Department of Health

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

Report

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Executive Summary

1. On 17 July 2003, the Government announced its response for England[1] to the Office of Fair Trading (OFT) report *The control of entry regulations and retail pharmacy services in the UK*[2].

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[3].

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 Patricia Hewitt, the Secretary of State for Health, on 13 June 2006[4] are at **Annex A**.

4. The Department has now completed its review and wishes to thank all those who have contributed to the report, particularly those who sent in responses to the consultation and attended public listening events in the summer of 2006.

5. The main report comprises:

    - an analysis of the statistical data on community chemists, their applications to provide NHS services to NHS Primary Care Trusts (PCTs), PCT decisions and appeals and comment on the data;

    - an analysis of applications to PCTs and their decisions on pharmacies exempted since April 2005 from the control of entry requirements;

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

    - a commentary on the extent of the reforms' economic impact to date;

      and

    - a qualitative review of the reforms including the results of consultation and feedback from the listening events.

6. Annexes contain selected statistical data and other information collected during the course of the review as well as a summary of the consultation responses and the full feedback from the listening events.

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[1] House of Commons Written Ministerial Statement, Secretary of State for Trade & Industry, 17 July 2003 Cols 76WS – 79WS.

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

[3] The NHS(Pharmaceutical Services) Regulations 2005 – SI 2005/641 as amended principally 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

[4] http://www.publications.parliament.uk/pa/cm200506/cmhansrd/cm060613/wmsindx/60613-x.htm

Summary of findings

7. Chapter 3 analyses statistical data on contractors providing NHS pharmaceutical services. On the evidence so far, the balanced package of reform measures has achieved the goal of opening up the market and providing more convenient services but without jeopardising the vast majority of the existing pharmacy network or causing widespread upheaval or change. NHS data show that 143 new pharmacies opened to provide NHS services in England during 2005/06. This is a net increase of 120 or just over 1% on numbers in 2004/05. The majority of new applications used the reformed “control of entry” test. The most common exemption route used was to apply to open a 100 hours a week pharmacy. Applications were not evenly spread across the country. A number of PCTs reported a rate of zero or just one application in 2005/06, many in metropolitan areas. However, nearly a third of all applications made under the reformed test or as an exemption were dealt with by just the 10% of PCTs with the highest rate of applications per 100,000 population. Grant of an application - and in particular grant of a 100 hours a week pharmacy - does not necessarily result in the pharmacy then opening to provide services.

8. Exempt pharmacies provide proportionally more local enhanced services than existing pharmacies. A PCT with greater social deprivation is no more or less likely to receive a new application to open a pharmacy under the reformed control of entry test than a PCT which does not have such deprivation. However, there was some evidence that PCTs with greater social deprivation received more applications under one of the exempt routes than would be expected by chance. There is no evidence so far of a detrimental impact on access to pharmaceutical services in deprived areas. There was no correlation between the rate of existing pharmacies per 100,000 head of population and the rate of applications received per 100,000 head of population. The costs to PCTs of processing new applications received in 2005/06 were between £1.3m and £2.6m. Where PCT decisions to approve applications under the reformed test are appealed, there has been an increase in 2006/07 in the proportion of cases where the Appeal Unit has endorsed the PCT decision.

9. Chapter 4 reviews the historical data and explores the extent of the economic impact of the reforms to date. In the past 10 years, the number of prescription items dispensed has increased by 47% whilst the number of community pharmacies has increased by 1%. Of the 9,872 English pharmacies, 56% are part of chains of companies with six or more outlets, compared to about a third 15 years ago. The greatest proportion of pharmacies opening in 2005/06 were within 500 metres of another. This reverses the trend of the previous 10 years. The proportion of pharmacies being paid extra to provide services out-of-hours (evening and at weekends) fell from 45% to 31% in 2005/06.

10. Of the population as a whole, 99%, including those in the most deprived areas can get to a pharmacy by car, walking or public transport within 20 minutes. Between 2003 and 2006, the percentage of people who could not get to a pharmacy within 10 minutes by walking or using public transport fell from 16.2% to 15.7%. Of those people living in the 10% most deprived areas in England, 77% can get to a pharmacy by public transport or walking within 10 minutes, compared to 84% nationally. Between 2003 and 2006, the number of GP surgeries within 10 minutes walk of a pharmacy has increased, and the number of pharmacies with one or two other pharmacies within 10

minutes walk has also increased. There is no national evidence yet of pharmacies clustering, although individual PCTs report this happening locally.

11. The prices of general sales list medicines are about 25% to 30% cheaper in supermarkets than in independent and multiple pharmacies. However, using sales weights that reflect the pattern of sales used in independent pharmacies reduces the price differential with supermarkets to about 15%. Pharmacy-only medicines supplied over-the-counter are about 10% cheaper in supermarkets. These results are similar to those of 2003. However, the gap between supermarkets and independent/multiple pharmacies, for over-the-counter General Sales List medicines, may have widened a little.

12. Chapter 5 gives a qualitative overview of the reforms, including results from the three-month consultation and feedback from a series of listening events. Patients, the NHS and business considered it was too early to judge the full impact of the reforms.

13. Patients welcomed extended hours, improved accessibility where new pharmacies had opened and the higher range and quality of services now available under the new contractual framework. However, these were not universal experiences with some reporting no noticeable difference, especially in rural areas. Patients were concerned the reforms, especially the introduction of 100 hours a week pharmacies, and moves to focus healthcare services on larger sites, could jeopardise access and choice in the longer term.

14. The NHS experience has varied widely. Some PCTs experienced considerable extra work, whilst others reported little, if any. Where the reforms have opened up the market, PCTs find that access has improved but exempt pharmacies in particular hinder their ability to plan service provision to meet local needs by diverting resources away from specialist clinical services. There is little evidence of innovation to date as a result of the reforms, with the new contractual framework, rather than these reforms, being the most important driver for change. PCTs have found that having robust local pharmaceutical needs assessments in place has helped them assess new applications. However, the new regulatory system is complex and the administrative burdens and costs from new procedures and tighter timescales are generally higher with most PCTs reporting the benefits did not compensate for this increase.

15. Business also gave a mixed response. Some reforms were welcome, particularly the new procedures for minor relocations. Many contractors were concerned the exemptions could lead to long-term reduction in choice and none reported business certainty had improved. Some business respondents called for complete deregulation - others that there should be no further move in that direction. The reforms have had no effect on the 134 contractors who only supply appliances (such as stoma care and incontinence aids).

16. Chapter 6 sets out the Department's conclusions of this review against the aims of the reforms and in the context of the White Paper *Our Health, Our Care, Our Say.* It concludes the reforms have so far achieved the aim of opening up the market with a modest but uneven impact on promoting choice and competition although it is too early to predict whether this will continue. There was some evidence that PCTs with greater social deprivation received more applications under one of the exempt routes than would be expected by chance and there is no discernible adverse impact on access to services in such areas. Access has improved where new 100 hours a week pharmacies

open or where new pharmacies are located at or close to GP surgeries and exempt pharmacies are providing proportionately more enhanced services. However, no significant impact on prices of medicines has been found.

17. Whilst the new legislative regime has delivered benefits in terms of quicker processes for some types of application, this is tempered by the regime being complex, time-consuming and offering no greater certainty and reliability to business. Overall, whilst these results show that the balanced approach was the appropriate way to proceed, the impact has been somewhat erratic and patchy, hampering PCTs' ability to plan service provision and match supply to needs and meet the new direction set by the White Paper. Community pharmacy is well placed to contribute to this new direction. However, given PCTs' responsibilities for strategic planning and commissioning, it is questionable whether, even after reform, the control of entry system is a suitable vehicle to enable PCTs to meet these responsibilities.

1 Introduction

1.1 This report sets out the findings of the Department of Health's review of the progress made on a balanced package of reform measures for England introduced in April 2005 to the regulatory system known as "control of entry."

1.2 This fulfils the undertaking given in July 2003 when the Government announced its response for England to the Office of Fair Trading (OFT) report *"The control of entry regulations and retail pharmacy services in the UK"*.

1.3 The terms of reference and methodology for the review, as announced to Parliament by, Patricia Hewitt, Secretary of State for Health, on 13 June 2006, are at **Annex A**.

1.4 As part of the review, the Department published a consultation document seeking views of patients and consumers, the NHS and business on the impact of the reforms to date. The consultation document is available at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4138960&chk=wBwCeL.

1.5 Where individual NHS Primary Care Trusts (PCTs) are cited in this report, these relate to the 303 PCTs that existed up to 30 September 2006. On 1 October, PCT reconfiguration took effect and there are now 152 PCTs in England.

2 Background to the legislation and this report

"Control of entry"

2.1 "Control of entry" is the system by which the NHS determines whether a pharmaceutical contractor can provide NHS pharmaceutical services. It does not determine whether a contractor can set up in business or not. There are just under 10,000 pharmaceutical contractors in England providing NHS services which are either pharmacies or appliance contractors.

2.2 A contractor wishing to provide NHS services in England applies to the relevant PCT under the NHS (Pharmaceutical Services) Regulations 2005. The PCT - in most cases - invites comments from interested parties locally including patient and consumer groups, and then makes a decision. The PCT 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. Special arrangements also apply in rural "controlled" areas where doctors may also be authorised to dispense.

2.3 More information about the legislation is available in Departmental guidance for Primary Care Trusts which accompanies the 2005 Regulations on its website at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4107573&chk=5TqNtc

The Office of Fair Trading report and recommendation

2.4 The Office of Fair Trading (OFT) announced an enquiry into retail pharmacy services in October 2001. 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. 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). This recommended abolition of the statutory entry controls to improve competition, to reduce prices for medicines sold over the counter and to improve access to, and the quality of, pharmaceutical services.

The Government response and balanced package of measures

2.5 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 recommended by introducing a balanced package of reforms to the regulatory system.

2.6 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;

and

iii) to reform and modernise the operation and administration of the regulatory system.

Aims of the reforms

2.7 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.

Further work

2.8 The Department of Health consulted on these proposals in the autumn of 2003. *Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992*, is available on the Department’s website. Results from this consultation fed into the work of an expert Advisory Group, the *Advisory Group on the Reform of the NHS (Pharmaceutical Services) Regulations 1992*, which the Department set up 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. These are also available on the Department’s website.

2.9 On 18 August 2004[5], and in a further written statement to the House of Commons on 7 September 2004[6], 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 the 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 to be concluded later in 2004. The reforms were to be introduced in tandem with that framework once finalised.

2.10 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 enacted in the Health Act 2006 which received Royal Assent in July 2006. This review does not consider these proposals further as they have yet to be implemented.

The new regulations

2.11 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 6 above). The regulations cover the reformed procedures governing control of entry, the "fitness to practise" regime for 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

2.12 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 £1,911 million is available to support the framework in 2006/07.

2.13 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 some 40% now 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.

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[5] Department of Health Press Release 2004/0310 *Better access to pharmacies and more choice for patients*
[6] House of Commons Written Ministerial Statement *Pharmacy Services (Control of Entry Regulations)* Minister of State for Health Cols 98WS – 102WS

2.14 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)

2.15 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.

2.16 PCTs can in addition commission local enhanced services. 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, emergency hormonal contraception, needle exchange and substance misuse services. New services can also be developed locally.

Local pharmaceutical services contracts

2.17 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 (LPS) 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 some 270 such LPS 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.

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

2.18 Following introduction of these reforms, the Secretary of State for Health published in January 2006 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.

2.19 In the White Paper, the Department committed to develop the contractual framework for community pharmacy services in line with these ambitions. This review of progress therefore takes account of that wider context and direction for service development.

3 Statistical data

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.

Key findings

- On the evidence so far, the balanced package of reform measures has achieved the goal of opening up the market and providing more convenient services but without jeopardising the vast majority of the existing pharmacy network or causing widespread upheaval and change
- 143 new pharmacies have opened to provide NHS services in England during 2005/06 – a net increase of 120 or just over 1% on 2004/05
- The majority of new applications used the reformed control of entry test
- The most common exemption route was a 100 hours a week pharmacy
- Applications were not evenly spread across the country – over half of all PCTs reported zero or just one application in 2005/06 – and just under a third of these were in metropolitan areas
- On a population basis, nearly 30% of all applications made under the reformed test or as an exemption were dealt with by just the 10% of PCTs with the highest rate of applications per 100,000 population
- Grant of an exempt application does not necessarily lead to the pharmacy opening
- Pharmacies opening under the exemptions are providing proportionately more local enhanced services than existing pharmacies
- A PCT with greater social deprivation is no more or less likely to receive a new application under the reformed control of entry test than a PCT which does not have such deprivation
- There is no evidence so far of a detrimental impact on access to services in deprived areas
- However, there was some evidence that PCTs with greater social deprivation received more applications under one of the exempt routes than would be expected by chance
- There was no correlation between the rate of existing pharmacies per 100,000 head of population and the rate of applications received per 100,000 head of population
- The costs to PCTs of processing new applications received in 2005/06 were between £1.3m and £2.6m
- Where PCT decisions to approve applications under the reformed test are appealed, the proportion of cases in 2006/07 where the Appeal Unit endorses the PCT's decision has increased over 2005/06

Introduction

3.1 The NHS Information Centre for Health and Social Care publishes data on pharmaceutical services provision. Returns are made annually by PCTs using form PHS1 giving information on pharmacy numbers, openings and closures, applications and decisions and the services provided.

The Information Centre collects other data from the Prescription Pricing Division[7] (PPD) of the NHS Business Services Authority and the Family Health Services Appeal Unit of the NHS Litigation Authority. The PPD data are based on payments to community pharmacies. As payments may take place up to three months after pharmacies submit their invoices, this can lead to discrepancies between PCT and PPD data about the number of community pharmacies active at 31 March each year. A fuller explanation of these differences is given in **Annex D.**

3.2 The Information Centre published an England-only interim bulletin[8] for 2005/2006 in July 2006 derived from PCTs' PHS1 returns and its final bulletin[9] for services in England and Wales in November 2006. Both bulletins are available on the website at www.ic.nhs.uk

Total numbers in contract

3.3 PCT data returns show that the total number of community pharmacies in contract with PCTs in England as at 31 March 2006 was 9,872. The total number of new openings shown on PHS1 returns was 143, with 23 pharmacies closing. This represents a net increase of 120 pharmacies (or 1.23%) compared with 31 March 2005[10].

3.4 This compares with an original proposition in the Regulatory Impact Assessment accompanying the new regulations[11] of a net 300 additional pharmacies during the first year. One reason why the net increase may be lower than assumed then is that pharmacies have up to nine months from the date of the grant in which to open before the grant lapses. A total of 339 applications were granted during 2005/06 for new pharmacies with a further 221 outstanding as at 31 March. It is reasonable to assume that a proportion of these will proceed to open during 2006/07.

3.5 Whilst modest, the increase in the total number of new openings in 2005/06 is more than the total of new openings in the previous three years combined. It is also higher than any other year since 1991/92 (the next highest, when 80 pharmacies opened in England but 54 closed leaving a net gain of just 26). On this measure, and in the light of the evidence to date, the balanced package of measures has achieved the goal of opening up the market.

3.6 Over the previous 10 years to 2004/05, there were minor fluctuations in the number of pharmacies. Year on year net differences range from plus 11 to minus 10. The total numbers fluctuated between 9,736 in 2004/05 and 9,785 in 1997/98. During the whole of that 10-year period there was a net increase of just four pharmacies. However, as noted above, there was a net increase of 120 pharmacies in 2005/06 over 2004/05.

[7] Formerly the Prescription Pricing Authority to 31 March 2006
[8] *General Pharmaceutical Services in England 2005-06 Emerging Findings* July 2006. The NHS data quoted in this report reflect figures derived from the interim bulletin but updated to take account of the final bulletin.
[9] *General Pharmaceutical Services in England and Wales 1996/97 – 2005/06*
[10] The PHS1 returns do not identify the proportion of these approvals which were among 301 English and Welsh applications made prior to 31 March 2005 under the 1992 regulations but carried forward for decision during 2005/06. However, the majority of these applications would have concerned either minor relocations or changes of ownership of existing pharmacies.
[11] *Final Regulatory Impact Assessment* Department of Health March 2005, para 5.14

Openings and closures of community pharmacies in deprived areas in 2005/06:

3.7 From PPD data, there were 9,736 pharmacies in contract with PCTs in England as at 31 March 2005. Of these, 1,538 pharmacies (16%) were in deprived areas[12], and 8,571 pharmacies (88%) were in urban areas. There were significantly more community pharmacies in deprived areas than would be expected by chance. This is not surprising, as indices of Health Deprivation and Disability contribute to Index of Multiple Deprivation scores, and it is likely that people in more deprived areas will have a greater need for health service provision.

3.8 From PPD data, 273 pharmacy premises opened in the period 1 April 2005 to 31 March 2006. These data differ from the number of openings reported in paragraph 3.3 above, because they include existing contractors relocating their premises. In deprived areas, 45 pharmacies opened (17% of all openings). In urban areas, 240 pharmacies opened (88% of all openings). Both these figures are in line with the existing proportions of pharmacies in deprived and urban areas from the previous year.

3.9 In the period 1 April 2005 to 31 March 2006, 137 pharmacy premises closed (this includes contractors relocating to new premises). In deprived areas, 34 pharmacies closed which represented 25% of all closures. Again, these data differ from PCT returns for the reasons already given. Whilst small compared to overall numbers, the number of closures in deprived areas is statistically significantly higher than the proportion of existing pharmacies in such deprived areas. This contrasts with urban areas where 121 pharmacies closed (or 88% of all closures) which is in line with the existing proportion of pharmacies in urban areas. Overall, the evidence so far does not indicate that the reforms have jeopardised the vast majority of the existing pharmacy network.

3.10 A case study analysis of openings and closures, the distances between pharmacies and the effect on deprivation and urban areas in West Yorkshire which reported a high level of activity is set out on page 29 below.

Services provided

3.11 More than 1 in 3 pharmacies provided advanced services during the first year of the new contractual framework. 3,842 pharmacies provided 148,195 individual patient Medicines Use Reviews and Prescription Interventions, or an average of just under 39 interventions per participating pharmacy.

3.12 16,920 local enhanced services (which are individually contracted by PCTs) were provided by contractors. A contractor may provide more than one kind of local enhanced service. There were 19 categories of local enhanced service in 2005/06[13].

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[12] The smallest areas for which 2001 Census data are released are Census Output Areas (COAs or OAs); these typically include 125 households. However, more detailed data cannot be released for OAs without risk of disclosure. ONS have therefore aggregated the OAs into larger areas known as Super Output Areas (SOAs). There are lower-layer and middle-layer SOAs. Upper-layer SOAs have not yet been defined. Lower-layer SOAs have an average population of 1,500 and a minimum of 1,000; they are designed not to cross boundaries of wards (as at April 1998).The 2004 Index of Multiple Deprivation is calculated for lower-layer SOAs, and was used to identify the most deprived 10% of lower-layer SOAs, referred to as 'deprived areas' in this section of the report.

[13] An independent pharmacist prescribing service, the 20th local enhanced service, was introduced under the *NHS (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006*, of 8 March 2006 and available on the Department's website.

3.13 By category, the four services most frequently provided account for 55% of all local enhanced services. These four services were supervised administration (for drug misusers receiving methadone treatment), stop smoking support, supply by patient group direction and minor ailment services. The majority of these were in place prior to 1 April 2005[14].

3.14 A patient group direction service is where a pharmacist supplies a particular medication directly to a patient under an agreed local protocol without the need for the patient to have a specific prescription. Typically, this is used to provide emergency hormonal contraception services to women of childbearing age.

3.15 A pharmacist-led minor ailments scheme is where patients, exempt from prescription charges, have their minor ailments such as hay fever or head lice, managed by a community pharmacist and can have medicines supplied on the NHS. The pharmacist may not always issue a medicine. They may just give advice to the person about how to manage that ailment. This scheme is aimed at patients who would have otherwise gone to their GP for a prescription for the management of that ailment.

3.16 The four services least frequently provided and accounting for under 1% of the total were a schools service, supplementary prescribing, anticoagulant monitoring and prescriber support services. A supplementary prescribing service is one where a pharmacist is able to prescribe medicines within an individual clinical management plan agreed with the patient and an independent prescriber, who is always a doctor. Prescriber support services comprise support and advice from pharmacist contractors to other health care professionals on the clinical and cost effective use of drugs, prescribing policies and guidelines and repeat prescribing. Commissioning of these services is likely to increase over time since supplementary prescribing and anticoagulant monitoring are specialist clinical services requiring additional training and/or registration.

3.17 New pharmacies under contract by virtue of one of the four new exemptions provided 629 local enhanced services or 3.7% of the total. Exempt pharmacies are required to provide any local enhanced services a PCT specifies in advance of receiving the application. As exempt pharmacies represent no more than 1.35% of the total number of pharmacies in England, whilst overall numbers are small, they are nonetheless contractually obliged to provide proportionately more local enhanced services than existing pharmacies. They are therefore contributing to the goal of providing more convenient access to such services. The four services most frequently provided and accounting for 60% of all such services were the same as in paragraph 3.13 above. However, the most frequently provided (116 or 17.4%) was a minor ailment scheme. Seven local enhanced services have not been commissioned by PCTs from exempt pharmacies at all, including disease specific medicines management and prescriber support services.

[14] See also a University of Manchester study based on a survey of 74% of PCTs that found broadly similar results. *Bradley, F., Elvey R., Ashcroft D.M., and Noyce P.: Commissioning Services and the new community pharmacy contract (3).* Pharmaceutical Journal, 19 August 2006, page 224

Applications made under the reformed "control of entry" test

3.18 There were 486 applications[15] in total in England made under the reformed control of entry test (see Table 1 on page 23). This compares with 423 equivalent applications in 2003/04 and 338[16] applications in 2004/05 under the previous regulatory regime.

3.19 The number of applications granted in 2005/06 was 113 or 23%. This compares with 117 applications approved in 2003/04 (28%) and 123 approved in 2004/05 (36%). These figures do not take account of any subsequent appeals.

3.20 Therefore, under the reformed test, the number of applications approved has remained more or less the same compared to the previous two years. However, as more applications were received in 2005/06, the overall approval rate has gone down. This is perhaps to be expected as applicants and PCTs were dealing with the new requirements of the reformed control of entry test. More information about appeals concerning these types of applications is given at paragraphs 3.55 *et seq* below.

3.21 The data indicate that applications are unevenly spread around the country with some PCTs experiencing considerable market activity under this provision, whilst others experienced little or none. Further analysis is at paragraphs 3.38 *et seq* below.

3.22 There is also evidence that some PCTs have experienced a fairly constant interest in this application route whilst others encountered an initial "burst" of activity following the introduction of the reforms with interest then tailing off significantly. This was in part to be expected as a number of applicants who had not succeeded in getting approval under the previous regulatory system, and who did not wish to apply under one of the new exemptions, would now wish to make an application under the reformed procedure. Nonetheless, we have not discerned a consistent pattern of market activity.

Case study: Humberside

In North and North East Lincolnshire PCTs, nine applications were received under the reformed control of entry test during 2005/06, of which seven were refused and two carried forward to 2006/07. A further three applications under this regulation have been received in the six months to September 2006 of which two were refused and one was pending. All came from existing contractors. The relatively large number is attributed to applications relating to various sites put forward for planning permission for new medical centres.

Across the Humber, East Yorkshire and Yorkshire Wolds and Coast PCTs received nine applications under the reformed control of entry test of which six were received in the first two months of the new regime. Of these nine, the PCTs approved one, refused seven and carried forward one to 2006/07. In the six months to the end of September 2006, the PCTs did not receive any reformed control of entry test applications.

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[15] Data for applications received under the reformed control of entry test (regulation 12) include 134 applications for England made under the previous 1992 regulations but carried forward to 2005/06. The results of these applications are not separately identified within PCT data returns.

[16] The data for 2003/04 and 2004/05 are for England and Wales combined.

The four new exemptions

3.23 Table 1 sets out data on the number of applications received under one of the four new exemptions to the “control of entry” test. The exemptions are:

- Out of town approved retail developments
- Pharmacies opening more than 100 hours a week
- New large one-stop primary care centres
- Wholly mail order or internet based pharmacies.

3.24 A total of 390 applications were received to 31 March 2006 of which 226 or 58% overall were granted. This compares to an overall “success” rate of 23% for applications made under the reformed control of entry test (see above). A further 51 (13%) were refused, 17 (4%) were withdrawn and 96 (25%) applications were outstanding as at 31 March 2006.

3.25 A number of other differences between the use and “success” of the exemptions are apparent.

100 hours a week pharmacies

3.26 By far the most common exempt application was for a pharmacy opening more than 100 hours a week. This accounted for 271 (69%) of all exempt applications with 156 approved (58%). This route also has the highest number of refusals, with 28 applications refused, or 55% of the total of all exempt applications refused. However, the rate of refusal is low at around one in ten applications. A further 72 applications were outstanding at 31 March – by far the largest proportion (75%) of all the outstanding exempt applications.

3.27 Fifteen applications were withdrawn, representing 88% of all those withdrawn. We have learnt from PCTs that this was most likely to be because an applicant, whilst waiting for determination of whether a shopping centre development qualified as exempt or not, submits an additional application for a 100 hours a week pharmacy. If a favourable decision on the shopping development is then made, the 100 hours a week application is withdrawn.

3.28 One unanticipated outcome from the introduction of exempt applications is the emergence of “copycat” multiple exempt applications relating to the same area or PCT[17]. These have particularly involved 100 hours a week pharmacies. In West Hull, for example, (see case studies below) there is evidence of “jockeying for position” close to a new Local Improvement Finance Trust (LIFT) investment development. Elsewhere, the fact that applications are granted has not necessarily led to new pharmacies opening. This can be because of building or planning difficulties, or the applicant simply not proceeding to open the premises.

[17] A University of Manchester study found that 25% of approved exempt applications were situated within just 11 PCTs (5% of the respondent sample). *Bradley F., Elvey R., Ashcroft D.M., and Noyce P.: Commissioning services and the new community pharmacy contract (1).* Pharmaceutical Journal, 5 August 2006, page 161

Case studies

In West Hull, the PCT received four 100 hours a week exempt applications between March and June 2006, three from large multiples or supermarkets and one from an independent contractor. All of these were approved. A further application for a 100 hours a week pharmacy was received in October 2006. If this is approved, and all the pharmacies proceed to open, West Hull will have five 100 hours a week pharmacies by early 2007. Two of the 100 hours a week pharmacies would be within 100 metres of each other, as well as being close to two other existing pharmacies.

In central Bradford, two applications for 100 hours a week pharmacies were received in April and June 2005. These were both granted and the pharmacies have since opened. A further four applications to open 100 hours a week pharmacies were then received between July and September 2005 - all from smaller contractors - which were also granted. However, these contractors did not proceed to open pharmacies and all four applications had lapsed by the end of July 2006.

In Nottinghamshire, a successful application from one large contractor for a 100 hours a week pharmacy led to three similar applications from two other large contractors within the same vicinity. One application was refused, which was upheld on appeal. Two were approved, of which one has since lapsed.

Out of town approved retail developments

3.29 There were 69 applications (18% of all exempt applications) for an out-of-town shopping centre development. Of these, 51 were granted and therefore this represents the highest "success" rate for any of the four exempt categories at 74%. Ten applications were refused and one withdrew.

3.30 Seven applications were outstanding as at 31 March 2006 (10% of the total received) suggesting that many contractors who wished to make use of this exemption had already done so in the first year.

3.31 A total of 139 out-of-town retail areas were originally approved for the exemption in April 2005. The Department published the approved list on its website and, from August 2005, established an independent review process. This considers whether existing or new retail areas should remain or, as appropriate, be included on the approved list. Details of the process are on the Department's website.

3.32 To September 2006, the Department had commissioned 22 reviews of which:

- 19 were to include new retail areas on the list; and
- three were to review areas already included.

3.33 As a result, a further 16 areas have now been included, two refused, three confirmed as appropriate to remain on the list and one outstanding. There are, as at November 2006, a total of 155 listed retail areas.

3.34 Whilst we made no estimates as to how much this exemption would in fact be used, pharmacy applications have now been granted in just over a third of all the approved retail areas.

New one-stop primary care centre pharmacies

3.35 There were 10 applications to open in new large one-stop primary care centres - the lowest number of the four exemptions. Only one was approved, none was withdrawn and two were outstanding as at 31 March 2006. Seven (70%) were refused. This may in part be explained by the number of regulatory criteria that apply to this particular exempt route - more than for any of the other categories. The numbers are small, but this is the highest refusal rate for any of the exemptions. Some PCTs reported increased interest in this route since April 2006.

Wholly mail-order and internet-only based pharmacies

3.36 Forty applications were received of which 18 (45%) were granted, with a further 15 outstanding as at 31 March 2006. Six were refused and one withdrew. Although overall numbers are small, the relatively large proportion remaining to be decided at just over a third suggests that interest in this new exemption route picked up over the course of 2005/06.

New applicants

3.37 For new applicants, the overall combined approval rate for 2005/06 for applications under the reformed test or for one of the four exemptions is 39%. This compares to an approval rate under the previous regime for applications under the control of entry test only of 28% in 2003/04 and 36% in 2004/05. Not surprisingly, it is the introduction of the four exemptions, and particularly the 100 hours a week exemption, which has led to the increase in the overall approval rate in 2005/06. This is made more significant given the total number of applications under either route in 2005/06 is more than double the totals in either of the previous two years.

Table 1: Analysis of applications and decisions under the reformed test and the four new exemptions (1 April 2005 - 31 March 2006)

	Reformed control of entry test[18]	**Four new exemptions**					
Number of applications		Out of town large shopping developments over 15,000 sq m gross lettable floor space	Pharmacies intending to open more than 100 hours per week	Consortia establishing a new one stop primary care centre	Wholly mail order or internet based pharmacy services	Total for four new exemptions	Grand Total (reformed control of entry test and four new exemptions)
Received between 1 April 2005 – 31 March 2006 (excluding appeals)	486	69	271	10	40	390	876
Total number:							
- Granted	113	51	156	1	18	226	339
- Refused	223	10	28	7	6	51	274
- Withdrawn	25	1	15	0	1	17	42
- Outstanding at 31 March 2006 (excluding appeals)	125	7	72	2	15	96	221
Total Percentage:							
- Granted	23%	74%	58%	10%	45%	58%	39%
- Refused	46%	14%	10%	70%	15%	13%	31%
- Withdrawn	5%	1%	6%	0%	3%	4%	5%
- Outstanding at 31 March 2006 (excluding appeals)	26%	10%	27%	20%	38%	25%	25%

Source: The Information Centre for Health and Social Care

[18] Includes 134 applications under the previous regulatory regime carried forward from 2004/05 – see footnote 15 above.

Socio-demographic analysis

3.38 We examined PCT data to determine whether applications had drawn a comparable interest around the country, and whether there had been a particular impact on PCTs with greater social deprivation[19] (given that there is likely to be a greater call for pharmaceutical services in such areas).

Overall distribution of applications across deprived and non-deprived PCTs

3.39 A total of 876 applications were made to open a community pharmacy under the reformed control of entry test or the four new exemptions. Of the 876 applications, 101 (12%) were made within the most deprived 10% of all 303 PCTs. Of the 486 applications made under the reformed control of entry test, 49 (10%) applications were received in PCTs with greater social deprivation. Neither of these results was statistically significant.

3.40 Of the 390 applications made under the four exempt routes, 52 (13%) were received in deprived PCTs. This result was statistically significant, indicating that such PCTs received more applications under one of the four exempt routes than would be expected by chance. It should be noted, however, that any minor revision to individual PCT data would distort this finding. Overall, we have not discerned evidence so far of any detrimental impact on access to pharmaceutical services in deprived areas.

Data on PCTs receiving a low rate of applications to open a community pharmacy under the reformed control of entry test or four new exemptions in 2005/06

3.41 As the populations of PCTs vary considerably, we analysed the number of applications per 100,000 head of population to identify PCTs that received unusually high or low numbers of applications to open a community pharmacy. Due to rounding, we designated those PCTs that received only one application and had large populations, a rate of zero applications per 100,000 head of population.

3.42 It might be expected that new applications to open a community pharmacy in 2005/06 would primarily be made in PCTs that have few existing pharmacies, but this is not the case. There was no correlation between the rate of existing pharmacies per 100,000 head of population and the rate of applications received per 100,000 head of population. For example, Central Suffolk PCT reported one of the lowest rates of existing pharmacies but received no applications to open a community pharmacy, whilst Central Derby PCT, which has one of the highest rates of existing pharmacies, reported one of the highest rates of applications.

[19] The 2004 Index of Multiple Deprivation (IMD) scores and mid-2003 population estimates for the 303 PCTs in existence up to 1 October 2006 were used to identify the most deprived 10% of PCTs, referred to as "deprived PCTs" in this report. The 2004 IMD scores and population estimates were sourced from the former Office of the Deputy Prime Minister (ODPM) and Office for National Statistics (ONS). IMD deprivation scores are produced at the level of lower-layer Super Output Areas (LSOA), and LSOA deprivation scores may vary within an individual PCT.

Combined analysis of applications made under the reformed control of entry test or four new exemptions

3.43 Table 2 (see page 27) sets out the relationship between the social deprivation of PCTs and the rate of applications received per 100,000 head of population. 59 PCTs (19% of all PCTs) received a rate of zero applications per 100,000 head of population to open a community pharmacy under the reformed control of entry test or four new exemptions in 2005/06, with 162 PCTs (53%) receiving one or no such applications. However, the data indicate that the most deprived PCTs were no more or less likely to receive low numbers of such applications than would be expected by chance.

Applications made under the reformed control of entry test

3.44 135 PCTs (45%) received a rate of zero applications per 100,000 head of population under the reformed control of entry test, with 234 PCTs (77%) receiving a rate of one or no applications. The most deprived PCTs were no more or less likely to receive low numbers of such applications than would be expected by chance.

Applications made under the four new exemptions

3.45 When looking at applications made under one of the four new exempt routes, 136 PCTs (45%) received a rate of zero such applications per 100,000 head of population, with 252 PCTs (83%) receiving a rate of one or no applications made under the exemptions. The most deprived PCTs were no more or less likely to receive low numbers of such applications than would be expected by chance.

Data on PCTs receiving a high rate of applications to open a community pharmacy under the reformed control of entry test or four new exemptions in 2005/06

Combined analysis of applications made under the reformed control of entry test or four new exemptions

3.46 The 30 PCTs (10% of all PCTs) which received the highest rate of applications per 100,000 head of population to open a community pharmacy under the reformed control of entry test or four new exemptions received a total of 252 such applications. This represents 29% of 876 such applications in 2005/06. These 30 PCTs received between four and 13 applications per 100,000 head of population. Although six (20%) of these 30 PCTs were in the most deprived 10% of all PCTs, this result did not reach statistical significance.

Applications made under the reformed control of entry test

3.47 The 30 PCTs which received the highest rate of applications per 100,000 head of population under the reformed control of entry test received a total of 184 such applications (38% of all 486 applications made under the reformed control of entry test). These 30 PCTs received between three and 12 applications per 100,000 head of population. Two (7%) of these 30 PCTs were in the most deprived 10% of all PCTs, which does not significantly differ to what we would expect by chance.

Applications made under the four exemptions

3.48 When looking at applications made under the four exemptions, the 30 PCTs that received the highest number of applications per 100,000 head of PCT population received a total of 134 such applications (34% of all 390 applications made under the exemptions), with each of these PCTs receiving between two and eight applications per 100,000 head of population. Five (or 17%) of these 30 PCTs were in the most deprived 10% of all PCTs. However, this is not statistically significant.

Figure 1: Rate of applications received per 100,000 head of PCT population under the reformed control of entry test and the four new exemptions, by deprivation of PCTs

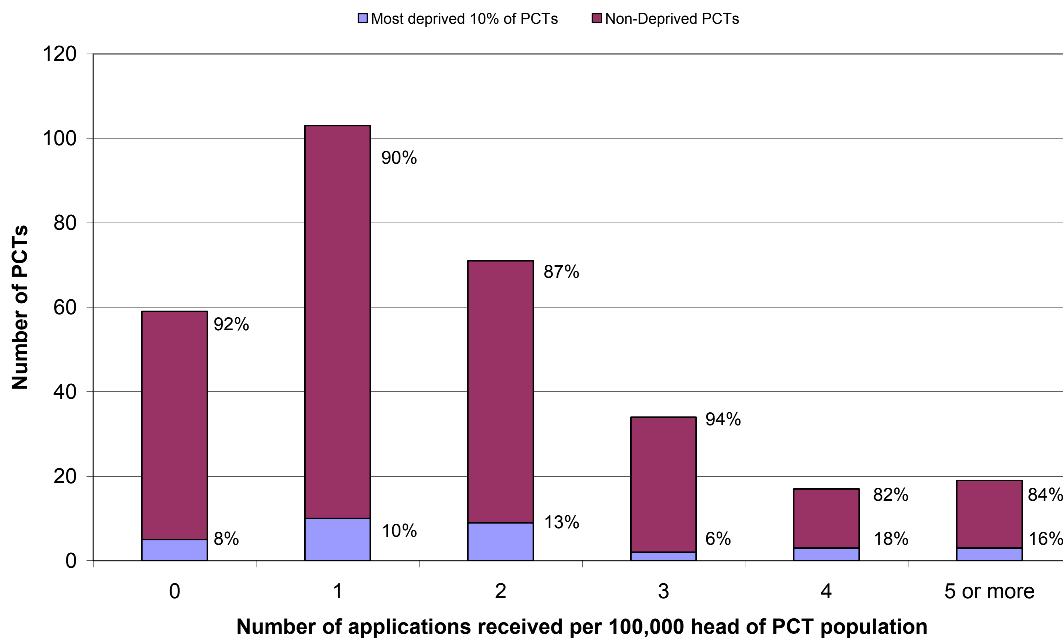
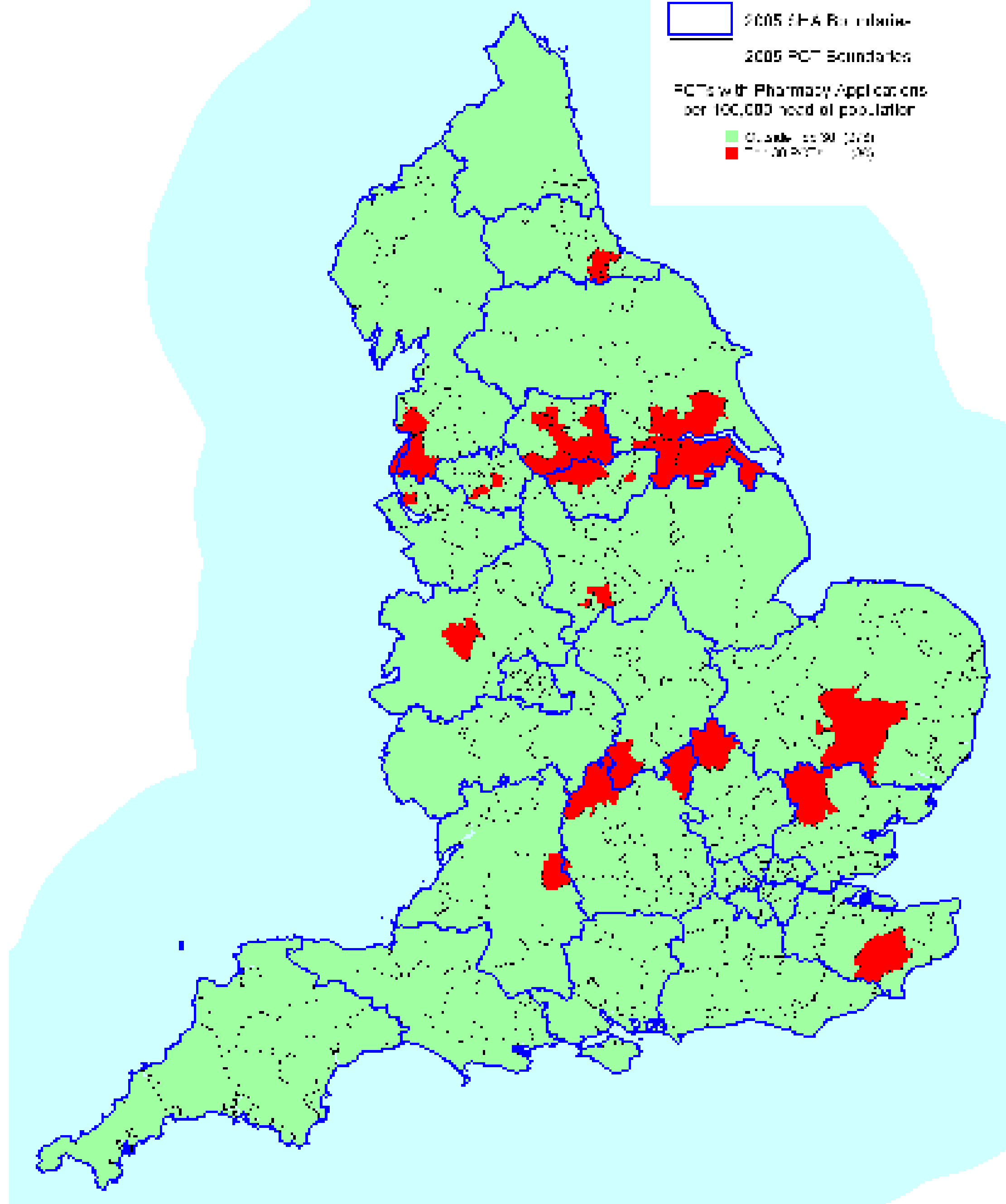


Table 2: Rate of applications made under the reformed control of entry test and four new exemptions by 100,000 head of population and social deprivation of PCTs (1 April 2005 - 31 March 2006)

	Reformed control of entry test		**Four new exemptions**		**Combined analysis of applications made under the reformed control of entry test and four new exemptions**	
Number of PCTs	*Deprived PCTs*	*Non-deprived PCTs*	*Deprived PCTs*	*Non-deprived PCTs*	*Deprived PCTs*	*Non-deprived PCTs*
PCTs receiving a rate of zero applications	12	123	11	125	5	54
PCTs receiving a rate of zero or one application	25	209	26	226	15	147
30 PCTs receiving the highest rate of applications	2	28	5	25	6	24
% of PCTs						
PCTs receiving a rate of zero applications	*9%*	*91%*	*8%*	*92%*	*8%*	*92%*
PCTs receiving a rate of zero or one application	*11%*	*89%*	*10%*	*90%*	*9%*	*91%*
30 PCTs receiving the highest rate of applications	*7%*	*93%*	*17%*	*83%*	*20%*	*80%*

Figure 2: Map showing 30 PCTs with highest rate of applications per 100,000 head of PCT population



Case Study: Applications to open new pharmacies and distances in West Yorkshire

Pharmacies in contract

Data from the 15 West Yorkshire PCTs indicated a high level of market activity in 2005/06. There were 417 community pharmacies in contract with PCTs in West Yorkshire at 31 March 2005 (4% of all 9,736 pharmacies). 73 pharmacies (18% of the 417 West Yorkshire pharmacies) were in deprived areas of West Yorkshire, which is higher than the national average for pharmacies in such areas. 382 pharmacies (92% of the 417 West Yorkshire pharmacies) were in urban areas.

Applications to open

West Yorkshire PCTs received 70 applications to open a new community pharmacy under the reformed control of entry test (25) and the four new exemptions (45) between 1 April 2005 and 31 March 2006. Of these 70 applications, 38 (54%) were approved. 18 (26%) were refused, four (6%) were withdrawn and 10 (14%) carried forward to 2006/07.

Of the 45 exempt applications 30 (67%) were granted, five (11%) were refused, four (9%) were withdrawn and six (13%) carried forward. The 100 hours exemption was the most popular with 36 applications, which constituted 51% of all applications and 80% of applications made under the exemptions. Five of the 30 approvals subsequently lapsed.

Full postcode information, which was required for further socio-demographic analyses, was available for 52 of these applications (74% of the 70 applications). 32 (or 62%) of these 52 applications were granted. 40 (77%) of these 52 applications were made under one of the four new exemptions and 27 (68%) were granted.

Applications in deprived/urban areas

15 (or 29%) of the total 52 applications were made to open a pharmacy in a deprived area of West Yorkshire, which is significantly higher than the existing 18% of West Yorkshire pharmacies that were in deprived areas. 13 (or 33%) of the 40 applications made under the four exemptions were to open a pharmacy in a deprived area of West Yorkshire, which is also significantly higher than the existing proportion of pharmacies in deprived areas of West Yorkshire.

48 (92%) of the 52 applications were to open a pharmacy in urban areas of West Yorkshire and 37 (93%) of the 40 exemption applications were to open a pharmacy in urban areas. Both these figures are in line with the existing 92% of West Yorkshire pharmacies in urban areas at 31 March 2005.

Distances between existing premises and new applicants

The 52 applications to open a pharmacy in West Yorkshire listed only 39 unique premises, as some contractors submitted dual applications for the same premise under the “pharmacies opening at least 100 hours a week” and “out-of-town approved retail developments” exemptions, or submitted new applications for the same premises, having had a previous application rejected earlier in the year. 29 (or 74%) of the 39 premises listed in applications were within 500m of the nearest existing pharmacy - almost double the national average for 2005/06. Only four (or 10%) of these 39 applications were for premises over 1 km from the nearest existing pharmacy, well below the national average, which itself showed a reverse of the trend over the previous years of more pharmacies opening at some distance from their neighbours.

Analyses of the distances between the 39 premises listed in applications to open a pharmacy in West Yorkshire showed that 24 (62%) of the 39 premises were over 1km from the nearest neighbouring applicant’s premises, while 11 (28%) were within 500m.

Conclusion

The data indicate that applications in West Yorkshire were more likely than the national average to be for premises in deprived areas of West Yorkshire, which already had a higher rate than the national average for pharmacies in such areas. Applications were likely to be closer to existing pharmacies, although further away from premises addresses listed by other applicants.

Applications made under the reformed procedures - minor relocations etc

3.49 The major reform introduced by the new regulations in order to simplify and speed up decisions on other types of application relate to a pharmacy wishing to relocate its premises. Where the distance is under 500 metres, the PCT decides this administratively without consulting local interests and must do so within 30 days.

3.50 Table 6 to the statistical bulletin (see footnote 8) shows there were 491 applications for relocations under 500 metres and 21 for relocations over 500 metres (where the PCT does consult local interests before deciding the application).

3.51 Of these, 366 and 8 respectively were granted - or 74.5% and 38.1% - giving an overall approval rate of 73%. A total of forty applications were refused, giving an overall failure rate of 7.8% or one application in twelve. Thirty eight applications were withdrawn and sixty were outstanding as at 31 March 2006.

3.52 This is a marginally lower approval rate than under the previous 1992 regime for minor relocations where it varied from 76% - 83% between 1995/96 and 2004/05. However, this may in part be attributable to PCTs having to operate the new regulatory criteria and also to the number of withdrawn and pending decisions at 31 March 2006 which represented almost a fifth of all such applications received during the year.

Costs for PCTs

3.53 We estimate the cost for a PCT to process an application varies between £1,482 and £2,937 according to its nature and complexity. This is based on estimates of the time it takes PCTs to receive and check applications, undertake site visits, circulate applications, receive comments and prepare reports for the decision panel and issue determinations etc. Some costs may be reduced where there are savings through PCTs sharing agency arrangements. The costs of appeals against PCT decisions are not included.

3.54 The costs for PCTs of processing 876 new applications received under regulations 12 and 13 in 2005/06 were between £1.3m and £2.6m. For the 30 PCTs who dealt with 29% of all these applications, the average cost to each PCT varied from approximately £12,400 to £24,700. These costs are incurred whether or not an application is successful, and if successful, whether the pharmacy then proceeds to provide NHS services or not.

Appeals on decisions

3.55 Tables 8 and 9 to the statistical bulletin (see footnote 8) on emerging findings show that the NHS Litigation Authority Appeal Unit dealt with 91 appeals under the regulations to 31 March 2006.

3.56 Of these, the applicant appealed in 51 cases. The majority of these (44) concerned decisions on applications under either the reformed control of entry test or a PCT's refusal of an exempt application. 40 appeals were dismissed and four allowed. The remaining seven appeals concerned either minor relocations or decisions relating to rural areas, two of which were withdrawn.

3.57 The remaining 40 appeals were lodged by other parties. Sixteen of these concerned decisions on applications under the reformed test or exempt applications. Seven of these were allowed (i.e. the original PCT decision was overturned) and nine were dismissed (i.e. the Appeal Unit upheld the original PCT decision). Of the remaining 24 appeals, 14 concerned decisions on applications from doctors to dispense in rural areas (of which a number concerned PCTs decisions on special transitional arrangements in place in Spring 2005 for approving dispensing doctor premises), and 10 concerned decisions on minor relocations.

Further analysis of appeals under the reformed control of entry test.

3.58 There is, in reality, around six months between making a new application and then appealing any decision. Hence, appeals relating to the main provisions of the new regulatory system only began to flow from late summer 2005 onwards. The Appeal Unit has provided additional statistical information for the period to September 2006 - in effect, yielding approximately a year's worth of data.

3.59 These show that in the period to March 2006, the Appeal Unit dealt with 53 appeals concerning PCT decisions on applications made under the reformed control of entry test. It dealt with a further 85 appeals under this regulation in the six months to September 2006.

3.60 Table 3 below shows the outcome of these appeals

Table 3 – analysis of appeals under the reformed control of entry test

1 April 2005 - 31 March 2006			
Granted by PCT	15	Appeal allowed – application refused	8
		Appeal dismissed – application proceeds	7
Refused by PCT	38	Appeal allowed – application proceeds	3
		Appeal dismissed – application fails	35
1 April 2006 - 30 September 2006			
Granted by PCT	38	Appeal allowed – application refused	14
		Appeal dismissed – application proceeds	24
Refused by PCT	47	Appeal allowed – application proceeds	7
		Appeal dismissed – application fails	40

3.61 Therefore the overall rate for appeals in the period to March 2006 where applications did in fact proceed was 18.9% (10 out of 53). In the following period to September 2006, the overall rate for appeals where applications did in fact proceed increased to 36.5% (31 out of 85).

Commentary on appeals

3.62 Details of appeals decisions are posted on the Appeal Unit's website at http://www/nhsla.com/FHSAU/Pharmacy/2005/Regulations/. Certain themes emerge from these decisions (excluding those concerning controlled localities) and are discussed below.

3.63 First, the data in Table 3 suggest that PCTs, where deciding in favour of an application under the reformed control of entry test, have become more robust in their reasons for so doing over the period concerned. The proportion of successful appeals against a favourable PCT decision declined in the six months to September 2006 compared with the period to March 2006. However, the overall rate at which the Appeal Unit endorsed the original PCT decision (i.e. whether the PCT approved or refused the application) was broadly the same at 79.2% and 75.3% respectively in the two periods concerned.

3.64 *Choice* – arguments about the extent of "choice and competition" were a major theme of appeals under the reformed control of entry test. Where PCTs refused these applications, this was usually after considering there was adequate provision within the neighbourhood. In the period February to September 2006, 20 applicants argued in favour of allowing the application in order to improve the choice of provider locally. However, such arguments have not convinced the Appeal Unit, as only one of these appellants was successful.

3.65 Over a third of appeals up to 30 September 2006, (43) related to applications for premises near or in health centres or GP surgeries, 14 of the appeals relating to minor relocations involved this particular aspect.

3.66 *Neighbourhood* – the Appeal Unit continued to hear appeals on the question of neighbourhood. This term is not defined in the Act or the regulations and is a decision based on the facts and circumstances relating to a particular application. This was a feature of the 1992 regulations as well. The appeals generally centred on applicants, other interested parties or PCTs disagreeing on the size and make-up of a neighbourhood.

3.67 There were also a number of cases involving one contractor arguing that a large supermarket out of town could in effect be treated as a neighbourhood in its own right. These appeals more likely result from a decision of the High Court under the previous regulatory regime[20]. The Appeal Unit dismissed the majority of these appeals.

3.68 *Minor relocations* – determination of the "neighbourhood" was also a feature of appeals against decisions on applications for minor relocations under 500 metres. Otherwise, the grounds for appeal were similar to those dealt with under the previous regulatory regime and revolved around determination of matters such as the definition of minor relocation, what constituted a barrier to access, or whether the minor relocation was in fact to a new neighbourhood.

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[20] *R V FHSAA ex parte Boots the Chemists* (Cribbs Causeway) 24 May 1996

Appeals on exemptions

3.69 *Exemptions* – up to 30 September 2006, there were four appeals concerning decisions on exempt applications. This smaller figure is not surprising since

(a) there is a high PCT approval rate; and
(b) only the applicant has a right of appeal against a PCT decision.

3.70 In other words, the Appeal Unit only hears cases where a PCT has refused an exempt application. Two of the appeals involved applications under the 100 hours a week exemption and the provision of local enhanced services specified by the PCT concerned. The Appeal Unit found in favour of the PCT in both cases. The other two appeals concerned whether an exempt application could proceed in a neighbourhood where there were pre-existing LPS schemes in place or, as featured above, the definition of neighbourhood.

4 The extent of the reforms' economic impact to date

Key findings

- In the past 10 years, the number of prescription items dispensed has increased by 47% whilst community pharmacies have increased by 1%
- 56% of the 9,872 English pharmacies are in chains of six or more outlets
- The greatest proportion of pharmacies opening in 2005/06 were within 500 metres of another – this reverses the trend of the previous 10 years
- The proportion of pharmacies being paid extra to provide services out-of-hours (evening and at weekends) fell from 45% to 31% in 2005/06
- 99% of the population, including those in the most deprived areas, can get to a pharmacy by car, walking or public transport within 20 minutes
- Between 2003 and 2006, the percentage of people not within 10 minutes' travel of a pharmacy by public transport or walking fell from 16.2% to 15.7%
- 77% of people living in the 10% most deprived ares in England can get to a pharmacy by public transport or walking within 10 minutes, compared to 84% nationally
- Between 2003 and 2006, the number of GP surgeries within 10 minutes walk of a pharmacy has increased, and the number of pharmacies with one or two other pharmacies within 10 minutes walk has increased
- There is no national evidence yet of pharmacies clustering, although individual PCTs report this happening locally
- Prices of general sales list (GSL) medicines are about 25% to 30% cheaper in supermarkets than in independent and multiple pharmacies. However, using sales weights that reflect the pattern of sales used in independent pharmacies reduces the price differential with supermarkets to about 15%
- Pharmacy-only medicines are about 10% cheaper in supermarkets
- These results are similar to those of 2003. The gap between supermarkets and independent/multiple pharmacies, for GSL medicines, may have widened a little

Summary historical analysis of openings, closures, distances and opening hours

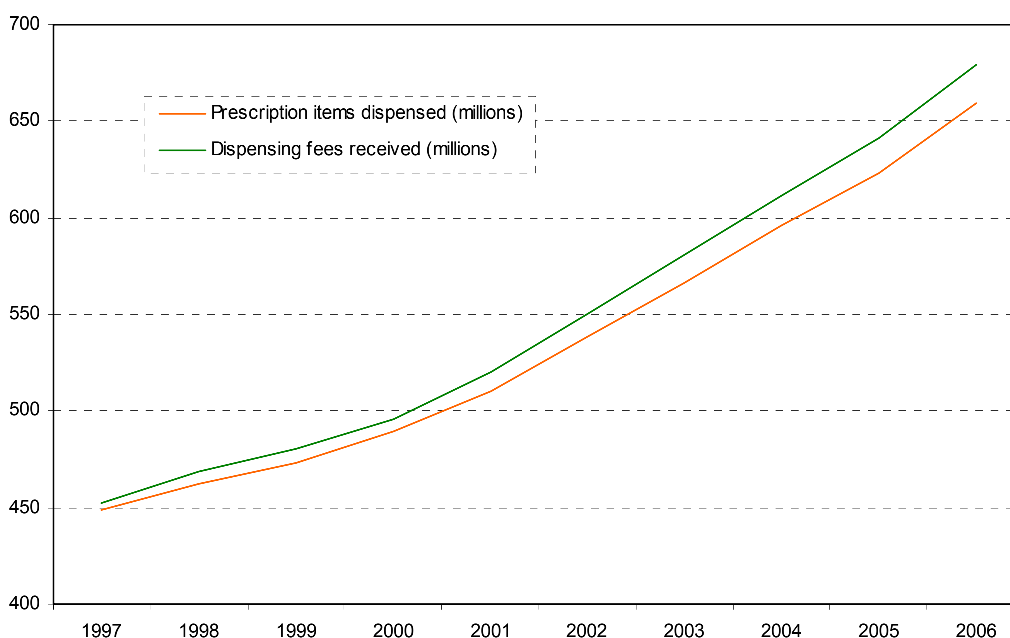
Community pharmacy dispensing activity

4.1 Table 4 and Figure 3 show the total dispensing activity for the year ending 31 March of each year. In 2005/06, the increase in the number of prescription items dispensed, dispensing fees received, and average number of fees per pharmacy followed a year-on-year trend. The number of prescription items dispensed has increased by 47% over the last ten years, whilst the number of community pharmacies has increased by 1%.

Table 4: Community pharmacy dispensing activity

Year	Pharmacies in contract	Number of prescription items dispensed (millions)	Number of dispensing fees received (millions)	Average number of fees per pharmacy
1997	9,775	448.7	452.4	46,291
1998	9,785	462.2	468.7	47,899
1999	9,782	473.5	480.2	49,093
2000	9,767	489.3	496.2	50,824
2001	9,765	509.9	520.5	53,307
2002	9,756	538.3	549.7	56,347
2003	9,748	566.3	580.3	59,530
2004	9,759	596.5	611.8	62,691
2005	9,742	623.2	641.5	65,854
2006	9,872	659.7	679.3	68,808

Figure 3: Number of prescription items dispensed and dispensing fees received at 31 March 1996/97 - 2005/06



Source: The Prescription Pricing Division of the NHS Business Services Authority

Pharmacies in chains of six or more (multiples)

4.2 Table 5 and Figure 4 show the number and percentage of pharmacies in a "multiple chain" at the end of each year. A multiple chain is defined as consisting of six pharmacies or more. Groups of five or fewer pharmacies are regarded as "independent". The number of pharmacies in multiple chains as at 31 March 2006 was 5,604 or 56.8% of the total. This represents an increase of 195 during 2005/06[21]. It continues a trend consistently seen since at least the early 1990s when around a third of all pharmacies were in such chains. The increase in 2005/06 is in line with the average increase in preceding years.

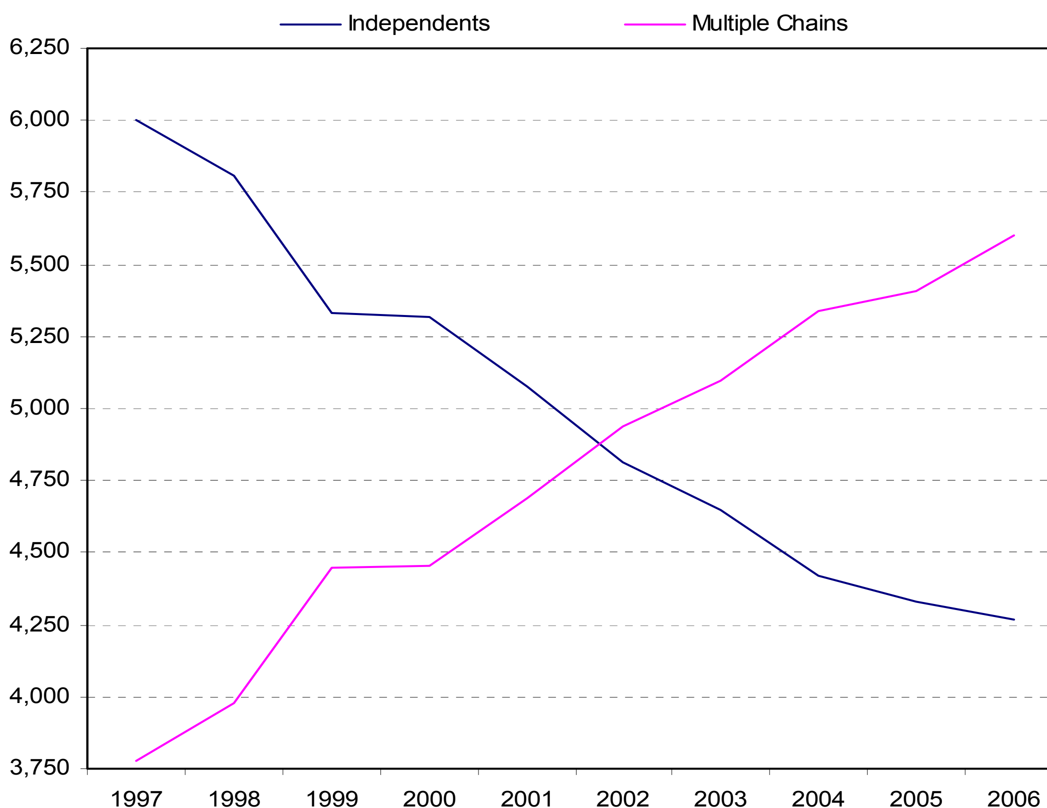
Table 5: Number and percentage of community pharmacies in England in chains of six or more in contract with PCTs at 31 March 1996/97 – 2005/06

Year	Pharmacies in contract	Number of pharmacies in chains of 6 or more	Percentage of pharmacies in chains of six or more
1997	9,775	3,777	38.64%
1998	9,785	3,978	40.65%
1999	9,782	4,448	45.47%
2000	9,767	4,452	45.58%
2001	9,765	4,692	48.05%
2002	9,756	4,941	50.65%
2003	9,748	5,098	52.30%
2004	9,759	5,341	54.73%
2005	9,742	5,409	55.52%
2006	9,872	5,604	56.77%

Source: The Prescription Pricing Division of the NHS Business Services Authority

[21] The approved merger of Alliance Unichem plc and Boots plc, and takeovers of part of the Cohens and Scholes chains by Lloyds plc, and of P Williams Ltd by the United Co-operative Group during 2005 and 2006 do not affect these figures.

Figure 4: Market structure of community pharmacies in contract with PCTs in England at 31 March 1996/97 – 2005/06



Source: The Prescription Pricing Division of the NHS Business Services Authority

Community pharmacies opening by distance to the nearest pharmacy

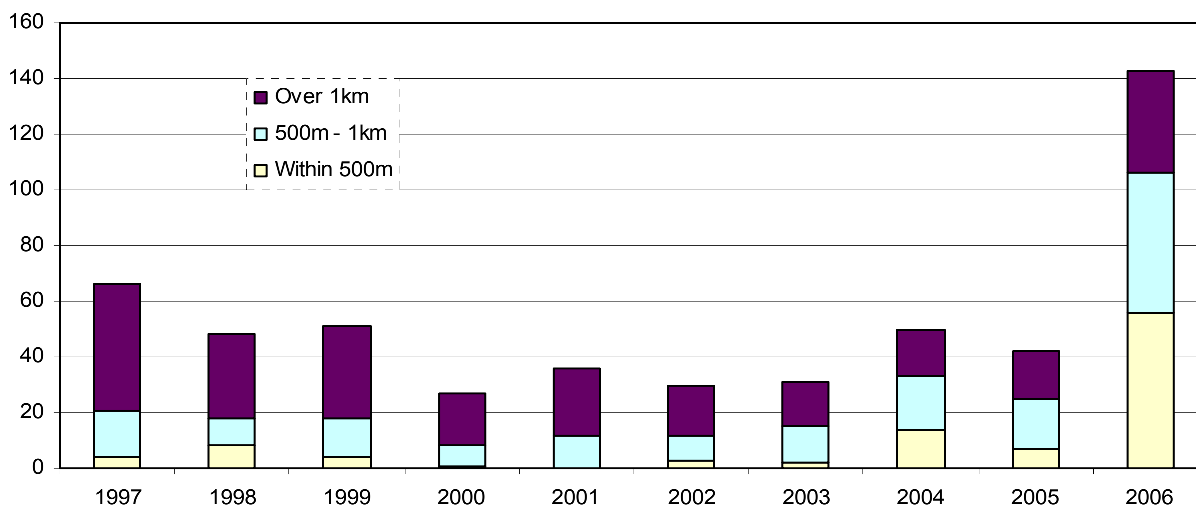
4.3 Table 6 and Figure 5 show the number of community pharmacy openings for the year ending 31 March each year. Of 143 openings in 2005/06, the greatest proportion of these (39%) was within 500m of the nearest pharmacy, and the lowest (26%) over 1 km away. This is a reversal to the trends seen in all previous years since 1996/97, where the lowest proportion of openings was within 500m of the nearest pharmacy. It is reasonable therefore to attribute this change to the reforms. It is however worth noting that the 37 pharmacies opening more than 1 km from the next nearest represent the highest number of such pharmacies since 1996/97 and more than double the number of the previous two years combined.

Table 6: Community pharmacies opening by distance to the nearest pharmacy at 31 March 1996/97 – 2005/06

Year	Totals		Within 500m		500m - 1km		Over 1km	
1997	66	(100%)	4	(6%)	17	(26%)	45	(68%)
1998	48	(100%)	8	(17%)	10	(21%)	30	(63%)
1999	51	(100%)	4	(8%)	14	(27%)	33	(65%)
2000	27	(100%)	1	(4%)	7	(26%)	19	(70%)
2001	36	(100%)	0	(-)	12	(33%)	24	(67%)
2002	30	(100%)	3	(10%)	9	(30%)	18	(60%)
2003	31	(100%)	2	(6%)	13	(42%)	16	(52%)
2004	50	(100%)	14	(28%)	19	(38%)	17	(34%)
2005	42	(100%)	7	(17%)	18	(43%)	17	(40%)
2006	143	(100%)	56	(39%)	50	(35%)	37	(26%)

Source: The Information Centre for Health and Social Care

Figure 5: Community pharmacies opening by distance to the nearest pharmacy at 31 March 1996/97 – 2005/06



Source: The Information Centre for Health and Social Care

Community pharmacies closing by distance to the nearest pharmacy

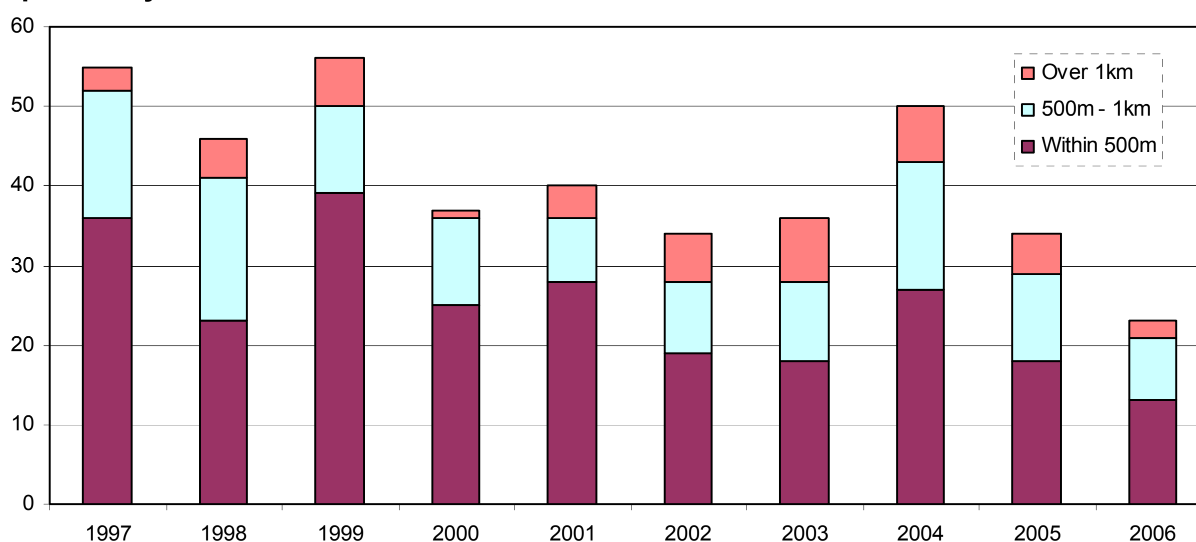
4.4 Table 7 and Figure 6 show the number of community pharmacies closing for the year ending 31 March each year. This information is provided by PCTs using the PHS1 forms. There were 23 closures for the year ending 31 March 2006, the lowest for the 10 years reported. For all 10 years, the majority of closures are within 500m of the nearest pharmacy. The pattern of closures in 2005/06, in terms of distance to the next nearest pharmacy, broadly corresponds to previous years.

Table 7: Community pharmacies closing by distance to the nearest pharmacy at 31 March 1996/97 – 2005/06

Year	Totals		Within 500m		500m - 1km		Over 1km	
1997	55	(100%)	36	(65%)	16	(29%)	3	(5%)
1998	46	(100%)	23	(50%)	18	(39%)	5	(11%)
1999	56	(100%)	39	(70%)	11	(20%)	6	(11%)
2000	37	(100%)	25	(68%)	11	(30%)	1	(3%)
2001	40	(100%)	28	(70%)	8	(20%)	4	(10%)
2002	34	(100%)	19	(56%)	9	(26%)	6	(18%)
2003	36	(100%)	18	(50%)	10	(28%)	8	(22%)
2004	50	(100%)	27	(54%)	16	(32%)	7	(14%)
2005	34	(100%)	18	(53%)	11	(32%)	5	(15%)
2006	23	(100%)	13	(57%)	8	(35%)	2	(9%)

Source: The Information Centre for Health and Social Care

Figure 6: Community pharmacies closing by distance to the nearest pharmacy at 31 March 1996/97 – 2005/06



Source: The Information Centre for Health and Social Care

Community pharmacies receiving payment for additional agreed hours

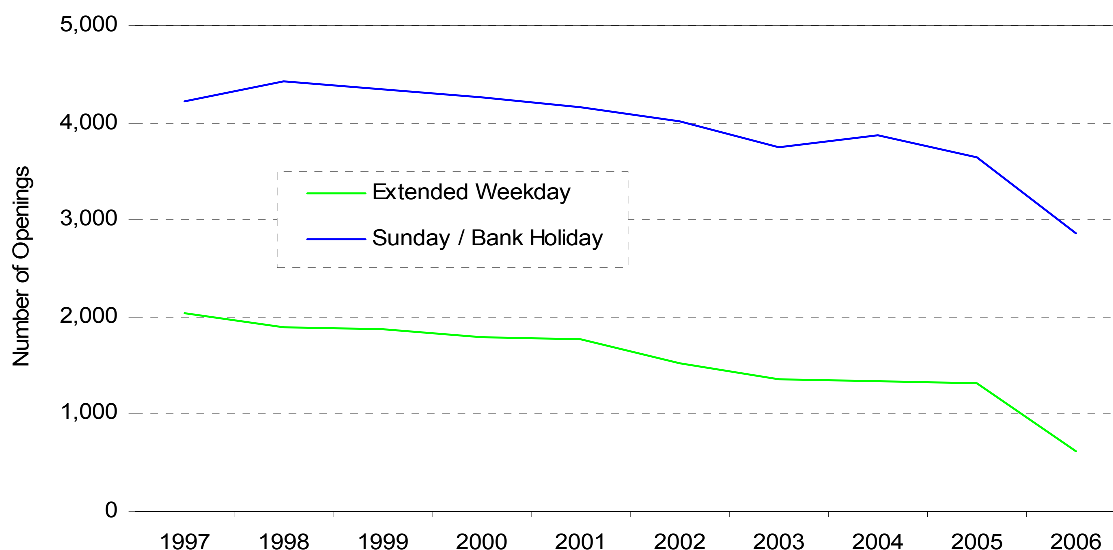
4.5 Table 8 and Figure 7 show the number of community pharmacies receiving payment for additional agreed hours as at 31 March each year. The two categories of extended hours are weekdays opening (usually before 9 a.m. or after 5.30 p.m.) and Sundays and Bank Holidays. Some pharmacies provided both. The majority of payments for each year were made for Sunday or Bank Holiday openings. The proportion of pharmacies receiving these payments declined gradually from 52% to 45% between 1998 and 2005. In 2006, this downward trend increased with a further reduction to 31%. The largest fall proportionately was seen in extended weekday openings, where there were more than 50% fewer contractors in 2006 over 2005. This can be attributed to an extension in contractual hours from 30 to 40 hours per week from 1 April 2005 and new pharmacies providing services for more than 100 hours a week, thus reducing the need for PCTs to commission extended hours.

Table 8: Community pharmacies receiving payment for additional agreed hours at 31 March 1996/7 – 2005/2006

Year	Pharmacies in contract	Totals		Extended weekday openings		Sunday / Bank Holiday openings	
1997	9775	4,906	(50.2%)	2,042	(20.9%)	4,224	(43.2%)
1998	9785	5,102	(52.1%)	1,884	(19.3%)	4,428	(45.3%)
1999	9782	4,961	(50.7%)	1,882	(19.2%)	4,342	(44.4%)
2000	9767	4,906	(50.2%)	1,789	(18.3%)	4,268	(43.7%)
2001	9765	4,810	(49.3%)	1,769	(18.1%)	4,149	(42.5%)
2002	9756	4,638	(47.5%)	1,524	(15.6%)	4,015	(41.2%)
2003	9748	4,412	(45.3%)	1,355	(13.9%)	3,754	(38.5%)
2004	9759	4,405	(45.1%)	1,331	(13.6%)	3,861	(39.6%)
2005	9736	4,431	(45.3%)	1,313	(13.5%)	3,639	(37.4%)
2006	9872	3,146	(31.3%)	621	(6.3%)	2,869	(29.1%)

Source: The Information Centre for Health and Social Care

Figure 7: Community pharmacies receiving payment for additional agreed hours at 31 March 1996/7 to 2005/6



Source: The Information Centre for Health and Social Care

Accessibility of pharmacies

Introduction

4.6 We commissioned an analysis from transport planning consultants[22] of the time it would take a person to get to their nearest pharmacy in 2003 and in 2006. The data and methodology for this type of analysis only became available in 2004.

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[22] "Pharmacy Accessibility: Calculation Methodology and Results", 18 August 2006; produced by Derek Halden Consultants.

4.7 In summary, the average time taken to reach a pharmacy has fallen between 2003 and 2006, but the change is small, reflecting the fact that there has been a modest net increase in the number of pharmacies over the three years.

Methodology

4.8 We provided two data sets, listing pharmacies in England as at 31st March 2003 and 2006. The consultants calculated the population who could travel to a pharmacy by (a) car and (b) public transport (P/T) within 10, 20 and 30 minutes. Where walking at a standard speed of 4.8 km/hr was quicker than public transport, the walk time has been used.

4.9 The same population (2001 Census) and public transport database was used for both years. Therefore, any changes solely reflect changes in pharmacies rather than in the distribution of people or in public transport.

Results

4.10 Table 9 shows an improvement in accessibility of pharmacies by every measure. In particular:

- The percentage of people not within 10 minutes' PT/walk of a pharmacy fell from 16.2% to 15.7%
- Other things being equal therefore, the number of people who could not get to a pharmacy within 10 minutes either by public transport or by walking fell by 3.4%.[23]

[23] This does not take account of any estimated increase in the total population of England over this period.

Table 9: Population of England by travel time to nearest pharmacy

	< 10min	< 20min	< 30min	All
Car				
2003	48,609,273	48,854,816	48,886,556	49,138,831
2006	48,628,061	48,855,912	48,888,038	49,138,831
PT/Walk				
2003	41,163,059	48,652,799	48,954,724	49,138,831
2006	41,435,264	48,691,158	48,962,011	49,138,831

Percentages

	< 10min	< 20min	< 30min	< All
Car				
2003	98.9%	99.4%	99.5%	100.0%
2006	99.0%	99.4%	99.5%	100.0%
PT/Walk				
2003	83.8%	99.0%	99.6%	100.0%
2006	84.3%	99.1%	99.6%	100.0%

4.11 Table 10 repeats the calculations using only those people who lived in the 10% of most deprived lower layer super output areas[24] as defined by the 2004 Index of Multiple Deprivation produced by the former Office of the Deputy Prime Minister.

4.12 The data show proportionately that more people in these areas than the national average are not within 10 minutes of a pharmacy by walking or using public transport. There is an improvement in accessibility of pharmacies by most measures, although some were unchanged. In particular:

- The percentage of people in these areas not within 10 minutes walk or by public transport of a pharmacy fell from 23.5% to 22.9%.
- Other things being equal therefore, the number of people in these areas who could not get to a pharmacy by public transport or walking within 10 minutes fell by 3.4%.[25]

[24] See footnote 12 above.
[25] It is not known if the total population of the most deprived areas rose or fell over this time, as the latest population estimates by SOA are for 2003.

Table 10: Population of England resident in 10% most deprived SOAs by travel time to nearest pharmacy

	< 10min	< 20min	< 30min	All
Car				
2003	4,904,073	4,911,355	4,911,548	4,934,825
2006	4,904,464	4,911,355	4,911,548	4,934,825
PT/Walk				
2003	3,776,498	4,870,972	4,904,362	4,934,825
2006	3,804,752	4,881,778	4,909,683	4,934,825

Percentages

	< 10min	< 20min	< 30min	All
Car				
2003	99.4%	99.5%	99.5%	100.0%
2006	99.4%	99.5%	99.5%	100.0%
PT/Walk				
2003	76.5%	98.7%	99.4%	100.0%
2006	77.1%	98.9%	99.5%	100.0%

4.13 Table 11 shows the average time in minutes to get to a pharmacy. Times tend to be lower in more deprived areas, because such areas are rarely rural. This means that people in such areas are not often very far from a pharmacy.

4.14 All of these average times have fallen. The reduction is greatest for those people using public transport or walking in the most deprived areas. However, the proportion of people in deprived areas more than 10 minutes away from a pharmacy by public transport/walk is still 45% higher than for the population as a whole.

Table 11: Average Travel Time to a Pharmacy, in minutes

	2003	2006	% reduction
All areas			
PT/Walk	9.797	9.731	0.7%
Car	3.249	3.240	0.3%
10% most deprived areas			
PT/Walk	7.715	7.340	4.9%
Car	1.810	1.784	1.4%

Clustering of pharmacies near to GP surgeries

4.15 We explored from data supplied by the consultants the extent of any clustering of pharmacies near to GP surgeries. Tables 12 and 13 give the results. These data show, for each GP surgery in England, the number of pharmacies within five and 10 minutes' walk of the surgery, in 2003 and 2006. The same list of GP surgeries was used for both calculations, so that no changes between 2003 and 2006 would be due to changes in the location of surgeries.

4.16 The chief changes are that the number of surgeries with no nearby pharmacy has decreased, while the number of surgeries with just one nearby pharmacy has increased. This suggests that the increase in pharmacies has been in areas with no nearby pharmacy, rather than increasing the clustering of pharmacies in areas already well provided.

Table 12: Clustering: Number of pharmacies within 5 minutes' walk of a surgery

No. of pharmacies	0	1	2	3	4	5	All surgeries
No. of surgeries, 2003	4023	4622	1158	108	64	5	9980
No. of surgeries, 2006	3914	4715	1174	108	64	5	9980
Change, 2006 on 2003	-109	93	16	0	0	0	

Table 13: Clustering: Number of pharmacies within 10 minutes' walk of a surgery

No. of pharmacies	0	1	2	3	4	5	All surgeries
No. of surgeries, 2003	1993	6394	1404	120	64	5	9980
No. of surgeries, 2006	1912	6466	1410	123	64	5	9980
Change, 2006 on 2003	-81	72	6	3	0	0	

Clustering of pharmacies near to each other

4.17 Tables 14 and 15 also calculated from data supplied by the consultants, show, for 9,871 pharmacies in England, the number of other pharmacies within 5 and 10 minutes' walk of a pharmacy in 2003 and 2006. The main changes are that the number of pharmacies with no other pharmacy nearby has decreased, while the number of pharmacies with just one other pharmacy (or possibly two pharmacies) nearby has increased. This again suggests that, overall, the increase in pharmacies has been in areas with no nearby pharmacy, rather than increasing the clustering of pharmacies in areas already well provided. The reduction in pharmacies with no others nearby could also be explained by the closure of isolated pharmacies. However, this explanation would contradict the analysis in paragraph 4.16 above which shows that the number of surgeries with no nearby pharmacy has decreased and the increase in pharmacies has been in areas with no nearby pharmacy.

4.18 However, from the returns made by PCTs and discussed in Chapter 3, certain PCTs have experienced some clustering of pharmacies relative to one another.

Table 14: Clustering: Number of other pharmacies within 5 minutes' walk of a pharmacy							
No. of other pharmacies	0	1	2	3	4	5+	total
No. of pharmacies, 2003	6102	2153	1010	341	91	44	9741
No. of pharmacies, 2006	5982	2335	1057	349	117	31	9871
Change, 2006 on 2003	-120	182	47	8	26	-13	

Table 15: Clustering: Number of other pharmacies within 10 minutes' walk of a pharmacy							
No. of other pharmacies	0	1	2	3	4	5+	total
No. of pharmacies, 2003	3896	2233	1586	973	518	535	9741
No. of pharmacies, 2006	3830	2331	1647	969	551	543	9871
Change, 2006 on 2003	-66	98	61	-4	33	8	

Price Comparisons of Pharmacy Only and General Sales List Medicines

Introduction

4.19 The full Competition Assessment contained in the Department of Health's 2003 response to the OFT's recommendation quoted estimates of price relativities between different groups of suppliers[26].

4.20 At that time, average prices in supermarkets were estimated to be 6% cheaper on "P"[27] medicines and 20% cheaper on "GSL" medicines compared to independents and multiple pharmacies. This compared to the OFT estimate that supermarkets were 20% cheaper overall (though they used a smaller basket of products).

4.21 The Department has conducted a further price comparison exercise relating to prices for June 2005 and June 2006 for the top 30 selling P and GSL products[28] covering seven types of outlets:

- Independent pharmacies – individual pharmacy shops or chains of five or fewer shops
- Multiple pharmacies – pharmacy chains of six or more shops
- Grocers (supermarkets) with an in-store pharmacy
- Grocers (supermarkets) without an in-store pharmacy
- Other grocers - smaller grocery chains – e.g. Balfour, Londis
- Convenience stores – smaller independent convenience stores
- Forecourts – garage forecourts and service stations.

A full list of sample coverage is shown in **Annex E** Tables 1 and 2.

[26] *Proposals to Reform and Modernise the NHS (Pharmaceutical Services) Regulations 1992*, Annex C – para 3.2.
[27] A "P" (pharmacy) medicine may only be supplied from a retail pharmacy under the supervision of a pharmacist. A "GSL" (general sales list) medicine may be supplied from a wider range of retailers, such as stores, supermarkets and garages.
[28] Many of these products come in different strengths and pack sizes. The unit of comparison was at the strength/pack level, so there are many more than 30 P and GSL prices to compare.

4.22 Comparing prices requires matched samples of products to be compared across the retail outlets. Prices can be compared between one type of retailer and one other type of retailer (a bilateral comparison) or across all retailers (a multilateral comparison). In practice, matched samples are larger for bilateral comparisons than for multilateral comparisons.

4.23 In addition, price comparisons require weights to attach to each product in the matched samples. Two sets of weights have been used:

- Weights that reflect aggregate product sales (summed across all the outlets covered) – *aggregate weights*
- Weights that reflect the sales mix of one of the outlets being considered – *own weights.*

4.24 These two sets of weights are described in more detail below.

Results

Aggregate Weights

4.25 **Annex E** Tables 3 and 4 shows the price comparison results using aggregate weights. Effectively, this says what would be spent in aggregate if all products were bought from one type of outlet compared to another outlet (where the sample is all products that were matched across the outlets being compared).

Bilateral Comparisons – GSL medicines

4.26 The first two columns of figures show bilateral comparisons versus independent pharmacies. This shows that independent pharmacies are roughly on a par with multiples, other grocery stores, and convenience stores. Garage forecourts tend to be about 14-18% per cent cheaper and supermarkets about 30% cheaper.

4.27 There is little change in this pattern over the two periods. Strictly speaking, the nature of bilateral comparisons means that one cannot necessarily draw conclusions about price relativities between, say, multiples and supermarkets from these first two columns, as the sample of products will differ.

4.28 The third and fourth column of figures shows the price relativities when the sample is matched to multiple pharmacies. A similar pattern emerges, with multiples on a par with independents, other grocers, and convenience stores. Garage forecourts are about 13% cheaper and supermarkets about 26% cheaper.

4.29 The rest of the columns continue with the various permutations of bilateral comparisons – however, the general picture remains that supermarkets are generally the cheapest, garage forecourts in the middle of the range, and independents, multiples, other grocers, and convenience stores on a par, but highest priced.

Bilateral comparisons: Pharmacy Only Medicines

4.30 Again, the bilateral comparisons suggest that independents and multiples are on a par, but supermarkets tend to be about 10% cheaper.

Multilateral comparisons: GSL Medicines

4.31 **Annex E Table 4** shows the results of the multilateral comparisons. This shows that, for products available in all seven types of outlets, independents, multiples, convenience stores other grocers, and garage forecourts tend to be on a par (though independents tend to be the cheapest of this group, and convenience stores / other grocers a little more expensive). Supermarkets are at least 20% cheaper compared to other outlets.

4.32 These results differ a little from the bilateral comparisons, where the latter show a greater price differential between supermarkets and other outlets[29] (in particular independents and multiples).

Multilateral Comparisons P Medicines

4.33 For products available in all three groups of outlets where P medicines can be sold, independents and multiples tend to have similar prices, whilst supermarkets tend to be 10% cheaper. This is similar to the bilateral comparisons.

"Own Weights"

4.34 The composition of sales can have a bearing on relative prices. For example, if a given outlet type specialises in particular types of medicines, then it is possible that the prices of these medicines will be set at levels that are more competitive. The degree to which particular outlets specialise in particular types of medicines will be masked when using aggregate weights.

4.35 Various sensitivity tests have been carried out to assess the affect of applying different weights (reflecting different patterns of sales). For example, applying weights that reflect the pattern of sales seen in independent pharmacies (see **Annex E** Table 5), shows a similar pattern of relative prices for independents versus other outlets to that reported above, except, in the case of bilateral comparisons with supermarkets, supermarket prices of GSL products appear to be only about 15% cheaper. The price differential between independents and forecourts also narrows significantly when independent pharmacy weights are used. Relative prices of P medicines remain at similar levels to those reported above.

4.36 A similar picture emerges if weights that reflect the sales patterns of multiple pharmacies are used. Here the relative prices of GSL products are about 20% cheaper for supermarkets compared to multiples (as opposed to approximately 25% when using aggregate weights).

Discussion

4.37 This analysis shows that, using aggregate sales weights, supermarket prices of GSL medicines are about 25% to 30% cheaper than independent and multiple pharmacies. P medicines tend to be about 10% cheaper. The price relativities for P medicines are similar to those reported in the previous study, but the gap appears to have widened slightly for GSL medicines.

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[29] The reason for this is that, when moving from the bilateral comparisons to multilateral comparisons, a significant number of matched products are removed from the sample, and these tend to be products that are disproportionately cheaper in supermarkets. This demonstrates the merit of focusing on bilateral comparisons rather then multilateral comparisons. A multilateral comparison confined to matched products sold in independents, multiples and supermarkets gives results similar to the bilateral comparisons.

4.38 Independents and multiples tend to have similar prices to other small grocers and convenience stores, but slightly higher than garage forecourts.

4.39 However, the wide gap on GSL medicines may in part be explained by the difference in sales patterns across the various outlets. As shown above, using sales weights that reflect the pattern of sales used in independent pharmacies reduces the price differential with supermarkets (and garage forecourts) to about 15%.

4.40 This comparison can only compare prices where there are exactly matched products. This may therefore miss some products that while essentially the same, may be called slightly different things in different outlets. This would cover own brand packs, which are generally cheaper than branded products.

5 A qualitative review of the reforms including results of consultation and feedback from public regional “listening events” and meetings with pharmacy and other organisations

Key findings

- Patients, the NHS and business considered it was too early to judge the full impact of the reforms
- Patients welcomed extended hours, improved accessibility where new pharmacies had opened and the higher quality and range of services
- However, these were not universal experiences with some reporting no noticeable difference, especially in rural areas
- Patients were concerned the reforms, especially the introduction of 100 hours a week pharmacies, and moves to focus healthcare services on larger sites, could jeopardise access and choice in the longer term
- The NHS experience has varied widely. Some PCTs experienced considerable extra work, whilst others reported little, if any
- Where the reforms have opened up the market, PCTs find that access has improved but exempt pharmacies in particular hinder their ability to plan service provision to meet local needs by diverting resources away from specialist clinical services. There is little evidence the reforms have contributed to innovation
- The new contractual framework, rather than the reforms to control of entry has been the most important driver for change
- PCTs have found the new regulatory system more complex and administrative burdens and costs are generally higher with most PCTs reporting the benefits did not compensate for this increase
- Business also gave a mixed response. Some reforms were welcome, particularly new procedures for minor relocations
- Many contractors were concerned the exemptions could lead to long-term reduction in choice and none reported business certainty had improved
- Some business respondents called for complete deregulation – others that there should be no further move in that direction

The consultation

5.1 As part of the qualitative review, the Department of Health invited views and comments from patients and consumers, business and the NHS on the operation of the reformed regulatory system. The consultation began on 13 June and ended on 12 September 2006. A copy of the consultation document is available at http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4138960&chk=wBwCeL

5.2 175 responses were received. We are grateful to all who replied to the consultation. The breakdown is:

Patients/Consumers	30
NHS	50
Business[30]	93
Other[31]	2

Public regional "listening events"

5.3 To augment the consultation, the Department hosted a series of regional "listening" events[32] in July 2006 to which patients and consumers, the NHS and business representatives were invited. These were supplemented by a further event in September for patients, patient groups and organisations in London. In all, 350 delegates attended. The purpose was to hear and exchange views and ideas in more detail on the operation of the regulations. We are grateful to members of the NHS Primary Care Contracting Team for organising and facilitating these events.

Evaluation of the listening events

5.4 The Primary Care Contracting Team sought delegates' views on the listening events. 112 questionnaires were returned, giving a response rate of 34%. Of those responding, 105 (93.6%) rated the events either excellent (28.5%) or good (65.1%). Average knowledge and skills levels were reported as:

Knowledge and skills: averages			
Before	After	Change (number)	Change (percent)
6.69	7.89	1.2	17.90%

Meetings with pharmacy and other organisations

5.5 We also undertook visits to selected PCTs, the Appeal Unit and met *Which?,* two contractors and the Pharmaceutical Services Negotiating Committee to hear their views on the operation of the reforms in more depth.

Main themes

5.6 Specific questions were asked in the consultation document and at the listening events of each group, for example whether there had been change locally, whether choice and the regulatory system had improved or not and whether the aims of the reforms had been met. We also invited views on how the working of the regulations could be improved. Below is a summary of the main themes expressed. Where figures are quoted, these reflect specific responses received to the consultation itself. For the full feedback on the listening events, please see **Annex C**. A fuller version of the 175 responses received (excluding one response sent in confidence) is available on request from Gillian Farnfield at the Department of Health on 0207 972 2700.

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[30] Includes pharmaceutical businesses, individual pharmacists, local pharmaceutical committees, pharmaceutical trade and representative bodies.
[31] The Office of Fair Trading and the Liberal Democrat Parliamentary Health Team
[32] In Preston, Birmingham, Leeds, Nottingham, Stansted, London, Reading and Exeter.

Race and Equality

5.7 No issues of race and equality were highlighted in the consultation responses received.

Patient and Consumer experience

5.8 Patients and consumers have previously given a positive assessment of community pharmacy services. For example, the Royal Pharmaceutical Society found in 1996 that 94% of the population visit a pharmacy at least once a year and that adults visit an average of 12 times a year. The consumer survey that the OFT included in their 2003 report found that 89% of respondents found it easy to get to their chosen pharmacy from home, whilst 86% said it was easy to get to a pharmacy from their GP surgery.[33] From the consultation in 2005 preceding the White Paper *Our Health, Our Care Our Say*, people expressed considerable satisfaction with pharmacy services, saying they were "accessible, friendly and expert"[34]. This reinforced findings from the Consumers' Association in 2002 that 88% of consumers felt pharmacists were trustworthy as a source of information about the accuracy and reliability of information on medicines, second only to GPs. Yet more recently, *Which?* found that just 3% of consumers would turn first to a pharmacy if they or a member of their family needed healthcare or treatment outside normal GP hours and only 1 in 10 who had sought out-of-hours care in the past year had consulted a pharmacy[35].

To what extent do you think the provision of pharmaceutical services has changed locally since April 2005?

5.9 Patients and consumers considered that it was too early to assess the overall impact of the changes. Four responses indicated there had been change, while two indicated there was little or no change. Where there had been an increase in the number of pharmacies, this tended to be in places where access was already good. Some patients felt new pharmacies tended to cluster in areas where there was already an adequate service available.

> "In many places, services haven't changed one iota"
> *Patient representatives at Preston listening event*
>
> "Three local shops in Cray Valley East area. Big improvement in them. More dispensers are being trained up"
> *Patient feedback at listening event*

5.10 Patients reported a number of improvements in the provision of services, with for example, more pharmacies prepared to offer a home delivery service for their medicines. They found a greater preparedness on the part of pharmacists and their trained staff to offer advice, to check and discuss patients' problems with their medication and to offer special dispensing aids (known as monitored dosage systems) which help patients take the right medicines at the right times. Some reported premises facilities much improved and welcomed that discussions with the pharmacist could now take place in designated private areas.

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[33] op. cit. Volume 1 paragraphs 1.15 and 5.14
[34] *Your Health, Your Care, Your Say Research Report*, Opinion Leader Research, London, January 2006, page 47
[35] *"Which Way? Negotiating the out-of-hours maze"* Which? 2006.

5.11 The introduction of the new 100 hours a week pharmacies were reported to have helped improve service accessibility, particularly during the "out of hours" periods at evenings and weekends. This had increased convenience and, in terms of the improvements in accessibility, were generally perceived as a positive development. A new community pharmacy adjacent to an A&E Department at a North West hospital was cited as particularly helpful. However, patients also held concerns about the as yet unknown longer-term impact such pharmacies would have on the existing network. As one patient representative commented, PCTs, who were best placed to determine where services were to be provided, were unable to plan services as a result of exempt pharmacy applications.

> "Choice of services has improved due to the new [100 hours a week] pharmacy, but will be diminished if the network of local pharmacies is lost as a result . . . Regulations could be improved by restricting the number of 100 hours a week pharmacies to 1 in 100,000 per population. There is no need for further duplication and more 100 hours a week contracts just put more pressure on the availability of pharmacist locums"
> *Patient representative at Exeter listening event*

5.12 Similarly, patients were concerned that the introduction of new large "one-stop" primary care centres which had pharmacies within them could have a destabilising effect on existing pharmacies if this were to lead to a significant shift in business away from those contractors and a reduced level of access in the future.

5.13 The improvements reported were not uniform. Other patients reported that service provision out of hours had deteriorated (perhaps reflecting that fewer PCTs now commission a rota service), that not every pharmacy had changed practice with the introduction of the new contractual framework, that the pharmacist was not always accessible at times when patients wished to see them, and that services were not particularly innovative.

To what extent do you think you have more or less choice of these services since then?

5.14 Patient reaction here was mixed. Three replies felt choice had improved, whilst six felt choice had either not improved or had worsened. Whilst some patients indicated they appreciated the improvements in choice of contractor through for example supermarkets opening for longer hours and being able to dispense medicines, others also expressed concern about the market drift where larger pharmacy companies were taking over smaller competitors and that this had led to - or would in the future - a monopoly provider locally.

5.15 Some patients reported no noticeable difference because they used the most familiar and nearest pharmacy and had had no reason to look further afield for alternatives. This finding is not surprising given that earlier reports[36] have shown patients tend to use the same pharmacy. Patients also preferred to have continuity of the professional service and to see the same pharmacist each time they visit – especially if they are using the pharmacy to obtain more clinical services, such as monitoring their blood.

[36] E.g. the OFT 2003 report op. cit. Volume 2 paragraph D.15, page 85. "When having prescriptions made up, respondents [to an OFT-commissioned consumer survey] proved to be creatures of habit. 94% said they have a 'usual' chemist."

5.16 There were either no improvements in choice reported for rural or deprived areas, or in those areas where choice had improved it was not necessarily in the locations where patients felt it was most needed (for example, in the most deprived areas or where GP services were no longer available or had reduced). Other patients found that choice was more restricted if a pharmacy opened in a rural area which patients were then obliged to use[37], rather than continue to be able to use the dispensary at their local surgery.

> "One of the problems living in rural areas is lack of transport. If you cannot drive, afford a car or are too ill what can you do and even when there are buses, they often do not go where your doctor, hospital or pharmacy is sited"
> *Patient response, Leicestershire*
>
> "[My] access to services [in North Yorkshire] however has become much more problematic. I can no longer use the [doctors'] dispensary, so getting hold of medication is now a two-stop process. The pharmacy opens fewer hours than the health centre, so on occasions getting medication involves the wait of a day or even days, or a round trip of at least seven miles, which as a non-driver, means a lengthy trip on an infrequent bus service or a very expensive taxi ride. The current pharmaceutical services certainly don't fit the needs of this patient."
> *Patient representative at Leeds listening event*
>
> "Although it is still early days, the current exemptions to the regulations appear to have done little to promote new provision particularly in areas where there is limited pharmacy provision, not just in rural areas but also in socially disadvantaged areas of cities."
> *Which?*

5.17 Patients were concerned that choice will be inhibited where GP surgeries "direct" the patient to use a particular pharmacy to dispense their prescriptions. This should always be a matter for the patient to decide. It may also inhibit GPs and pharmacists working more closely together which patients welcome although, again, this should not have an unintended effect of reducing or eliminating choice by "cornering" healthcare provision locally.

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)?

5.18 One reported access to NHS pharmaceutical services as better, whilst three reported it as worse. Patients expressed concern about healthcare facilities becoming over-concentrated. The example of a large market town in the North was cited where all the GP practices had merged on one site in a large health centre with a new pharmacy. It was now more difficult for patients in outlying areas to travel to the centre by public transport and would entail repeat visits if not all the services are available when needed. Such problems were made worse on Sundays when public transport was reduced, or for the elderly who may not have access to private cars. They were also concerned that this may lead to a reduction in services if pharmacies in the outlying areas were to become unviable.

[37] When a pharmacy opens in a designated rural area, patients living within 1.6km of the new pharmacy generally must switch to the pharmacy rather than continue to use their dispensing surgery. Without this, a new pharmacy which would offer a much wider range of services than the dispensary would probably not be viable. Any patient who has serious difficulty getting to the new pharmacy can, with PCT approval, continue to use the dispensing surgery.

"Pharmacies are open more hours than GPs. Pharmacy services are particularly useful now GPs do not provide emergency Saturday surgeries. Panel members are more likely now to approach a pharmacist to ask a question now instead of waiting for an appointment with a GP"
Ian Millar: Chair, Local Service Users Panel, Hillingdon, lay PCT member

"Access to pharmaceutical services easier – more shops on more user-friendly sites. Not all comply with the Disability Discrimination Act"
Patient representatives at Nottingham listening event

"Services have not improved in areas of deprivation – more information should be made available to advertise services"
Patient representatives at London listening event

5.19 Three patients indicated that access was more difficult in rural areas - where patients need a flexible range of provision to meet their needs. This will include GP dispensing services, medicines delivery services and adequate out of hours provision as well as access to pharmacies. *Which?* commented more widely

"The new pharmacy contract, pharmacist prescribing, and the direction for NHS services outlined in the White Paper and elsewhere offer significant opportunities to develop explicitly patient-centred pharmacy services that add value to the current experience of patients, service users and consumers. This wider role will be of increasing importance given the ageing population, growing incidence of chronic and long-term illnesses and the emphasis on self-care. In order to fulfil this wider role, pharmacy must be regarded as an integral part of primary care, with the PCT taking a proactive role in commissioning local pharmacy services to meet the needs of the local community, identifying needs and gaps in provision. In particular, PCTs should be actively commissioning new pharmacy provision in areas that do not currently have good access to pharmacy provision… Such an approach is all the more important because of wider health reforms and new initiatives resulting from the White Paper *Our Health, Our Care, Our Say*, such as opening out-patient clinics, GP surgeries or out-of-hours clinics …. This not only has the potential to make healthcare more convenient and accessible for consumers, it may also give those outlets a significant advantage over other community pharmacies because so many people go directly from the doctor's surgery to the pharmacy to collect their medication. It is therefore crucial PCTs are mindful of the potential impact of these initiatives on local pharmacy provision when making their decisions.
Which?

In what way do you think service provision could be enhanced in future?

5.20 Patients identified three main areas for further consideration. First, easily accessible basic information was needed on new pharmacies' opening times and which pharmacies could be accessed out of hours. Patients would welcome more information about the new contractual framework and for this to explain what it was setting out to do and the services a patient could expect to be available.

5.21 Second, where improvements to service provision were being made, these should be available to all patients in all areas. Patients appreciated a home collection and/or delivery service although they expressed concerns about security and safety if the patient or representative is not at home to receive, or if the items are left elsewhere to be collected. Related to this, patients found a telephone reminder service helpful for their repeat medication. The provision of aids to help them remember take the right medicines at the right times was also welcomed.

5.22 Third, patients appreciated a better-integrated approach with doctors and pharmacists, particularly in respect of widening repeat dispensing schemes. Minor health ailments could be dealt with by pharmacists in the community, and pharmacies should carry out routine testing e.g. blood tests, blood pressure, anti-coagulant monitoring, instead of at surgeries requiring an appointment. This should result in less unnecessary duplication of service provision. Whilst more co-operation between GPs/pharmacists/patients would help deliver an integrated, patient-focused pharmaceutical service, particular consideration should be given to patients' needs and their ability to access services when planning and building new one-stop healthcare centres.

> "The best way to take services forward in the future is to engage GPs to provide the electronic transfer of prescriptions. This could alleviate the need for patients to make unnecessary journeys to the surgery, just to hand in a piece of paper and then make another journey 4 – 8 hours later to collect the medication from a pharmacy."
> *North East Derbyshire Patient and Public Involvement (PPI) Forum*
>
> "…an enhanced NHS where pharmacists can play an active role in advising/treating patients, supporting and where appropriate in place of GP practices as part of an integrated service of pharmacist, GP and secondary care. The patient chooses the healthcare provision to fit their health requirements. Co-operation with social care services will be necessary."
> *Solihull PPI Forum*

Are there other changes you would like to see?

5.23 Patient and consumer group representatives raised a number of other issues, which whilst not directly related to this review, are relevant to the provision of pharmaceutical services.

5.24 Medicines Use Reviews could be more rigorously targeted e.g. for those patients who cannot afford all their medicines or for patients who may be over-ordering their regular medicines unnecessarily. Patients placed particular emphasis on prescription orders being aligned to eliminate unnecessary visits to the surgery and/or pharmacy.

5.25 Ideally, generic medicines should have common packaging to avoid confusion and patients be reassured that these are of the same quality and efficacy. If not, patients should be supplied the brand that suits them best, rather than choice being made on the basis of a cheaper brand or generic equivalent. Labels should be in print large enough to see and read and the patient information always available in English. Patients considered it good practice for the pharmacist to give verbal advice because writing can be too small on leaflets and some patients may not understand all the information provided.

5.26 Patients were concerned that pharmacy facilities were not always suitable for providing additional services – e.g. the consultation area was not private enough or conversations could be overheard.

NHS Representatives

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)?

5.27 Many of the 50 NHS replies were on behalf of a number of PCTs. Some PCTs reported many applications for new pharmacies whilst others had had few, if any, reflecting the data reported in Chapter 3. PCTs noted that applicants refused under the previous regime were now taking advantage of the reforms to apply successfully to establish a pharmacy. Most PCTs reported an increase in the number of minor relocations, with use being made of the cross-PCT border facility. Fifteen responses indicated that the regulatory changes had made an impact on the provision of NHS pharmaceutical services, whilst six felt the changes had had no impact. Six responses indicate that access remained difficult in rural and more deprived areas. Otherwise, the NHS, as with patients and contractors, found it too early to assess the overall impact of the reforms, and particularly the extent to which the new exemptions would affect existing local pharmacies.

> "This increase in service [100 hours a week pharmacies] has allowed some wider access to out of hours services for those people who have their own transport etc. but it has not helped and in some cases has made worse, the problem for those living in more rural and deprived areas."
> *NHS Employers*
>
> ".. have had four applications for 100 hours a week pharmacies in the PCT area. With one exception, there is no [pharmaceutical] need. In each case, a pharmacy was almost next door. Two of the applications, which were approved, had still not opened a pharmacy yet after over six months.
> *North Hertfordshire and Stevenage PCT*
>
> "The reforms have had very little impact so far… but now we have received an application for a 100 hours a week pharmacy…"
> *Cornwall PCTs*
>
> "There has been very little impact. Have had far fewer applications than under the 1992 regulations"
> *Bedford PCT*

5.28 PCTs felt that new applications had not tended to be situated in deprived or rural areas, as larger companies did not tend to see these areas as their main market. Where pharmacies were setting up in out of town shopping centres, these served different populations to the area in which they were located. PCTs were therefore funding patients from outside their own area.

5.29 By far the largest single category on which the NHS commented was the introduction of 100 hours a week pharmacies (41 responses). The exemption was considered to have improved access for patients overall and especially outside normal trading hours. However, 10 expressed concern that this could have a potential negative impact on existing contractors.

If these were lost, the 100 hours a week pharmacy might in the future simply give notice of closure and apply under the reformed test offering much-reduced hours. However, this had not happened yet.

5.30 PCTs reported being unable to fund all the directed services they would wish to, because of the financial pressures they were facing from exempted pharmacies.

> "Moreover, where out of town and 100 hours a week pharmacies have become prolific due to the exemptions under control of entry for these businesses, PCTs are using funds to repeatedly pay for essential services. This is to the detriment of the provision of enhanced services, as PCTs find that there are no funds left to pay for more innovative services. For example, one PCT we are aware of has four 100 hours a week pharmacies in close proximity. This has resulted in funds that were earmarked for pharmacy enhanced services now being used for essential services."
> *NHS Employers*

To what extent have the reforms improved choice and competition for services, their quality and innovative nature?

5.31 Responses to the consultation were evenly balanced. 15 felt that choice and competition had improved, whilst 15 felt that it had not improved. PCTs reported increased access for medicines and related products but that the new locations were not necessarily where they would have planned to improve access. As an example, rota services in town centres were stopping because a 100 hours a week pharmacy would open up in the outskirts. This gave better access and choice to patients in the outskirts of the town, but not necessarily for those living in the town centre who required pharmacy services out of hours.

> "…very little [impact] as all the areas in the metropolitan areas are saturated with pharmaceutical services"
>
> "changed mindset of contractors – now more open to provide services"
>
> *NHS representatives at regional listening events*

5.32 PCTs reported the new reforms appeared to have stimulated existing contractors to be more willing to undertake local enhanced services, perhaps encouraged by the possibility of new competition. The impact on quality and innovation was, however, uncertain. Innovation and new service provision tended to be linked more to the introduction of the new contractual framework which was an important driver for change, rather than to these reforms. Primary reasons for this were that PCTs did not have the resources to pay for a more innovative service model and because not all PCTs had finalised robust Pharmaceutical Needs Assessments for their areas. Ten responses mentioned that the development of these local assessments had been of use. However, five respondents either reported that PCTs were unable to plan services coherently because of the introduction of the exemptions or were prevented from determining where best to commission services.

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> “The reforms have provided patients with a greater choice of pharmacy in the areas in which the ‘100 hours a week’ pharmacies have opened, in addition the longer opening times provide for access at times that are convenient for patients. To date the reforms do not seem to have been a driver for quality and innovation, that role is instead taken by the new contractual framework, which does encourage both quality and innovation.”
> *Dr Peter Magirr – Pharmacy Joint Planning Group, Sheffield PCTs*
>
> “Would appear that it has definitely improved choice to patients and in certain circumstances, improved range of services and additional services such as emergency hormonal contraception. However, PCTs have to work within budgetary constraints – and patient expectation of pharmacy can be hampered when PCT cannot afford to commission extra services.
> *NHS representative at regional listening event*

5.33 PCTs shared the concerns of others, that in the longer term, choice might be more restricted if the introduction of the exempt pharmacies led to the closure of established local businesses.

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?

5.34 PCTs generally reported that administrative burdens had increased, owing to the complexity of the regulations, the need to consult more widely and the more stringent time limits for deciding applications. However, views were mixed as to whether or not the benefits outweighed these additional burdens. 31 responses indicated that administrative burdens had increased and 11 that costs were higher, with one indicating that administrative burdens had increased and one that costs were the same as before. Five felt that the benefits of the changes outweighed these burdens and costs, whilst 21 felt that they did not.

> “There has been an enormous increase in applications. Applications for minor relocations have been very complicated. Setting up the control of entry sub-committees for applications has been a drain on PCT resources…. It has cost the PCT a lot in terms of time, staff, and queries with respect to new applications and minor relocations”
>
> “Administrative burden and costs of increased consultation and notification requirements have tightened up systems. More robust and gives more confidence when we go to appeal… Workload appears to be evening out over time. Neutral as to whether these outweigh benefits and costs.”
>
> “…Significantly increased administrative burden for necessary or desirable applications especially if going to appeal. Exemption applications have reduced burden...”
> *NHS representatives at regional listening events*

"In terms of administrative burden, we have seen major companies submitting multiple applications in respect of the same location. First under the normal necessary or desirable criteria and then under the 100 hours a week exemption when the first application was rejected (having processed the application and carried out consultations and held oral hearings). In another case Two applications were received from the same company in respect of the same premises first as a 100 hours a week exemption and then under the 15,000 sq m Retail Park exemption when the site was added to the approved list. This has required the PCT to replicate the consultation procedures."
Darlington and five other North East PCTs

"All in all, the added administrative burden … can probably be offset against costs savings as a result of greater procedural efficiency and an assurance that contractors admitted to PCTs are 'fit to practise.'"
Ealing PCT

5.35 The benefits were seen as enabling PCTs to clarify and strengthen their procedures, with pharmacies opening sooner and offering more services. Increased costs arose from monitoring new pharmacies, supporting pharmacies in implementing the new contractual framework and new pharmacies creating additional pressures on PCT budgets where they meet minimum qualifying levels for payments. PCTs also reported a rise in duplicate or repeated "vexatious" applications which seemed to have increased with the shortened timescales.

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

5.36 NHS respondents offered a number of suggestions as to how the regulatory regime could be improved. The application process could be streamlined with a simplified application form or if some of the details required could be held on a central database to avoid duplication. Application forms were not always completed correctly, leading to PCTs having to return these for amendment. A common cause was that applicants were not reading the PCT's pharmaceutical needs assessment before filling the forms. The regulations should also include a way of preventing repeat or duplicate applications, unless there had been a significant material change in local circumstances. Eleven PCT respondents therefore also supported introducing charges for applications to act as a further deterrent.

"Charges for applications should be introduced to prevent opportunistic applications"
Bradford and Airedale PCTs

5.37 The NHS echoed patients' and contractors' concerns about the extent to which 100 hours a week pharmacies should be permitted. One suggestion was to allow an initial pharmacy on a first come, first served, basis and then subsequent applications would be considered under the "necessary or desirable" test. Alternatively, a limit should be placed on the number of such pharmacies in geographical locations, using the local pharmaceutical needs assessment as the means to gauge this. For those pharmacies that appeared not to be adhering to the hours requirements, PCTs were concerned that the range of available measures were sufficiently robust.

> "The process needs to be simplified. There are no safeguards for the NHS regarding leapfrogging, quality or cost."
> *Pharmacy Applications Committee, East Hampshire, Fareham and Gosport PCTs*
>
> "There are still no safeguards for the NHS with regard to ensuring improved quality; implementation; disproportionate costs and unreasonable applications"
> *Guildford and Waverley PCT*

5.38 More generally, PCTs felt that the need to consult on exempt applications raised expectations unnecessarily though appreciated this enabled greater scrutiny to ensure the application met the relevant criteria. 29 asked for more guidance on monitoring 100 hours a week pharmacies and funding to support this additional work. PCTs felt in the main that some protection was helpful for local pharmaceutical contracts but this could be manipulated so that it presented a complete barrier to new applications.

5.39 Two NHS representatives wanted the particular protection for local pharmaceutical services schemes in respect of exempt applications under regulation 13 (1) reviewed.

> ".. there is also the view that this regulation is being used to block applications that will have no effect on the actual LPS provision"
> *London PCTs*

5.40 A wider concern was that the reforms, and in particular the introduction of the four exemptions took away a PCT's ability to plan service provision where most needed.

> "…. the balance of power re pharmaceutical service development should rest with PCTs, i.e. the PCT should have the right to request applications under the exemptions, which cannot then be challenged by other contractors but should not be required to accept such applications from contractors"
> *Cheshire PCTs*
>
> "The PCT is therefore carrying a financial and contractual responsibility for, in all likelihood, four pharmacies which it does not need according to its pharmaceutical needs assessment, and which are not, substantially, providing services to the PCT's patients."
> *Newham PCT*
>
> "Alternatively, consideration could be given to complete revision of the reactive concept of Control of Entry in favour of a proactive approach, whereby NHS dispensing is deregulated but PCTs are empowered (and appropriately funded) to commission all other community pharmaceutical services"
> *Hampshire and Isle of Wight Practitioner and Patient Services Agency*.

"If the policy intention is to open up the marketplace, though still retaining some control, we believe that replacing the necessary or desirable test with the prejudice test in all instances would be a way of achieving this. This would shift the balance towards approval unless it could be shown that by doing so the proper provision of pharmaceutical services would be prejudiced. A more robust definition of "prejudice" might be needed. … It occurs to us that substituting the "necessary or desirable" test for "prejudice" in GP outline consent applications might be a more economical way, from an administrative point of view, in controlling GP dispensing – in other words, approval would be given only if it were necessary or desirable for the adequate provision of pharmaceutical services."
Norfolk PCTs

Business experience

To what extent have you made use of the reforms since April 2005?

5.41 Overall, business experience of the reforms varied. 10 responses indicated that contractors had made use of reforms, with four indicating they had not. Contractors who had used the new procedures for minor relocations under 500m reported these as a positive reform as well as the ability now to relocate across PCT borders. Contractors also said that the new exemptions meant that applications which had previously been refused under the 1992 regulations could now be approved (mirroring the NHS experience above). Other representatives reported they had made little use of the reforms although they had noticed increased market activity by receiving details of new applications. Business generally reported little evidence of innovation in proposing how services would be provided, and that there had been a number of duplicate or repeated applications which promised to improve or provide more 'choice' but which had failed to be approved.

5.42 For appliance contractors, "the changes have had no impact on activities" (*British Healthcare Trades Association*) and are "totally confined to the role of the pharmacy contractor" (*Salts Healthcare Ltd*).

To what extent do you think the reforms have impacted on the choice of and competition for services locally, their quality and innovative nature?

5.43 As with patient groups, business felt it was too early to assess the overall impact. In responses, reactions were mixed with six saying there is improved choice, whilst five felt it had not improved or had worsened.

"…. the new contracts have increased choice for patients. They now have pharmacies in many locations previously denied to them, locations that reflect the changes in shopping patterns that have taken place in the last decade."
Company Chemists' Association

"… One of the intentions of the reforms was to promote an increase in consumer choice, but the Society has yet to see any evidence that this has occurred"
Royal Pharmaceutical Society of Great Britain

".. this has been the biggest area of disappointment.. Our experience has been that both PCTs and the Appeal Unit have not accepted that 'choice of service providers' means 'choice within the neighbourhood'"
Healthcare Pharmacies - Assura Pharmacy

> "…when viewed at a national level, pharmacy contractors (both independent and multiple) have taken advantage of the changes to control of entry regulations to open more pharmacies . . . However, the impact on pharmacy choice and competition is more mixed at a local level. The application of market forces is a blunt and unreliable tool to use in trying to ensure choice and accessibility of service provision [because of duplicate applications at popular sites, new openings, clustering in high population areas and little evidence of increase in rural or deprived areas]"
> *Alliance Boots plc*
>
> "Has choice been widened? Possibly for those with their own transport who can easily travel to an out-of-town location. However, to the population in general (particularly the elderly and/or those with transport problems), the answer is even more ambiguous. Two pharmacies more-or-less next door to one another, offering the same services to those able to easily travel out-of-town, hardly represents choice …. when many of the services are already available on the patients' doorsteps in their local neighbourhoods."
> *Dr Christopher Dunn – Swindon and Wiltshire Local Pharmaceutical Committee (LPC)*

5.44 As with the NHS, by far the largest response concerned the introduction of 100 hours a week pharmacies (59 responses) with 11 concerned these would lead to the loss of existing local pharmacies. In the longer term, contractors felt the exemptions would reduce choice if they resulted in the closure of existing established pharmacies which were unable to match services and/or opening hours. Contractors were also concerned that the reforms affected the longer-term ability of PCTs adequately to fund local enhanced services. This was exacerbated where a PCT encountered a large number of exempt pharmacies opening which put further unanticipated pressures on the pharmacy budget. Contractors reported that the exemptions, and the automatic approval of minor relocations under 500 metres was encouraging pharmacies to re-cluster around surgeries (although the national data reported in Chapter 4 do not support this).

To what extent does the new regime provide more or less certainty and reliability for business?

5.45 No business responses indicated the new regime had provided more certainty or reliability. 33 indicated there was now less, principally because of the "diluting" effect new entrants have on the existing market and the uncertainty of whether new exempt applications would be forthcoming.

> "The new regime reduces reliability and confidence in business and hence reduces investment in improving facilities or first-hand experience in developing new services."
> *Contractor at regional listening event*

5.46 12 respondents commented that 100 hours a week pharmacies already impacted - or would - on staffing levels in existing pharmacies or would reduce workforce availability more generally. Business reported this as undermining investment confidence and, in turn, the PCT's ability to plan strategically. 15 mentioned the development of pharmaceutical needs assessments as positive and useful because this enabled contractors to see gaps in provision. However, an influx of new pharmacies using the exemptions did not necessarily lead to those gaps being filled. Seven felt that PCTs were unable to plan services as a result of the introduction of the exemptions.

> "If a contractor wishes to open a pharmacy, they are able to do so under the exempt categories. This allows contractors to plan where they feel it is appropriate to provide pharmacy services and work with the PCT…. However, the fact that there is no limit on the number of exempt pharmacies that can be opened means that there is always uncertainty about when and where the next pharmacy will open. This could lead to a lack of innovation as contractors choose not to invest for fear of being usurped…. However… increased competition leads to improved services for patients and we would continue to argue that complete deregulation is the path to follow."
> (*Superdrug plc)*
>
> "…much of the new regulation provides significantly less certainty to business and this is having a negative effect on investment and patients. The 100 hours a week exemption category is clearly being abused and not used as was intended…"
> *(Lincolnshire Co-operative Ltd*)

5.47 Pharmacies opening at least 100 hours a week were thus perceived as having a powerful impact, particularly if they were opening up in areas already well-served, or this or other exemptions were being used as a means to "leap-frog" to the most commercially attractive location. This perception increased where GP surgeries were also making use of the exemption. Contractors expressed particular concerns about the short-term impact on local provision if increasing numbers of GP surgeries apply to open their own pharmacies on-site. 11 responses were concerned with the emergence of GPs running/owning pharmacies, whilst 10 were concerned about or reported evidence of GP-run pharmacies directing patients to their own pharmacies.

> The regulatory regime needs to have stronger measures to prevent direction of prescriptions by practices to health centre based or GP owned pharmacies, as well as internet pharmacies, to ensure a level playing field.
> *North and East Devon LPC*

5.48 This contrasted with the position for local pharmaceutical services contractors who under the reformed procedures enjoy some "protection" from new entrants.

5.49 Whilst automatic approval of relocations under 500 metres was welcome, the criteria for relocations over 500 metres meant the outcome of such applications remained as uncertain as ever. Business expressed strong concern over any proposals to de-regulate the market further.

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?

5.50 Nine felt that the new requirements had been more onerous and costly to businesses, whilst four felt these were either not more onerous or were unchanged. Again, business reported the reformed minor relocation procedures as more business-friendly, since the process was both speedier and cheaper. The shortened timescale for PCT processing of applications was appreciated as it led to less opportunity for "blocking" applications.

5.51 However, business attributed most benefits to the new pharmacy contractual framework rather than these reforms. Business was concerned that there was a lack of clarity on the question of ‘choice’, which in turn had led to more appeals. Whilst the reformed procedures bedded in, business would continue to be uncertain as to the longer-term impact and the costs and time involved.

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

5.52 Contractors put forward a number of suggestions as to how the working of the regulatory regime could be improved. The application process was considered complex and would be more usable if a checklist and glossary of terms was produced to aid applicants. Greater consistency in the way in which PCTs reached decisions would improve business confidence, together with more clarification as to how the criteria of “competition and choice” were to be applied, though it was noted that the courts had yet to hear cases on this aspect of the reforms. It was also suggested that an interim appeal body be established by setting up a specialist area board to consider PCT decisions before the Appeal Unit in order to cut down on the potential numbers of appeals and judicial reviews

5.53 Contractors concerned about the impact of the exemptions called for improved monitoring of pharmacies opening at least 100 hours a week, with more guidance and specific funding for PCTs to support their introduction (27). Like the NHS, exempt applications generally should be subject to a PCT impact assessment, or a limit placed on their numbers either in respect of a given neighbourhood, or by means of a minimum distance between them (19). Alternatively, a PCT’s pharmaceutical needs assessment should designate areas where exempt applications would or would not be permitted.

5.54 In its response, the Pharmaceutical Service Negotiating Committee (PSNC) put forward a number of proposals for improving the working of the regulatory regime and advised that successive exempt applications could be used to “block” bona fide applications made under the reformed control of entry test. The PSNC suggested that legislation should permit a PCT to reject an application unless it satisfied that the applicant has demonstrated through its business plan or has provided other suitable evidence that he will be in a position to provide services if the application is granted.

5.55 Contractors also called for improved clarity on the working of the out of town shopping centre exemption as to how such an area is either included or excluded on the approved list. The Department should review the criteria and conditions for the one stop primary care centre exemption (nine) and more guidance was called for on distance-selling pharmacies, particularly those which are internet-based and the monitoring requirements as to how such pharmacies provide essential services (three). Appeal rights for exempt applications should be extended to include those affected (four).

5.56 A number of individual pharmacists responding (10) called for abolition of control of entry itself as it impeded new pharmacists from setting up in business. Similar arguments were deployed within these responses.

> “”..the conditions of the revised “control of entry” are still far too onerous”
> *Individual pharmacist*

5.57 Overall, the reforms were considered to send out a mixed message to business. The National Pharmacy Association concluded

> "The balanced package conveys a mixed message to pharmacists. On the one hand, government is encouraging pharmacists to expand their contribution to healthcare through an increased clinical role and, as part of this, to invest in their pharmacy practices. On the other hand, as the result of some of the reforms in the balanced package of measures the government is creating uncertainty for pharmacists and for the pharmacy network. At a time when pharmacists should be dedicating their energies to investing in developing their clinical role and enhancing their healthcare contribution they will, instead, be diverted into protecting their pharmacies from pharmacies opening under an automatic exemption. These automatic exemptions will be granted without any consideration of the Pharmaceutical Needs Assessment or Strategic Services Delivery Plan in the local area and thereby frustrate and undermine the role of PCTs in planning local pharmacy services."

6 Conclusion

Key findings

- This chapter considers the impact of the reforms against their original aims and in the context of the White Paper *Our Health, Our Care, Our Say*
- The reforms have achieved so far the aim of opening up the market with a modest but uneven impact on promoting choice and competition
- It is too early to predict whether this will continue
- There has been no significant discernible negative differential impact in terms of social deprivation – whilst closures in deprived areas were proportionately greater, PCTs with greater social deprivation received significantly more exempt applications
- Access improves where new 100-hour pharmacies open or where new pharmacies are located at or close to GP surgeries
- Exempt pharmacies are providing proportionately more enhanced services but no significant impact on the prices of medicines has been found.
- The new legislative regime has delivered benefits in terms of quicker processes for some types of application
- However, this is tempered by the regime being complex, time-consuming and offering no greater certainty and reliability to business
- Overall, whilst these results show the balanced approach was the appropriate way to proceed, the impact has been somewhat erratic and patchy, hampering PCT's ability to plan service provision and match supply to needs and meet the new direction set by the White Paper
- Community pharmacy is well-placed to contribute to this new direction but given PCTs' responsibilities for strategic planning and commissioning, it is questionable whether, even after reform, the control of entry system is a suitable vehicle to enable PCTs to meet these responsibilities

Impact on overall aims of the reforms and recent White Paper

6.1 As set out in Chapter 2, 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.

6.2 The review also has to be considered against the wider drive behind the recent White Paper *Our Health, Our Care, Our Say* to bring patient care closer to home and increase access to healthcare in the community. In summary, the White Paper calls for:

- a much greater focus on earlier prevention and interventions which promote better health;
- readily available advice and support for those who need it - especially people with long-term medical needs and their carers;

- more choice in where patients can go for their services; and
- a greater say in how, when and where they are provided.

6.3 Therefore, as with other areas of service provision, pharmaceutical services in future 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 address the health inequalities that exist.

6.4 In terms of contractor numbers, the reforms have achieved their aim of opening up the market with a modest impact in promoting patient and consumer choice without jeopardising the existing pharmacy market. More pharmacies opened in 2005/06 than any other year since 1997/98. Over 500 pharmacy approvals or applications in the process of being decided have carried forward to 2006/07. It is reasonable to conclude therefore that a fair proportion of these have since proceeded to open or will do so over the course of the year.

6.5 However, it is unclear whether an increase in pharmacy numbers is the beginning of a longer-term trend, or simply the release of “pent-up” demand for new pharmacies refused under the previous regime which have now succeeded. The data suggest that some PCTs (e.g. East Yorkshire) experienced an initial burst of activity which then tailed off. Other areas (e.g. West Hull) show there has been considerable activity in the first six months of 2006/07.

6.6 The report also notes that the expansion in choice has not been uniformly spread across the country. This is to be expected in part. There is no quota or “target rate” for the number of pharmacy contractors per PCT. In certain areas of the country, such as London, contractor numbers have traditionally comfortably exceeded the national average and London PCTs generally reported low levels of interest. Where there has been activity this has mainly been from new exempt applications. Yet elsewhere, for example in Derby, which has traditionally also been well served by pharmacies, the market has not been deterred from making applications. Nor, so far, is the converse true. The data do not show that a previous low rate of pharmacies locally per head of population has stimulated market interest.

6.7 Nationally, in aggregate, there appears to be little significant differential impact on choice depending on the level of deprivation, or comparing rural with urban areas. However, this probably masks a greater differential impact for some PCTs locally. Just 30 PCTs - or 10% of the total - dealt with nearly 30% of all new applications. There is a noticeable “M62” effect here with a significant number of these PCTs adjacent to the M62 from the Humber to the Mersey being affected, with other pockets of activity in the North East, West and South Midlands, East Anglia and Kent.

6.8 In 2005/06, the data also show that, although small, the numbers of pharmacies closing are greater than would otherwise be expected in deprived areas, though PCTs with greater social deprivation received significantly more exempt applications than would be expected by chance. Conversely, and at a national level, this does not seem to have had an adverse impact on the time it takes to get to the nearest pharmacy. If anything, this has improved slightly for people in deprived areas, although again, this may mask variations locally. Overall, there is no discernible adverse impact on access to services in deprived areas.

6.9 In terms of improved access, exempt pharmacies are pro rata providing more local enhanced services commissioned from PCTs than existing contractors are. Where such pharmacies set up, patients are able to benefit from improved provision. However, in terms of accessing over-the-counter (OTC) medicines, the report finds no significant impact as a result of the reforms. The price differentials between supermarkets and other types of outlet appear to have widened using aggregate sales weights, but this may reflect the pattern of dispensing. The price differentials for medicines which can only be supplied from a pharmacy are similar to results seen in 2003. Of perhaps more interest, the prices of OTC medicines for independent and multiple pharmacies are not out of line with other (non-supermarket) grocers/ convenience stores. Arguably, therefore, the market conditions which independent and multiple pharmacies face may be more akin to those which convenience stores encounter rather than large supermarket retailers.

6.10 Two significant impacts on improved accessibility and convenience can however be attributed to

i) the introduction of new 100 hours a week pharmacies which are reported to have improved access to services, especially during weekday evenings, or at locations which patients and consumers find convenient and appropriate to their needs. They have also reduced the need for PCTs to commission additional opening hours from existing contractors; and

ii) new pharmacies opening either as part of, or close to, GP surgeries.

6.11 However, concerns have been raised at the listening events and in responses to the consultation about the longer-term impact both these types of new pharmacy will have on existing contractors. Patients and consumers who do not live close to these new facilities are concerned they should be able to continue to make use of local facilities which are most easily accessible to them. The NHS - and business - echoed these concerns.

6.12 Nationally, the analysis of pharmacy post-code data shows no significant evidence so far of pharmacies now clustering either near to GP surgeries or to another pharmacy. However, reports from individual PCTs show that such clustering has taken place and continues to do so.

6.13 Feedback from consulting on the operation of the new system indicates certain aspects have become more business-friendly and in particular, the simpler procedures for dealing with many minor relocations, the shorter periods for deciding applications and the likelihood of gaining automatic acceptance of an exempt application, provided all the criteria were met. Whilst the new regime has compelled the NHS to review its processes to ensure they were robust - and PCTs generally welcomed development of local pharmaceutical needs assessments as a positive contribution to this - the time limits have not always been practical for PCTs to meet. Business reports that whilst there have been improvements - and no example has been cited of a PCT not discharging its responsibilities - there remains inconsistency across PCTs in terms of adhering to time limits and the reasons why they have reached their decisions. Data on appeals show that cases continue to be heard within a reasonable timeframe and there has not, as far as the Department is aware, been a challenge to the Appeal Unit or to a PCT by way of a judicial review. However, many businesses - and NHS respondents – said the new system was more complex to understand and administer. Therefore, the reforms had yet to prove their worth.

6.14 Therefore, no company reported that the new system gave them more certainty and reliability. The main cause was the prospect of future successful exempt applications in any given area. This was also a concern for PCTs who find it difficult to plan coherently for service provision and development against this backdrop, incurring unplanned costs when such new pharmacies open and meet the relevant minimum qualifying thresholds under the contractual framework.

6.15 Whilst there are improvements reported in terms of better access and choice, and these results show that the balanced package of reform measures was the appropriate way to proceed, overall, the impact of the reforms has been somewhat erratic and patchy. It is not possible to predict from these results whether and where new applications will arise. The market also shows some unusual behaviour where, for example, the receipt of one new exempt application leads to a rush of similar applications from competitors. This impact is even more marked where the subsequent grant of such applications does not in fact lead to improvements in choice because successful applicants are either unable to open a pharmacy, or subsequently let their grants lapse. Such factors will therefore tend to hamper a PCT's ability to plan service provision strategically and match supply to where pharmaceutical needs are greatest.

"Perhaps what is required is for PCTs to control the commissioning of new pharmacies actively: The recent White Paper *Our Health, Our Care, Our Say*, talks about earlier prevention and intervention, particularly for patients with long-term conditions and their carers. It appears likely that the amendments made so far to the control of entry arrangements may be to the detriment of these patient groups. PCTs need more powers to direct and support services for these populations - 100 hours a week pharmacies etc take away the power and discretion that PCTs need to place services in the right place based upon assessment of local requirements."
NHS Employers

6.16 Provided the relevant criteria are met, applications are more likely than in previous years to be granted. If the trend seen in 2005/06 continues, entry to the market will largely be determined by contractors, with PCTs remaining passive recipients of applications. This may deliver more competition and choice in the longer term but it does not sit well with PCTs' new responsibilities and, following their reconfiguration in October 2006, the need for them to develop their role as strategic commissioners of primary care services under the White Paper and to promote better public health. Community pharmacy is well placed to take advantage of this new direction. However, it is questionable whether the control of entry system, even after reform, can now be judged a suitable vehicle to enable PCTs to meet their responsibilities for patient-focussed pharmaceutical care.

Department of Health

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

Annexes

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ANNEX A - Terms of reference and methodology

The terms of reference were:

“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 methodology adopted for this report was

- 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.

ANNEX B - list of organisations invited to comment

All Party Parliamentary Pharmacy Group

Association of the British Pharmaceutical Industry

Association of Independent Multiple Pharmacies

Better Regulation Executive

British Healthcare Trade 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 – Summary of feedback from “listening events”

See separate document:

ANNEX D – Differences in NHS pharmaceutical services data

1. The pharmaceutical services data provided by the Information Centre for Health and Social Care has been collected from two main sources: The Primary Care Trusts (PCTs) and the Prescription Pricing Division (PPD) of the Business Services Agency.

2. The PCTs provide pharmaceutical services data via an annual survey called a PHS1. This mandatory document is sent to all PCTs in England and has a 100% completion rate. It requests information on pharmaceutical services provision within the local PCT area up to 31 March of a financial year. The data provided by the PCTs covers the following areas: The provision of local enhanced services, the collection and disposal of unwanted medicines and the advice given to nursing and residential care homes. The PHS1 also requests information on the number of applications received to open, close or relocate a pharmacy contractor.

3. The PPD provides pharmaceutical data via a report called a C20. The C20 provides information on openings, closures and relocations of pharmacy contractors. It also details the business conducted within the financial year, i.e. items dispensed and costs incurred, and it assigns a unique ID to every pharmacy contractor who has been active during the financial year.

4. The fundamental difference between the two sources of information is that the C20 is financially driven, as it is based on payments made to pharmaceutical contractors and provides a detailed picture of pharmacy activity within each PCT over a 12-month period, whilst the PHS1 provides a general snapshot of pharmacy activity within a PCT from a commissioning organisational perspective.

5. The differences in these datasets result in differences in the figures presented for the net openings and closures of pharmacies between 1 April 2005 and 31 March 2006. At 31 March 2006, the Primary Care Trusts reported via the PHS1 survey form that 143 new pharmacies opened and 23 closed. A net increase of 120 pharmacies. For the same period, the Prescription Pricing Division (PPD) reported via the C20 financial report a net increase of 136 pharmacies.

6. There are a number of factors that may influence the difference in the reported figures. For example, the PPD may not complete the payments due to a pharmacy contractor until several months after the pharmacy has closed. Therefore the PPD may continue to pay a pharmacy contractor which has closed down during the financial year for several months beyond the end of the financial year. This can lead to small discrepancies between PCT and PPD data about the number of community pharmacies active at 31 March each year.

7. There may also be some variation in the way that PCTs report on openings and closures. The net figures reported on the PHS1 may not take into account any relocations or change of ownership. If a contractor relocates to other premises, or the contracting business is subject to a change of ownership, this does not result in a change in the number of local pharmaceutical contractors. The C20 data, reports on every pharmacy that has opened, closed or relocated as each of these processes will involve a new contract and business or ID number.

ANNEX E – List of Products Included in Price comparison

Table 1: List of products included in price comparison

P	GSL
BAZUKA	ANADIN EXTRA
BENYLIN	BEECHAMS ALL IN 1
BROLENE	BEECHAMS FLU PLUS
CALPOL	BENYLIN
CANESTEN	BONJELA
CO CODAMOL	CALPOL
CO CODAMOL W8P	E 45
COVONIA	GAVISCON
CUPROFEN	GAVISCON COOL
DAY NURSE	HALLS SOOTHERS
IBULEVE	IMODIUM JDC
IBUPROFEN TABS 400	LEMSIP
IMODIUM JDC	LEMSIP MAX
LEVONELLE ONE STEP	LOCKETS
MEDISED	MENTHO LYPTUS
MIGRALEVE	NICORETTE
NICORETTE	NICOTINELL
NIGHT NURSE	NIQUITIN CQ
NUROFEN	NUROFEN
NUROFEN CHILD	OLBAS
NUROFEN PLUS	OLG GEN P REL ADLT
NYTOL	RENNIE
OPTICROM	SAVLON
OPTREX INFECT EYES	SENOKOT
OTEX	SEVEN SEAS C L O
PARACODOL	STREPSILS
PARAMOL	SUDOCREM
PIRITON S.M	TUNES
SOLPADEINE PLUS	VASELINE INTEN CAR
SUDAFED	ZOVIRAX CSC
SYNDOL	

Table 2: Outlet Coverage

IMS Pharmatrend Panel Coverage						
Grocers without In-Store Pharmacies	Grocers with In-Store Pharmacies	Multiple Pharmacies	Independent Pharmacies (data received from these data warehouses)	Convenience	Forecourts	Other Grocers
Tesco Sainsbury Asda Safeway/Morrisons Waitrose (to be added in 2006)	Tesco Sainsbury Asda Safeway/Morrisons	Lloyds Day Lewis Manichem Rowlands W R Evans H.A. McParlands Linthorns	Chemtec Hudley Hutt McClernons Multepos McKays Park Positive	T&S TM CTN	Granada Forecourts Granada Services Esso Texaco BP BP Local Tesco Express	Balfour Londis Alldays

Table 3: Bilateral Comparisons – aggregate Weights

Bilateral Comparisons

	GSL											
	Independent Pharmacy		Multiple Pharmacy		Grocers With Pharmacy		Grocers Without Pharmacy		Other Grocers		Convenience	
	Jun-05	Jun-06	Jun-05	Jun-06	Jun-05	Jun-06	Jun-05	Jun-06	Jun-05	Jun-06	Jun-05	Jun-06
Independent Pharmacy	**100**	**100**										
Multiple Pharmacy	98	95	**100**	**100**								
Grocers With Pharmacy	72	70	73	74	**100**	**100**						
Grocers Without Pharmacy	71	70	73	74	100	99	**100**	**100**				
Other Grocers	104	99	102	101	131	128	130	127	**100**	**100**		
Convenience	104	103	101	104	133	134	133	134	99	103	**100**	**100**
Forecourts	86	82	88	87	123	119	123	120	94	96	95	93

	P			
	Independent		Multiple Pharmacy	
	Jun-05	Jun-06	Jun-05	Jun-06
Independent Pharmacy	**100**	**100**		
Multiple Pharmacy	102	101	**100**	**100**
Grocers With Pharmacy	90	91	89	91

Table 4: Multilateral Comparisons – aggregate Weights

Multilateral Comparison	GSL		P	
	Jun-05	Jun-06	Jun-05	Jun-06
Independent Pharmacy	**100**	**100**	**100**	**100**
Multiple Pharmacy	103	103	102	101
Grocers With Pharmacy	78	80	90	91
Grocers Without Pharmacy	79	80		
Other Grocers	105	106		
Convenience	104	108		
Forecourts	100	101		

Table 5: Bilateral Comparisons – Independent Sales Weights

	GSL		P	
	Jun-05	Jun-06	Jun-05	Jun-06
Independent Pharmacy	**100**	**100**	**100**	**100**
Multiple Pharmacy	102	99	102	101
Grocers With Pharmacy	84	84	91	92
Grocers Without Pharmacy	85	84		
Other Grocers	101	97		
Convenience	102	101		
Forecourts	95	96		