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PSNC Briefing 097/13: Guide to the Market Entry Regulations

1 April 2013 marked a new era in market entry. Applications for inclusion in a pharmaceutical list are now considered by NHS England (through their Area Teams) and the 'market entry test' is now an assessment against the pharmaceutical needs assessment produced by the local authority's Health and Wellbeing Board (and until they have completed one, the former PCT's version). The exemptions introduced in 2005 have been removed (other than the exception for distance selling pharmacies) and 'neighbourhoods' are no longer relevant for relocations.

LPCs and PSNC are both recognised as representing pharmacy contractors on NHS matters, and these matters are largely set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. More than half of those regulations are taken up with market entry and it is therefore unsurprising that many of the queries LPCs and PSNC receives are related to market entry. This briefing aims to cover the most commonly raised points.

Support from LPCs and PSNC

LPCs represent pharmacy contractors, and may be asked for advice on the regulations so that they can make applications. Those applications may be contentious such as opening another pharmacy in direct competition with another contractor (who is also represented by the LPC) or it may be non-contentious, such as a relocation into adjacent premises, a change of ownership, or an application in a rural area not currently covered by a community pharmacy.

Contractors may also ask for assistance in identifying the relevant points to be made in the contractor's representations on an application which affects his own pharmacy. LPCs themselves are also statutory consultees on applications.

LPCs are able to give a limited amount of assistance to a contractor who seeks guidance on the provisions that are relevant to an application – for example, they can identify the process of making an application, for responding to a consultation, and highlight any special conditions that applicants must satisfy in order to be granted an application. LPCs must not be asked to take an anti-competitive stance as that would be beyond the remit of the organisations, and could also lead to a breach of the competition legislation.

LPCs are not able to give legal advice, and contractors who want legal advice on the market entry regulations will need to seek this from a qualified solicitor or counsel.

Applicants who are not on any pharmaceutical list are not currently represented by LPCs. They will need to obtain guidance from other sources (although the information available on the PSNC website is open to all, and might be a helpful starting point). Applicants who are on a pharmaceutical list, but applying in an LPC area where they are not currently established have no rights to seek the support of that LPC but may ask their own LPC for guidance on identifying relevant provisions.

PSNC's main role is ensuring that the market entry regulations are fit for purpose and that any developments that could impact on the arrangements are identified to the Department of Health, so that amendments may be considered. PSNC also provides support to LPCs on the questions that arise about their responses as consultees,

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and where required, PSNC may also be able to assist the LPC to deal with queries from contractors (although if the matters are complex, it is likely that the contractor would need to be directed to seek legal advice).

Pharmaceutical Needs Assessments

The Pharmaceutical Needs Assessment is produced by the local authority's Health and Wellbeing Board at least every four years. Until April 2015, the PNA produced by the former PCT may be used until the HWB has produced its own. The process for revising the PNA is detailed, and could easily take 6 – 12 months to complete. Between versions of the PNA a supplementary statement may be issued to record changes in the provision of pharmaceutical services (e.g. the opening or closure of a pharmacy) but a supplementary statement cannot be used to record changes to the needs for pharmaceutical services.

The PNA will identify the pharmaceutical services that are needed, those that are provided, and hence those which are needed but not currently provided. It will also identify pharmaceutical services which are not needed, but which, if they were to be provided, would bring about improvements in or better access to pharmaceutical services. Again, such services that are provided are identified in the PNA. The PNA will also include details of other NHS services commissioned in the area which have an impact on the need to commission pharmaceutical services.

There is no appeal right against a PNA. If a PNA has been produced inadequately, it may be possible to challenge it by way of Judicial Review, but such action is costly, and must commence as soon as possible after publication, and in any event no later than three months after publication. A person dissatisfied with a PNA would need to seek expert legal advice on options if a legal challenge is contemplated.

Applications

An applicant must submit an application form, a fee, and if they are not already on a pharmaceutical list, their fitness to practise declarations. NHS England has a comprehensive collection of application form templates as well as guidance to its Area Teams on the processing of applications. Applicants as well as contractors who have been invited to make representations, should look at the guidance on the NHS England website.

It is crucial to the success of an application, that all required information is produced by the applicant – whilst the Area Team can ask for further information, there is no obligation to seek additional information that would help influence their decision. If an application is incomplete, the Area Team should request the missing information and the application will not be taken as a valid application, until all missing information has been produced. This has an impact on the timescales for the determination of the application, since the clock does not start until the application is complete.

It is always for the applicant to decide if and when to make an application – there is a fee associated with each application, and once an application has been made, this will enter the public domain and other interested parties may consider making applications in the same area. The decision to make the application should therefore take into account the prospect of success with that application.

Fees

Applications must be accompanied by a fee in most cases – see the Pharmaceutical Services (Fees for Applications) Directions 2013. An exception exists allowing the Area Team to waive the fee where it has invited the applicant to make that application.

Support

As the policy intent of the regulations is to put the commissioners in the driving seat, an application is not simply

processed in isolation. The Area team is required by the regulations to consider, before it seeks representations from interested parties, whether it would be beneficial to consider other applications alongside the application. This could arise for example if an application appeared to be meeting part of the needs identified in the PNA, where the Area Team thinks that opening up the opportunity to apply to others, in the light of that first application, may stimulate a more comprehensive offering. For this reason, applications must be as strong as possible, as the Area Team is not obliged to accept an application on a first past the post principle.

If the Area Team does decide to defer an application to invite other applications, it must do so for no longer than 6 months. The application is put on hold pending other applications.

The Area Team may also defer an application if there are other applications in the pipeline, or if there are relevant appeals in process.

Timescales

A common complaint received by LPCs and PSNC is that applications have not been determined promptly. The time-scales are set out in paragraph 27 of Schedule 2 of the pharmacy regulations.

If the application is a notifiable application (the meaning of which is set out in paragraph 18 of that schedule) including all routine applications as well as relocations, distance selling applications and relocations combined with change of ownership, then NHS England must endeavour to determine the application as soon as is practicable, and unless there is deferral of the application (see above) must determine it within 4 months of the date on which it had received all the information it required to determine the application.

For the applications which are not 'notifiable' such as change of ownership, NHS England must determine the application within 30 days of receiving all the information it needed.

These limits can be extended is there is 'good cause' for delay. No attempt is made to describe what would amount to good cause, but it is not expected by PSNC that staff holidays would be 'good cause'. These time limits are set out in regulations because the Minister believes there should be robust procedures for a timely determination – and organisations that have a duty to do something within a specified period would need a really good reason to taken longer.

Paragraph 28 then requires NHS England to notify its determination as soon as practicable.

If an applicant is concerned about the amount of time being taken, then the first step is to take the matter up with the official at NHS England's Area Team that is handling the application. If the response is unsatisfactory, the concern can be escalated to the director of commissioning at the Area Team. If the concerns remain unresolved NHS England's regional office could be contacted.

PSNC is sometimes asked whether legal action can be taken, to force NHS England to make the determination. It may sometimes be possible to challenge through the courts, but expert legal advice would be needed, and of course once the matter has been referred to the courts the court system itself may introduce further delay, so legal action would probably be considered the last resort.

Exemptions / Exceptions

The change in the market entry test to refer to the PNA means that it is no longer necessary to have exemptions to the test for the large out of town retail developments, the one stop primary medical centres, or the pharmacies undertaking to provide pharmaceutical services for at least 100 hours per week. These exemptions therefore cannot be used by an applicant (although existing pharmacies and those granted under the exemption continue).

There was a transitional arrangement so that these three types of application which had reached the end of the 45 day consultation period before 1 September 2012, continue to be processed under the 2005 Regulations, until the premises open, or applications lapse. In effect, such an application should have been determined before the end of 2012, and a standard application (not preliminary consent) would therefore be expected to have opened no later than the end of September 2013 otherwise it would lapse. Although the rules on the time limits for opening are clearly set out in the regulations, there are a number of factors that can apply which means the actual last day for opening cannot be calculated without reference to the Area Team's records. LPCs may want to check with their Area Teams, to determine whether there are still exempt pharmacies in the system which have yet to open – this can have an effect on the discussions that the LPC will have with their Health and Wellbeing Boards, as preparations are made to update PNAs.

There were misunderstandings about whether a 100 hour pharmacy would be able to apply to reduce its hours. The regulations have made it clear that such pharmacies cannot apply to reduce their hours.

The exemption for distance selling pharmacies continues. The reason this exception (as it is now called) is required, is because a true internet or mail order pharmacy, servicing a population spread throughout the country, cannot argue a strong enough case for meeting needs set out in a local PNA, nor could it be said to bring about a significant benefit under an unforeseen benefits application. New conditions have been introduced in regulation 64, which requires the pharmacy to be able to provide essential services safely, without face to face contact at the premises, and must ensure that persons anywhere in England are able to access the essential services.

There have been several applications refused by NHS England, and some of these have been the subject of appeals to the NHS Litigation Authority's Family Health Services Appeals Unit. In several cases, the applicant had failed to satisfy the Area Team or the Appeals Unit, that they would be able to provide all the essential services without face to face contact at the pharmacy. In some cases, SOPs had not been provided, and in others, the SOPs had not been sufficient to satisfy the Area Team or the Appeals Unit. It is likely that over time, the new requirements will be tested further, both at the Appeals Unit and in the High Court. Applicants and affected contractors wishing to make representations on applications may find it helpful to examine similar cases that have been considered by the Appeals Unit, and of course, legal advice may be needed to establish the latest position as to how the exemption requirements should be interpreted.

PSNC has published further guidance on the regulations surrounding Distance Selling Pharmacies on its website.

Making representations on applications

A pharmacy contractor that in the opinion of the Area Team is likely to be affected by an application if it were to be granted, will be notified if the application is a 'notifiable' application.

If invited to make representations, they will be taken into account only if they are substantial (e.g. they contain a reasonable attempt to describe the reasons why the application should be granted or refused). There will be a right of appeal in most cases, but only if the pharmacy contractor made a reasonable attempt to express the grounds for opposing the application.

When invited to make representations, or when given a right to appeal it is essential to comply with timescales as late submissions will not be permitted.

If you have queries on this PSNC Briefing or you require more information please contact Steve Lutener, Head of Regulation.