EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (LOCAL PHARMACEUTICAL SERVICES ETC.) REGULATIONS 2006

2006 No. 552

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This instrument governs the arrangements to allow Primary Care Trusts to make Local Pharmaceutical Services (LPS) schemes without requiring the approval of Secretary of State for each scheme. It provides an alternative legal framework for the provision of pharmaceutical and other services under locally agreed contracts.

3. Matters of special interest to the Joint Committee on Statutory Instruments *or* the Select Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 To date LPS has been in "pilot" phase. It was introduced by Section 28 of the Health and Social Care Act 2001.

4.2 Under "pilot" arrangements, all proposed schemes must have the approval of Secretary of State before commencement with DH, Secretary of State in effect setting the timetable for processing and arranging approval.

4.3 The primary legislation included a provision that subject to certain conditions LPS could move from "pilot" to mainstream status. The effect of mainstreaming is that LPS schemes would be approved and commissioned by PCTs without requiring prior approval by Secretary of State

5. Extent

5.1 This instrument applies to England only.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Local Pharmaceutical Services (LPS) were introduced following the establishment of similar arrangements for Personal Medical Services (PMS) and Personal Dental Services (PDS). This supports Department of Health policy to enable Primary Care Trusts (PCTs) to arrange the provision of healthcare services to reflect local needs.

7.2 LPS provides an alternative legal framework for the provision of pharmaceutical and other services under locally agreed contracts where such arrangements might not easily be made under national contractual arrangements for pharmacy, The National Health Service (Pharmaceutical Services) Regulations 2005.

7.3 In setting up arrangements for the pilot phase a wide consultation was undertaken with individuals, pharmacy contractors and their representatives, the Pharmaceutical Services Negotiating Committee, with NHS Confederation, National Pharmaceutical Association, Royal Pharmaceutical Society, General Practice Committee and the National Association of Primary Care.

7.4 Responses to local contracting were generally favourable. Many suggestions were incorporated in the final shape of LPS, for example, pharmacy contractors are permitted a 'right of return' where they had moved wholly from a national contract to LPS or to hold an LPS contract alongside a national contract, subject to certain conditions. There was also support for the in-built flexibility, which LPS afforded commissioners and providers especially those who wished to break the link between income and dispensing volume as this allowed the focus to move improving quality and range of services. More recently LPS pilots have provided useful learning which has been used in developing the new contractual framework for community pharmacy.

7.5 Throughout the pilot phase, feedback and views were taken from LPS providers and their representatives as well as the NHS. In addition, a national evaluation has been conducted and all LPS schemes reviewed before moving to make arrangements for mainstreaming LPS.

7.6 As this instrument imports the main features and is very similar overall to the provisions used throughout the pilot phase, it was agreed that further consultation was not required for these regulations.

7.7 The instrument also incorporates requirements for the provision of information on the suitability of applicant LPS providers as well as fitness to practise information, now accepted as standard requirements following the Shipman Reports.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

Theresa Prendergast at the Department of Health Tel: 020 7972 1118 or e-mail: Theresa.prendergast@doh.gsi.gov.uk can answer any queries regarding the instrument.

REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

The National Health Service (Local Pharmaceutical Services etc.) Regulations 2006.

2. Purpose and intended effect of measure

(i) The objective

To provide for local pharmaceutical services contracts (LPS) to be made by Primary Care Trusts (PCTs) without the need for individual scheme approval by Secretary of State (SofS), as is required in the 'pilot' phase. This measure enables PCTs to undertake contracting activity without the bureaucracy entailed in the current arrangements.
This will also put LPS on a similar footing to Primary Medical Services (PMS) and Primary Dental Services (PDS).

(ii) The background

The Health and Social Care Act 2001 provided for regulations to be made to develop Local Pharmaceutical Services (LPS) pilot schemes in England - S Is 888, 2016 and 2861 of 2002 refer[1]. Pilots have been running since 2002. During the pilot phase all proposals have to be submitted for approval by SofS within a timetable set down by Department of Health.

As Dispensing is a 'core' service, all LPS schemes must include dispensing whether to some or all patients. In addition, LPS contracts allow the inclusion of a broad range of services not normally associated with pharmacies including provision of training and education.

Participation in LPS by PCTs and providers is entirely voluntary. Where LPS providers are already on the NHS pharmaceutical list of a PCT, they may have an LPS contract in addition to national pharmaceutical arrangements or they may move to LPS completely. In such cases there is a right of return to the NHS pharmaceutical list (a list held by a PCT of those providing pharmaceutical services under regulations[2]) at any time.

Regulations provide that, in developing schemes, consultation with existing pharmacy providers, general practice and patient representatives must take place. In addition, PCTs must undertake an assessment of the impact the scheme would have on existing pharmacies and general practices in the neighbourhood or if bordering another PCT it must request the other PCT to also undertake an impact assessment. The requirements for both consultation and impact assessment would be carried into LPS mainstream regulations.

[1] The National Health Services (Local Pharmaceutical Services) Regulations 2002
[2] The National Health Service (Pharmaceutical Services) Regulations 2005

Pharmaceutical services must be provided to certain standards set out in Regulations or agreed as part of the contract. In all cases, PCTs are required to monitor contracts in the same way as they do other contracts, to satisfy themselves that standards are met. In professional matters, The Royal Pharmaceutical Society continues to have a regulatory role, as currently, across all community pharmacies.

The Health & Social Care Act 2001 also provided that LPS may be 'mainstreamed' i.e. section 40 may be brought into force, when the results of pilots had been assessed. The principal effect of bringing section 40 into force would be that PCTs could make LPS schemes without needing prior approval of Secretary of State (SofS).

LPS mirrors PMS and PDS in that it provides a means of local contracting for pharmaceutical and other services. Without this, PCTs have to rely on the NHS (Pharmaceutical Services) Regulations, which do not have the flexibility that a local contract would have.

(iii) Risk assessment

A national evaluation has been undertaken and the results of this are that LPS is a useful commissioning tool. In addition, all pilots have been reviewed by DH officials and soundings taken from NHS, pharmacy contractor representatives and others. These have all indicated that LPS is valued as a contracting mechanism in designing local services to meet patient need. This is likely to increase as PCTs seek to develop their commissioning capacity under the White Paper *Our Health, Our Care, Our Say*. Without the these Regulations, LPS will remain as it is, with approval of all schemes centrally. This is inconsistent with public and health policy objectives of devolving decision-making to local level.

(iv) Consultation

A wide consultation took place when LPS pilot schemes were established and comments were used to help shape LPS with many suggestions incorporated in the subsequent secondary legislation. It is now proposed to mainstream the 'pilot' scheme and to include provisions as to a contractor's fitness to practice which apply to all those who provide pharmaceutical services whether through LPS or not.

3. Options

The following two options were considered:

Option 1 Leave things unchanged
Option 2 Mainstream LPS

4. Benefits

Option 1

Economic

LPS remains subject to central overview and approval.

Social

No additional benefits to patients from continuing with current arrangements have been identified.

Environmental
LPS schemes often form part of the services provided as part of community regeneration. Pharmacies also provide services for the collection of unused medicines for onward transmission and safe disposal.
No further environmental benefits have been identified.

Option 2

Economic

The pilot phase of LPS has meant that processes and templates have been developed by PCTs that have LPS schemes in place and these have been shared widely.
The reduced timescale to implementation of pilots, where Secretary of State for Health's approval is not required, would allow PCTs to make the most of any economic benefits that might be gained in particular situations, for example, where local authority developments are being drawn up PCTs will be able to input with the knowledge that the timetable to deliver any commitment for LPS schemes is under its control – it does not have to rely on a timescale set centrally. To date, LPS has also been used as part of Local Improvement Finance Trust (LIFT) schemes.
LPS allows for provision of services not normally associated with pharmacy, such as improved training, making it possible to include a range of services within a single contract. This facility has yet to be exploited but it could be used to produce a cohesive range of services for specific health conditions.
Learning and development may also be included in an LPS scheme, for example, one pilot scheme provides learning and development for local community pharmacists as part of an LPS scheme, thus helping to disseminate learning across local pharmacies.

Processing costs at DH would be reduced, as would the costs of assessing pilot applications by expert panels and SHA and PCT input time as well as the preparatory costs of around £12,000 per scheme.

Social

Existing benefits would continue and depending on how widespread the use of LPS by PCTs, benefits could spread to a larger number of people. Current pilot schemes include provision of services where access to GP services is difficult, out of hours pharmaceutical services, services for specific groups, for example, elderly people. LPS has also been used to provide pharmaceutical services in a specific location to serve a community as part of a local regeneration scheme.

Environmental

As with option 1, LPS schemes often form part of the services provided as part of community regeneration. Pharmacies also provide services for the collection of unused medicines for onward transmission and safe disposal.

5. Costs

Option 1

Economic

Costs to DH and others in terms of time and labour for processing LPS 'rounds' would continue as would preparatory funding costs.
No new costs have been identified under this option.

Social

The benefits identified under Option 2 above will not be realised.

Environmental

There are no new environmental costs from continuing with current arrangements.

Option 2

Economic

No new economic cost impacts have been identified. LPS is an agreement between a PCT and an LPS Provider. As with any contracting situation, neither side can be compelled to enter into agreement. Currently PCTs have processes in place to handle proposals in the pilot phase and will need to extend these to include the function of decision-making about whether to approve proposals or not.

Social

There are no new social costs from the proposals.

Environmental

There are no new environmental costs from the proposals.

Business sectors affected

The measures apply mainly to providers of community pharmacy services.

6. Equity and Fairness

Individuals or bodies corporate may be LPS providers. However, as dispensing is a core service, all providers must arrange to meet the requirements of the Medicines Act 1968, for example, providers who are not registered pharmacists will have to arrange for a pharmacist to provide the dispensing element of the contract.

As indicated earlier, LPS schemes may be sited in a wide variety of locations and may provide services for some or all patients, depending on the services to be provided within the contract. A number of existing pilot schemes are based in areas of deprivation or are aimed at those who may have mobility issues, for example, elderly populations or mothers with young children.

Rural Proofing

The LPS provisions allow for LPS schemes in rural areas. The provision of a range of pharmaceutical services and other services under LPS, depending on the range of services agreed between the PCT and the LPS provider, may offer improvements in services and other benefits to rural communities. LPS may for example offer services not locally available at present such as better out of hours access or advice to care homes. Where patients currently have their medicines dispensed by their doctor, the PCT will carry out an impact assessment to ensure that the benefits of any LPS proposal outweigh any disadvantages to those patients who would no longer receive their doctors' dispensing services .

Race Equality

No particular issues of race equality have been identified either in relation to LPS providers or the populations they serve. LPS can be used to provide PCTs with a contracting mechanism to target services for specific groups. For example, an LPS scheme operating in Camden PCT targets certain of its services to a Bangladeshi population.

7. Consultation with small business: the Small Firms' Impact Test

Just under half of all NHS pharmacy contractors may be described as small businesses. They are represented by the Pharmaceutical Services Negotiating Committee (PSNC). PSNC have been consulted and have been involved in discussions since pilots commenced. From the outset there was support for the fact that LPS cannot be used to circumvent regulations and requirements for inclusion in PCT pharmaceutical lists. There is also support for the fact that existing pharmacies may provide services under the NHS (Pharmaceutical Services) Regulations as well under an LPS contract and that participation in LPS is voluntary.

8. Competition Assessment

In a Competition Filter Test less than half the nine questions were answered 'yes' – for details see Annex A.
These regulations are enabling in nature allowing PCTs to contract locally for pharmaceutical and other services. The overall outcome of the test suggests that LPS offers greater opportunity for new and prospective providers to compete and that while there are start-up costs associated for any new entrants to the market, these should not deter entry.

9. Enforcement and Sanctions

PCTs must ensure that LPS agreements comply with contractual arrangements and appropriate regulations. LPS contracts also allow for specific monitoring and scrutiny arrangements as the parties agree. The Health Care Commission also has powers of inspection as has the Royal Pharmaceutical Society for professional purposes. There is provision in regulations, reflected in LPS contracts that where the provider fails to comply with terms, the PCT may terminate the contract .

10. Monitoring and Review

The Department of Health meets representatives of professional and contractor groups and the NHS regularly, at which times these requirements would be reviewed and formally at least every 3 years.

11. Summary and Recommendation

Option 2 best meets the governments objective to move the pharmacy provision in line with PMS and PDS.

Option	Total cost per annum Economic, environmental, social	Total benefit per annum Economic, environmental, social
1 Do nothing.	No additional costs. PCTs rely on timetable and deadline set by DH for approval. Processes and systems already established	As currently, LPS provides a mechanism to commission local schemes. Such contracts provide a mechanism for PCTs to provide services not available through current national contract arrangements.
2. Mainstream LPS	PCT sets its own timetable therefore able to respond quickly to meet identified needs locally. Processes and systems already established and learning available from pilot phase.	The move to PCTs agreeing contracts with no prior approval of Department of Health will help get rid of a layer of red-tape. It will allow PCTs to set their own timetables and commission pharmaceutical and other services as required, for the benefit of local populations. DH and other costs of the current central approvement process reduced.

12. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Jane Kennedy

Date: 2nd March 2006

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Annex A

COMPETITON ASSESSMENT: INITIAL COMPETITION FILTER

NOTE, FOR THE TIME-BEING, THIS ASSESSMENT IS FROM THE PERSPECTIVE OF A MOVEMENT TO COMMISSIONING OF LOCAL PHARMACEUTICAL PHARMACY SERVICES BY PCTS WITHOUT REQUIRING APPROVAL FROM DEPARTMENT OF HEALTH BEFORE IMPLEMENTATION.

If more than half of the questions are answered "yes" the filter is passed and a full Competition Assessment is required.

Question 1

4.14 In the market(s) affected by the new regulation, does any firm have more than 10 per cent market share?

4.15 The answer to question 1 indicates the likelihood that any firm in the market has a degree of market power. Where a single firm or a group of firms serve a large proportion of the market (i.e., have large market share) they are more likely to have market power.

Yes – Lloyds 10.9% (source Office of Fair Trading (OFT) report "*The control of entry regulations and retail pharmacy services in the UK" January 2003* – based on number of outlets).

In October 2005, Boots plc and Alliance Unichem announced a proposed merger which if it goes ahead will give the combined operation around 17% of retail pharmacy outlets in the UK

Question 2

4.16 In the market(s) affected by the new regulation, does any firm have more than 20 per cent market share?

4.17 The higher level of market share may indicate greater market power, and is therefore more of a concern.

No (source OFT as above – based on number of outlets)

Question 3

4.18 In the market(s) affected by the new regulation, do the largest three firms together have at least 50 per cent market share?

4.19 For question 3, take the largest three market shares and add them together. If this gives more than 50 per cent, the answer should be yes. This question identifies further degrees of market power and also identifies cases where a few large firms may be able to act together.

No Top 3 firms – Lloyds, Boots and Moss hold 27.8% of market (source OFT as above – based on number of outlets)

Question 4

4.20 Would the costs of the regulation affect some firms substantially more than others?

4.21 Consideration should be given, but not confined, to the following issues. The answer to question 4 will be yes if, for example, costs of paperwork or administration affect smaller firms to a substantially greater extent than larger firms, or if significant costs are imposed on particular companies because of the resources they use or where they are located.

4.22 Policy makers will have to use some judgement in judging what is 'substantial'. It is important to consider whether there will be an impact on competition or whether the more heavily affected firms can absorb the effect and remain in business. In answering this question, it is important to ensure that firms are compared only if they are competing against each other. The intention is to establish if some firms are disadvantaged in the competitive process.

Yes – new entrants face higher costs than incumbents. On the other hand, these could be mitigated depending on the outcome of contract discussions with the commissioning PCT. However, on-going costs are likely to be at a level similar to like size providers.

Question 5

4.23 Is the regulation likely to affect the market structure, changing the number or size of firms?

4.24 Question 5 expands on question 4 to highlight the consequences of the regulation for the structure of the industry. For example, will some firms have to leave the market or will they merge with other firms to survive? As for question 4, the answer will depend on the policy makers' judgement of the likely effects. Discussions with industry bodies and other interested parties during the consultation process may help.

No – LPS is entirely voluntary.

Question 6

4.25 Would the regulation lead to higher set-up costs for new or potential firms compared with the costs for existing firms? [yes/no]

4.26 This question focuses on the initial entry barriers in the form of set-up costs. Consideration should be given, but not confined, to the following issues. In answering question 6, the introduction of licensing or restrictions on location may inhibit the entry of new firms into the market. If new firms cannot enter the market then incentives for new product development, innovation and growth may be dampened.

No – there will be start-up costs for any new contractor entering the market but LPS does not impose additional costs on new entrants that existing contractors would not pay and therefore should not deter entry.

Question 7

4.27 Would the regulation lead to higher ongoing costs for new or potential firms compared with the costs for existing firms?[yes/no]

4.28 This question focuses on ongoing costs, which would affect new firms' performance even after they entered the market. As for question 6, it is relevant to consider any situations that would favour existing firms over new entrants to the market. This may include the extent to which there may be time lags in introducing the regulations for existing firms. If new firms have to meet requirements immediately, but existing firms have a period of grace ('grandfathering') there would be a differential introduced.

No – on-going costs are likely to be the same for all similar sized pharmacies, assuming similar services.

Question 8

4.29 Is the market characterised by rapid technological change? [yes/no]

4.30 Consideration should be given, but not confined, to the following issues. The answer to question 8 would be yes if, for example, firms in the market were continually innovating to introduce new methods of production or new products. Examples of such markets include IT and telecoms. However, it may also be the case that the affected market has recently experienced a greater level of innovation and product/process development than previously. This would also lead to a yes answer to question 8. The reason for identifying those markets experiencing rapid technological change is that there is a risk that regulation may restrict innovation in such markets.

Yes – the market is undergoing some technological change in terms of increased electronic messaging, connection to NHS IT systems and robotics. However, LPS does not affect these developments.

Question 9

4.31 Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products? [yes/no]

4.32 Consideration should be given, but not confined, to the following issues. Minimum standards or requirements are one way in which firms' freedom to choose product type or quality can be restricted. Other examples include restrictions on prices charged, the quantities of certain inputs used (eg, pesticides for farmers) or the location of certain activities. All will have the effect of removing one way in which firms can compete, and therefore represent a distortion to competition.

No – LPS is entirely voluntary. However PCTs will wish to determine the range of services and agree these with LPS contractors

The outcome of the competition filter

Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10 per cent market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20 per cent market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50 per cent market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	Yes
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
Q8: Is the market characterised by rapid technological change?	Yes in part
Q9: Would the regulation restrict the ability of firms to choose the price, quality, range or location of their products?	No

On the basis that only three of the questions are answered yes, a full competition assessment is not required.