

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

Information for Primary Care Trusts
Chapter 11

Distance-selling premises

August 2012

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Performance	Social Care / Partnership Working

Document Purpose	Best Practice Guidance
Gateway Reference	17930
Title	Market entry by PNAs - Information for PCTs - Chapter 11
Author	Dept of Health - Medicines and Pharmacy
Publication Date	August 2012
Target Audience	PCT CEs, SHA CEs, Directors of PH, Pharmacy organisations, Primary Care Trust Commissioning, Patient groups
Circulation List	
Description	Guidance on the NHS (Pharmaceutical Services) Regulations 2012 - distance-selling applications
Cross Ref	The NHS (Pharmaceutical Services) Regulations 2012 and accompanying documents
Superseded Docs	The NHS (Pharmaceutical Services) Regulations 2005 Accompanying directions and guidance
Action Required	n/a
Timing	n/a
Contact Details	Gillian Farnfield MPI - Community Pharmacy Policy 4th Floor, Skipton House 80 London Road SE1 8LH 0207 972 2700
For Recipient's Use	

Contents

Contents.....	2
Chapter 11: Distance-selling premises.....	3
Introduction.....	3
Distance-selling premises.....	3
Information to be included in all excepted applications for distance-selling premises	5
Additional information to be provided where the applicant is not already included in the PCT's pharmaceutical list	7
Undertakings to be provided by all applicants	9
Preliminary matters to consider following receipt of an application.....	11
Failure to provide undertakings	11
Missing relevant information or documents	12
Refusal prior to notification of applications because of the language requirement for some NHS pharmacists.....	13
Refusal of applications on fitness to practise grounds prior to notification.....	14
Deferral of applications prior to notification on fitness to practise grounds	15
Action following decisions to defer an excepted application for distance-selling premises...	15
Notification.....	16
Parallel notifications.....	19
Content of notifications	19
Determination of applications	20
Flexibility with regard to determining applications.....	20
Oral hearings.....	20
Persons barred from taking part in decision making on excepted applications.....	22
Timetable for determining applications	22
Refusal, deferral and conditional inclusion in pharmaceutical lists of chemists on fitness to practise grounds	23
Refusal: same or adjacent premises	24
Refusal of distance-selling applications.....	25
Distance-selling premises: conditions limiting service provision to distance selling.....	25
Conditions relating to directed services	26
Notification, taking effect of decisions and rights of appeal	27
Notification of decisions	28
Template notice of commencement to be included with a notice of decision.....	29
Appeals to the Secretary of State by the applicant.....	29
Third party rights of appeal to the Secretary of State where an application is granted	29
Action to be taken by the PCT following notification of an appeal decision	31
Taking effect of listing decisions: general	32

Chapter 11: Distance-selling premises

1. This chapter deals with pharmacy applications for *distance-selling premises*. *Distance-selling premises* are defined in the 2012 Regulations as ‘*listed premises*, or potential pharmacy premises, at which *essential services* are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises’ (**Regulation 2**).

Introduction

2. Part 4 of the 2012 Regulations makes provision for *excepted applications*. The name arises because Section 129(2A) and (2B) do not apply to such applications and consequently they are “excepted” from the market entry test. They are therefore not required to meet a need, or to secure improvements or better access, to services.
3. Applications for *distance-selling premises* fall within this category of applications but must meet certain criteria and these are listed in **regulation 25**. There are also specific conditions in place for those who are granted inclusion on an NHS pharmaceutical list (**Regulation 64(3)**). These apply to those who apply under this exception under the 2012 Regulations and, subject to a transitional provision, those who were granted inclusion under the 2005 Regulations (**Regulation 64(1)**)
4. If an *excepted application* fails to meet any one of these criteria, it must be refused (**Regulation 25(2)**).

Distance-selling premises

Key points

- must provide the full range of *essential services* during opening hours to all persons in England presenting prescriptions;
- cannot provide *essential services* face to face;
- must have a responsible pharmacist in charge of the business at the premises throughout core and supplementary opening hours;
- must be registered with the General Pharmaceutical Council (GPhC); and
- must have premises within the PCT’s area.

5. *Distance-selling premises are excepted applications* because such applications can face obstacles in proving a need for their services within a locality, as they tend to serve populations living across a much wider area. Previously, businesses providing such services did so from established premises. A new applicant for such a pharmacy would face difficulty in proving a need for a purely postal (in the case of mail order) or remote delivery (in the case of internet-based) pharmacy service by reference to the area in which it proposed to locate. Demand would likely be very small. Patients drawn from a much wider catchment area, extending beyond the boundaries of the PCT, may well value such a service offering both improved convenience and choice.
6. The definition in **regulation 2** of “distance-selling premises” covers more than just internet pharmacies, but there is no definition of an “internet pharmacy” in law. In effect, an internet-based pharmacy is a registered pharmacy business that operates like any mail order company in that it receives and fulfils orders for medicines “remotely” from a patient or customer rather than face to face as in a traditional pharmacy.
7. Thus, to qualify as an *excepted application*, a wholly mail order or internet-based pharmacy must not provide NHS *essential services* direct to patients on the premises. It may, however, sell or supply goods that are not NHS-related. It may also provide advanced or enhanced services from its premises where these services can be provided wholly separately from the provision of *essential services* at the premises.
8. As with traditional retail pharmacies, wholly mail order or internet-based pharmacies must have premises that are registered with GPhC. All pharmacies, whether or not they provide online services, are subject to the same statutory requirements, including the requirements relating to responsible pharmacists.
9. *Distance-selling premises* must be included in the pharmaceutical list of the PCT in which the premises are located in order to provide NHS *pharmaceutical services*. If they are not included in such a list, they may not provide NHS *pharmaceutical services*.
10. All such pharmacies will also need to provide the complete range of *essential services* as set out in **Schedule 4**. As indicated above, these *essential services* cannot be provided on a face-to-face basis. Therefore, the means of delivery of such services will inevitably vary from traditional shop-front pharmacies. The full range of *essential services* must, however, be available from such pharmacies for their weekly 40 core contractual hours though many may be available for longer (supplementary hours).
11. NHS Primary Care Commissioning has prepared a briefing paper¹ to assist PCTs in understanding the requirements for service provision by this type of pharmacy.

¹ <http://www.pcc.nhs.uk/distance-selling-pharmacies> (log-in required)

Market entry by means of pharmaceutical needs assessments: distance-selling premises

12. PCTs should ensure they have set up adequate monitoring arrangements for ensuring such pharmacies are not providing *essential services* to people from or in the vicinity of the registered pharmacy premises, for example by having a “shop-front” to the registered pharmacy or delivering medicines to customers waiting in the premises’ car park.
13. The PCT may contract with such pharmacies for the provision of directed services that can be provided face-to-face, but should ensure no element of enhanced services requires the provision of *essential services*. For example, the enhanced service of supervised consumption of methadone would require the pharmacy to dispense the methadone for subsequent consumption. The dispensing of methadone is an essential service and therefore this enhanced service could not be provided at the contractor’s premises.

Information to be included in all excepted applications for distance-selling premises

14. 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.
15. When submitting an *excepted* application for *distance-selling premises*, 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, a *distance-selling* application;
 - a statement of whether the application is an *excepted application*;
 - the name and address of the applicant i.e. the name and address of the sole trader/partnership²/body corporate;
 - if the applicant is a sole trader, their GPhC registration number;

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.

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- if the applicant is a partnership, each partner's GPhC registration number³;
- 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;
- the total proposed opening hours for the premises (i.e. both *core opening* and *supplementary opening hours*);
- where the application includes for 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;
 - confirmation that the premises are accredited in respect of the provision of the 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.

16. The applicant must confirm that the application is an *excepted* rather than a *routine 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 application 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.
17. If the applicant fails to provide a precise location with the *excepted application*, this would be classed as missing relevant information for the purposes of **paragraph 11 of Schedule 2**.
18. Where an applicant submits an *excepted 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**

19. Where the application is for an *excepted application*, **paragraph 8 of Schedule 2** requires the applicant to include details that explain:
- why they believe the application satisfies the criteria set out in **regulation 25**, read with the definitions in **regulation 2**; and

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

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- why the application should not be refused under **regulation 25(2)**(see box below for further information on this).

Example

A PCT receives an *excepted application* for *distance-selling premises*. The location for the premises is the same as another pharmacy run by the applicant.

Regulation 25(2) requires the applicant to explain how the pharmacy procedures will secure:

- the uninterrupted provision of *essential services* during opening hours to persons anywhere in England who request those services; and
- the safe and effective provision of *essential services* without face to face contact between any person receiving the services, whether on their own behalf or on behalf of someone else, and the applicant or the applicant's staff.

In addition, they must explain why the PCT should not refuse the application by virtue of **regulation 31** (refusal for same or adjacent premises).

Therefore, in this case, the applicant would need to explain why the services provided at existing pharmacy on that site should not be considered part of the same service as the services that will be provided if the *excepted application* was approved.

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

20. **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, 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.
21. 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 and a declaration that each partner is 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.

22. 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;
 - 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 entitled to be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968;
 - the services they undertake to provide, if the services consist of or include the supply of appliances; and
 - if the applicant has other premises registered with the GPhC, the registration number(s) for those premises.
23. **Paragraph 3 of Schedule 2** requires them 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 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 guidance⁴. 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 *excepted application for distance-selling premises*.
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

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

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 it 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**; or
 - undertake to provide any missing information required under those paragraphs to its *home PCT* and confirm to the PCT to whom it is making the *excepted application for distance-selling premises* 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 *excepted application* is submitted or the *home PCT*. If the applicant does wish to use this flexibility, the PCT to which the *excepted application* is made must *notify* the *home PCT* of that *excepted application* and seek a recommendation from it as to whether or not the *excepted application* should be refused or deferred under **regulation 33 or 34** i.e. on fitness to practise grounds (**paragraph 13(1) of Schedule 2**).
29. The *home PCT* is required to consider whether the *excepted application* should be refused on fitness to practise grounds, and having done so must make a recommendation to the PCT that received the *excepted application* within 30 days of receiving the *notification* (**paragraph 13(2) of Schedule 2**).
30. The recommendation must set out all the relevant facts and be fully reasoned (**paragraph 13(3)(a) of Schedule 2**). If the recommendation is that the application be 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(3)(b) of Schedule 2**). The PCT should note that this is only a recommendation by the *home PCT* and therefore the PCT could come to a different conclusion if it so wished based on the facts before it.

Undertakings to be provided by all applicants

31. In addition to the information required in **Paragraphs 1 to 6 and 8 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:

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- the application is withdrawn;
- until the application is finally determined, be that by the PCT, or on appeal the FHSAU or First-tier Tribunal (FTT), 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) of Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
 - the application is withdrawn;
 - until the application is finally determined, be that by the PCT, or on appeal the FHSAU or FTT, 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)**;
- in particular, to provide all the services and perform all the activities at those 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**);
- 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 the date the premises are included in the PCT's pharmaceutical list;
 - 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 the applicant is offering to provide a *directed service* and the PCT has indicated within its PNA that there is a need for that 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 *excepted application* for *distance-selling premises* 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 their application, they

may not have been able to give the undertakings required in **paragraph 9(d) of Schedule 2**. Where this is the case, the PCT should 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 offers to provide a directed service for which there is no identified need within the PNA, the PCT is under no obligation to commission this.

32. The obligation on the applicant to provide information or documentation required by **paragraphs 1 to 6 and 8 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 must not use this provision simply to avoid determining, or to delay determining, an application.

Preliminary matters to consider following receipt of an application

33. On receipt of an *excepted application for distance-selling premises*, there are a number of preliminary matters, which the PCT must consider before proceeding with it. These matters are set out in **Part 2 of Schedule 2** and PCTs may wish to develop a checklist to ensure they consider all the matters prior to notifying the application.

Failure to provide undertakings

34. 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**).
35. 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**).

Missing relevant information or documents

36. 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).
37. 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 any fitness to practise information required under **paragraph 3 of Schedule 2** for all the partners in a partnership.
38. The PCT may make the request at any time between receiving and determining the *excepted application for distance-selling premises* 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.
39. 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**).
40. 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(2)(a) of Schedule 2**).
41. If the applicant considers that the PCT's request is not reasonable, 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**).

Market entry by means of pharmaceutical needs assessments: distance-selling premises

42. 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.
43. 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**).
44. 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 an *excepted application for distance-selling premises*. 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 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.

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

45. Where the PCT receives an *excepted application for distance-selling premises*, 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**).

46. DH issued interim guidance⁵ regarding language knowledge for GPs. PCTs may find this useful when assessing the applicant's level of knowledge of English.
47. If the *excepted application for distance-selling premises* is from a person who is not already included in the PCT's pharmaceutical list at other premises, then it will need to determine before *notification* whether or not it must refuse the application under **regulation 30 (paragraph 15 of Schedule 2)**.

Example

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

Prior to *notification*, it checks the fitness to practise information that is submitted with the application and it is noted that the pharmacist qualified in Switzerland.

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 *excepted 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 as a pharmacist.

Refusal of applications on fitness to practise grounds prior to notification

48. Where the PCT receives an *excepted application for distance-selling premises* from a person who is not already included in its pharmaceutical list at other premises, 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**).

⁵ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111901 Gateway reference 13564

Example

A PCT receives an *excepted application for distance-selling premises* from a pharmacist that is not already included in its pharmaceutical list. Prior to notifying the application to interested parties, it checks the fitness to practise information and it is noted that the pharmacist is the subject of a national disqualification. The PCT therefore refuses the application under **regulation 33(1)**.

Deferral of applications prior to notification on fitness to practise grounds

49. When the PCT receives an *excepted application for distance-selling premises* 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 34** i.e. on fitness to practise grounds (**paragraph 14(1) of Schedule 2**).
50. If the PCT decides to defer consideration of the application on fitness to practise grounds before *notification*, 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 exception to this would be where the application has been withdrawn or the PCT is required to treat it as withdrawn (see below).
51. If the applicant has a *home PCT*, the PCT that received the 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 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 delay in notifying that occurred for other reasons, for example, a delay in providing the necessary undertakings. PCTs must not use waiting for a *home PCT's* recommendation as the reason for holding up a notification.

Action following decisions to defer an excepted application for distance-selling premises

52. Where the PCT decides to defer consideration or determination of an *excepted application for distance-selling premises*, it must:
 - *notify* the applicant of its decision and the reasons for it; and

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- 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**).
53. 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*.
54. Where the applicant is not already included in the PCT's pharmaceutical list and the PCT decides to defer the *excepted 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**).
55. If the applicant informs the PCT within the specified period that they do not wish to proceed with the *excepted 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

56. 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 or 16 of Schedule 2**, or to defer it, the PCT must give notice of an *excepted application* for *distance-selling premises* to:
- the LPC for its area, which may be an LPC that it shares with another PCT;
 - the 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 was granted;
 - any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application was 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

Market entry by means of pharmaceutical needs assessments: distance-selling premises

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**).

57. 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**).
58. It is recommended that the PCT records its reasoning for why it believes persons have a significant interest in the outcome of the application.
59. For *distance-selling applications*, it is sufficient to *notify* those persons listed above along with the nearest neighbouring PCT(s). There is no need to *notify* all PCTs of such applications.
60. 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 was 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

The PCT receives an *excepted application for distance-selling premises* 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.

61. 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;

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- any person in its pharmaceutical list whose interests the PCT believes might be significantly affected if the application was 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 was granted;
 - any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application was 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**).
62. 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.
63. 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**)
64. 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.
65. 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.
66. 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

67. If the PCT wishes to consider two or more applications together and in relation to each other, it is required by **paragraph 22(3) of Schedule 2** to give notice to the applicants of its intention to do so.

Content of notifications

68. **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**)
69. 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**).
70. 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.
71. If the applicant advises the PCT that they consider:
- any information 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**).

72. 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 an *excepted application for distance-selling premises*. They request that their name is removed from 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.

Determination of applications

Flexibility with regard to determining applications

73. The PCT is able to determine an *excepted application for distance-selling premises* 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).
74. The PCT may determine an *excepted 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.
75. 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 together then it may do so but it must give notice of this to the applicants concerned before determining the applications.

Oral hearings

76. 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.

77. If the PCT decides to hear oral representations prior to determining an *excepted application* 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**)
78. **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 *excepted applications for distance-selling premises* 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 on the application in their written representation.
79. 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.
80. If the PCT decides at or after the oral hearing that an 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 excepted applications

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

Timetable for determining applications

82. **Paragraph 27 of Schedule 2** requires PCTs to determine *excepted applications* which are *notifiable* applications 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**).
83. 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 month time period starts
PCT receives a deficient <i>excepted application for distance selling premises</i>	The four month time 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. It then restarts, back at the beginning, at the point all the relevant information or documentation is received.
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 time period initially starts at the point the application, and all relevant information, 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, the applicant has updated their application and has indicated that it wishes the application to proceed.

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

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

85. 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 *excepted application for distance-selling premises*, or alongside. Whichever course of action is taken, the PCT must come to a decision on the fitness to practise information in advance of determining the *excepted application*. It is not possible for PCTs to approve the *excepted application*, subject to the satisfactory approval of the fitness to practise information.
86. Part 6 of the 2012 Regulations sets out the grounds on which the PCT:
- must or may refuse the *excepted application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 33**);
 - may defer consideration of the *excepted application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 34**); and
 - may grant the *excepted application* for inclusion in the pharmaceutical list subject to efficiency conditions and conditions to combat fraud (**Regulation 35**).
87. Further information on these provisions can be found in guidance⁶ issued by DH.
88. Where the *excepted application* has been made by someone who is not already included in the PCT's pharmaceutical list, there are additional actions that the PCT must undertake prior to determining the *excepted application*. **Paragraph 23(1) of Schedule 2** requires the PCT to:
- where the applicant is an individual, check with NHS Business Services Authority Counter Fraud Service, now better known as NHS Protect⁷ 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 NHSLA⁸) 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

⁶ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206 Gateway reference 4728

⁷ <http://www.nhsbsa.nhs.uk/fraud>

⁸ <http://www.fhsaa.tribunals.gov.uk/index.htm>

Market entry by means of pharmaceutical needs assessments: distance-selling premises

conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information 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** (i.e. on fitness to practise grounds) or whether conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information 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.

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

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

90. If the PCT is minded to impose conditions under **regulation 35** (conditional inclusion) then 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**).

Refusal: same or adjacent premises

91. Where the premises within *an excepted application for distance-selling premises* 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**.

92. The PCT must refuse *an excepted application for distance-selling premises* 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

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- 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)**).

93. 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.

Refusal of distance-selling applications

94. **Regulation 25(2)** sets out two circumstances when PCTs must refuse *excepted applications for distance-selling premises*.

95. **Regulation 25(2)(a)** requires PCTs to refuse applications if the premises to which the application relates are on the same site or in the same building as a provider of primary medical services with a patient list. This is one of the safeguards previously promised in connection with this type of application to avoid circumstances arising where patients of the provider of primary medical services inadvertently present prescriptions for dispensing at the pharmacy, even though such dispensing to patients on the site is not permitted.

96. The second reason for refusing such an application is where the PCT is not satisfied by the *pharmacy procedures* for the premises are likely to secure:

- the uninterrupted provision of *essential services* throughout the opening hours of the premises to persons anywhere in England who request those services (**Regulation 25(2)(b)(i)**); and
- the safe and effective provision of *essential services* without face to face contact between any person receiving these services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff (**Regulation 25(2)(b)(ii)**).

Distance-selling premises: conditions limiting service provision to distance selling

97. When considering an *excepted application for distance-selling premises*, **regulation 25(2)** sets two specific conditions that applications must meet. Once such applications are approved and the applicant is included in the PCT's pharmaceutical list, **regulation 64(3)** places further conditions on that inclusion. It also applies to applications for *distance-selling premises* that were approved under **regulation 13(1)(d)** of the 2005 Regulations.

98. These conditions remain even if the pharmacy successfully applies to relocate to new premises (**Regulation 64(2)(b)**). The conditions are:
- the contractor must not offer to provide *pharmaceutical services*, other than *directed services*, to persons who are present at the pharmacy premises (**Regulation 64(3)(a)**). For these purposes, a person is “present at” the premises if they are in the vicinity of those premises;
 - the means by which the contractor provides *pharmaceutical services*, other than *directed services* must be such that any person receiving those services does so otherwise than at the pharmacy premises (**Regulation 64(3)(b)**);
 - the pharmacy premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list (**Regulation 64(3)(c)**);
 - the *pharmacy procedures* (as required by section 72A(3) of the Medicines Act 1968⁹ for the premises must be such as to secure:
 - the uninterrupted provision of *essential services* during opening hours to persons anywhere in England who request those services; and
 - the safe and effective provision of *essential services* without face to face contact between any person receiving the services (whether it is on their own or on someone else’s behalf) and the contractor or the contractor’s staff (**Regulation 64(3)(d)**); and
 - there should be nothing in a distance selling contractor’s practice leaflet, publicity material, or in direct communications with patients to suggest that the *essential services* the contractor is supplying are for particular areas of England, i.e. are anything other than a nationwide operation. Also that they do not dispense drugs or appliances ordered on NHS prescription forms or repeatable prescriptions presented by particular categories of patient. This is to ensure that the contractor provides *essential services* to all categories of patient and not, for example, that their business is tailored towards servicing care homes (**Regulation 64(3)(e)**).
99. PCTs may not vary or remove these conditions (**Regulation 64(4)**).

Conditions relating to directed services

100. Where the *excepted application for distance-selling premises* is made under the 2012 Regulations and as part of the application, the applicant undertook:
- to provide the *directed services*, if the PCT commissioned them within three years, of the date the premises are included in the pharmaceutical list;

⁹ <http://www.legislation.gov.uk/ukpga/2006/28/section/30/prospective> as amended by SI 2006/2407

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- if the *directed services* were 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)**.

101. 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 to unreasonably withhold agreement to the service specification.
102. However, for the condition to apply, the PCT is required to commission the services within three years of the date on which the new premises are included in the pharmaceutical list.
103. 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 a mutually convenient commencement date for the *directed services* (**Regulation 66(6)(b)**), whichever is the sooner.
104. PCTs may not vary or remove the condition imposed by virtue of **regulations 66(3) to (5) (Regulation 66(7))**.

Notification, taking effect of decisions and rights of appeal

105. Once the PCT has made a decision on the *excepted application*, it must as soon as practicable *notify* certain persons of its decision (**paragraph 28(1) of Schedule 2**).
106. The 2012 Regulations make provision for certain persons to have a right of appeal against the PCT's 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;

Market entry by means of pharmaceutical needs assessments: distance-selling premises

- information on the FHS AU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website¹⁰. If there is a right of appeal on a matter related to fitness to practise, the appeal is to the FTT and its contact details must instead be provided by the PCT.

107. 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

108. Once the PCT has made a decision on the *excepted application for distance-selling premises*, it must, as soon as is practicable, *notify* certain persons of its decision (**paragraph 28(3) of Schedule 2**). Those persons are:

- the applicant;
- any LPC for its area which may be an LPC that it shares with another PCT;
- any LMC for its area which may be an LMC that it shares with another PCT; and
- any person notified under **paragraph 19** (including by a neighbouring PCT) who made representations under **paragraph 19(4) of Schedule 2**.

109. 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. The *notification* of the decision must include a statement from the PCT of the reasons for that decision (**paragraph 28(6) of Schedule 2**).

110. If the PCT decided to consider two or more applications together pursuant to **paragraph 22(3) of Schedule 2**, it must give notice to each applicant of the decision taken with regard the other application(s) considered with their application (**paragraph 28(5) of Schedule 2**).

¹⁰ <http://www.nhsla.com/ContactUs/>

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

111. If the PCT grants the *excepted 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. in the case of pharmacy premises *essential* 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;
 - 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**).
112. The PCT may wish to pre-populate the form where it holds the information.

Appeals to the Secretary of State by the applicant

113. **Paragraph 36(1) of Schedule 2** gives the applicant rights of appeal against certain PCT decisions. The right of appeal against 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 to the FHSAU against a decision by the PCT:
- to refuse the application on grounds set out in **regulation 25**;
 - to refuse the application on some of the grounds set out in Part 5 or;
 - to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**; or
114. 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**).

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

115. **Paragraph 30(1) of Schedule 2** gives third party rights of appeal against certain PCT decisions that are not fitness related. The 2012 Regulations refer to these as third party rights of appeal as they are persons other than 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 NHSLA's FHSAU.

116. 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**).
117. **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.
118. 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;
 - they made written representations about the application under **paragraph 19(4) of Schedule 2**; and
 - the PCT that made the decision is satisfied that within their written or oral representations they 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**)
119. 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 carefully consider to whom it gives third party appeal rights and should not give them to persons who did not make a reasonable attempt to express their grounds for opposing the application.
120. 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 an *excepted application for distance-selling premises*, 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 not attempted to express their grounds for opposing the application, and indeed had not indicated whether they opposed or supported the application.

121. When a person with third party rights of appeal appeals to the FHS AU, 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**).
122. 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 FHS AU against the PCT's determination not to give them rights. They must *notify* the FHS AU 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 on the procedural point is successful then 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

123. Once the FHS AU 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**).
124. For the purposes of the 2012 Regulations, the FHS AU's decision becomes the PCT's decision on the matter unless the FHS AU's decision is overruled by a court (**paragraph 11 of Schedule 3**).
125. If the FHS AU has granted or confirmed the grant of the *excepted 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 FHS AU makes its determination (**paragraph 10(2) of Schedule 3**).

126. Generally, where the FHS AU grants or confirms the grant of an *excepted 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 FHS AU given under **paragraph 9(2)(b) of Schedule 3**. However, these “gradualisation” arrangements do not apply where the new pharmacy premises are distance-selling premises, as the presence of distance-selling premises are discounted for the purposes of considering whether a patient can receive services from a dispensing doctor (See Chapter 15 for further information on this).

Taking effect of listing decisions: general

127. If the *excepted application* is granted, the applicant is required to submit a valid *notice of commencement* informing the PCT that they are to 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 as the applicant is not obliged to open on such a day.
128. 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**)
129. Where the applicant undertakes to commence the provision of services within a period of less than six months and 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.

130. 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 , unless the grant is appealed by a person with third party appeal rights, in which case the period starts on the date of determination of an unsuccessful appeal.
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 was 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 to the FTT	The applicant can temporarily accept the condition and open within the normal timeframes, but if it prefers, it can await the outcome of the decision of the FTT. If the FTT confirms the PCT's decision or imposes a different condition, the applicant must within 30 days of being notified of the FTT's decision, <i>notify</i> 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 (or won it on appeal), the six months starts at the date of the FTT's decision.

131. 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**).
132. During the six month period following grant of the *excepted 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, then the grant of that application lapses (**paragraph 34(4) of Schedule 2**).

133. 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; 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**.
134. Should the applicant fail to submit their *notice of commencement* within that extended period, then the grant of that *excepted application* lapses (**paragraph 34(4) of Schedule 2**).
135. Where the PCT approves an 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 of that application, the *notice of commencement* shall cease to have effect (**paragraph 34(5)(a) of Schedule 2**).
136. If, on appeal, the FHSAU grants or confirms the grant of the *excepted 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 an *excepted application for distance-selling premises*. 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.