



Pharmaceutical Services Negotiating Committee



# The 'New' Market Entry Regulations

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Pharmaceutical Services Negotiating Committee



# Where are they!





# Aims and Objectives

*Aims (subject to the regulations being laid)*

- To consider the new market entry tests to be applied, and
- To answer questions about the market entry test
- Today's position, in the absence of regulations, is to continue with that, but with a warning that anything could change!



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# Areas to cover

Legislation

Pharmaceutical Needs Assessments

Routine Applications

Excepted Applications



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# Primary Legislation

National Health Service Act 2006 (& 1977)

Amended by Health Act 2009

Health and Social Care Act 2012



# Secondary legislation

## NHS (Pharmaceutical Services) Regulations 2005

- Sets out:
  - Necessary or expedient test
  - Exemptions
  - Minor relocations
  - Change of Ownership
  - (plus rural, FtP, Terms of service)

## The National Health Service (Pharmaceutical Services) Regulations 2012



## Pharmaceutical Needs Assessments

- PCTs must have published by 1 February 2011
- Schedule 3A of current Regulations requires:
  - Statement of current provision
  - Statement of current or future needs
  - Statement of services which are not needed, but which would bring about improvements or better access

*(Schedule 1 in proposed regulations)*



## **‘Current need’ test (s129(2A))**

129(2)(c) an application for inclusion in a pharmaceutical list must be granted if the PCT is satisfied as mentioned in subsection (2A)

129(2A) The PCT is satisfied as mentioned in this subsection if, having regard to its needs statement and to any matters prescribed by the Secretary of State in the regulations, it is satisfied that it is necessary to grant the application in order to meet a need in its area for the services or some of the services specified in the application.





# Example of a PNA – Essential services

*Access to medicines - 'In summary the pharmaceutical services currently provided by each of the eight 100 hour pharmacies in the PCT area meet identified needs in the population'.*



# Regulation 13

If a Primary Care Trust receives a routine application; and granting it, or granting it in respect of some only of the services specified in it, would meet a current need for pharmaceutical services, ... included in its pharmaceutical needs assessment in accordance with paragraph 2(a) of Schedule 1, ...



## PNA Needs – Enhanced services

*Stop Smoking – ‘It is estimated that although better than the average for England, almost one adult in six smokes’*

*‘PCTs set smoking cessation targets based on 37 quitters per 1000 smokers in 2008/9 and will need to plan for 44.8 per 1000 smokers in 1010/11. Current performance data show that this represents a significant challenge and further work is required in this area. Commissioning of smoking cessation services also needs to be strengthened to achieve WCC standards’.*



- 129(2A) The PCT is satisfied as mentioned in this subsection if, having regard to its needs statement and to any matters prescribed by the Secretary of State in the regulations, it is satisfied that it is necessary to grant the application in order to meet a need in its area for the services or some of the services specified in the application



## Regulation 13 (again)

in determining whether it is satisfied the Primary Care Trust must have regard to the matters set out in paragraph (2) -

- Whether desirable to consider applications from others;
- since publication of the PNA there have been changes to the needs that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;
- Whether granting the application would only meet the current need in part, and if granted it would be unlikely in the foreseeable future that the remainder would be met



## Regulation 13 (again)

whether it is satisfied that—

- the current need mentioned in paragraph (1)(b) was for services other than essential services, and
- granting the application would result in an increase in the availability of essential services in the area of the Primary Care Trust;



# Consider other applications?

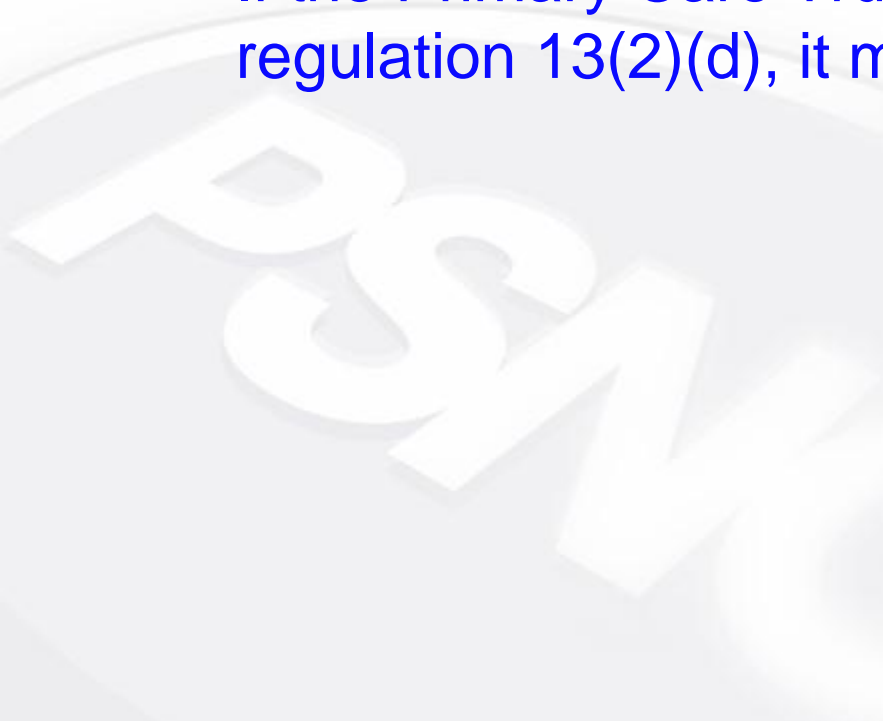
14(1) it may defer determination of the application;

- invite applications from other persons to offer to meet the current need that the applicant is offering to meet; and
- consider, at the same time as the applicant's application, any application it receives
- but it must not defer consideration of the application for longer than 6 months.



## **Changes since PNA cause would cause detriment to essential services**

- If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(d), it must refuse the application.







# Applicant would meet the need only in part

- If no likelihood of the remaining needs being met – the PCT must refuse the application.
- If it is not unlikely the remaining needs will be met – the PCT must only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in its area.



## **For enhanced service only, which increases essential service provision**

- If the Primary Care Trust is satisfied as mentioned in regulation 13(2)(g), it must only grant the application if it is satisfied that to do so would secure improvements, or better access, to pharmaceutical services in its area.



# Summary of Needs applications

- PCT can defer
- PCT obliged to grant if meet needs, but
- Can / Must refuse in some cases, and
- Can grant in some cases only where there is also an improvement in or better access to pharmaceutical services.

LPCs will see from this part of the test, that it will have an invaluable role in ensuring the PCT adopts the right processes



# Future Needs applications

- Treated in the same way as current need (powers to defer to invite other applications, obligation to refuse, conditions on granting etc)
- Can also defer if it is satisfied that it would be desirable until some or all of the future circumstances specified had arisen.



# Improvements or better access

- PCT has discretion as to whether to grant
- As with 'needs' but must have regard to
  - Whether there is a reasonable choice in the PCT area
  - Whether there are people with a protected characteristic with needs that are difficult to access
  - Whether there are innovative proposals with regard to delivery of Pharmaceutical services



# Unforeseen benefits

- Where not relying on part of PNA
- PCT considers whether granting would cause significant detriment to proper planning of pharmaceutical services in its area, or the arrangements it has in place for pharmaceutical services
- If so – it must refuse application;



## Unforeseen benefits (2)

whether, it is satisfied in light of

- Choice
- Easier access for persons with protected characteristic
- Innovative approaches in delivery of pharmaceutical services,

granting the application would confer significant benefits on persons in its area which were not foreseen when it published its pharmaceutical needs assessment

The PCT may grant.



# Excepted applications

- Change of Ownership
- Relocations
- Distance selling





# Relocations

- No distance or neighbourhood test. Will be granted if:
  - Not significantly less accessible
  - Will not result in a significant change in the arrangements for pharmaceutical services in the PCT area
  - Does not cause significant detriment to proper planning of pharmaceutical services
  - Same services – no interruption unless PCT consents



# Distance selling

- Only 'exemption' carried forward
- Cannot be in same site or building as provider of primary medical services.
- Uninterrupted provision of essential services throughout opening hours
- PCT to be satisfied that procedures allow service without face to face contact between any person receiving the services (whether on their own or on someone else's behalf) and the applicant and their staff



# 100 hours, one stop and large retail

- Proposal is to continue with existing
- But no new applications
- Earl Howe said last week that 100 hours pharmacies were at the forefront of his radar!



# Timing

- Consultation ended January
- Advisory Group met to consider response
- Papers have gone to Minister
- Once Minister is satisfied, goes to an internal legislative scrutiny committee
- Then will be laid at least 21 days in advance of coming into force
- As negative resolution, 40 days for opposition



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# Questions

