Regulations under the Health Act 2009: Market entry by means of Pharmaceutical Needs Assessments

Information for Primary Care Trusts
Chapter 7

Improvements or better access to services

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Chapter 7: Improvements or better access to services

1. This chapter deals with *routine applications* submitted to secure improvements or better access identified within a Primary Care Trust (PCT's) pharmaceutical needs assessment (PNA).

Introduction

2. Within its PNA, a PCT may have identified *pharmaceutical services* that are not provided in the PCT's area but which would, if provided, secure improvements, or better access, to *pharmaceutical services* (**paragraph 4 of Schedule 1**), for example a pharmaceutical needs assessment (PNA) identifies that better access could be achieved by extending opening hours in the evenings or weekends.

3. The PCT may decide to:

- invite applications to meet these identified needs at the appropriate time;
- wait and see what applications are received;
- commission an enhanced service, if appropriate; or
- commission a local pharmaceutical services (LPS) contract (see separate guidance[1]).

4. When a *routine application* to secure improvements or better access is received, the PCT must have regard to certain matters set out in **regulations 17 and 19**. However, before progressing any further, there are a number of issues which the PCT must consider.

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083442 Gateway reference 8808

Information to be included in all routine applications to secure improvements or better access

5. **Part 1 of Schedule 2** sets out the information that is to be provided in the application to the PCT. Some of the requirements relate to all applications, whereas others are for specific types of application.

6. When submitting a *routine application* to secure improvements or better access, the following information must be included (**paragraph 1 of Schedule 2**):

- the name of the PCT to which the application is made (this is the PCT in whose area the proposed premises will be);
- the type of application being made, for example an application to secure improvements or better access identified in the PNA;
- a statement of whether the application is a *routine* or *excepted application*;
- the name and address of the applicant i.e. the name and address of the sole trader/partnership[2]/body corporate;
- if the applicant is a sole trader, the General Pharmaceutical Council (GPhC) registration number. A pharmacist does not have to provide their GPhC registration number if their business is as a dispensing appliance contractor (DAC) and not a pharmacy contractor;
- if the applicant is in a partnership, each partner's GPhC registration number[3]. A pharmacist does not have to provide their GPhC registration number if the partnership is a DAC and not a pharmacy contractor;
- if the applicant is a body corporate for the purposes of the Medicines Act registration rules, the name and GPhC registration number of the superintendent pharmacist. If the applicant is a DAC, they are not required to have a superintendent pharmacist;
- where the application is for premises that are not already listed for the applicant, for example new premises:
    - the address of the premises, where known, or if the address is not known, the applicant's *best estimate* of where the proposed premises will be;
    - whether the applicant is currently in possession of the premises;
    - the proposed core opening hours for the premises; and
    - the total proposed opening hours for the premises (i.e. both *core opening* and *supplementary opening hours*).
- where the application includes the provision of *directed services*;
    - details of the *directed services* to be provided;
    - confirmation that the applicant is accredited to provide the services, where the PCT requires such accreditation;

[2] If the applicant is a partnership then the address given in the application should be the one to which they wish all correspondence to be sent.

[3] The Medicines Act 1968 requires all partners to be pharmacists.

- confirmation that the premises are accredited in respect of the provision of services, where the PCT requires such accreditation; and
- where relevant, a floor plan showing the consultation area where the applicant proposes to offer the *directed services*, unless one cannot be provided for reasons that the PCT accepts as good cause, for example the premises are not in the applicant's possession.

7. The applicant must confirm whether the application is a *routine* or an *excepted application* (**paragraph 1(3) of Schedule 2**). They cannot switch between the two types of application once the application has been made to the PCT. Should the applicant wish to change the type of application, they are required to withdraw the first application and submit a second application, along with the relevant fee.

8. Where the applicant does not have an address for the proposed premises, **paragraph 1(7)(a)(ii) of Schedule 2** requires the applicant to give their *best estimate* of where the proposed premises will be. The PCT must be satisfied that:

- it is the *best estimate* that the applicant can reasonably make at the time; and
- any specific location within that *best estimate* would lead the PCT to come to the same decision on the application (**paragraph 1(10) of Schedule 2**).

9. It is particularly important that the PCT is clear where the proposed premises are likely to be in order that it can be satisfied that the application will secure the identified improvements or better access. It is also important because, if approved, the applicant will be required to notify the PCT of the eventual address for the proposed premises (**paragraph 31 of Schedule 2**) and the PCT must be satisfied at that point that the proposed premises are within the range of possible locations covered by the original *best estimate*. It will not at that stage be able to re-evaluate whether the *best estimate* that it accepted was appropriate.

10. This second requirement ensures that if the application is approved, when the applicant submits the precise location of the premises to the PCT, there is nothing new in terms of the decision that the PCT has already taken i.e. if the applicant had listed those premises in their original application, the PCT would have come to the same conclusion.

11. The PCT will also need to consider whether the *best estimate* allows them to establish whether the proposed premises are within a controlled locality, within two kilometres of a neighbouring PCT or within an LPS designation. Where necessary, the PCT should go back to the applicant for clarification.

12. PCTs and applicants may find maps useful when establishing the *best estimate* for the location of proposed premises.

Example

The PCT's PNA identified that a pharmacy providing *essential* and *advanced services*, minor ailments and smoking cessation services – Monday to Saturday, within a large village will lead to better access to *pharmaceutical services*. A *routine application* is received offering to secure this access in full. However, no premises have been secured and the applicant has given their *best estimate* for the pharmacy as the High Street. The village is very linear and this estimate covers a distance of two kilometres.

A site visit is undertaken and it is noted that there are a number of commercial units in the village centre which is located between 41 and 55 High Street. The majority of the village is centred on this location, as well, although houses continue sporadically along the High Street to 145.

If the application is approved and the applicant subsequently locates the premises at 145 High Street, then it is unlikely to fully secure better access due to the distance to be travelled to access the services.

The PCT decides it is not satisfied with the *best estimate* and asks the applicant to provide further information on a more precise location. The applicant then submits a map which shows that they intend to open within one of the commercial units in the village centre. The PCT is satisfied with this description of the applicant's *best estimate*.

13. If the applicant fails to provide either a precise location or a *best estimate* of the premises location within the *routine application*, this would be classed as missing relevant information for the purposes of **paragraph 11 of Schedule 2**.

14. Where an applicant submits a *routine application* for premises which are:

- already *listed chemist premises*; or
- are adjacent to or in close proximity to *listed chemist premises*.

paragraph 6 of Schedule 2 requires the applicant to include in their application, details that explain why the application should not be refused pursuant to **regulation 31**.

15. Where the applicant is making a *routine application* and is seeking to satisfy the PCT that granting the application would secure improvements or better access, they must explain in the application how they intend to secure those improvements, or better access, either in whole or in part (**paragraph 7(1)(a)) of Schedule 2**). It is not sufficient to say that the application will do this.

16. The unforeseen benefits test can only be applied to applications that are submitted under **regulation 18(1)**. The PCT cannot apply this test to an application to which **regulation 17** applies, and where the applicant submits a *routine application* to secure improvements or better access, they cannot ask for the test to be applied to that application (**paragraph 7(2) of Schedule 2).** More information on the unforeseen benefits test can be found in Chapter 8.

Example

A *routine application* is submitted to secure an improvement to *pharmaceutical services* that is identified within the PCT's PNA. The PCT undertakes its preliminary checks and notifies interested parties of the application. Shortly after notification, the PCT receives, determines and approves an *excepted application* from a pharmacy that wishes to relocate to secure that improvement. The person who submitted the *routine application* to open a new pharmacy to secure the improvement asks the PCT to consider it as an unforeseen benefits application instead – the unforeseen benefit being that the population would have better access to *pharmaceutical services* due to two pharmacies being within the same area.

The PCT refuses the request by virtue of **paragraph 7(2) of Schedule 2** and continues to process the *routine application* as one to which **regulations 17 and 19** apply. By virtue of **regulation 19(5)**, it will be required to refuse the application, on the basis that regulation 17(2)(f) applies.

Additional information to be provided where the applicant is not already included in the PCT's pharmaceutical list

17. **Paragraph 2 of Schedule 2** requires the applicant to provide additional information where they are not already included in the PCT's pharmaceutical list in respect of other premises. Where the applicant is an individual, they are required to provide their full name, sex, date of birth, private address and phone number; a declaration that they are a registered pharmacist (i.e. they are registered with the GPhC), and if they have other premises registered with the GPhC, the registration number(s) for those premises.

18. If the applicant is a DAC, their premises are not required to be registered with the GPhC (there is no equivalent regulatory body for DACs) and they are not required to be a registered pharmacist.

19. Where the applicant is a partnership, they are required to provide:

- each partner's full name, sex, date of birth, private address and telephone number; a declaration that they are a registered pharmacist (i.e. they are registered with the GPhC), and if they have other premises registered with the GPhC, the registration number(s) for those premises; and
- a declaration that the applicant is or will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968. DACs are not required to complete this declaration.

20. If the applicant is a DAC, their premises are not required to be registered with the GPhC (there is no equivalent regulatory body for DACs). Additionally, the partnership is not required to consist only of registered pharmacists.

21. Where the applicant is a body corporate, they are required to provide:

- the registered name and any other name under which the applicant trades;
- the company's registration number (this is their Companies House registration number);
- the registered office for the body corporate and any fixed line telephone number relating to that office;
- the private address and date of birth of the superintendent pharmacist (not required by DACs);
- the name, private address and date of birth of each director (excluding the superintendent pharmacist), and if any director is a registered pharmacist, their GPhC registration number;
- a declaration that the applicant is or will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968 (DACs are not required to complete this declaration); and
- if the applicant has other premises registered with the GPhC, the registration number(s) for those premises.

22. If the applicant is a DAC, their premises are not required to be registered with the GPhC.

23. **Paragraph 3 of Schedule 2** requires applicants to provide certain fitness to practise information on:

- the individual making the application; or
- where it is a partnership, each partner; or
- where it is a body corporate, the director(s) and (unless it is a DAC) any superintendent pharmacist.

24. **Paragraph 4 of Schedule 2** sets out further information that must be provided where the applicant is a body corporate and not already included in the PCT's pharmaceutical list for other premises.

25. Further information on these requirements can be found in separate guidance[4]. PCTs must ensure that none of the information provided under **paragraphs 3 and 4 of Schedule 2** – and no private addresses, private telephone numbers or dates of birth – are circulated with the application as part of the notification exercise. The PCT must also ensure that all fitness to practise checks are completed and a decision made on the applicant's suitability for inclusion in the pharmaceutical list before determining the *routine application* to secure improvements or better access.

26. Where the applicant is a body corporate with a registered office in England, **paragraph 5 of Schedule 2** makes provision for them to provide the information required by **paragraphs 3 and 4** to their *home PCT* instead. If they have already provided that information to their *home PCT* for another application, they need not provide that information again.

27. If the applicant wishes to use this flexibility, then they must:

- confirm to the PCT to whom it is making the application that their *home PCT* already has the information required under **paragraphs 3 and 4 of Schedule 2**; or
- undertake to provide any missing information required under those paragraphs to its *home PCT* and confirm to the PCT to whom they are making the *routine application* secure improvements or better access when that has taken place.

28. It is for the applicant to decide whether or not to use this flexibility, not the decision of the PCT to whom the *routine application* to secure improvements or better access is submitted or the *home PCT*.

[4] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206
Gateway reference 4728

Undertakings to be provided by all applicants

29. In addition to the information required in **paragraphs 1 to 7 of Schedule 2**, applicants are required to provide the following undertakings:

- to notify the PCT within seven days of any material change to the information provided in the application (**paragraph 9(a) of Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
    - the application is withdrawn;
    - the application is finally determined, be that by the PCT, or on appeal, the Family Health Services Appeal Unit (FHSAU) of the NHS Litigation Authority (NHSLA) or the First-Tier Tribunal, or following an appeal through the Courts; or
    - if the application is granted, when the applicant commences the provision of *pharmaceutical services*, to which the application relates.
- to notify the PCT if they are included, or apply to be included, in any other *relevant list* (**paragraph 9(b) or Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
    - the application is withdrawn;
    - the application is finally determined, be that by the PCT, or on appeal, the Family Health Services Appeal Unit (FHSAU) of the NHS Litigation Authority (NHSLA) or the First-Tier Tribunal, or following an appeal through the Courts; or
    - if the application is granted, when the applicant commences the provision of *pharmaceutical services*, to which the application relates.
- at the premises to which the application relates, to comply with all the obligations that are to be their terms of service under **regulation 11 (paragraph 9(c)(i) of Schedule 2**);
- to provide all the services and perform all the activities at proposed *pharmacy premises* that are required under the terms of service to be provided or performed as, or in connection with, *essential services* (**paragraph 9(c)(ii) of Schedule 2**); and
- if the applicant is seeking to provide *directed services* as part of the application, an undertaking:
    - that they will provide the *directed services* if the PCT commissions them within three years of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates;
    - if the services are commissioned by the PCT, that they will provide them in accordance with an agreed service specification; and
    - the applicant will not unreasonably withhold agreement to a service specification (**paragraph 9(d) of Schedule 2**).

Agreed service specifications

Where a PCT has indicated within its PNA that improvements or better access would be secured by a *directed service*, where that service is an enhanced service, the PCT should have a service specification.

In most instances, there is already likely to be such a specification and PCTs are advised to send that to the applicant at the point the *routine application* to secure improvements or better access is received so that the applicant is aware of what they will be required to provide should the application be successful. If the applicant has not seen the specification in advance of submitting the application, they may be reluctant to give the undertakings required in **paragraph 9(d) of Schedule 2**. Where this is the case, the PCT should nevertheless request the applicant to give the required undertakings and only begin to process the application once these are received.

Where there is no such service specification, the PCT must be able to describe the service in broad enough terms to allow itself flexibility, but narrow enough to allow the applicant to give the required undertakings in **paragraph 9(d) of Schedule 2**. Failure by the PCT to give sufficient information to allow the applicant to give the undertakings is not sufficient reason to delay the processing of the application. PCTs are therefore advised to ensure they have service specifications drafted for all the services identified within their PNA. Where the applicant was unable or unwilling to give the undertakings in their application, the PCT should request the applicant to give the required undertakings and only begin to process the application once these are received.

Example

The PNA requires the provision of an emergency hormonal contraception scheme but no service specification exists currently. The PCT publishes information that the service specification will be based on the template service specification published on the Pharmaceutical Services Negotiating Committee (PSNC) website and, for the avoidance of doubt, will include age ranges from 14 upwards (under a patient group direction (PGD)).

The PCT specifies that pharmacists providing the service will have successfully completed a Centre for Postgraduate Education (CPPE) or equivalent course (agreed in advance by the PCT) and the service will be required at all times the pharmacy is open, i.e. there must be a pharmacist present who meets the training requirements at all times.

So that there is no misunderstanding about the level of fees, the PCT states that the payments for the service will be as agreed with the Local Pharmaceutical Committee (LPC), or if no agreement is reached, they will be set at no less than the average fees paid by PCTs within the Strategic Health Authority area.

Publicising this amount of detail will ensure that the PCT can, when it decides to commission the service, set out a service specification appropriate at the time, within the broad description. The applicant will also be able to give the undertakings, knowing the extent of the likely service specification.

30. The obligation on the applicant to provide information or documentation required by **paragraphs 1 to 7 and 9 of Schedule 2** is only discharged if the PCT is satisfied that no relevant information or documentation is missing (**paragraph 10 of Schedule 2**). The PCT must have good cause to believe that there is relevant information or documentation missing and may not use this provision as a reason not to determine, or to delay determining, an application.

Preliminary matters to consider following receipt of an application

31. On receipt of a *routine application* to secure improvements or better access, there are a number of preliminary matters which the PCT must consider before notifying the *routine application* to interested parties. These matters are set out in **Part 2 of Schedule 2** and in paragraphs 32 to 45, 50 to 51 and the subsequent table below. PCTs may wish to develop a checklist to ensure they consider all the matters prior to notifying the application.

Missing relevant information or documents

32. Where the PCT considers that the application has not provided all the relevant information or documentation, it may request that missing information or documentation and shall specify the timescale within which it is to be submitted (**paragraph 11(1) of Schedule 2**). The PCT should only request information or documentation that is required to determine the application i.e. information or documentation that is relevant to the application. The PCT should not request information that is not relevant to the application (see the example below).

33. The timescale must be reasonable and will depend on what information or documentation is required, for example, a timescale of one week may be reasonable to provide the GPhC registration number of the superintendent pharmacist required under **paragraph 1(6) of Schedule 2** but a longer period may be required to provide the fitness to practise information required under **paragraph 3 of Schedule 2** for all the partners in a partnership.

34. The PCT may make the request at any time between receiving and determining the *routine application* to secure improvements or better access, but it must consider whether or not it needs to request missing information or documentation prior to notifying the application as required by **paragraph 18 of Schedule 2 (paragraph 11(3) of Schedule 2)**. In the interests of fairness and transparency and to make sure those

notified of the application have all the relevant information, the PCT may wish to ensure they have any missing information or documentation prior to notifying the application.

35. The applicant is required to provide the information or documentation within the specified timescale and where they are unable to meet the timescale, they must notify the PCT of the delay (**paragraph 11(1)(b)(i) and (ii) of Schedule 2**). Additionally, they must tell the PCT if they are unable to meet the original timescale and specify a date by which the information or documentation will be provided (**paragraph 11(1)(b)(ii) of Schedule 2**). The PCT must be satisfied that the delay and the length of the delay are for good cause (**paragraph 11(2)(a)(ii) of Schedule 2**).

36. If the applicant refuses to comply with a request for missing information or documentation within the timescale specified by the PCT, or by any subsequent date specified by the applicant and agreed with the PCT, the application is to be treated as withdrawn by the applicant (**paragraph 11(1)(b)(iii) of Schedule 2**).

37. If the applicant considers that the PCT's request is not reasonable, then they may notify the PCT of that and seek a review by the PCT of the reasonableness of the request – see box below (**paragraph 11(1)(b)(iii) of Schedule 2**).

38. If the applicant seeks a review, the PCT is required to reconsider its request for missing information or documentation. The 2012 Regulations are silent as to the procedure for this review. PCTs may therefore wish to develop and agree a process with their LPC for this. In the interests of fairness and transparency, the review should be conducted by a different person/committee to that which determined the information or documentation is missing. PCTs may wish to consider whether the dispute resolution processes they have in place for other primary care contractors are suitable for this purpose.

39. If following the review, it is determined that any or all of the requested information or document must after all be provided, the applicant must be told of the timescale (which must be reasonable) within which it is to be provided. Should the applicant not comply with the request, then the application is to be treated as withdrawn by the applicant (**paragraph 11(2)(b)(i) of Schedule 2**).

40. If following the review, it is determined that the information or documentation need not be provided, the original request made under **paragraph 11(1) of Schedule 2** is to be treated as withdrawn i.e. the applicant is not required to provide it (**paragraph 11(2)(b)(ii) of Schedule 2**).

Example

A shared service agency receives a *routine application* to secure an improvement or better access to *essential* and *advanced services* in a locality. On checking the application, it is noted that the applicant has stated the pharmacy will be in premises that are currently residential. The agency asks the applicant to provide evidence that they have applied for or been given approval by the local planning department for change of use.

The applicant considers this request to be unreasonable as it is not material to their application and asks for a review to be undertaken.

The PCT's pharmacy application panel considers the request for a review and agrees that as this information is outside the requirements of the 2012 Regulations, the request is unreasonable. The applicant is advised that the request for that information is withdrawn.

Failure to provide undertakings

41. On receipt of an application, the PCT should check that the applicant has given all the undertakings required by **paragraph 9 of Schedule 2**. If the applicant has failed to do this, the PCT must, prior to notifying the application, request them to do so within a reasonable timescale (**paragraph 12(1) of Schedule 2**).

42. If the applicant fails to comply with this request within the PCT's timescale, the application is to be treated as withdrawn (**paragraph 12(2) of Schedule 2).**

Functions of a home PCT in relation to certain applications

43. Where the applicant is not already included in the PCT's pharmaceutical list and has a *home PCT* to whom they have provided the fitness to practise information required by **paragraphs 3 or 4 of Schedule 2**, the PCT to which the *routine application* is made must notify the *home PCT* of that *routine application* and seek a recommendation from it as to whether or not the *routine application* should be refused or deferred under **regulations 33 or 34**, i.e. on fitness to practise grounds (**paragraph 13(1) of Schedule 2**).

44. The *home PCT* is required to consider whether the *routine application* should be refused on fitness to practise grounds, and having done so, must make a recommendation to the PCT that received the *routine application* within 30 days of receiving the notification (**paragraph 13(2) of Schedule 2**).

45. The recommendation must set out all the relevant facts and be fully reasoned (**paragraph 13(2)(a) of Schedule 2**). If the recommendation is that the application is refused or deferred under **regulation 33 or 34** on fitness to practise grounds, the PCT that received the application must send a copy of the recommendation to the applicant and seek their views as to the accuracy of the facts set out by the *home PCT* (**paragraph 13(2)(b) of Schedule 2**). The PCT should note that this is only a recommendation by the *home PCT* and the PCT could, therefore, come to a different conclusion if it so wished based on the facts before it.

Refusal prior to notification of applications because of the language requirement for some NHS pharmacists

46. Where the PCT receives a *routine application* to secure improvements or better access, if the applicant (sole traders and partnerships only), has qualified as a pharmacist in Switzerland or an European Economic Area State other than the UK, the PCT must be satisfied that the applicant has the necessary level of knowledge of English which is necessary for the provision of services in the PCT's area (unless the applicant is already on the PCT's pharmaceutical list)(**Regulation 30**).

47. The Department of Health issued interim guidance[5] regarding language knowledge for GPs. PCTs may find this helpful when assessing the applicant's level of knowledge of English.

48. If the *routine application* to secure improvements or better access is from a person who is not already included in the PCT's pharmaceutical list at other premises, it will need to determine before notification whether or not it must refuse the application under **regulation 30 (paragraph 15 of Schedule 2**).

Example

A *routine application* is received from a pharmacist who is not already included in the PCT's pharmaceutical list at other premises.

Prior to notification, the PCT checks the fitness to practise information that is submitted with the application and it is noted that the pharmacist grew up in Argentina but qualified in Switzerland.

[5] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111901

The PCT requests evidence of the level of knowledge of English and then meets with the pharmacist. After considering all the evidence, the PCT is not satisfied that the pharmacist has the level of knowledge of English which is necessary for the provision of *pharmaceutical services* in its area. It therefore refuses the *routine application* under **regulation 30** and notifies the applicant of its decision and the reasons for it. Had the applicant qualified in Argentina, this regulation would not have applied as it would have been for the GPhC to resolve the issue of language competency prior to registration.

Refusal of applications on fitness to practise grounds prior to notification

49. Where the PCT receives a *routine application* to secure improvements or better access from a person who is not already included in the PCT's pharmaceutical list at other premises, then prior to notification it must consider whether or not it must refuse that application under **regulation 33(1)** – mandatory refusal on fitness to practise grounds (**paragraph 16 of Schedule 2)**.

Example

The PCT receives a *routine application* from a pharmacist who is not already included in the PCT's pharmaceutical list. Prior to notifying the application to interested parties, it checks the fitness to practise information provided and it is noted that the pharmacist is the subject of a national disqualification. The PCT, therefore, refuses the application under **regulation 33(1)**.

Matters to which the PCT must have regard and their consequences

50. Once all the above preliminary checks are completed, the PCT may then move on to the next stage of the process. **Regulation 17(2)(a)** sets out a number of matters which the PCT must have regard to at this stage. The PCT will need to work through each of the matters, possibly using a template checklist. Where one of the matters relates to the application in hand, the PCT should check the consequence of that matter set out in **regulation 19(1) to (3)**.

51. The following table sets out the matters, their consequence and provides an explanation of each:

Matters to have regard to when considering *routine applications* to secure improvements or better access – regulation 17	**Consequence of these matters – Regulation 19**	**Explanation**
17(2)(a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;	*19(1) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(a), it may-* *(a) defer determination of the application;* *(b) invite applications from other persons to offer to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to meet; and* *(c) consider, at the same time as the applicant's application, any application it receives-* *(i) as a consequence of the invitation issued in accordance with sub-paragraph (b), or* *(ii) that, even if it was not received in response to that invitation, is in any event from another person offering to secure the improvements or better access mentioned in regulation 17(1) that the applicant is offering to secure,* *but it must not, pursuant to this paragraph, defer consideration of the application for longer than six months.*	On receipt of an application that offers to secure improvements or better access, the PCT needs to consider whether it wishes to invite other applications. If a PCT decides that it wishes to consider applications from other persons to secure the same improvements or better access, it may defer determining the application for up to six months whilst it invites applications from other persons. Once it has received any other applications to secure the same improvements or better access (whether these were received as a result of the invitation or were unrelated to the invitation), the PCT would then consider and determine all the applications at the same time. However, the PCT must not defer consideration of the original application for longer than six months.

17(2)(b) It is satisfied that another application offering to secure the improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;	*19(3) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(b) . . ., it may defer consideration of the application until it can be considered at the same time as the other application.*	If a PCT decides that it wishes to consider application (A) with another application (B) that it has received offering to secure the same improvements or better access, then it may defer determining application A until it can be determined at the same time as application B.
17(2)(c) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access mentioned in paragraph (1) is pending, and it would desirable to await the outcome of that appeal before considering the applicant's application;	*19(4) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(c) . . ., it may defer consideration of the application until after the appeal has reached its final outcome.*	The PCT has previously determined an application (A) that would secure the same improvements or better access as application (B) but an appeal has been made against the PCT's decision on A. If the PCT decides that it wishes to wait to see what the outcome of the appeal on application A is, it may defer making a decision on application B until the appeal decision is known.

52. **Regulation 17(3)** confirms that for the purposes of **regulation 17(2)(h),** the improvements or better access are to be treated as due to be met if:

- a person has successfully applied to provide the improvements or better access, but has yet to submit their *notice of commencement*;
- a person has entered into an LPS contract with the PCT and will provide services that will secure the improvements or better access, but has not yet commenced service provision.

53. PCTs should note that they may only defer a *routine application* to secure improvements or better access in order to invite other applications for up to six months (**Regulation 19(1)**). There are no time limits to the period of deferral where the PCT is awaiting the outcome of an appeal or where it wishes to consider the application with another that it has received.

54. While considering applications offering to meet the same improvements or better access together may be good practice and thus desirable in principle, the PCT should not do this where it would result in considerable delay to the determination of any particular application. The PCT may be notified informally that an application is to be expected in relation to an identified improvement or better access for which another application has already been received. **Paragraph 19 of Schedule 2** requires the PCT to give *notice* of a *routine application* to secure improvements or better access as soon as is practicable. To delay the consideration of an application received on the basis that a further application may be received in the future could lead to serious delay and run the risk of legal or other challenge.

55. Care has to be taken that the power on the part of the PCT to consider applications together is not exploited by potential applicants who seek effectively to block consideration of earlier applications.

Deferral of applications prior to notification

56. When the PCT receives a *routine application* to secure improvements or better access, it must consider as soon as is practicable and in any case prior to notifying the application, whether or not to defer consideration of that application under **regulation 16(1) to (4)** (**paragraph 14(1) of Schedule 2**).

57. If the PCT decides to defer consideration of the application before notification then as soon as it no longer has grounds to defer the application it must proceed as soon as is practicable with the notification (**paragraph 14(2) of Schedule 2**). The only exceptions to this would be where the application has been withdrawn or the PCT is required to treat it as withdrawn.

Example

The PCT receives a *routine application* to secure better access to the provision of appliances. However, it had already received and refused an application to secure the same access. The FHSAU is considering an appeal against that decision and the PCT therefore decides after completing its preliminary checks to defer this new application under **regulation 14(3)** until the outcome of the appeal is known.

The PCT is subsequently notified that the FHSAU has dismissed the appeal. The PCT therefore goes on to notify those persons listed in **paragraph 19 of Schedule 2**. If the FHSAU had instead allowed the appeal, the PCT would have been required under **paragraph 24 of Schedule 2,** to ask the applicant to update the application and if they wanted to proceed with the application before going on to notify it. If the applicant failed to respond, the application would be treated as withdrawn. If the applicant wished to proceed, in due course they would need, by virtue of **regulation 16(6)**, to satisfy the PCT on grounds of improvements or better access rather than meeting unmet need.

58. If the applicant has a *home PCT*, the PCT that received the *routine application* must wait for the *home PCT's* recommendation before deciding whether to defer the application under **regulation 34,** i.e. on fitness to practise grounds. In this instance, the PCT could only delay notification of the application to interested persons for fitness to practise reasons if the *home PCT's* recommendation which led the PCT to defer the application under **regulation 34** (**paragraph 14(3) of Schedule 2**) arrived during the course of a delay in notifying for other reasons. The PCT must not use waiting for a *home PCT's* recommendation as the reason for holding up a notification (**paragraph 14(3) of Schedule 2**).

Deferrals arising out of LPS designation

59. **Regulation 32** allows the PCT to defer the *routine application* to secure improvements or better access as a result of a LPS designation where it so wishes. This is a discretionary power and the PCT may choose not to defer an application. PCTs are advised to document their reasons for deferring or not deferring.

60. The PCT must be satisfied that the *relevant premises* are:

- premises or part of premises that are designated for LPS under **regulation 4** of the NHS (Local Pharmaceutical Services etc) Regulations 2006, as amended (the LPS Regulations); or
- located within an area that has been designated for LPS under **regulation 4** of the LPS regulations.

61. The PCT must also be satisfied that the designation has not been varied so that it no longer applies to the *relevant premises* or that it has been cancelled (**Regulation 32(2)**).

62. The *relevant premises* are defined in **regulation 32(3)** as:

- the premises or proposed premises detailed in the application; or
- where no particular premises are listed in the application, the premises are located at the best estimate that the PCT is able to make as to where the premises will be. In coming to this best estimate, the PCT will have had regard to the *best estimate* that the applicant gave in their application as required by **paragraph 1(7)(a)(ii) of Schedule 2**. In practice, the best estimates should be the same.

63. This provision allows the PCT to defer a *routine application* to secure improvements or better access whilst it is considering proposals for an LPS contract. PCTs may choose to use the power of designation, depending on local circumstances. The aim of a designation is to allow time for an LPS proposal to be worked up and procured. Designation therefore allows PCTs to mitigate the potentially adverse impact of any new community pharmacy beginning to operate in an area where the development or implementation of an LPS scheme is underway. This may be a critical factor where in some cases the PCT has to plan and commit to a longer-term development, for example commissioning and building new community health centre premises.

64. PCTs may wish to note that designations are subject to review and cancellation, particularly where an LPS scheme proposal has not been submitted to the PCT approval process within twelve months, beginning with the date of the original designation, or if the LPS procurement exercise is aborted. Further information on this subject can be found in separate DH guidance[6].

[6] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083442

Action following decisions to defer a routine application

65. Where the PCT decides to defer consideration or determination of a *routine application*, it must:

- notify the applicant of its decision and the reasons for it; and
- where possible, notify the applicant of the length of time that the application is being deferred. If necessary, the PCT can refer to a future event as opposed to a period of time (**paragraph 24(1) of Schedule 2**).

66. The PCT may advise the applicant of this decision either before or after it has carried out the notification exercise. It is suggested that in most instances, deferral will take place prior to notification.

67. Where the PCT decides to defer the *routine application* under **regulation 19(1)(a)**, it must invite other applications under **regulation 19(1)(b)** as soon as practicable and in such a manner as it sees fit (**paragraph 24(2)(a) of Schedule 2**).

68. Where the PCT decides to defer the *routine application* under **regulation 19(3)** it must, as soon as practicable, make arrangements to consider the other applications at the same time as this application (**paragraph 24(2)(b) of Schedule 2**).

69. Where the PCT decides to defer the *routine application* under **regulation 19(4)** it must, once the appeal has reached its final outcome, notify the applicant of that outcome. The PCT must also notify the applicant that they must then within a specified period of not less than 30 days update their application and notify the PCT whether or not they still wish to proceed with it (**paragraph 24(2)(c) of Schedule 2**). If the applicant informs the PCT within the specified period that they do not wish to proceed with the application the application is to be treated as withdrawn (**paragraph 24(3) of Schedule 2**). If the applicant fails to respond in the required manner the application is also to be treated as withdrawn.

70. Where the PCT decides to defer the *routine application* under **regulation 32**, it must:

- send the applicant a copy of the LPS designation that led to the decision;
- where the designation that led to the decision to defer is cancelled or varied so that the *routine application* may no longer be deferred, review the decision to defer;
- notify the applicant of the cancellation or variation; and
- require the applicant within a specified period of not less than 30 days to update their *routine application* and to notify the PCT as to whether or not they still wish to proceed with it (**paragraph 24(2)(e) of Schedule 2**).

If the applicant informs the PCT within the specified period that they do not wish to proceed with the application, the application is to be treated as withdrawn by the applicant (**paragraph 24(3) of Schedule 2**). If the applicant fails to respond in the required manner, the application is also to be treated as withdrawn.

71. Where the applicant is not already included in the PCT's pharmaceutical list and the PCT decides to defer the *routine application* under **regulation 34**, once the outcome of the cause of that deferral is known, the PCT must notify the applicant that they must within a specified period of not less than 30 days update their application and notify the PCT whether or not they still wish to proceed with it (**paragraph 24(2)(f) of Schedule 2**).

72. If the applicant informs the PCT within the specified period that they do not wish to proceed with the *routine application*, the application is to be treated as withdrawn by the applicant (**paragraph 24(3) of Schedule 2**). If the applicant fails to respond in the required manner, the application is also to be treated as withdrawn.

Notification

73. Once the PCT has considered the matters listed in **paragraphs 11** to **17 of Schedule 2** and has decided not to refuse the application under **paragraph 15, 16** or **17 of Schedule 2** or to defer it, the PCT must give *notice* of a *routine application* to secure improvements or better access to:

- the LPC for its area, which may be an LPC that it shares with another PCT;
- the Local Medical Committee (LMC) for its area which may be an LMC that it shares with another PCT;
- any person in its pharmaceutical list whose interests the PCT believes might be significantly affected if the application were granted;
- any person who is entitled to be included in its list because of the grant by the PCT or on appeal by the FHSAU, of a *routine* or *excepted application*, but who is not (yet) included, and whose interests the PCT believes might be significantly affected if the application were granted;
- any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application were granted;
- any local involvement network (LINk) for its area, and any other patient, consumer or community group in its area (for example Parish and Town Councils) which the PCT believes has a significant interest in the outcome of the application;
- if the proposed premises within the application are in or are within 1.6 km of a controlled locality in its area, any provider of primary medical services or any other person on its dispensing doctor list if it has one (i.e. doctors on the list who are performers as opposed to providers) who the PCT believes has a significant interest in the outcome of the application; and

- any other PCT or Local Health Board (LHB) any part of whose area is within 2 km of the proposed premises (**paragraph 19(1) of Schedule 2**).

74. Persons in the above list must receive *notice* of the application. The PCT is free to notify any other person who it believes has a significant interest in the outcome of the application, for example MPs, councillors (**paragraph 19(2) of Schedule 2**).

75. It is recommended that the PCT records its reasoning why it believes persons have a significant interest in the outcome of the application.

76. Other than LPCs, LMCs and neighbouring PCTs or LHBs, the PCT should note the requirement to notify only those who it believes might be significantly affected if the application were granted, or those it believes have a significant interest in the outcome. PCTs will therefore need to identify those relevant persons rather than automatically notifying everyone on their pharmaceutical list, dispensing doctor list and all providers of primary medical services.

Example

A PCT receives a *routine application* to secure improvements or better access and after completing its preliminary checks is ready to notify it as required by **paragraph 19 of Schedule 2**. The application is for premises on the outskirts of a town and is within 1 km of a controlled locality. Using the Exeter system, the PCT identifies all the dispensing patients living within the controlled locality and within 1.6 km of the proposed premises. It identifies that three GP practices have dispensing patients within this area. One practice has five dispensing patients, one has 300 dispensing patients and the other has 500 dispensing patients within this area. The PCT decides that the practice with only five dispensing patients in the area would not have a significant interest in the outcome of the application and does not notify them of the application. This decision is noted in the paperwork for the application.

77. Where a neighbouring PCT is notified under **paragraph 19(1)(g) of Schedule 2** it must, within 14 days of receiving the notification, give *notice* of the application to:

- the LPC for its area if this is different to the notifying PCT's LPC;
- the LMC for its area if this is different to the notifying PCT's LMC;
- any person in its pharmaceutical list whose interests the PCT believes might be significantly affected if the application were granted;
- any person who is entitled to be included in its list because of the grant of a *routine* or *excepted application*, but who is not (yet) included, and whose interests the PCT believes might be significantly affected if the application were granted;
- any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application were granted;
- any LINk for its area, and any other patient, consumer or community group in its area which the PCT believes has a significant interest in the outcome of the application; and
- if the proposed premises within the application are within 1.6 km, of a controlled locality in its area, any provider of primary medical services or any other person on its dispensing doctor list if it has one (i.e. doctors on the list who are performers as opposed to providers) who the PCT believes has a significant interest in the outcome of the application (**paragraph 19(3)(a) of Schedule 2**).

78. Once it has notified the above listed persons, it is required to confirm this to the PCT that received the application (**paragraph 19(3)(b) of Schedule 2**). PCTs should note their duty to give *notice* of applications received from neighbouring PCTs. There is no appeal right against failure to do so, therefore the only recourse for a person who feels they have been adversely affected by such a failure is through the Courts.

79. Those persons who have been notified may make written representations about the application to the PCT to whom the application was made provided they do so:

- within 45 days of the date on which notice of the application was given to them; or
- for persons notified under **paragraph 19(2) or (3)** within such longer period as the PCT that received the application may specify (**paragraph 19(4) of Schedule 2**)

80. Where a PCT has notified a neighbouring PCT or LHB about an application, it may wish to allow 59 days for responses. As the neighbouring PCT must circulate the notification within 14 days of receipt, this will ensure those persons notified by the neighbouring PCT have at least 45 days within which to consider the application.

81. PCTs may like to contact their neighbouring PCTs to seek contact details for the person to whom the applications should be sent. This will ensure that applications are passed on in a timely manner.

82. The general expectation is that notified persons will have 45 days to respond from the date on which they receive the notification, and the PCT's power to extend should only really be needed and used in exceptional circumstances.

Parallel notifications

83. There may be occasions where a *routine application* to secure improvements or better access will result in premises opening in an area that is or may be a *controlled locality*. This will require the PCT to consider whether or not it needs to make or revise a determination as to whether or not an area is a *controlled locality*, or is part of a *controlled locality*. Where this is the case, it must give *notice* of the *routine application* at the same time as it gives *notice* of its intention to make such a determination under **regulation 38(1)** (**paragraph 20(1) of Schedule 2**).

84. Once the PCT has issued notice under **regulation 38(1),** it must defer consideration of any *routine application* where:

- the applicant is seeking the listing of *pharmacy premises*; and
- the outcome of the *routine application* could be affected by the PCT's decision as to whether the area is or is not a *controlled locality*, or is or is not part of a *controlled locality* (**Regulation 38(4)**).

85. If the *routine* application is deferred, **paragraph 24(2)(g) of Schedule 2** requires the PCT to proceed with the determination of whether the area is or is not to be part of a *controlled locality* as soon as practicable.

86. The *routine application* is deferred until:

- the PCT has determined whether the area in question is or is not a *controlled locality*, or is or is not part of a *controlled locality*; and
- the proceedings relating to that determination have reached their final outcome (i.e. any appeal to the FHSAU has been heard)(**Regulation 38(4)**).

87. The PCT may also receive a *routine application* to secure improvements or better access that requires it to consider whether or not the proposed premises are within a *reserved location*. Where this is the case, it must consider giving *notice* of the *routine application* at the same time as it gives *notice* of its intention to make such a determination under **regulation 41(4)** (**paragraph 20(2) of Schedule 2**).

88. See chapter 14 for further information on *controlled localities* and *reserved locations*.

89. If the PCT wishes to consider two or more applications together and in relation to each other, for example where it has deferred a *routine application* under **regulation 14(2)** in order to invite other applications, it is required by **paragraph 22(3) of Schedule 2** to give *notice* of its intention to do so.

Content of notifications

90. **Paragraph 21(1) of Schedule 2** sets out the information that must be contained within the notification letter. As well as sending a copy of the application, the PCT must inform those it is notifying:

- of their right to make representations under **paragraph 19(4)**;
- of the circumstances in which *notified* persons would be permitted to make oral representations should the PCT subsequently decide to hold an oral hearing; and
- where the PCT intends to consider the application at the same time as another application, notification of that intention (**paragraph 21(1)(a) of Schedule 2**)

91. When notifying of applications, PCTs must ensure that they send sufficient information to enable those notified to make informed representations as to whether or not the application should be granted (**paragraph 21(1)(b) of Schedule 2**). PCTs are not, however, required to provide copies or excerpts of their PNA with the notification letter (**paragraph 21(2) of Schedule 2**).

92. PCTs must not send any private personal information or fitness to practise information provided by the applicant under **paragraphs 2** to **4** or by their *home PCT*, where relevant (**paragraph 21(3) of Schedule 2**). This includes any private addresses, private telephone numbers or dates of birth that may have been supplied.

93. If the applicant advises the PCT that they consider:

- any information that they have supplied as part of the application to be confidential; and
- that they do not consent to that information being disclosed as part of the notification,

the PCT must withhold that information if it believes that the full disclosure principle does not require it to provide that information to those notified of the application (**paragraph 21(4) of Schedule 2**). If the PCT does withhold any information under **paragraph 21(4) of Schedule 2,** it must inform those notified of the application of the nature of the information that is being withheld (**paragraph 21(6) of Schedule 2**).

94. The full disclosure principle means that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application. The only exception is where it is fair and proper for that information to be withheld (**paragraph 21(5) of Schedule 2**) from that individual. Where the PCT is in any doubt as to whether the full disclosure principle applies, it should seek legal advice.

Example

A pharmacist who is currently employed at a local pharmacy submits a *routine application* to secure improvements or better access identified in the PNA. They request that their name is removed from all the documentation before it is circulated as they do not wish their employer to know they are applying.

The full disclosure principle applies in this case and therefore the PCT is required to disclose who is applying.

Flexibility with regard to determining or deferring applications

95. The PCT is able to determine or defer a *routine application* to secure improvements or better access as it sees fit, unless the Regulations provide to the contrary (**paragraph 22(1) of Schedule 2**). An example of this is **paragraph 26 of Schedule 2** which sets out who cannot take part in the decision-making process.

96. The PCT may determine a *routine application* without holding an oral hearing if it considers that oral representations are unnecessary (**paragraph 22(2) of Schedule 2**). Where a decision is taken not to hold an oral hearing, it is good practice to document that decision.

97. The PCT may consider two or more applications together and in relation to each other, but must give *notice* of this intention (**paragraph 22(3) of Schedule 2**). This should be done as part of the notification exercise. However, if the PCT decides after the notification exercise that it wishes to consider two or more applications, it may do so but must give *notice* of this to the applicants concerned before determining their applications.

Oral hearings

98. Oral hearings are not required to be held for every application decision and PCTs should make a judgement on when it is necessary to do so. This is likely to be based on the complexity of the application, previous applications in the area and any appeals, particularly upheld appeals, to the FHSAU regarding those applications, and the number and type of representations made in respect of the application from those notified of it.

99. If the PCT decides to hear oral representations prior to determining a *routine application* then it must:

- give the applicant and any *additional presenters* not less than 14 days' *notice* of the time and place for the oral hearing; and
- advise the applicant who else has been invited to make representations at the hearing. This may include other applicants, where the PCT has decided to determine two or more applications together (**paragraph 25(1) of Schedule 2**).

100. **Paragraph 25(2) of Schedule 2** defines a person as an *additional presenter* if:

- the application to which the hearing applies is a *notifiable application* (which all *routine applications* are);
- they were given *notice* of the application and made representations in accordance with **paragraph 19(4)**. As part of the representations, the person must have indicated that they would wish to make oral representations if an oral hearing took place and they must have identified a matter about which the PCT considers it would be desirable to hear further evidence about from the person at the oral hearing; and
- the PCT is satisfied that the person made a reasonable attempt to express their views adequately on the application in their written representation.

101. Written representations must therefore take a view on whether the application should be refused or granted, and the reasoning for that view. It is for the PCT to then decide whether they wish to hear further evidence on those reasons at the oral hearing. PCTs should note that simply saying that you would wish to attend an oral hearing without giving a view on the application is not sufficient. If a person notified of an application does not state in their written representations that they would wish to make oral representations, the PCT is not required to invite them to an oral hearing if it decides to hold one.

102. If the PCT decides at or after the oral hearing that the application is to be deferred, it may hold a further oral hearing once the period of deferral has expired if it so wishes (**paragraph 25(3) of Schedule 2**). This is a matter for the PCT to make a decision on and it is not obliged to hold a further hearing.

Persons barred from taking part in decision making on routine and excepted applications

103. **Paragraph 26 of Schedule 2** sets out a list of persons who may take no part in determining or deferring any routine or excepted application. Further information on this can be found in Chapter 3.

Timetable for determining applications

104. **Paragraph 27 of Schedule 2** requires PCTs to determine a *routine application* to secure improvements or better access as soon as it is practicable to do so and within four months of the date on which all the required information and documentation was received by the PCT (**paragraph 27(b)(i) of Schedule 2**).

105. The only exceptions to this timescale are where the PCT has deferred the application under the 2012 Regulations or where it has good cause for a delay. The table below summarises when the timescale starts and stops.

Scenario	**Point at which four months starts**
PCT receives a deficient *routine application*	The four-month period initially starts at the point the application is received. It then stops at the point the PCT discovers it is deficient, for example not all the relevant information or documentation is received or the PCT is not satisfied with the applicant's *best estimate* of the location of the premises. It then restarts at the point all the relevant information or documentation is received.
PCT defers a *routine application* to meet an identified need in order to invite other applications to meet that same need.	The four-month period initially starts at the point the application is received. It then stops at the point the PCT decides to defer it in order to invite other applications. It then restarts at the closing date for invited applications as long as the original application is not delayed for more than six months. If the PCT wishes to defer and invite other applications, this must be done promptly.
PCT defers a *routine application* to meet an identified need in order to consider it with a later one.	The four-month period initially starts at the point the first application is received. It then stops at the point the PCT decides to defer it in order to consider it alongside another application. It then restarts at the point the second application catches up with the original one.
PCT defers a *routine application* to meet an identified need to await the outcome of an appeal on another application offering to meet the same need.	The four-month period initially starts at the point the first application is received. It then stops at the point the PCT decides to defer it in order to wait for the appeal decision. It then restarts at the point the appeal decision is known.

PCT decides to defer a *routine application* where the proposed premises are located in an LPS designation.	The four-month period initially starts at the point the application is received. It then stops at the point the PCT decides to defer it due to an LPS designation. It then restarts when the proposed premises no longer fall within that designation.
PCT defers an application for inclusion in the pharmaceutical list by a person not already included in it on fitness to practise grounds (**Regulation 34**).	The four-month period initially starts at the point the application is received. It then stops at the point the PCT decides to defer it on fitness to practise grounds set out in **regulation 34**. It then restarts when the outcome of the cause for deferral is known.

106. Good cause for delaying an application will very much depend on the facts of the case.

Example

The PCT receives a relocation application under **regulation 24** from an existing pharmacy that wishes to move to part of a new health centre (the PNA identifies that a new pharmacy providing *essential* and *advanced services* and certain *enhanced services* would improve access to that population). The PCT duly notifies interested parties under **paragraph 19 of Schedule 2**.

Halfway through the notification period, it receives a *routine application* for the same location which is offering to meet the secure the better access in full. As the relocation application is not offering to provide all the specified enhanced services, the PCT decides it has good cause to defer the relocation application to consider it with the *routine application.*

If, however, the PCT decided that it did not have good cause to defer the relocation application, then it would need to be satisfied before granting it that doing so was not to the significant detriment of proper planning of the provision of *pharmaceutical services* in its area (**Regulation 24(1)(c)**).

Determining the application

107. Where the PCT receives a *routine application* to secure improvements or better access identified within its PNA and:

- granting it would secure these improvements, or better access, to *pharmaceutical services* in general, or specific *pharmaceutical services* in particular; or
- granting it in respect of some of the *pharmaceutical services* that the applicant is offering to provide will secure improvements, or better access, to *pharmaceutical services* in general, or specific *pharmaceutical services* in particular,

section 129(2A) of the 2006 Act requires the PCT to consider and be satisfied about certain matters (**Regulation 17(1)**).

108. This subsection of the 2006 Act states:

(2A) The Primary Care Trust is satisfied as mentioned in this subsection if, having regard to its needs assessment 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.

109. This means that if the PCT is satisfied, having taken into account additional matters set out in the Regulations, that granting the application would secure improvements or better access identified in the PNA, then it may, but need not grant the application.

110. The matters referred to in this Section of the 2006 Act and in **regulation 17(1)** are set out in **regulation 17(2)** and also in Parts 5[7], 6[8] and 7[9] of the Regulations. For each matter set out in **regulation 17**, there is a consequence set out in **regulation 19**. PCTs will therefore need to read the two regulations in conjunction.

111. The PCT will need to work through each of the matters set out in **regulation 17(2)**; possibly using a template checklist. Where one of the matters relates to the application in hand, they should check the consequence of that matter set out in **regulation 19**.

[7] Regulations 30 to 32 i.e. refusal due to language requirements, refusal due to same or adjacent premises and deferrals due to LPS.

[8] Regulations 33 to 35 i.e. refusal or deferral or conditional inclusion on fitness to practise grounds

[9] Regulations 40 and 44 i.e. refusal or deferral or conditional inclusion on fitness to practise grounds

112. Effectively, **regulations 17 and 19** inform the decision that the PCT will come to on *routine applications* that have been submitted to secure improvements or better access identified in the PNA.

113. The following table sets out the matters, their consequences and provides an explanation of each:

17(2)(d) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the Primary Care Trust that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area;	*19(5) If the Primary Care Trust is satisfied as mentioned in regulation 17(2)(d) . . ., it must refuse the application.*	The profile of *pharmaceutical services* in a PCT's area may change and the PNA may need to be revised to reflect the change. It is likely, however, that applications may continue to be submitted. This provision allows the PCT to refuse an application if there have been changes to the profile of *pharmaceutical services* in its area since the PNA was produced, such that to approve the application would have a detrimental effect on the provision of *pharmaceutical services*. For example, the PNA identified better access to services for night shift workers at a factory in its area, and invites applications from providers willing to provide 24-hour services. The factory owners relocate their business and a number of local businesses serving the factory workers close as a result.

		The PCT concludes that granting an application for a new 24-hour pharmacy close to the site of the former factory would now threaten the viability of existing *pharmaceutical services* providers and increase the likelihood of them joining the flight of small businesses from the area, to the detriment of local residents.
17(2)(e) whether it is satisfied that- *(i) granting the application would only secure the improvements or better access mentioned in paragraph (1) in part, and* *(ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;*	*19(5) If the Primary Care Trust is satisfied as mentioned in regulation 17(2). . .(e) . . ., it must refuse the application.*	When considering an application, if the PCT is satisfied that granting the application would only partly secure the improvements or better access and it is unlikely that the rest of that benefit would be met in the reasonably foreseeable future then it must refuse the application. For example, the PCT identifies in its PNA that residents in student halls of residence would benefit from better access to *pharmaceutical services* if a new pharmacy opened nearby offering both essential services, an enhanced service providing emergency hormonal contraception and an out of hours service. An applicant offers to provide the essential but not the enhanced services. The PCT concludes that it probably would not be able to secure the enhanced services it wants for the student population if it approves the application.

17(2)(f) whether it is satisfied that, since the publication of the Primary Care Trust's pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in its area or in the area of another Primary Care Trust- *(i) pharmaceutical services from listed chemist premises, or* *(ii) local pharmaceutical services from LPS premises;*	*19(5) If the Primary Care Trust is satisfied as mentioned in regulation 17(2) . . .(f) . . . it must refuse the application.*	If since the PNA was published, the improvements or better access have been met by another person, or are due to be met by another person, then the PCT must refuse the application. This could include an application that has been approved but the pharmacy has not yet opened. The PCT would need to be satisfied that the first applicant did intend to open the pharmacy and was not effectively blocking any other applications.
17(2)(g) whether it is satisfied that- *(i) the improvements or better access mentioned in paragraph (1) were in respect of services other than essential services, and* *(ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the Primary Care Trust;*	*19(5) If the Primary Care Trust is satisfied as mentioned in regulation 17(2) . . . (g) …., it must refuse the application.*	If the PCT is satisfied that the improvements or better access relate only to advanced and/or enhanced services and granting the application would result in an undesirable increase in the availability of *essential services*, the PCT must refuse the application.

17(2)(h) whether the application needs to be deferred or refused by virtue of any provision of Parts 5 to 7.	There is no consequence in **regulation 19**. PCTs should refer to Parts 5 to 7 of the 2012 Regulations.	Part 5 sets out three specific grounds for refusal or deferral of *routine applications* submitted under Part 3 of the 2012 Regulations. They do not relate to fitness to practise and are refusal due to language requirements for some *NHS pharmacists;* refusal for same or adjacent premises; and deferrals arising out of LPS designations. Part 6 makes provision for refusal, deferral and conditional inclusion in the pharmaceutical lists on fitness to practise grounds. Part 7 makes provision for refusal and deferral of routine applications in controlled localities in certain circumstances.

Deferral whilst a determination relating to a controlled locality is made

114. The PCT may have deferred the *routine application* whilst it made a determination as to whether or not the premises in the application are in a *controlled locality*.

115. Once the proceedings have reached their final outcome, the PCT may no longer defer the *routine application*. It may be that once the determination has been made, the applicant wishes to withdraw their application. In the absence of any communication to this effect from the applicant, the PCT should continue to deal with the *routine application*.

116. If it has been determined that the premises are within a *controlled locality* and the PCT approves the *routine application*, it will need to consider what action it needs to take under **regulation 50(4)** or **(5)** (postponement or the discontinuation of arrangements for the provision of *pharmaceutical services* by doctors). Further information on this can be found in Chapter 15.

Refusal, deferral and conditional inclusion in pharmaceutical lists of chemists on fitness to practise grounds

117. Where the applicant is not already included in the PCT's pharmaceutical list, they will also have to have submitted information on their fitness to practise (**paragraphs 2 to 4 of Schedule 2**). The PCT may process this information either in advance of processing the *routine application* to secure improvements or better access, or alongside. Whichever course of action is taken, the PCT must come to a decision on the fitness to practise information in advance of the *routine application*. It is not possible for PCTs to approve the *routine application*, subject to the satisfactory approval of the fitness to practise information.

118. Part 6 of the 2012 Regulations sets out the grounds on which the PCT:

- must or may refuse the *routine application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 33**);
- may defer consideration of the *routine application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 34**); and
- may grant the *routine application* for inclusion in the pharmaceutical list subject to efficiency conditions and conditions to combat fraud (**Regulation 35**).

119. Further information on these provisions can be found in guidance[10] issued by the Department of Health.

[10] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206 Gateway reference 4728

120. Where the *routine application* has been made by someone who is not already included in the PCT's pharmaceutical list in respect of other premises, there are additional actions that the PCT must undertake prior to determining the *routine application*. **Paragraph 23(1) of Schedule 2** requires the PCT to:

- where the applicant is an individual, check with the NHS Business Services Authority (BSA) Counter Fraud Service, now better known as NHS Protect[11] whether the applicant has any record of, or is under investigation for, fraud;
- where the applicant is a body corporate, check with NHS Protect whether any director or the superintendent pharmacist has any record of, or is under investigation for, fraud;
- where the applicant is an individual, check whether the Secretary of State who has delegated this function to the NHSLA[12] holds any information on the applicant that is relevant to the PCT's consideration of whether the application should be refused or deferred under **regulation 33 or 34** (i.e. on fitness to practise grounds) or whether conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information can be accessed by PCTs via a secure website;
- where the applicant is a body corporate, check whether the NHSLA holds any information on any director or the superintendent pharmacist that is relevant to its consideration of whether the application should be refused or deferred under **regulation 33 or 34** or whether conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information can be accessed by PCTs via a secure website; and
- take up references from the referees provided under **paragraph 3(8) of Schedule 2** and check those references.

121. Once the PCT has received and considered any information received as a result of these checks, it must consider whether:

- the *routine application* should be refused or deferred under **regulations 33 or 34**; or
- conditions should be imposed on the applicant under **regulation 35**.

122. If the PCT is minded to impose conditions under **regulation 35**, before it decides that it will impose conditions, it must notify the applicant of its intention. This must take place at least seven days before the determination that conditions will be imposed, and the applicant must be given the opportunity to make written or, potentially, oral representations before the PCT makes its decision (**paragraph 23(2) of Schedule 2**).

[11] http://www.nhsbsa.nhs.uk/fraud
[12] http://www.fhsaa.tribunals.gov.uk/index.htm

Refusal: same or adjacent premises

123. Where the premises within a *routine application* to secure improvements or better access are:

- already included in the PCT's pharmaceutical list; or
- adjacent to or in close proximity to premises that are already included in the PCT's pharmaceutical list,

the applicant will have had to explain why their application should not be refused pursuant to **regulation 31**.

124. The PCT must refuse a *routine application* to secure improvements or better access where:

- a person on the pharmaceutical list (which does not have to be the applicant) is providing (or has undertaken to provide) *pharmaceutical services* from the premises mentioned in the application or from adjacent premises; and
- the PCT is satisfied that it is reasonable to treat the applicant's proposed services as part of those services that are already being provided, and so the premises listed in the application and the existing premises should be treated as the same site (**Regulation 31(2)**).

125. The purpose of this regulation is to prevent a contractor from applying for multiple inclusions in the PCT's pharmaceutical list at the same address with no benefit to patients.

Conditions relating to directed services

126. Where a *routine application* to secure improvements or better access is made under the 2012 Regulations and as part of the application, the applicant undertakes:

- to provide the *directed services* specified in the PNA, if the PCT commissioned them within three years of the date the premises are included in the pharmaceutical list;
- if the *directed services* are commissioned by the PCT, to provide them in accordance with an agreed service specification; and
- not to unreasonably withhold agreement to the service specification,

Regulation 66(4) states that their inclusion in the PCT's pharmaceutical list is subject to the condition set out in **regulation 66(5)**.

127. This condition is that at those premises the applicant must:

- provide the *directed services* (and this condition applies to any future owners of the listed premises);
- provide the *directed* services in line with an agreed service specification; and
- not unreasonably withhold agreement to the service specification.

128. However, for the condition to apply, the PCT is required to commission the services within three years of the date on which the premises are included in the pharmaceutical list.

129. The condition takes effect on the date which PCTs may, under **regulation 66(6)(a)** specify as the date on which service provision is to commence, or alternatively the date that the PCT and contractor can agree as a mutually convenient commencement date for the *directed services* (**Regulation 66(6)(b)**), whichever is the sooner.

130. PCTs may not vary or remove the condition imposed by virtue of **regulations 66(3)** to **(5)**.

Example

Within their PNA, a PCT has identified benefit from better access to *pharmaceutical services*. In addition to the provision of *essential services*, the PNA identifies the desirability of advanced services, smoking cessation, emergency hormonal contraception, witnessed methadone consumption and needle exchange. A *routine application* is submitted under **regulation 12** and is approved by the PCT. As part of the application, the applicant has undertaken to provide the specified *directed services* and it is a condition on their inclusion in the PCT's pharmaceutical list that they do so.

The PCT has agreed service specifications for the enhanced services which are being provided by pharmacies within its area already. The only exception is the needle exchange service which the PCT is in the process of commissioning and has received applications from other contractors indicating that they find the service specification acceptable. Following discussions with the PCT, the applicant advises that it is not willing to provide this service as it is felt that the requirements are too onerous.

In this instance, as other contractors find the service specification to be acceptable, it would be unreasonable for the applicant to withhold agreement of the specification. The applicant fails to provide the undertaking to provide the service as required by **paragraph 9(d) of Schedule 2** and therefore the *routine application* is treated as withdrawn by virtue of **paragraph 12(2) of Schedule 2**.

If the *routine application* was granted and two years later, the PCT finally set the remuneration for the needle exchange service which both the new contractor and the other contractors considered was not appropriate, it would not be unreasonable for the new contractor to withhold agreement to the service specification and they would not be in breach of the **regulation 66(5)(b)** condition of their listing.

Notification, taking effect of decisions and rights of appeal

131. Once the PCT has made a decision on the *routine application*, it must as soon as practicable notify certain persons of its decision (**paragraph 28(1) of Schedule 2)**.

132. The 2012 Regulations make provision for certain persons to have a right of appeal against the PCT decisions. Where an appeal right is provided in accordance with the Regulations, a person who is entitled to appeal must be provided with the following:

- notification of their right to make an appeal;
- confirmation of their entitlement to make an appeal within 30 days from the date of the PCT's letter; and
- information on the FHSAU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website[13]. If there is a right of appeal on a matter related to fitness to practise, the appeal is to the First-Tier Tribunal[14] and its contact details must be provided by the PCT.

133. It should be noted that rights of appeal should still be given to those persons who are entitled to be given rights even in the event of the decision being in favour of them. There may potentially be a part of the decision which they do not agree with and are therefore entitled to appeal this part of the decision.

Notification of decisions

134. The persons who must be notified as soon as practicable of the PCT's decision are:

- the applicant;
- the LPC for the PCT's area which may be an LPC that it shares with another PCT;
- the LMC for the PCT's area which may be an LMC that it shares with another PCT;
- any person who is included in the PCT's pharmaceutical list, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believes might be significantly affected by the decision;
- any LPS chemist with whom the PCT is in contract and whose interests the PCT believes might be significantly affected by the decision;

[13] http://www.nhsla.com/ContactUs/
[14] http://www.fhsaa.tribunals.gov.uk/AboutUs.htm

- any LINk or other patient, consumer or community group in the PCT's area which the PCT believes has a significant interest in the decision;
- if the proposed premises are in or within 1.6 km of a controlled locality in the PCT's area, any provider of primary medical services or any other person (who is a performer but not a provider of primary medical services) on its dispensing doctors list, if it has one, who the PCT believes has a significant interest in the decision;
- any other persons that the PCT notified under **paragraph 19(2) of Schedule 2** (other persons who in the opinion of the PCT have a significant interest in the outcome of the application) and who made representations about the application under **paragraph 19(4) of Schedule 2**; and
- any other PCT or LHB any part of whose area is within 2 km of the proposed pharmacy premises to which the decision relates (**paragraph 28(1) of Schedule 2**).

135. This list may well be the same as the list of persons who were initially notified of the application. However, PCTs should check whether there have been any other applications that have been approved by either the PCT or on appeal the FHSAU or courts. This is because the person who submitted that other application may need to be notified of the decision on this later application if the PCT believes their interests may be significantly affected by this decision.

136. The requirement is to notify the decision as soon as is practicable. PCTs should aim to notify decisions within a week unless they have good cause not to do so. Each notification of the decision must include a statement from the PCT of the reasons for that decision (**paragraph 28(6) of Schedule 2**).

137. Any PCT notified of the decision under **paragraph 28(1)** is required by **paragraph 28(2) of Schedule 2** to notify certain persons of the decision as soon as is practicable. Those persons are:

- the LPC for the PCT's area if this is different to the LPC for the PCT that made the decision;
- the LMC for the PCT's area if this is different to the LMC for the PCT that made the decision;
- any person who is included in the PCT's pharmaceutical list, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believes might be significantly affected by the decision;
- any LPS chemist with whom the PCT is in contract and whose interests the PCT believes might be significantly affected by the decision;
- any LINk or other patient, consumer or community group in the PCT's area which the PCT believes has a significant interest in the decision; and

- if the proposed premises are within 1.6 km of a controlled locality in the PCT's area, any provider of primary medical services or any other person on its dispensing doctors list, if it has one (and who is a performer but not a provider of primary medical services), who the PCT believes has a significant interest in the decision.

138. The requirement is to notify the decision as soon as is practicable. The PCT should aim to notify decisions within a week unless they have good cause not to do so.

139. Once the neighbouring PCT has done this, it must notify the PCT who made the decision on the application that it has notified the interested parties listed above (**paragraph 28(2)(b) of Schedule 2**).

Template notice of commencement to be included with a notice of decision

140. If the PCT grants the *routine application*, it must send, with its decision letter, a *notice of commencement* for the applicant to complete and send when it is ready to start service provision. The *notice of commencement* must contain the following information:

- the address of the premises to which the application relates:
- the services that are to be provided from those premises i.e. *essential services* and any *directed services*;
- the date of the grant of the application;
- a declaration with regard to when the applicant intends to commence the provision of those services at those premises;
- in the case of pharmacy premises, the GPhC registration number of those premises; and
- a signature on behalf of the applicant and the date of *notice* (**paragraph 29 of Schedule 2**)

141. The PCT may wish to pre-populate parts of the notice where it holds the information.

Appeals to the Secretary of State by the applicant

142. **Paragraph 36(1) of Schedule 2** gives the applicant rights of appeal against certain PCT decisions. The right of appeal on decisions that are not fitness to practise related is to the Secretary of State who has delegated this function to the FHSAU. The applicant may appeal against a decision by the PCT:

- to refuse the application on grounds set out in Parts 3 to 5 or 7 of the 2012 Regulations;
- where the PCT is not satisfied that a notification under **paragraph 31 of Schedule 2** is valid (notification of premises where a *best estimate* was given in the original application;

- to refuse to accept that a notification under **paragraph 32(2) of Schedule 2** is a valid notification (a change to the premises listed in the original application prior to opening;
- to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**; or
- to give *notice* under **paragraph 35 of Schedule 2** requiring the commencement of *pharmaceutical services*.

143. The *notice* of appeal is only valid if it includes a concise and reasoned statement of the grounds of the appeal (**paragraph 36(2) of Schedule 2**).

144. Applicants may appeal against decisions to refuse under the following regulations in Part 3:

- Regulation 14(4);
- Regulation 16(5);
- Regulation 19(5);
- Regulation 21(5); or
- Regulation 22.

145. Applicants may appeal against decisions to refuse under the following regulations in Part 5:

- Regulation 30; or
- Regulation 31.

146. Applicants may appeal against decisions to refuse under the following regulations in Part 7:

- Regulation 40; or
- Regulation 44.

Third party rights of appeal to the Secretary of State where an application is granted

147. **Paragraph 30(1) of Schedule 2** gives third party rights of appeal against certain PCT decisions. The 2012 Regulations refer to these as third party rights of appeal as they are persons other those who are party to the application and decision i.e. persons other than the applicant and the PCT. The right of appeal is to the Secretary of State who has delegated this function to the FHSAU.

148. If the PCT considers that a person notified under **paragraph 28 of Schedule 2** is a person with third party rights of appeal then it is required to notify them of that fact in their decision letter (**paragraph 30(4) of Schedule 2**).

149. **Paragraph 30(2)** confirms that for the purposes of **Schedule 2** a person has third party rights of appeal if they were entitled to receive notification of the decision to grant the application by virtue of **paragraph 28(5) of Schedule 2** – i.e. they were notified because their application was considered together with and in relation to the application to which the decision letter relates.

150. Other persons with third party rights of appeal are those:

- who were required to be notified of the application because they are on the PCT's pharmaceutical list or are entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believed might be significantly affected by the decision. This could be the PCT that granted the application, or a PCT any part of whose area is within 2 km of the proposed premises and was given *notice* of the application;
- had made written representations about the application under **paragraph 19(4) of Schedule 2**; and
- where the PCT that made the decision was satisfied that within their written or oral representations they had made a reasonable attempt to express their grounds for opposing the application. Their grounds for opposing the application must not amount to a challenge to the legality or reasonableness of the PCT's PNA or to the fairness of the process by which the PCT undertook that assessment and must not be vexatious or frivolous (**paragraph 30(3) of Schedule 2**)

151. The PCT should not give third party rights of appeal to all persons included in the pharmaceutical list or entitled to be included on that list who made representations. The PCT must consider carefully to whom it gives third party appeal rights and should not give them to persons who did not made a reasonable attempt to express their grounds for opposing the application.

152. Third party rights of appeal may not be given to LPCs, LMCs, LPS chemists, GPs, LINks or other patient, consumer or community groups.

Example

Following notification of a *routine application*, the PCT received a number of responses. Several responses did not indicate whether or not they supported the application. Such persons were not given third party rights of appeal as they had made no attempt to express their grounds for opposing the application, and indeed had not indicated whether they opposed or supported the application.

153. When a person with third party rights of appeal appeals to the FHSAU, their *notice* of appeal must contain a concise and reasoned statement of their grounds of appeal and must be sent within 30 days of the date on which they were notified of the PCT's decision (**paragraph 30(5) of Schedule 2**).

154. If a person believes that they should have been given third party rights of appeal by the PCT that made the decision but were not, they may appeal to the FHSAU against the PCT's determination not to give them rights. They must notify the FHSAU within 30 days of the date on which they were notified of the PCT's decision on the application but not given third party rights of appeal. Within that notification, they must give concise and reasoned statements as to their grounds of appeal against the decision not to give them third party rights of appeal and also against the PCT's decision on the application (**paragraph 30(6) of Schedule 2**). If their appeal is successful, they will gain third party rights of appeal in relation to the decision to grant the application.

Action to be taken by the PCT following notification of an appeal decision

155. Once the FHSAU has determined any appeal, the PCT will be notified of the decision. This notification will also include a statement of the reasons for the decision and the findings of fact (**paragraph 10(1) of Schedule 3**).

156. For the purposes of the 2012 Regulations, the FHSAU's decision becomes the PCT's decision on the matter unless the FHSAU's decision is overruled by a court (**paragraph 11 of Schedule 3**).

157. If the FHSAU has granted or confirmed the grant of the *routine application*:

- the PCT must send the applicant a template *notice of commencement*; and
- the six months within which to open take effect from the date the FHSAU makes its determination (**paragraph 10(2) of Schedule 3**).

158. If the FHSAU grants or confirms the grant of the *routine application*, the PCT must proceed as soon as is practicable to take such action under **regulation 50(4)** or **(5)** (postponement or the discontinuation of arrangements for the provision of *pharmaceutical services* by doctors) as it thinks fit, subject to any directions of the FHSAU given under **paragraph 9(2)(b) of Schedule 3**.

Conditional grant of applications where the address of the premises is unknown

159. Applicants may not always be able to identify within their *routine application* the full address of their proposed premises but will instead have given their *best estimate* as to where they will be. If the application is approved by the PCT or on appeal by the FHSAU, it is a condition of the grant of their application that they notify the PCT of the full address within six months of the date:

- on which the PCT notifies them of its decision under **paragraph 28 of Schedule 2**; or
- if the PCT's decision was appealed, the FHSAU notified its decision to grant or confirm the PCT's decision to grant the application (**paragraph 31(2)(a) of Schedule 2**).

160. The PCT may not vary or remove this condition (**paragraph 31(5) of Schedule 2**) and if the applicant fails to comply with the condition, the grant of their application lapses (**paragraph 31(6) of Schedule 2**).

161. If the grant of the original *routine application* is subject to an appeal by a person with third party rights of appeal, the six month period starts on the date on which the appeal is determined by the FHSAU (**paragraph 31(2)(b) of Schedule 2**).

162. Within 14 days of receiving the notification of the full address:

- the PCT must satisfy itself whether or not it is valid. In order to be valid, the PCT must be satisfied that the premises fall within the original *best estimate* given by the applicant (**paragraph 31(3) of Schedule 2**);
- the PCT must notify the applicant of whether or not it is satisfied that it is a valid notification;
- if it is so satisfied the PCT must notify the address to those persons notified of the decision to grant the application; and
- if the PCT is not satisfied then it must notify the applicant of its decisions and the reasons for them and explain how the applicant may exercise their rights of appeal under **paragraph 36(1)(b) of Schedule 2**.

163. The only question that the PCT is to consider at this point, therefore, is whether the actual address is within the range of locations covered by the *best estimate*. The PCT does not need to re-open the question of whether or not the reasons it originally gave for granting the application are still valid.

164. There is no right of appeal for third parties against the PCT's decision that the address is in fact within the *best estimate*. The only recourse for a third party who disagrees with the PCT's decision is via a judicial review.

Changes to the premises specified in an application after its grant but before the listing of the premises

165. Following the grant of the *routine application* which gives a specific address of where the premises would be, there may be occasions when the applicant is unable to open at that address. **Paragraph 32 of Schedule 2** makes provision for the applicant to change the address at which they intend to open.

166. Where an applicant wishes to change the premises at which they are to open, they are required to notify the PCT of the new address within:

- four months of the date on which they were sent *notice* of approval of the application; or
- if the grant of the application was appealed to the FHSAU by a person with third party rights of appeal, four months of the date on which the appeal was determined (**paragraph 32(2) of Schedule 2**).

167. In order for the notification to be valid, the PCT must be satisfied that there is good cause for the change and that the new address would neither:

- result in significant change to the arrangements that are in place for the provision of LPS or of *pharmaceutical services* (other than those provided by a person on a dispensing doctor list) in any part of its area or in a controlled locality of a neighbouring PCT where that controlled locality is within 1.6 km of the new address; nor
- cause significant detriment to the proper planning of the provision of *pharmaceutical services* in its area (**paragraph 32(3) of Schedule 2**).

168. If the PCT receives a notification of a new address then it must, within 14 days of receiving it:

- notify the applicant of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;

- if the PCT is not satisfied that it is a valid notification, it must include with that notification the reasons for its decision and an explanation of how the applicant may exercise their rights of appeal under **paragraph 32(5) of Schedule 2**.
- if it is satisfied that it is a valid notification, notify the new address to the persons notified of the decision to grant the application and include within that notification the reasons for its decision, and if the person has a right of appeal under **paragraph 32(5) of Schedule 2** an explanation of how that right of appeal may be exercised (**paragraph 32(4) of Schedule 2**).

169. A person, other than the applicant, will have third party rights of appeal in relation to a paragraph 32 notification if:

- their application was originally considered together with this application under **paragraph 28(5) of Schedule 2**; or
- they were notified of the decision on the original application either by the PCT or a neighbouring PCT because they were included in that PCT's pharmaceutical list; or

- they were entitled to be included in that list because of the grant of a *routine* or *excepted application* but are not yet included, and their interests the PCT believes would be significantly affected by the decision.

170. Such a person may appeal against the PCT's decision to amend the premises listed in the original application as long as they send a valid notice of appeal to the FHSAU within 30 days of the date on which they are notified of the change in premises (**paragraph 32(5) of Schedule 2**). The notice must include a concise and reasoned statement of the grounds of the appeal (**paragraph 32(6) of Schedule 2**).

Taking effect of listing decisions: general

171. If the *routine application* is granted, the applicant is required to submit a valid *notice of commencement* informing the PCT that they will commence the provision of services in the next 14 days (**paragraph 34(2) of Schedule 2**). The PCT then includes the applicant in their pharmaceutical list with effect from the date on the *notice of commencement*. If the date that the applicant intends to commence service provision is a public or bank holiday, the PCT may include the applicant and the premises in its pharmaceutical list, although the applicant is not obliged to open on such a day.

172. In order to be in the correct form, the *notice of commencement* must:

- include the information required under **paragraph 29 of Schedule 2**; and
- be in the same format as the version sent to the applicant by the PCT with its decision letter (**paragraph 34(3) of Schedule 2**)

173. Where the applicant undertakes to commence the provision of services within a period of less than six months and prior to the determination of the application that undertaking was not withdrawn, the *notice of commencement* must be sent within that period otherwise it will be invalid (**paragraph 34(4)(a) of Schedule 2**). If the applicant fails to submit their *notice of commencement* within this shorter timescale, the grant of the application lapses.

174. For all other applications the *notice of commencement* must be sent within six months of the dates shown in the following table (**paragraph 33(4)(b) of Schedule 2**).

Scenario	**Date on which the six month period starts**
Application granted by the PCT	Date on which the applicant is sent notice of the PCT's decision to approve under **paragraph 28 of Schedule 2**.
Refusal of the application was successfully appealed by the applicant	Date on which the FHSAU determines the appeal.
In the course of granting the application, a decision is taken to impose a condition in accordance with **regulation 35** (conditional inclusion on fitness to practise grounds) and that condition is appealed by the applicant. The applicant chooses not to open pending the outcome of the appeal.	Date on which the FHSAU determines the appeal. If at the time the First-Tier Tribunal determines the appeal, the applicant is not included in the pharmaceutical list and the First-Tier Tribunal confirms the PCT's decision or imposes a different condition, the applicant must within 30 days of being notified of the First-Tier Tribunal's decision, notify the PCT as to whether or not it wishes to withdraw the application. If the applicant notifies that they do not wish to withdraw the application the six months starts at the date of First-Tier Tribunal's decision.
The application is granted subject to a condition imposed by virtue of **paragraph 31 of Schedule 2** (conditional grant where the full address of the premises was unknown)	Date on which the applicant subsequently validly notifies the PCT of the address of the premises.
The application is granted subject to a condition imposed by virtue of **paragraph 31 of Schedule 2** (conditional grant where the full address of the premises was unknown) and the applicant successfully appeals against the PCT's decision that the notification of the full address is invalid.	The date on which the applicant is sent notice of the PCT's decision to approve under **paragraph 28 of Schedule 2**, or the FHSAU determined any appeal in relation to the original decisions on the application. The unsuccessful appeal does not extend the window period for opening.

The applicant successfully notifies of a new address under **paragraph 32 of Schedule 2**.	Date of the decision to amend the premises.
The applicant notifies of a new address under **paragraph 32 of Schedule 2**, the PCT does not accept it as a valid notification and the applicant successfully appeals.	Date on which the appeal is determined.
The applicant notifies of a new address under **paragraph 32 of Schedule 2**, the PCT does not accept it as a valid notification and the applicant unsuccessfully appeals.	Date on which the applicant is sent notice of the PCT's decision to approve under **paragraph 28 of Schedule 2** or the FHSAU determined any appeal in relation to the original decision on the application. The unsuccessful appeal does not extend the window period for opening.
The applicant successfully notifies of a new address under **paragraph 32 of Schedule 2** but a third party appeals against the PCT's decision.	The FHSAU sets the date by which the *notice of commencement* must be sent.

175. If the applicant fails to submit their *notice of commencement* within the correct timescale, the grant of that application lapses (**paragraph 34(4) of Schedule 2**).

176. During the six month period following grant of the *routine application*, the PCT may approve a longer period not exceeding a further three months (**paragraph 34(4)(c)(i)) of Schedule 2**). Should the applicant fail to submit their *notice of commencement* within that extended period, the grant of that application lapses (**paragraph 34(4) of Schedule 2**).

177. Under **paragraph 34(4)(c)(ii) of Schedule 2**, the FHSAU may allow a longer period of time if:

- the grant is appealed by a person with third party appeal rights;
- a decision to accept a notification of new premises under **paragraph 32 of Schedule 2** is appealed by a third party;
- the applicant appeals a notice to commence service provision made under **paragraph 35 of Schedule 2**; or
- the applicant successfully appeals against the PCT's decision not to allow a longer period under **paragraph 34(4)(c)(i) of Schedule 2**.

178. Should the applicant fail to submit their *notice of commencement* within that extended period, the grant of that application lapses (**paragraph 34(4) of Schedule 2**).

179. Where the PCT approves a *routine application* and issues a *notice of commencement* and the FHSAU subsequently receives a valid notice of appeal from a person with third party appeal rights relating to the grant, the *notice of commencement* shall cease to have effect (**paragraph 34(5)(a) of Schedule 2**).

180. Similarly, where the PCT accepts a notification of new premises under **paragraph 32 of Schedule 2** and the FHSAU subsequently receives a valid notice of appeal from a third party relating to that decision, the *notice of commencement* shall cease to have effect (**paragraph 34(5)(b) of Schedule 2**).

181. If, on appeal, the FHSAU grants or confirms the grant of the *routine application* for an extension of the time period within which to open, the PCT is required to send to the applicant another template of the *notice of commencement* (**paragraph 10(2)(a) of Schedule 3**).

Example

The PCT approves a *routine application* to secure better access. It issues its decision and template *notice of commencement* to the applicant. It issues its decision to interested parties as required by **paragraph 28 of Schedule 2**.

An appeal against the PCT's decision is subsequently made to the FHSAU by a person with third party appeal rights. The template *notice of commencement* sent by the PCT ceases to have effect.

The FHSAU considers the appeal and dismisses it and the PCT sends a second template *notice of commencement* giving the applicant six months from the date of the FHSAU's determination within which to open.

Notice requiring the commencement of pharmaceutical services

182. Following the approval of the *routine application*, **paragraph 35(1) of Schedule 2** allows the PCT to give notice to the applicant to commence the provision of *pharmaceutical services*. This is a reserve power that should only be used in exceptional circumstances. There are two exceptions to this. Firstly, the grant cannot have lapsed, and secondly it is not under appeal to the FHSAU or First-Tier Tribunal.

183. If the PCT gives notice that service provision is to commence, but afterwards a valid notice of appeal is given against the grant, the PCT's notice lapses (**paragraph 35(2) of Schedule 2**).

184. When giving notice, the PCT cannot require service provision to commence within the next 30 days: a longer period of notice must be given. Nor can the PCT require service

provision to commence later than nine months after the date on which the applicant was notified that their application had been approved, assuming that a three month extension had been given (**paragraph 35(3) of Schedule 2**) i.e. once a grant has lapsed, the PCT cannot require the applicant to provide services.

185. The PCT then includes the applicant on their pharmaceutical list on the date specified in the notice, unless the decision to give notice is appealed (**paragraph 35(4)(a) of Schedule 2**).

186. If the notice is appealed, the applicant is included in the pharmaceutical list as follows:

- if the appeal is discontinued, 30 days after the applicant discontinues the appeal;
- if the appeal is unsuccessful, 30 days after the appeal is determined; or
- the specified date,

whichever is the latest (**paragraph 35(4)(b) of Schedule 2**).