

**Review of progress on reforms in  
England to the “Control of Entry”  
system for NHS pharmaceutical  
contractors**

**Consultation Document**

**June 2006**

**Gateway reference: 6559**

# Department of Health consultation on the review of progress on reforms in England to the “Control of Entry” system for NHS pharmaceutical contractors

## Introduction

1. On 17 July 2003, the Government announced its response for England<sup>1</sup> to the Office of Fair Trading (OFT) report *The control of entry regulations and retail pharmacy services in the UK*<sup>2</sup>.
2. This announcement set out a balanced package of reform measures to the regulatory system known as “control of entry.” The majority of these reforms were introduced by revising NHS regulations in April 2005<sup>3</sup>.
3. The announcement also committed the Government to review progress in mid-2006 and to publish the findings. The terms of reference and methodology for this review, as announced to Parliament by Andy Burnham, Minister of State at the Department of Health, are at **Annex A**.
4. The Department expects to complete the review and to publish a report by the end of October 2006.

## Consultation to inform the review of progress

5. As part of this progress review, the Department of Health now invites views and comments from patients and consumers, the NHS, business and other key stakeholders on the operation of the reformed regulatory system.
6. A list of organisations to whom this consultation document has been sent is at **Annex B**.
7. Comments and views should be sent **by Tuesday 12<sup>th</sup> September 2006** to

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

Fax 0207 972 2953  
Or by e-mail to : [gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk)

8. An expandable Word document electronic reply form is attached at **Annex C** for respondents who wish to use this.

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<sup>1</sup> House of Commons Written Ministerial Statement, Secretary of State for Trade & Industry, 17 July 2003 Cols 76WS – 79WS.

<sup>2</sup> The full report (revised March 2003) is available at <http://www.offt.gov.uk/News/Publications/Leaflet+Ordering.htm>  
Ref oft 609

<sup>3</sup> The NHS(Pharmaceutical Services) Regulations 2005 – SI 2005/641 as amended by SI 2005/1015, SI 2005/1501 and SI 2006/552. These regulations are available from The Stationery Office or the Office of Public Sector Information website at [www.opsi.gov.uk/stat.htm](http://www.opsi.gov.uk/stat.htm)

## Regional “listening” events

9. To augment this consultation, the Department is hosting a series of regional “listening” events in July 2006 to which patients and consumers, the NHS and business representatives are invited to attend. The purpose is to hear and exchange views and ideas in more detail on the operation of the regulations. **Annex D** provides information on the dates and venues for these events. Places are limited. To book, please visit the website of NHS Primary Care Contracting at [www.pcc.nhs.uk](http://www.pcc.nhs.uk)

## Confidentiality Disclaimer

10. Comments, views and information sent in response to this consultation and expressed at the listening events may need to be shared with colleagues within the Department of Health and other Government departments. They may also be included and published in a summary of responses to this consultation. The Department assumes respondents give their consent for the Department to do this and, if replies are received by e-mail, that this consent overrides any confidentiality disclaimer generated by an individual’s or organisation’s IT system, unless, when replying, respondents specifically include a request not to disclose some or all of their reply.

## Compliance with Cabinet Office Code of Practice on Consultation

11. This consultation follows the Cabinet Office Code of Practice on consultation. The Code of Practice is available in the consultations section of the Department of Health’s website. In due course, a summary of views received to the consultation will be included in the final report to be published on the Department’s website.
12. The consultation criteria in the Code of Practice are at **Annex E**.
13. Any complaint about aspects of this consultation should be sent to:

Steve Wells  
Consultations Co-ordinator  
Department of Health  
Skipton House  
80 London Road  
LONDON SE1 6LH

e-mail: [Steve.Wells@dh.qsi.gov.uk](mailto:Steve.Wells@dh.qsi.gov.uk)

## **Background and context to this review of progress**

### ***“Control of entry”***

14. “Control of entry” is the system by which the NHS determines whether a contractor can provide NHS pharmaceutical services. The law governing the provision of these services in England is set out in Sections 41 - 43 of the NHS Act 1977. The control of entry system, originally introduced in 1987, was substantially reformed under the NHS (Pharmaceutical Services) Regulations 2005 SI 2005/641 (as amended) which came into force from 1 April 2005.
15. Contractors are either pharmacists (who supply medicines and certain appliances) or appliance contractors (who can only supply appliances such as incontinence and stoma aids, dressings, bandages etc.). Collectively, they are termed “chemists”. The control of entry system does not control whether a chemist can set up in business or not. Rather it governs whether a chemist can provide NHS services. However, for many chemists, it may be unviable to operate a business unless they can do so.
16. In brief, a chemist wishing to provide NHS services in England applies to the relevant Primary Care Trust (PCT) under the Regulations. The PCT - in most cases - invites comments from interested parties locally including patient and consumer groups, and then makes a decision. Under Section 42 of the Act it has to decide whether it is “necessary or desirable” to grant the application in order to secure adequate provision of pharmaceutical services locally. This is the “control of entry” test. A PCT deals administratively without consulting on certain other types of applications (for example, a minor relocation of premises). Most types of decisions by PCTs are appealable to an independent NHS appeal body – the Family Health Services Appeal Unit of the NHS Litigation Authority.

### ***Rural issues***

17. Under certain circumstances, a doctor may also dispense medicines or appliances to his patients. This largely takes place in rural areas designated as such by the PCT and is subject to conditions. Doctors can only dispense to their own patients who live within the designated area and more than 1.6 kilometres from their nearest pharmacy. The main purpose is to ensure patients in rural areas who might have difficulty getting to a pharmacy can access the medicines they need.
18. The PCT must be satisfied that when a doctor wishes to apply to dispense, it would not prejudice the proper provision of medical, pharmaceutical or dispensing services locally. This is known as the “prejudice” test. There is no “control of entry” test for a doctor to pass. However, a chemist wishing to open in a rural area must pass both the “control of entry” and “prejudice” tests.
19. More information about the law and the background to the operation of the control of entry system and the special circumstances applying in rural areas is available in Departmental guidance for Primary Care Trusts which accompanies the 2005 Regulations. This is available on the Department’s website at [http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4107573&chk=5TqNtc](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107573&chk=5TqNtc)

### ***The Office of Fair Trading report and recommendation***

20. The Office of Fair Trading (OFT) announced an enquiry into retail pharmacy services under Section 2 of the Fair Trading Act 1973 in October 2001. It published its report, *The control of entry regulations and retail pharmacy services in the UK* in January 2003 (and a revised version in March 2003).
21. This OFT enquiry was one of three studies launched following the White Paper "Opportunity for All in a World of Change." The OFT has responsibility to advise where laws and regulations create barriers to entry and competition, or channel markets in a particular direction, thereby holding back innovation and progress.
22. The OFT recommended abolition of the then current statutory entry controls on chemists who can dispense NHS prescriptions to improve competition, to reduce prices for medicines sold over the counter and to improve access to, and the quality of, pharmaceutical services.

### ***Government response***

23. Following an interim response on 26 March 2003, the Government published its final response for England to the OFT report on 17 July 2003. Whilst not accepting the OFT's recommendation in full, it announced its intention to move cautiously in the direction of deregulation by introducing a balanced package of reforms to the regulatory system.
24. In summary, that package of measures comprised three strands:
  - i) to introduce new criteria of choice and competition for a "necessary or desirable" chemist within the current regulatory framework;
  - ii) to exempt fully applications from pharmacies from the control of entry requirements:
    - a) in large shopping developments over 15,000 square metres;
    - b) to pharmacies that intend to open for more than 100 hours a week;
    - c) to those that are part of a consortium to establish one of the new one-stop primary care centres;  
  
(subject to all such pharmacies providing a full and prescribed range of services, appropriate to local needs, determined by the PCT); and
    - d) to exempt wholly internet or mail-order based pharmacy services, subject to such pharmacies providing the full range of essential services at that time still to be agreed within a new national contractual framework for community pharmacy (see paragraphs 31 et seq. below);  
  
and
  - iii) to reform and modernise the operation and administration of the regulatory system.

## ***Aims of the reforms***

25. The overall aims of the reforms were to:
- promote consumer choice and to harness the benefits of increased competition;
  - improve further the accessibility and convenience of pharmaceutical services;
  - make the regulatory system more business-friendly;
  - provide more certainty and reliability for companies who depend upon that system; and
  - make the process less time-consuming, ensuring PCT decisions were taken quickly and with ready access to a sound appeals mechanism. For example, PCTs now have four months, including 45 days for consultation, in which to decide applications. The time limit for more straightforward applications on which consultation is not required is 30 days.

## ***Consultation on the reforms***

26. The Department of Health then consulted on these proposals in the autumn of 2003. *Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992*, available on the Department's website, set out the details of the proposed reforms and invited comments to feed into the work of an expert Advisory Group which the Department set up.

## ***Advisory Group on the Reform of the NHS (Pharmaceutical Services) Regulations 1992***

27. The Department set up an Advisory Group in August 2003 under the chairmanship of Anne Galbraith, then Chair of the Prescription Pricing Authority. The role of the Group was to consider and advise how best to implement the reforms. The Group reported in January 2004. The Executive Summary of their report was published in March 2004 and the full report in March 2005 on the Department's website.

## ***Implementation of the proposals and Advisory Group recommendations***

28. On 18 August 2004<sup>4</sup>, and in a further written statement to the House of Commons on 7 September 2004<sup>5</sup>, the Government announced that it had accepted the great majority of the Group's recommendations and would now proceed to implement the reforms, with some amendments. Most of these reforms would be introduced by amending the regulatory system in the then NHS (Pharmaceutical Services) Regulations 1992. Key elements of the reforms were either implicitly or explicitly linked to a new contractual framework for NHS community pharmacies. At the time, negotiations on that framework were still continuing. The reforms would be introduced in tandem with the new framework once it was finalised.

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<sup>4</sup> Department of Health Press Release 2004/0310 *Better access to pharmacies and more choice for patients*

<sup>5</sup> House of Commons Written Ministerial Statement *Pharmacy Services (Control of Entry Regulations)* Minister of State for Health Cols 98WS – 102WS

29. The Government also confirmed its intention to introduce two further reforms requiring primary legislation. These were to enable reasonable charges, but not full cost recovery, for applications to provide NHS pharmaceutical services, and to allow PCTs, in assessing applications, to take into account the improvements applicants would bring to the provision of, or access to, over-the-counter medicines and other healthcare products and advice. These measures were included in the Health Bill introduced to the House of Commons on 17 October 2005 and currently before Parliament.

### ***The new Regulations***

30. The NHS (Pharmaceutical Services) Regulations 2005 (SI 2005/641) came into force on 1 April 2005 and have been further amended (see footnote 3 on page 1). The regulations cover the procedures governing control of entry, the “fitness to practise” regime for chemist contractors and also reforms to rural NHS dispensing arrangements introduced at the same time, as well as setting out the requirements of the new contractual framework for community pharmacy and the terms of service for appliance contractors and dispensing doctors.

### ***The new contractual framework for community pharmacy***

31. The new framework went live on 1 April 2005. This is designed to improve patient and consumer access to pharmacy services, to expand the range of services a community pharmacist can deliver to patients, and to make better use of the skills of pharmacists and their staff. In doing so, it will extend choice for patients and help to reduce some of the workload pressures on general practice. Funding of £1,766 million was available to support the framework in 2005/06 and negotiations with pharmacy contractors are continuing on funding for 2006/07.
32. The framework introduced three levels of services to be provided by community pharmacies:- essential, advanced and local enhanced services. All pharmacies have been required to deliver essential services since 1 October 2005 and many will provide advanced services. It is up to PCTs to work with contractors to commission local enhanced services in line with the PCT’s local assessment of pharmaceutical needs.
33. The essential services a pharmacy must provide are:
- dispensing and repeat dispensing including the supply of compliance support to those eligible under the Disability Discrimination Act
  - an electronic transmission of prescriptions service
  - disposal of unwanted medicines
  - promotion of healthy lifestyles
  - support for self care and signposting to other professionals
  - clinical governance (setting out minimum professional standards for a contractor such as patient surveys, clinical audit, staff management and training programmes etc)
34. To provide advanced services, pharmacists and/or their premises also need to be accredited. There is one current advanced service – a medicines use review and prescriptions intervention service. This is designed to help improve a patient’s knowledge and use of the drugs they take. It helps identify any problems, side-effects or adverse reactions the patient may be experiencing and ways in which these may be overcome.

35. There are 19 types of local enhanced services a PCT can commission. These might include a comprehensive out-of-hours service, minor ailment schemes so that patients do not need to see a doctor for a prescription to obtain their medicines, palliative care services, emergency hormonal contraception, needle exchange and substance misuse services. New services can also be developed locally.

#### ***Local pharmaceutical services contracts***

36. Separate to the new contractual framework, a PCT can also contract directly with a chemist under the Health and Social Care Act 2001, to provide local pharmaceutical services. Local pharmaceutical services provide an alternative legal framework for the provision of pharmaceutical and other services where these might not so easily be made under national arrangements. A broad range of other services not traditionally associated with community pharmacy, including training and education, may be included in a contract. They can also be used to support pharmacies serving more isolated or sparsely populated areas. There are around 270 such contracts at present, including some 230 "essential small pharmacy" contracts which provide additional financial support to secure the provision of NHS pharmaceutical services in areas where a pharmacy might otherwise be unviable. There are just under 10,000 chemist contractors in all in England providing NHS services.

#### ***White Paper "Our Health, Our Care, Our Say"***

37. On 30 January 2006, the Secretary of State for Health published the White Paper *Our Health, Our Care, Our Say – a new direction for community services*. This sets out the Government's programme to reshape community based health and social care provision, to put the needs of patients first, to make sure everyone has equal access to high-quality services and to get best value for money for the NHS.
38. This signifies a fundamental shift in the direction and delivery of services for the future. There is to be a much greater focus on earlier prevention and interventions which promote better health. Advice and support should be readily available for those who need it - especially people with long-term conditions and their carers. Patients must have more choice in where to go for their services and a greater say in how, when and where they are provided. So, as with other areas of service provision, pharmaceutical services must fit the needs of the patient - not the other way round. They must also be readily accessible. This is especially true for under-served or deprived areas to help break down the health inequalities which exist.
39. The Government is committed to developing the contractual framework for community pharmacy services in line with the ambitions set out in the White Paper. It is important therefore that this review of the progress in reforming the "control of entry" arrangements takes full account of that wider context and direction for service development.

#### ***Suggested areas to consider in responding to this consultation***

40. Respondents are welcome to comment on any aspect of the reforms of the control of entry regime to contribute to the review of progress. The Department would also welcome comments on the application of these reforms to the wider context of a new contractual framework for community pharmacy services and the recent White Paper as explained above.

41. The Department would particularly welcome views and perspectives on:

***The patient and consumer experience***

42. Two of the key aims of the reforms have been to promote more choice for consumers from harnessing the benefits of increased competition between chemists and to improve further the accessibility and convenience of pharmaceutical services for patients. These aims complement the extended range of essential services which pharmacies are now required to provide under their new NHS contractual framework and the extra services many are already or will be providing. Ready access to a pharmacy can be particularly important for those who may not have their own transport or cannot easily use other forms of transport (public or private) and for those who may live in more socially deprived areas where a pharmacy can play an important role in providing healthcare services.
- *To what extent do you think the provision of pharmaceutical services has changed locally since April 2005?*
  - *To what extent do you think you have more or less choice of these services since then?*
  - *To what extent is it easier or more difficult to access services when you need them (the Department particularly welcomes views from patients and consumers with transport problems or who may live in more socially deprived areas)?*
  - *In what way do you think service provision could be enhanced in future?*
  - *Are there other changes you would like to see?*

***The NHS experience***

43. The reforms have had a number of impacts on PCTs. They were designed to streamline the application and decision-making processes, to make them less time-consuming and to ensure PCT decisions were taken quickly. For example, PCTs now have four months, including 45 days for consultation, in which to decide applications. The time limit for more straightforward applications on which consultation is not required is 30 days. PCTs can also approve automatically premises relocations under 500 metres, and for the first time, where these cross PCT boundaries. The reforms were also designed to help PCTs take quick decisions where appropriate. For example, PCTs can reject certain types of applications which do not meet designated criteria. The reforms also introduced certain safeguards. For example, a PCT can only approve a pharmacy application under one of the first three exemptions provided the applicant undertakes to provide specified services, and to remove them if they do not. An exempt application cannot be approved if it is in the same neighbourhood as a current local pharmaceutical services (LPS) contractor.
- *To what extent have the reforms impacted on the provision of and access to pharmaceutical services locally since April 2005 (particularly where there are transport difficulties or for more socially deprived areas)?*
  - *To what extent have the reforms improved the choice of and competition for services, their quality and innovative nature?*
  - *To what extent have the new requirements for determining applications (e.g. the links to the new contractual framework, exempt applications must meet certain minimum criteria, increased consultation requirements, deadlines for decisions) reduced or increased the administrative burden and costs on PCTs?*
  - *If you consider these have increased, do you consider the benefits outweigh those burdens and costs?*

- *How could the working of the regulatory regime be improved? For example, are the safeguards proportionate and reasonable?*

### **The business experience**

44. Two of the key aims for introducing the reforms for business were to make the regulatory system more business-friendly and to provide more certainty and reliability for companies who depend upon that system. As mentioned above, in doing so, the reforms were intended to make the process less time-consuming, ensuring PCT decisions were taken quickly and with ready access to a sound appeals mechanism. The new regulations also introduced other measures with a different impact on business. For example contractors must begin providing services within a much shorter period once approved (a maximum of 9 months as opposed to three or more years previously) or the approval lapses. And the counterbalancing safeguard to an application being approved automatically under one of the first three exemptions is that business must undertake to provide the services the PCT specifies locally are needed. An exempt application cannot be approved if it is in the same neighbourhood as a current local pharmaceutical services (LPS) contractor.
- *To what extent have you made use of the reforms since April 2005?*
  - *To what extent have the reforms impacted on the choice of and competition for services locally, their quality and innovative nature?*
  - *To what extent does the new regime provide more or less certainty and reliability for business?*
  - *To what extent do the new requirements for applications (e.g. the links to the new contractual framework, exempt applications must meet certain minimum criteria) make the process more or less business-friendly? Has this reduced or increased the burden and costs for business? If this has increased, do the benefits outweigh the burden and costs?*
  - *How could the working of the regulatory regime be improved? For example, are the safeguards proportionate and reasonable?*

### **Conclusion**

45. This consultation document invites the views of patients and consumers, the NHS and business on the operation of the reformed regulatory system for NHS pharmaceutical services as introduced in April 2005 in England, as part of a wider review of progress the Department is undertaking.
46. Comments and views should be sent **by Tuesday 12<sup>th</sup> September 2006** to

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

Fax 0207 972 2953  
 Or by e-mail to: [gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk)

**Department of Health  
 Medicines Pharmacy and Industry Group  
 June 2006**



## HOUSE OF COMMONS

*Notice of Written*

### **Ministerial Statement**

**Title of Secretary of State/Ministerial  
head of department:**

Secretary of State for Health

**Subject of Statement:**

Review: NHS pharmacy “control of entry” reforms (England)

**Date on which written statement to be made:**<sup>1</sup>

**Tuesday, 13 June 2006**

1. Notice of written statements for the following day will be placed on the effective Orders of the Day. Otherwise, the notices will be placed on Future Business E (written ministerial statements). Notices may be given of written statements to be made not later than 5 sitting days after the day on which notice was given.

## WRITTEN MINISTERIAL STATEMENT

### DEPARTMENT OF HEALTH

Tuesday, 13 June 2006

The Secretary of State for Health: Written Ministerial Statement on review of progress on reforms to the “control of entry” system for NHS pharmacies in England 2006

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#### **Ms Patricia Hewitt**

On 17 July 2003, my Rt hon Friend the Secretary of State for Trade and Industry announced the Government’s response for England to the Office of Fair Trading (OFT) report *The control of entry regulations and retail pharmacy services in the UK* Official Report, col 76-79ws

This set out a balanced package of reform measures which we have introduced largely by amending secondary legislation effective from April 2005.

Two remaining measures are in the Health Bill currently before Parliament. These are charging for pharmacy applications and including provision for NHS Primary Care Trusts to take into account, when assessing competing applications, the improvements they would bring to the provision of, or access to, over-the-counter medicines and other healthcare products and advice.

The announcement in 2003 also committed the Government to review the progress made by these reforms in mid-2006 and to publish the findings.

I have decided the review should go ahead as promised.

The terms of reference are:

To review and to report:

progress in implementing the balanced package of reform measures introduced in England from April 2005 on the control of entry system for NHS pharmaceutical services;

their effect on access to and the choice of, NHS pharmaceutical services for patients, taking account of the new contractual framework in place since April 2005;

their impact for consumers and the retail pharmacy market; the extent to which the operation of the new regulatory system is proportionate to the aims and objectives of the reforms; and

to publish the findings.

The review will be led by Department of Health officials in conjunction with colleagues in the NHS and other Government Departments.

The methodology will comprise:

a quantitative analysis of NHS Primary Care Trust (PCT) and other centrally sourced statistical data on community pharmacies, their applications to provide NHS services to PCTs, PCT decisions and appeals. This will also explore what discernible effect the reforms have had on pharmacy services in rural and socially deprived areas. It will be augmented as necessary by follow-up with PCTs;

as a sub-set of this quantitative analysis, a further review of applications to PCTs and their decisions on pharmacies exempted since April 2005 from the control of entry requirements and their provision of NHS services.;

a comparative analysis of summary historical data on NHS dispensing by community pharmacies, openings and closures, distances between pharmacies and, where available, opening hours.;

taking account of the new contractual framework, a review of the extent of the reforms' economic impact to date, including discernible effects on services and their provision, competition, market structure, concentration and, if time series data are available for these, medicines pricing strategies.;

a qualitative review of the reforms. Building on recent patient satisfaction consultations and surveys, the Department will consult and invite PCTs, contractors, patients and consumer groups, health professionals and other interested parties to feed back views on the operation of the reformed procedures. This will examine: what impact there has been on access to services, particularly for those without transport or in more socially deprived areas; the quality of the services provided by community pharmacies following these reforms; how innovative they are and developments respondents may wish to see in future;

a series of public regional "listening" events to complement the consultation and further meetings with representative bodies and other organisations as required to consider the impact of the reforms in more detail.

I intend the report should be completed and published by the end of October 2006.

Further details of the consultation, which begins on Tuesday 13<sup>th</sup> June and ends on Tuesday 12<sup>th</sup> September are available on the Department of Health's website at

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

Copies of the consultation document have been placed in the Library.

### List of organisations to whom this consultation document has been sent

All Party Parliamentary Pharmacy Group  
Association of the British Pharmaceutical Industry  
Association of Independent Multiple Pharmacies  
Better Regulation Executive  
British Healthcare Trades Association  
British Medical Association – General Practitioners' Committee  
British Retail Consortium  
Commission for Patient and Public Involvement in Health  
Commission for Racial Equality  
Company Chemists' Association  
Consumers' Association  
Dispensing Doctors' Association  
Ethnic Minority Business Forum  
Federation of Small Businesses  
National Consumer Council  
National Patient Safety Agency  
National Pharmacy Association  
NHS Confederation  
Patients Association  
Pharmaceutical Services Negotiating Committee  
Royal College of General Practitioners  
Royal Pharmaceutical Society of Great Britain

## ANNEX C

### Form for responding to the Department of Health consultation on the review of progress on reforms in England to the “Control of Entry” system for NHS pharmaceutical contractors

Name and address:

If responding on behalf of an organisation please state the name and address of the company/organisation etc and address if different

Telephone:

E-mail:

Comments and views should be sent **by Tuesday, 12 September 2006** to

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

Fax 0207 972 2953

Or by e-mail to : [gillian.farnfield@dh.gsi.gov.uk](mailto:gillian.farnfield@dh.gsi.gov.uk)

## Questions:

### ***The patient and consumer experience***

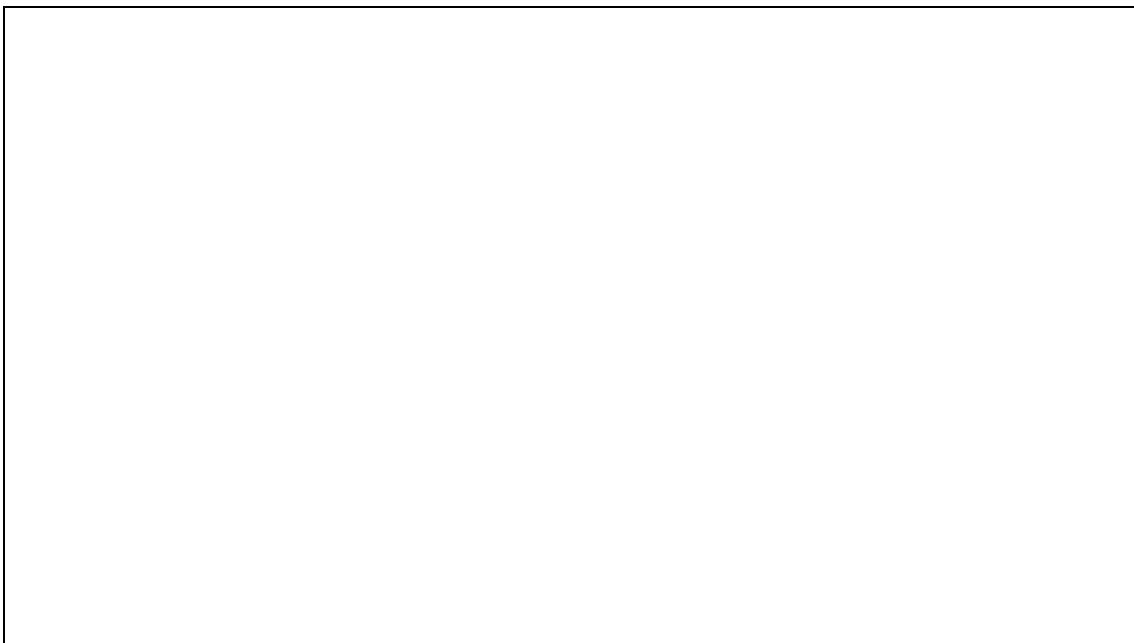
Two of the key aims of the reforms have been to promote more choice for consumers from harnessing the benefits of increased competition between chemists and to improve further the accessibility and convenience of pharmaceutical services for patients. These aims complement the extended range of essential services which pharmacies are now required to provide under their new NHS contractual framework and the extra services many are already or will be providing. Ready access to a pharmacy can be particularly important for those who may not have their own transport or cannot easily use other forms of transport (public or private) and for those who may live in more socially deprived areas where a pharmacy can play an important role in providing healthcare services.

- *To what extent do you think the provision of pharmaceutical services has changed locally since April 2005?*
- *To what extent do you think you have more or less choice of these services since then?*
- *To what extent is it easier or more difficult to access services when you need them (the Department particularly welcomes views from patients and consumers with transport problems or who may live in more socially deprived areas)?*
- *In what way do you think service provision could be enhanced in future?*
- *Are there other changes you would like to see?*

## ***The NHS experience***

The reforms have had a number of impacts on PCTs. They were designed to streamline the application and decision-making processes, to make them less time-consuming and to ensure PCT decisions were taken quickly. For example, PCTs now have four months, including 45 days for consultation, in which to decide applications. The time limit for more straightforward applications on which consultation is not required is 30 days. PCTs can also approve automatically premises relocations under 500 metres, and for the first time, where these cross PCT boundaries. The reforms were also designed to help PCTs take quick decisions where appropriate. For example, PCTs can reject certain types of applications which do not meet designated criteria. The reforms also introduced certain safeguards. For example, a PCT can only approve a pharmacy application under one of the first three exemptions provided the applicant undertakes to provide specified services, and to remove them if they do not. An exempt application cannot be approved if it is in the same neighbourhood as a current local pharmaceutical services (LPS) contractor.

- *To what extent have the reforms impacted on the provision of pharmaceutical services locally since April 2005 (particularly where there are transport difficulties or for more socially deprived areas)?*
- *To what extent have the reforms improved choice and competition for services, their quality and innovative nature?*
- *To what extent have the new requirements for determining applications (e.g. the links to the new contractual framework, exempt applications must meet certain minimum criteria, increased consultation requirements, deadlines for decisions) reduced or increased the administrative burden and costs on PCTs?*
- *If you consider these have increased, do you consider the benefits outweigh those burdens and costs?*
- *How could the working of the regulatory regime be improved? For example, are the safeguards proportionate and reasonable?*



### ***The business experience***

Two of the key aims for introducing the reforms for business were to make the regulatory system more business-friendly and to provide more certainty and reliability for companies who depend upon that system. As mentioned above, in doing so, the reforms were intended to make the process less time-consuming, ensuring PCT decisions were taken quickly and with ready access to a sound appeals mechanism. The new regulations also introduced other measures with a different impact on business. For example contractors must begin providing services within a much shorter period once approved (a maximum of 9 months as opposed to three or more years previously) or the approval lapses. And the counterbalancing safeguard to an application being approved automatically under one of the first three exemptions is that business must undertake to provide the services the PCT specifies locally are needed. An exempt application cannot be approved if it is in the same neighbourhood as a current local pharmaceutical services (LPS) contractor.

- *To what extent have you made use of the reforms since April 2005?*
- *To what extent do you think the reforms have impacted on the choice of and competition for services locally, their quality and innovative nature?*
- *To what extent does the new regime provide more or less certainty and reliability for business?*
- *To what extent do the new requirements for applications (e.g. the links to the new contractual framework, exempt applications must meet certain minimum criteria) make the decision-making process more or less business-friendly? Has this reduced or increased the burden and costs for business? If this has increased, do the benefits outweigh the burden and costs?*
- *How could the working of the regulatory regime be improved? For example, are the safeguards proportionate and reasonable?*

**REGIONAL “LISTENING” EVENTS**

At each venue there will be two 2-hour sessions for:

- 10.30 – 12.30            Patient and consumer groups and NHS representatives
- 13.30 – 15.30            Pharmaceutical services contractors and NHS representatives

A light sandwich lunch will be available from 12.30 - 1.30. The events are being facilitated by NHS Primary Care Contracting. For more details and to book a place visit their website at [www.pcc.nhs.uk](http://www.pcc.nhs.uk)

<b>Date</b>	<b>Venue</b>	<b>Area covering</b>
Wednesday 12 July	Preston Marriott Hotel Broughton, Lancs	North West
Thursday 13 July	Lakeside Conference Centre @ Aston Business School Birmingham	West Midlands
Monday 17 July	The Met Hotel Leeds	North East
Tuesday 18 July	The Nottingham Belfry Hotel Nottingham	East Midlands
Friday 21 July	Radisson Hotel Stansted Airport	East Anglia
Monday 24 July	Thistle Victoria Hotel Victoria, London	London/S. East
Thursday 27 July	Kirtons Farm Hotel Reading, Berkshire	South Central
Friday 28 July	The Gypsy Hill Hotel Exeter, Devon	South West

### CODE OF PRACTICE ON CONSULTATION

The criteria for consultation set out in the Cabinet Office Good Practice Guide on Consultation are:

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