or sections of its population to secure pharmaceutical

services. Similarly, it may be prudent for other PCTs to be capable of being LPS providers in the same way as any other prospective LPS provider. This would bring LPS into line with other primary care services, for example, primary medical services provided under PMS agreements.

16. The second is the removal of the restriction in paragraph 3(2) of Schedule 12, whereby any participant may withdraw from an LPS scheme (before an agreement is signed) but this right does not extend to the PCT itself. This appears to be unnecessarily restrictive in view of the fact that participation in LPS schemes is entirely voluntary.

What we propose to do

17. The Department would welcome views on whether the changes proposed to the legislation should allow for the situations described.

18. At this stage, the Department does not believe either of these proposals would have a significant impact on business, on the NHS or on the public. An Impact Assessment has therefore not been prepared.

Questions for consultation

The Department is inviting views on whether amendments to the legislation concerning local pharmaceutical services contracts should be introduced.

Do you agree that the proposed changes to LPS legislation are needed?

Are there other changes to the LPS legislation which the Department should consider?

No significant impact has been identified in respect of these proposals. If you believe they would have such an impact, please explain what this might be and how it might best be managed.

Chapter 7: Consultation questions

1. Chapters 2 – 6 of this consultation set out a number of questions about the proposals set out here on which the Department welcomes views.

2. A template for sending responses to this consultation and the associated Impact Assessments and other documents accompanying this consultation is available as a separate publication at www.dh.gov.uk/Consultations.

Equality Impact Assessment

3. The Department's Equality Impact Assessment is set out in the accompanying Impact Assessment document. The Department welcomes responses, particularly from those representing affected communities, to advise whether key equality issues have been raised and addressed as part of this consultation. If not, then the Department will take into account comments made or accept other suggestions to address matters of equality, and will conduct a further equality impact assessment based on those comments and suggestions, as the proposals set out in this consultation are developed.

Impact on small firms

4. The Impact Assessments include the Department's assessment of the effects of various proposals on small firms. As any changes to legislation would apply to all NHS contractors, the Department does not consider it would be appropriate to exempt (either fully or partially) smaller firms from these provisions.

5. The Department welcomes comments on the impact on small businesses of the proposals set out here and in particular:

- *How serious is the problem the proposals seek to address in relation to smaller firms?*
- *What changes will smaller firms have to make to the way their business operates?*
- *Is there likely to be a greater impact on the operations and performance of smaller business than others?*
- *What are the likely approximate costs and benefits of the proposals for small business?*

How to respond

1. Views on this consultation and associated documents should be sent by e-mail to: PWPCONS@dh.gsi.gov.uk by **Thursday 20th November 2008** using the template included with this document and published separately at www.dh.gov.uk/Consultations. Additional copies can be downloaded from www.dh.gov.uk/Consultations or writing to the address below.

2. Alternatively, responses can be sent by post to:

   Gillian Farnfield
   Area 453D
   Skipton House
   80 London Road
   London
   SE1 6LH.

3. A list of consultees is attached at **Annex A**.

National Listening Events

4. The Department will host with NHS Primary Care Contracting a series of national listening events to support this consultation. These will begin later in the autumn and details of how to book will be available as soon as possible at www.pcc.nhs.uk.

Consultation criteria

The Cabinet Office Code of Practice on Consultation sets out the criteria to be followed in written, public consultations:

- Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of policy;
- Be clear about what proposals are, who may be affected, what questions are being asked and the timescale for responses;
- Ensure that your consultation is clear, concise and widely accessible;
- Give feedback regarding the responses received and how the consultation process influenced the policy;
- Monitor their effectiveness at consultation, including through the use of a designated consultation co-ordinator; and
- Ensure consultations follow better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate.

The full text of the code of practice is on the Cabinet Office website at: www.cabinetoffice.gov.uk/regulation/consultation/code.asp.

Comments on the consultation process itself

The Code invites respondents to 'comment on the extent to which the criteria have been adhered to and to suggest ways of further improving the consultation process.' If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please contact:

Consultations Co-ordinator
Department of Health
Room 3E58
Quarry House
Quarry Hill
Leeds LS2 7UE
Email: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information that you have provided to be confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

ANNEX A – List of Consultees

All Party Pharmacy Group

Association of Independent Multiple pharmacies (AIMp)

British Healthcare Trades Association (BHTA)

British Medical Association - General Practitioners' Committee (BMA GPC)

British Retail Consortium

Company Chemists' Association (CCA)

Dispensing Doctors' Association

Ethnic Minority Business Task Force

Federation of Small Businesses

Independent Dispensing Appliance Contractors Association (INDAC)

Independent Pharmacy Federation

Long-term Conditions Alliance

National Association of Primary Care

National Consumer Council

NHS Alliance

Primary Care Pharmacists' Association

NHS Confederation

NHS Employers

NHS Litigation Authority (NHSLA)

National Pharmacy Association

Office of Fair Trading

Patients' Association

Pharmaceutical Services Negotiating Committee (PSNC)

Royal Pharmaceutical Society of Great Britain

Small Practices Association

Which?

ANNEX B – Current contractual and market entry arrangements for contractors providing NHS pharmaceutical services

Community Pharmacy Contractual Framework

1. *A Vision for Pharmacy for 2003* mapped out the ambition for a new contractual framework for community pharmacy to reflect modern service requirements and to help ensure community pharmacy is an integral part of the NHS and not just another shop on the high street.

2. The Pharmaceutical Services Negotiating Committee (PSNC) recommended the new framework to contractors who voted overwhelmingly in favour in November 2004.

3. The new framework went live from 1 April 2005 with all pharmacies providing essential services from 1 October 2005. PCTs are monitoring performance.

4. 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.

5. The framework provides 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.

6. Data from the NHS Business Services Authority indicate that, as at 30 May 2008, there were 10,306 pharmacies open in England. This compares with 10,133 as at 31 March 2007, 9,872 as at 31 March 2006 and 9,736 as at 31 March 2005[18], immediately before the entry system was reformed. This represents an overall increase of 570 pharmacies since reforms were introduced in April 2005. As at 31 March 2007, there were 164 appliance contractors supplying NHS appliances in England, of which 128 were actively dispensing appliances during 2006/07. In addition, there were some 130 pharmacies in Britain in 2002 without NHS contracts.

Local Pharmaceutical Services

7. Local Pharmaceutical Services (LPS) are provided under Chapters 2 - 4 of Part 7 of the NHS Act 2006, and Schedules 11 and 12 to that Act. LPS are arrangements made by PCTs with another party for the provision of such services. Such arrangements may also include the provision of services which are not LPS, but which may be provided under the 2006 Act, such as the provision of training and education (see section 134(3)).

8. The Information Centre includes data on the number of LPS contracts held by PCTs in Table 9a of the annual Statistical Bulletin. This shows there were 226 LPS contractors as at 31 March 2007, the majority of which (181) were contractors providing essential pharmaceutical service which were transferred over from national arrangements to individual LPS contracts from 1 April 2006.

Control of Entry for pharmacies and appliance contractors

9. These are rules derived from the NHS Act 2006 for determining whether a pharmaceutical contractor can provide NHS pharmaceutical services.

10. These are set out in the NHS (Pharmaceutical Services) Regulations 2005 SI 2005/641.

11. This is a devolved matter and each of the four countries has its own legislation.

[18] *General Pharmaceutical Services (Annual Bulletin) 2006/07* , Information Centre for Health and Social Care www.ic.nhs.uk/statistics-and-data-collections/primary-care/pharmacies/general-pharmaceutical-services-annual-bulletin-2006-07

12. In England, no new contractor can be entered onto a NHS list unless it is 'necessary or desirable'[19] to secure the adequate provision of pharmaceutical services locally. This is the 'control of entry' test.

13. If a new service provider is judged neither necessary nor desirable, then the NHS must refuse the application. There are rights of appeal. Introduced in the mid-1980s, this restricted market entry. The Office of Fair Trading recommended total deregulation in 2003 to improve competition, reduce prices and improve access to, and the quality of, pharmaceutical services.

14. In England, the Government responded with a package of reforms, moving cautiously in the direction the OFT recommended.

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

16. 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.

17. The reforms came into effect from 1 April 2005.

Remuneration arrangements for community pharmacies

18. Remuneration is determined in negotiations with the Pharmaceutical Services Negotiating Committee (PSNC), which represents community pharmacy contractors, and discussions with NHS Employers. The fees and allowances which this funding pays for include services, such as dispensing prescriptions and other essential services, provided under the national framework as well as advanced services.

19. Central funding also pays the fees and allowances for appliance contractors. Details are published monthly in the Drug Tariff.

20. In addition, contractors are reimbursed the costs of the NHS medicines, appliances and other items (such as gluten-free foods) prescribed and supplied.

[19] As proposed in Chapter 6 paragraph 5, the Department proposes amending the 2005 Regulations to align the wording of the test in Regulation 12 with section 129(2)(c) of the NHS Act 2006.

21. Local enhanced services are commissioned and funded separately by PCTs from their unified allocations.

Dispensing doctor arrangements

22. Dispensing in primary medical services is permitted under Part 7 of the NHS Act 2006 by virtue of the 2005 Regulations made under section 132 of the Act. Since 1 April 2004 (which carried forward previous measures in place since 1996), it is also permitted under Part 4 of the Act by virtue of Regulations made under section 94 for personal medical services and section 89 for general medical services. These are the National Health Service (General Medical Services Contracts) Regulations 2004[20] ('the GMS Regulations') (Schedule 6) (as amended) and the National Health Service (Personal Medical Services Agreements) Regulations 2004[21] ('the PMS Regulations') (Schedule 5) (as amended). The doctor involved in providing dispensing services must be a holder of, or employed or engaged by a holder of, a GMS contract, a PMS agreement or a APMS contract or alternatively be engaged by a PCT providing primary medical services under section 93 of the NHS Act.

23. The current rules under which doctors dispense stem largely from Regulation 30 of the National Health Insurance Commissioners Regulations 1912 (today's equivalent is in regulation 60 of the 2005 Regulations):

> 'Where an insured person is resident in a rural area at a distance of more than one mile from the place of business of a chemist who is on the list, or where the Committee are satisfied that an insured person by reason of distance or inadequacy of means of communication will have difficulty in obtaining any necessary drugs or appliances from a chemist or other persons on the list the Committee may, and shall, if the practitioner so desires make arrangements…'

24. In providing dispensing services, the doctor has to comply with the provisions of Schedule 2 of the NHS (Pharmaceutical Services) Regulations 2005 (Terms of Service of Dispensing Doctors). The GMS Regulations and PMS Regulations replicate equivalent provisions. A list of dispensing doctors is maintained by the PCT by virtue of regulation 69 of the 2005 Regulations.

25. A patient is eligible to receive dispensing services from their doctor if:-

- they would have serious difficulty in obtaining pharmaceutical services by reason of distance or inadequacy of communication; or

[20] S.I. 2004/291, as amended.

[21] S.I. 2004/627, as amended.

- they live in a 'controlled locality' at a distance of more than 1.6 km from a pharmacy; or
- they live in a 'controlled locality' and any pharmacy within 1.6 km is in a reserved location or is a distance-selling chemist.

26. A 'controlled locality' is defined as an area which has been determined to be rural in character. PCTs determine rurality. A 'reserved location' is an area in which the number of individuals on all patient lists for the area is less than 2,750. A 'distance selling chemist' is a chemist who provides pharmaceutical services from premises such that all persons receiving the services do so otherwise than at those premises – in essence a purely internet or mail order pharmacy.

27. Once a doctor has been granted outline consent and premises approval it is in most cases kept indefinitely. It can be passed from one doctor to another, for example, where the doctor retires and the practice continues with another doctor. However, approval for a doctor to provide dispensing services can be withdrawn if a chemist is granted approval to provide NHS pharmaceutical services within 1.6 km. In these cases, dispensing doctors are normally given a period of 'gradualisation' whereby patients transfer to the new pharmacy.

28. The total number of dispensing GP practices has remained very stable in recent years - 1,161 at March 2004, 1,153 at March 2005, 1,150 at March 2006, 1,138 at March 2007 and 1,147 at March 2008. Dispensing doctors provide dispensing services to around 3.4 million patients, representing under 7% of the total number of patients registered nationally with GP practices, or on average just under 3,000 patients per dispensing practice.

29. If a patient in a 'controlled locality' requests a doctor to provide him with pharmaceutical services, the doctor can only do so if he (or another doctor within his practice) has outline consent, and there is premises approval in relation to the premises from which the doctor will dispense.

30. Where a patient requests the provision of pharmaceutical services from his doctor, the doctor must apply for outline consent and premises approval under regulation 61, unless he (or another doctor within his practice) already has such consents and approvals.

31. The application for outline consent must specify the area in relation to which he wishes to be granted outline consent. The application for premises approval must specify the premises from which the doctor wishes to dispense. Approval may be granted for some or all of the premises for which approval is sought.

32. Outline consent will be refused in relation to any part of an area which is not within a controlled locality or which is within 1.6 km of any pharmacy. Premises approval will be refused for any premises which are within 1.6km of any pharmacy (regulation 18).

33. Outline consent will be withdrawn if the PCT approves an application from a pharmacist to open a pharmacy in that area (whether that area is controlled or not controlled) for any patient who now lives in a controlled area which is within 1.6km of the pharmacy premises. Before granting such an application, the PCT will have considered whether granting the application would be prejudicial to the delivery of primary medical services. If the application is granted, notice will be given to the doctor to cease (or gradually reduce) dispensing to the patients concerned. The doctor may be granted an often lengthy period of time in which to do so.

34. The fees and allowances payable to dispensing doctors are set out in the Statement of Financial Entitlements (SFE) published by the Department.

ANNEX C – National Clinical Assessment Service (NCAS) and the Safeguarding Vulnerable Groups Act 2006

The role of the National Clinical Assessment Service (NCAS)

1. The National Clinical Assessment Service (NCAS) was established in 2001 to work with NHS organisations and individual doctors where a doctor's clinical performance may be giving cause for concern. Its remit has since expanded to include dentists in both general practice and salaried dentists and it provides this service across the UK, across the public and private sectors of health. NCAS now handles between 700 and 1000 referrals per annum. From April 2009, a two-year pilot NCAS service will be extended to include pharmacists.

2. NCAS does not take on the role of an employer or contractor for health services, nor does it function as a regulator. It is established as an advisory body within the National Patient Safety Agency (NPSA), and the referrer retains responsibility for handling the case throughout the process. The support which NCAS provides can range from advice over the telephone, through more detailed and ongoing support and, where agreed appropriate, undertaking a full assessment of a practitioner's performance. NCAS' Back on Track resource provides tools which can be used to help, where possible, with the remediation of a practitioner who is in difficulty. It has developed significant experience in managing such situations and has also significantly reduced the number of long term NHS suspensions.

3. NCAS guiding principles are to be effective, authoritative, objective and fair. These principles underpin the way NCAS works. It does not provide legal advice but can advise NHS organisations on applying the relevant statutory policies and procedures, including, where applicable, the performers' list Regulations, as well as identifying where other relevant agencies might also assist. It has memoranda of understanding with a range of organisations including professional bodies, professional regulators, Royal Colleges, the Healthcare Commission and the Health Service Ombudsman. It also works closely with Postgraduate Deans and representatives of the profession as well as involving patient and public representatives in the work it does.

4. Employing organisations, managers or practitioners themselves can contact NCAS for advice to help a practitioner to deliver a safe and useful service to patients.

How does this affect pharmacists?

5. Work is ongoing to ensure local and national arrangements are in place to identify and respond to concerns about the performance of pharmacists. However, a governance gap arises where local or national systems are inadequate to identify and deal with concerns, or because information relating to unresolved concerns is not passed on effectively to the relevant parties who need to be aware of this

6. Local systems may be inadequate because there is no agreed procedure or staff working within them do not have adequate training, support or seniority. Patients and colleagues may not know how or when to refer a member of staff who may be getting into difficulty and there may be no single point of collation of information about a practitioner from a variety of sources.

7. The expansion of pharmacists' roles and their vital contribution to the safe use of medicines in the NHS point to the need for enhanced systems for identifying and addressing any performance difficulties. It has been agreed that NCAS with its expertise and experience can fill this governance gap for pharmacists.

8. Currently PCTs rely on the community pharmacy contractual framework and the NHS (Pharmaceutical Services) Regulations 2005 to address service concerns but this may not adequately support and address the underperformance of the individual practitioner. The application locally of provisions comparable with those for medical and dental performers can be a helpful tool in enabling the relevant Primary Care Organisation to secure the engagement in local processes of individual practitioners. Where necessary a decision can also be made to restrict or remove the practitioner on grounds of efficiency, fraud, or suitability but with the right of appeal preserved. Given the proportion of locum pharmacists who work in the NHS, without some statutory interface with individual clinicians, it is difficult to see how PCTs can fulfil their statutory duty of quality.

9. The benefits of a national NCAS service for pharmacists where there are concerns about their performance would be:

- avoiding harm to patients;
- boosting patients' and the general public's confidence;
- improving the welfare of the practitioner concerned;
- improving colleagues' morale; and
- improving team functioning/productivity.

Further information about the work of NCAS can be found on its website at: www.ncas.npsa.nhs.uk.

The Safeguarding Vulnerable Groups Act 2006

10. The Safeguarding Vulnerable Groups Act 2006 was introduced in response to a key recommendation of the Bichard Inquiry into the Soham murders. It provides the legal framework for a new vetting and barring scheme which will help prevent those who pose a risk of harm to children and/or vulnerable adults from gaining access to them through their work. Barring decisions will be made by the Independent Safeguarding Authority (ISA), a Non Departmental Public Body.

11. The new vetting and barring scheme, to be introduced on a phased roll-out from October 2009, will build on the current arrangements for pre-employment checks for people working with children and/or vulnerable adults in health and social care settings. This will replace the Protection of Children Act (POCA) scheme and the Protection of Vulnerable Adults (POVA) scheme and will supplement current arrangements for Criminal Records Bureau (CRB) Disclosures.

Requirements for ISA registration

12. The definition of 'vulnerable adult' for the purpose of the Safeguarding Vulnerable Groups Act is very wide. Section 59 of the Act provides that a vulnerable adult is, among other things, a person aged 18 or over who receives 'any form of health care'. The term 'health care' is also very wide and applies to health care provided in any hospital or community setting.

13. There are two categories of work in the Act in respect of which ISA registration will be required – 'regulated activity' and 'controlled activity'. Regulated activity is defined in Schedule 4 to the Act and includes:

    (i) training, teaching or instructing children or vulnerable adults;
    (ii) caring for or supervising children or vulnerable adults;
    (iii) the provision of assistance, advice or guidance to children or vulnerable adults;
    (iv) the provision of treatment or therapy to children or vulnerable adults.

14. Regulated activity applies where the activity is carried out frequently or overnight or satisfies a period condition of taking place on three or more days in any 30-day period. Activities carried out in a pharmacy setting which involve the provision of advice, assistance, guidance or medical treatment and which are carried out frequently, overnight or in line with this period condition will be regulated activity under the Act.

15. Controlled activity includes positions in primary care and hospital settings which are not regulated activity but which provide the opportunity to have any form of contact with a child or vulnerable adult or to access the health or social services records of a child or vulnerable adult. As with regulated activity, controlled activity applies where the activity is carried out frequently or overnight or satisfies the period condition of taking place on three or more days in any 30-day period. This may apply to some pharmacy staff, including counter staff whose roles do not involve the provision of advice, assistance, guidance or medical treatment but who nevertheless have contact with vulnerable adults or access to their health records.

16. Where an employer engages a person in regulated or controlled activity with children or vulnerable adults, they will first be required to check whether that person is ISA-registered. It will be an offence for an employer to permit an individual who is not ISA-registered, or who is barred, to work in regulated activity. It will also be an offence for a barred individual to work or seek work in regulated activity in either an employed or self-employed capacity. Employers will however be able to choose to employ a barred person in controlled activity, if they put appropriate safeguards in place.

Timing and cost of checks

17. The new vetting and barring scheme will be introduced over a five-year phasing period, beginning on 12 October 2009. Initially registration will be required for new staff entering regulated activity and staff changing jobs within regulated activity. Existing staff in regulated activity will be the next group of workers who will be required to join the scheme, beginning with staff who have never had a CRB Disclosure. This is likely to affect a large proportion of pharmacists and other pharmacy staff engaged in regulated activity, where they have not undergone CRB checks in the past. Staff in controlled activity will be required to join the scheme towards the end of the five-year phasing period.

18. The cost of registration with the ISA will be £64, comprising £36 for the CRB Enhanced Disclosure and a £28 fee to fund the running of the ISA. It will be a matter for individual employers to decide whether they wish to meet the costs of ISA registration on behalf of their employees or prospective employees. The ISA registration fee is a one-off fee and subsequent employers will be able to check an individual's ISA registration without charge.