

**Draft Regulations to the Health Act 2009 – market entry by means of Pharmaceutical Needs Assessments and quality and performance (market exit)**

**Consultation Reply Form**

**Closing date for responses: noon 25 January 2012. Please send your replies to:**  
[pnaentrycons@dh.gsi.gov.uk](mailto:pnaentrycons@dh.gsi.gov.uk) or alternatively send it by post to:

Gillian Farnfield  
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Medicines Pharmacy and Industry Group  
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80 London Road  
London  
SE1 6LH

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

<b>Response form</b>	
Name:	
Contact address including postcode:	
Organisation representing (if appropriate):	
Email	

## Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (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 you have provided as 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.

I do not wish my response to be published in a summary of responses

Are you responding:

- *as a member of the public*
- *as a health or social care professional*
- *as a pharmacist/appliance contractor*
- *on behalf of an organisation*

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input checked="" type="checkbox"/>

## Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at

<http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

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PNAs/quality and performance - consultation**

**Area of work:**

NHS	
Third Sector	
Regulatory Body (GPhC etc)	
Professional Body (LPC etc)	X
Education	
Trade Union/Negotiating body	
Pharmacy/appliance provider	
Local Authority	
Trade Body	
Manufacturer	
Supplier	
Other (Please give details)	

**In which of the following areas do you live: (please tick *one* box only)**

North East	
North West	
West Midlands	
South East	
London	
Humberside/Yorkshire	
East Midlands	
East of England	X
South West	
No answer	

**If you are responding on behalf of an organisation, please indicate which type of organisation you represent:**

Patients	
NHS – PCT/SHA	
NHS – GPs, nurses etc.	
Local Pharmaceutical Committee	X
Local Medical Committee	
Private Health/Independent Sector	
Third Sector	
Regulatory Body (GPhC etc)	
Professional Body	
Education	
Trade Union/Negotiating body	
Local Authority	
Trade Body	
Other (Please give details)	

**Organisations do not need to answer questions 1-7**

**1** What is your sex?

Tick one box only.

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>
Prefer not to say	<input type="checkbox"/>

**2** What is your Age?

Age	
Prefer not to say	

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**3** Are your day-to-day activities limited because of any health problem or disability which has lasted, or is expected to last at least 12 months?

Tick one box only.

- Yes, limited
- Yes, limited, a little
- No
- Prefer not to say

**4** Do you look after, or give any help or support to family members, friends, neighbours or others because of either long-term physical or mental ill-health/disability or problems related to old age?

Tick one box only.

- Yes
- No
- Prefer not to say

**5** What is your ethnic group?

Tick one box only.

**A White**

British

Irish

Any other White background, write below

**B Mixed**

White and Black

White and Black African

White and Asian

Any other Mixed background, write below.

**C Asian, or Asian British**

Indian

Pakistani

Bangladeshi

Any other Asian background, write below

**D Black, or Black British**

Caribbean

African

Any other Black background, write below

**E Chinese, or other ethnic group**

Chinese

Any other, write below

**F Prefer not to say**

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**6** What is your religion or belief?

Tick one box only.

Christian includes Church of England, Roman Catholic and all other Christian denominations.

- None
- Christian
- Buddhist
- Hindu
- Jewish
- Muslim
- Sikh
- Prefer not to say

Other, write below

**7** Which of the following best describes your sexual orientation?

Tick one box only.

Only answer this question if you are aged **16** years or over.

- Heterosexual Straight
- Lesbian / Gay Woman
- Gay Man
- Bisexual
- Prefer not to say

Other, write below

## Draft Regulations to the Health Act 2009 – market entry by means of Pharmaceutical Needs Assessments and quality and performance (market exit)

### Consultation

#### Consultation Questions

1. The Department welcomes comments and views from all interested parties on the draft Regulations for market entry, draft accompanying guidance and consultation Impact Assessment and consultation Equality Impact Assessment.
2. We would particularly welcome views on the following questions:

#### Chapter 1

**1. Do you agree the draft regulations enable market entry to be based on identification of current and future needs?**

Yes

**2. Are there any other matters which you feel need to be included in or omitted from the draft regulations which deal with applications based on current or future needs?**

Yes

#### **Comments**

*More robust arrangements may need to be in place to ensure extant Pharmaceutical Needs Assessments are current, whether due to recent review or the issuing of supplementary statements. Of the five PCT areas represented by Essex LPC only one has produced a supplementary statement since the PNA was published, despite changes occurring that the regulations suggest should be noted in such a statement: In effect, therefore, applications are being considered on past or outdated needs rather than current or future needs.*

*The regulations and accompanying guidance need to be more directive regarding future needs, for example the inclusion of timescales for new developments. This would reduce both opportunistic applications at the earliest hint of a planning application and a perception of “blocking” tactics whereby deferrals are unduly extended.*

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Chapter 3

3. **Do you agree the draft regulations that enable market entry in respect of applications offering to meet identified “current or future improvements” or “better access to pharmaceutical services” are applied?**

Yes

4. **Are there any other matters which you feel need to be included in or omitted from the draft regulations which deal with applications for “current or future improvements” or “better access to pharmaceutical services”?**

Yes

**Any other matters**

*There will need to be some clarity regarding definition of terms “improvements” and “better access” with regard to applications, as both are too vague to determine applications. These criteria must only apply to such services that the PCT, its successor organisation or other relevant commissioners commission, as there is otherwise no sanction against an applicant who fails to provide the improvements that secured the decision.*

*If, subject to parliamentary process, the PNA becomes the responsibility of the local Health and Wellbeing board, this regulation becomes particularly challenging, as PNA recommendations may be subject to the influence of elected councillors.*

Chapter 4

5. **Do you agree the draft regulations that enable market entry in respect of “unforeseen benefits”?**

No

6. **Are there any other matters which you feel need to be included in or omitted from draft regulations dealing with “unforeseen benefits”?**

Yes

**Any other matters**

*Any such innovation that changes pharmaceutical services to such an extent that an application should be considered on these grounds of “unforeseen benefits” should be good cause to review the PNA. As with comments under chapter 3 above, applications made on the basis of improvement to current offer should be limited to those services which are commissioned, as there is no sanction against a failure to provide such services otherwise.*

*Regulations should ensure that due regard is given to protect intellectual property*

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*rights in the event of a genuine innovation, applications notwithstanding.*

**7. Do the draft regulations provide a solution to the current difficulties dispensing appliance contractors (DACs) are facing in applying for entry to a PCT's pharmaceutical list?**

No

***If not, what alternative solution do you propose?***

*PCTs (and subject to parliamentary process their successor organisations) have statutory duties with regard to their local populations: Generally the location of a DAC premises is of little benefit to the local population and therefore regulations should be drafted to allow applications to be considered by the National Commissioning Board.*

**8. Do they provide an appropriate balance between enabling an improvement in the provision of appliances to patients whilst ensuring the NHS does not incur additional costs for little or no perceived benefit?**

No

## **Chapter 5**

**9. Do you agree with all the proposed exceptions to the new market entry test listed in paragraph 1 of Chapter 5?**

No

***If not, please tell us which types of application should be excepted from the new market entry test and the reasons why.***

*Distance-selling applications, unless the definition and terms of distance-selling pharmacies is extensively amended.*

**10. Do you agree that distance-selling applications should not be subject to the new market entry test?**

No

***If not, please reasons for your answer.***

*As with comments in chapter 4 above regarding DACs, a distance-selling pharmacy offers no local benefit to the population in a PCT's area, and therefore these applications should be considered by the National Commissioning Board.*

**11. Under the current 2005 regulations, an application for one of the four exemptions is refused if the neighbourhood in which the premises will be located is designated for LPS. Do you consider PCTs should continue to have the safeguard of being able to refuse distance-selling premises applications in an area where there is a LPS designation?**

Yes

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***If yes, please give reasons.***

*In addition to reasons given in 10 above, both PCTs (and successor organisations) and LPS providers take a higher level of business risk to develop services which meet specific local health needs, this safeguard provides some mitigation against the additional risk and ensures locally allocated DH funds benefit the population for which they were intended.*

**Chapter 6**

**12. Will the introduction of a “no significant change relocation” make relocating or administering relocations of pharmacy premises within a PCT’s area easier than the current “minor relocations” provisions?**

No

***If not, please give reasons.***

*Although the definitions regarding minor relocations are somewhat subjective there is a reasonable understanding of them and a number of well referenced precedence, appeals and judgements to inform decision making: There does not seem to be any clear advantage to changing this.*

**13. Are the conditions relating to “no significant change” applications clear? Do you have any comments about the new “no significant change or detriment” test?**

Yes

**Comments**

*The conditions are clear, but as with 12 above there does not seem to be any clear advantage over existing arrangements if relocations are to become excepted applications. Should the “no significant change” change be included in regulation, the current protection against leapfrogging, ie; the requirement for services to be provided from premises for at least a year before any further relocation is considered, should be retained.*

**Chapter 7**

**14. Do you consider the notifications and appeals procedures in the draft regulations adequate?**

Yes

**15. Do you consider the notification and appeal procedures in draft Schedules 2 and 3 clear?**

Yes

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Chapter 8

**16. Are the draft regulations sufficiently clear about how and under what criteria PCTs can initiate measures to deal with performance matters for chemist contractors?**

Yes

**17. Are these proportionate and reasonable?**

Yes

Chapter 9

**18. The intention of the Advisory Group has been to transfer the 2005 Regulations and amendments agreed by the Group since relating to rural dispensing without any significant change, but taking the opportunity to make the regulations clearer and make some agreed minor modifications. Do you agree with what has been done?**

No.

*The services provided by dispensing doctors which fall under pharmaceutical regulations should be subject to the same performance and quality monitoring as any other provider of pharmaceutical services, to ensure consistency of service for both patients and providers. It should not be acceptable for certain providers of pharmaceutical services to be subject to different monitoring arrangements and governance requirements.*

**19. Does the information which accompanies the regulations including the draft guidance adequately clarify the requirements and procedures set out in the draft regulations?**

Yes

**20. If Ministers were to proceed following consultation, do you have a view on whether the regulations should be implemented by PCTs or the NHS Commissioning Board, subject to Parliamentary process?**

Yes. (PCTs initially then NHS Commissioning Board subject to passage of Health Bill)

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**Comments**

*The regulations should be implemented with due promptness following consultation, as this is a natural progression from the 2009 regulations regarding duties to produce PNA. Regulations must make clear the relationship between the Pharmaceutical Needs Assessment and the local Joint Strategic Needs Assessment to ensure a transparent and objective process to identify pharmaceutical needs.*

*The role of Health and Wellbeing boards both in this matter and in the maintenance and updating of the Pharmaceutical Needs Assessment has been discussed by Essex LPC: The committee is of the view that this needs to be considered with some caution as there is a risk of undue influence from elected councillors and other stakeholders, and therefore either responsibility for Pharmaceutical Needs Assessments or a clear role in scrutinising these assessments against national standards should also transfer to the NHS Commissioning Board.*

**Further comments**

**21. Do you wish to make any other comments outside of the above questions?**

Yes

**Chapter 10**

**Impact Assessment**

**22. Do you have any comments on the draft impact assessment?**

Yes

**Comments**

*The data used to support the IA is almost two years old, and may need updating to provide a meaningful supporting document.*

**Equality Impact Assessment**

**23. Are there matters not included in the draft Equality Impact Analysis, which should be?**

No