

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

## Consultation Questions

### Response form

**Please fill in and/or tick the appropriate response:**

**Name:**

**Beta Buying Group**

**Contact address:**

**154 Enterprise Court  
Eastways Industrial Estate  
Witham , Essex**

**Postcode:**

**CM8 3YS**

**E-mail:       beta2@betauk.net**

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

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

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

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

**Are you responding:**

on behalf of an organisation? Yes ( x ) No ( )

If yes, please indicate your area of work:

Trade Body ( x )

Other (please give details)

The Beta Buying Group represents over 200 independent community pharmacies.

## Consultation Questions

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

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

##### **Questions for consultation**

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

Q1: *Do you agree the current market entry system should be changed to one based on pharmaceutical needs assessments (PNAs)?*

Yes ( )

No ( x )

Unsure ( )

##### Comments:

The DOH Pharmacy White Paper (Building on strengths –delivering the future) indicated that pharmacies are easily accessible based on the DOH's own survey. Why change a system that has led to good access? NHS resources should be used in areas where access remains a problem such a GP services, Dentistry and A &E.

In terms of PCTs being able to commission pharmacies where they want them- a comprehensive national review is needed in order to determine situations where PCTs have not been able to commission a pharmacy where it is needed. Have PCTs in such cases used the full options available to them including LPS?

We support the concept of PCTs undertaking robust PNA ( Assessments of Local Pharmaceutical Needs) and commissioning more services from pharmacy such as smoking cessation. However the control of entry system does not need to be changed in order for this to happen.

There needs to be a distinction made between the need for robust PNA and basing the whole control of entry system on them. Unfortunately the

consultation seems to indicate that in order to have robust PNAs the whole control of entry system need to change

The impact assessment on this issue is very misleading and again confirms the lack of distinction between robust PNAs and changing the control of entry system.

The impact assessment's estimated benefits of £548 million are solely on the basis of PCTs commissioning more smoking cessation services from pharmacies. However these benefits can be gained more easily by making smoking cessation and other key pharmacy schemes, directed enhanced services as proposed in white paper.

The impact assessment's estimated costs of £98,000 for all the PCTs in the country to have robust PNAs, is an enormous under-estimation. Furthermore the costs of changing a whole system have not been included in the impact assessment. There will be significant costs running into millions. PCTs will need time and manpower to adopt a new system and there will significant legal costs both for the NHS and pharmacy contractors. A local system will be much more complex and time consuming to administer. All this will result in reduced resources for front line patient care.

The DOH is keen to move away from the 'postcode lottery' in the provision of NHS services. However a local based market entry system will result in great variation in pharmacy entry requirements between PCTs. One only has to look at the commissioning of enhanced services from pharmacies. The white paper itself acknowledges huge variations between PCTs in terms of services commissioned from pharmacy. In many cases the number of services commissioned from pharmacy has little relation to the needs of the population or on the robustness of any needs assessment. They depends more on the PCT management's engagement and view of pharmacy. This unjustified variation will be extended to market entry for pharmacy under these proposals.

These proposals, far from bringing clarity, will create further uncertainty for pharmacy contractors. They will be less likely to invest in their business which the consultation itself acknowledges is important for improvements in patient services.

Lastly the consultation was launched in the summer and has not been debated adequately within pharmacy and also by the public. Given its importance and complexity, we would urge the DOH to allow a further three months for feedback on this consultation in order for a fuller debate to take place.

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q2: What safeguards may be appropriate to ensure transparent, fair and unbiased consideration of applications?*

Comments:

The current national system is the best safeguard against local bias.

*Q3: Do you agree that specific additional factors, as identified in this Chapter, should also be introduced to help PCTs determine applications?*

Yes ( x )

No ( )

Unsure ( )

What further comments do you have on the range of additional factors identified?:

Whilst we disagree with changing the current system without further review, we do feel that in any new system, as many additional factors as possible should be in place to reduce variation between PCTs and assist in a comprehensive consideration of applicants. The wider and long term impact of any new pharmacy on existing services is important. Also the views of the local population has to be a key factor when considering each new application.

*Q4: Should decisions be appealable and, if so, to whom?*

Yes ( x )

No ( )

Unsure ( )

If yes, to whom should they be appealable?

In order to ensure fairness there has to be an appeal mechanism. The NHS Litigation Authority has the necessary experience to handle this. However the current process needs to be speeded up.

*Q5: Do you agree exceptions to this new system may be necessary?*

Yes ( )

No ( )

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

Unsure ( )

If yes, what might these exceptions be?  
Don't agree with new system

*Q6: If introduced, do you agree such an approach should be piloted and evaluated before introduction?*

Yes ( )

No ( )

Unsure ( x )

Comments:

The problem with pilots is that proactive PCTs will volunteer to pilot and hence results may be positive. However PCTs who don't engage with pharmacy are the concern in all these reforms. These are the PCTs where the problems will arise –however they are unlikely to volunteer to be pilot sites.

## **Adequate powers to tackle poor performance**

### ***Questions for consultation***

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

*Q7: Do you think we should introduce explicit criteria of quality to govern market exit?*

Yes ( )

No ( X )

Unsure ( )

Comments:

Before any such new powers can be considered, there needs to be a comprehensive national review of the existing powers. Instances where PCTs have not been able to improve poor practice, due to a lack of powers, need to be considered. And in such instances did PCTs use the full powers available to them under the current system?

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

It is vital that existing legislation is fully examined before more legislation is brought in.

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q8: Do you consider existing legislative powers under 'fitness to practise' are adequate or not?*

Yes ( X )

No ( )

Unsure ( )

If not, what quality criteria might be used?

We are not aware of any instances where PCTs have not been able to bring about improvements in practice using existing mechanisms.

*Q9: Do you agree that PCTs should have the ability to issue remedial action notices with the consequence of de-listing if issues are not addressed satisfactorily within a set timescale or to withhold payments for contractors who do not perform to accepted quality and standards?*

Yes ( )

No ( X )

Unsure ( )

Comments:

See answers to previous questions

*Q10: If introduced, do you agree there should be an independent appeals mechanism?*

Yes ( X )

No ( )

Unsure ( )

Comments:

Whilst we do not agree with the need for further powers, if they are brought in then there should be an independent appeals mechanism.

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q11: Are there other factors the Department needs to consider?*

Other factors:

As indicated earlier a comprehensive national review of the existing system is required

## CHAPTER 3: Community pharmacies and pharmacists

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

#### **Questions for consultation**

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

*Q12: Do you agree we should we introduce direct LPS contracting arrangements for pharmacies wishing to open 100 hours per week?*

Yes ( )

No ( X )

Unsure ( )

**Comments:**

A comprehensive review of the benefits, local and long term impact of 100 hour pharmacies nationally is required.

Whilst this is being considered there should be a moratorium on further applications to prevent a flood of applications.

If this review decides that 100hour pharmacies are beneficial then the best option is number 2 – where applicants have to prove the need for a 100 hour pharmacy in the area where they wish to open. The LPS route will involve considerable time and legal expense and hence we do not support it.

It is also unclear to us how the DOH has worked out the estimated net benefits of 18 million by introducing this reform. The impact assessment is confusing and does not make it clear how this perceived benefit was derived.

*Q13: Do you agree safeguards are needed and, if so, what might these comprise (for example these could be expressed in terms of services, prices, standards, quality)?*

Yes ( X )

No ( )

Unsure ( )

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

Comments:

All fees should be in accordance with the national contract.

*Q14: Is it sensible that such pharmacies are required to provide a minimum specified level of service such as minor ailment schemes or services out of hours as identified or is this best left to local decisions and negotiations?*

Minimum specified level of service ( X )

Left to local decisions/negotiations ( )

Unsure ( )

Are there other factors to consider?

100 hour pharmacies will need to operate the hours that the PCT decides based on local needs. This should include as a minimum Christmas Day and Easter Sunday and into the early hours of the morning every day. This will improve access overnight to medications. It will also save NHS resources in commissioning out of hours and rota services.

Additionally the views of local residents must be paramount when considering such applications. Many 100 hour pharmacies have opened despite strong protests from local residents which is not acceptable in a patient led NHS. It is not sufficient to seek patient views just when completing a PNA. They have a right to express their views on each application.

## CHAPTER 5: Dispensing Appliance Contractors

### Market entry for dispensing appliance contractors

#### **Questions for consultation**

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

*Q35: Should we introduce a specific exemption for applications from dispensing appliance contractors?*

Yes ( )

No ( X )

Unsure ( )

Comments:

There is not evidence that the current system does not adequately meet patient need

*Q36: What specific requirements might be set out in the regulations such as the types, standards and the quality of services to be provided?*

Yes ( X )

No ( )

Unsure ( )

If yes, what might these be?

Appliance contractors need to work to the same standards as pharmacies.

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q37: What safeguards might be appropriate to ensure the NHS has a reasonable and proportionate control over any increases in costs through new dispensing appliance contractor premises?*

What safeguards might be appropriate?

Best way is not to change a system which seems to be working.

*Q38: Do the potential benefits of relaxed entry restrictions outweigh the potential costs as identified in the Impact Assessment?*

Yes ( )

No (X)

Unsure ( )

Comments:

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

***Questions for consultation***

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

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q39: Do you agree the Department should assess in 2009 whether regulation is needed to govern those who assist in the provision of appliances only?*

Yes ( x )

No ( )

Unsure ( )

Comments:

*Q40: Are there alternative approaches which might be considered?*

Comments:

*Q41: If a risk were to be established, do you agree the provisions of sections 149 and 150 of the NHS Act should be extended to include those who assist appliance contractors in the provision of services?*

Yes ( X )

No ( )

Unsure ( )

Comments:

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q42: Should self-employed appliance contractors be required to register with the Independent Safeguarding Authority and, if so, how ?*

Yes ( x )

No ( )

Unsure ( )

Comments:

*Q43: Should such requirements be subject to specific limitations - for example, applying only to contractors who fit appliances or who do so in patients' homes?*

Yes ( )

No ( x )

Unsure ( )

Comments:

Should apply to all contractors

## CHAPTER 6: Other changes to the legislation

### Amendments to the NHS (Pharmaceutical Services) Regulations 2005

#### **Questions for consultation**

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

*Q44: Do you agree the amendments proposed?*

Yes ( )

No ( X )

Unsure ( )

If not, which do you not agree with?:

We disagree with proposals to change the regulations in relation to 'inducements to gain business'. The concept of not excluding products which are supplied to encourage and promote better health such as providing exercise videos may seem logical. However it will be liable to abuse – where do you draw the line? There is no evidence that the current system is restrictive in any way and hinders good care so why change it?

100 hour pharmacies should not be allowed to vary their hours as this may affect the 'improved access' they are 'thought' to provide

*Q45: At this stage, no significant impact has been identified from these proposals. However, if you think these amendments would have a significant impact for PCTs or for business, please say what this is and how best any such impact might be managed.*

Significant impact/how might be managed:

*Q46: Are there other amendments you wish to propose that the Department should consider? If so, please say how they would clarify or improve the working of the regulatory system.*

Other amendments:

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

### Questions for consultation

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

*Q47: Do you agree that the proposed changes to LPS legislation are needed?*

Yes ( )

No ( X )

Unsure ( )

Comments:  
PCTs should not be allowed to become LPS providers. This goes against NHS policy to split provider and commissioning functions for PCTs

*Q48: Are there other changes to the LPS legislation which the Department should consider?*

Yes ( X )

No ( )

Unsure ( )

Other changes:  
LPS should only be allowed if a robust impact assessment does not show any significant impact on the existing network of pharmacies and hence local services for patients.  
The views of the local population to each specific scheme need to be the most important consideration.

**Pharmacy in England: Building on strengths - delivering the future – proposals for legislative change – consultation questions**

*Q49: No significant impact has been identified in respect of these proposals. If you believe they would have such an impact, please explain what this might be and how it might best be managed.*

Significant impact/how might be managed:

## Equality Impact Assessment

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

Comments on Equality Impact Assessment:

## Impact on small firms

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

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

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

Impact on small firms: