

## SCHEDULE 2

Regulation 10(6)

Applications in respect of pharmaceutical lists and the procedures to be followed

### PART 1

Information to be included in routine and excepted applications

#### **Information to be included in all routine and excepted applications**

1.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications.

(2) The name of the Primary Care Trust to which the application is made.

(3) The type of application being made (for example, the application is for inclusion in a pharmaceutical list and a change of ownership application), including a statement of whether the application is a routine or an excepted application.

(4) The name and address of the applicant (A).

(5) If A is an individual or a partnership carrying on a retail pharmacy business, A or each partner's registration number in the GPhC register.

(6) If A is a body corporate carrying on a retail pharmacy business, the name and registration number in the GPhC register of A's superintendent.

(7) If A is seeking the listing of premises not already listed in relation to A (whether or not A is already listed)—

(a) either—

(i) the address of the premises, or

(ii) if the address is not known and it is a routine application, A's best estimate of where the proposed premises will be;

(b) whether the applicant is currently in possession of the premises;

(c) the proposed core opening hours in respect of the premises; and

(d) the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).

(8) If A is seeking to provide directed services—

(a) details of the directed services to be provided;

(b) confirmation that A is accredited to provide the services, where that accreditation is a prerequisite for the provision of those services;

(c) confirmation that the premises are accredited in respect of the provision of the services, where that accreditation is a prerequisite for the provision of those services; and

(d) a floor plan showing the consultation area where A proposes to offer directed services (where relevant, unless one cannot be provided for reasons that are good cause).

(9) A is not entitled to ask for a routine application to be considered, in the alternative, as an excepted application, or for an excepted application to be considered, in the alternative, as a routine application.

(10) An estimate of the location of premises is only a "best estimate" for the purposes of subparagraph (7)(a)(ii) if the Primary Care Trust to whom the application is made is satisfied that—

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- (a) it is the best estimate that A can reasonably make at the time of the application of the location of the premises; and
- (b) its reasons for granting or refusing the application would be essentially the same if the applicant located, if the application was granted, at any location within the range of possible locations covered by the estimate.

**Information to be included in all routine and excepted applications for inclusion in a pharmaceutical list**

2.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

(2) If the applicant (A) is an individual or a partnership—

- (a) A's or each partner's full name;
- (b) A's or each partner's sex;
- (c) A's or each partner's date of birth;
- (d) A's or each partner's private address and telephone number;
- (e) a declaration that A or each partner is a registered pharmacist, if A is seeking entry in the list mentioned in regulation 10(2)(a);
- (f) if A is a partnership, a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act<sup>(1)</sup> (general provisions), if A is seeking entry in the list mentioned in regulation 10(2)(a); and
- (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register.

(3) If A is a body corporate—

- (a) A's registered name and any other name under which A trades;
- (b) A's company registration number;
- (c) A's registered office and any fixed line telephone number relating to that office;
- (d) the private address and date of birth of A's superintendent (if A is seeking entry in the list mentioned in regulation 10(2)(a));
- (e) the name, private address and date of birth of each director of A (who is not A's superintendent), and if any director of A (who is not A's superintendent) is a registered pharmacist, that director's registration number in the GPhC register;
- (f) a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act, if A is seeking entry in the list mentioned in regulation 10(2)(a); and
- (g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register.

(4) If the services that A undertakes to provide consists of or includes the supply of appliances, the appliances A undertakes to supply.

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(1) Section 69 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1, Part 12, and by S.I. 1976/1213, 2007/289 and 3101 and 2010/231.

### **Fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list**

3.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list, as regards any person (P) who is—

- (a) the individual who is making the application;
- (b) a partner in the partnership that is making the application; or
- (c) a director or (if A is seeking entry in the list mentioned in regulation 10(2)(a)) superintendent of the body corporate that is making the application.

(2) Details of whether P—

- (a) has been convicted of any criminal offence in the United Kingdom;
- (b) has been bound over following a criminal conviction in the United Kingdom;
- (c) has accepted a police caution in the United Kingdom;
- (d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging P absolutely (without proceeding to conviction); or
- (e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(2) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(3) (penalty as alternative to prosecution).

(3) Details of whether P has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which P is currently subject—

- (a) in the United Kingdom; or
- (b) elsewhere than the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's fitness to practise by a licensing body—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(6) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's professional conduct by an employer—

- (a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or
- (b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(7) If P is a pharmacist, details of P's—

- (a) pharmaceutical qualifications (including where obtained); and

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(2) 1995 c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; and the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1).

(3) 1992 c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and has been amended by the Social Security Fraud Act 2001 (c. 11), section 14.

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(b) professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why P was dismissed from any post (if not already covered by the details provided pursuant to sub-paragraph (6)(b)).

(8) If P is a pharmacist, names and addresses of 2 referees who are willing to provide references in respect of 2 recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, details of why and the names and addresses of alternative referees who are acceptable to the Primary Care Trust.

(9) If P is, to P's knowledge, or has been subject to any investigation or proceedings that could lead or could have led to P's removal from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(10) If P is, to P's knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(11) If P has been refused inclusion in, or conditionally included in, or contingently removed or suspended from, any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of same.

(12) If P is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

- (a) any deferment of that application; or
- (b) refusal or conditional inclusion where the refusal or conditional inclusion has not yet reached its final outcome.

(13) If P—

- (a) is the person making the application; and
- (b) qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom, details that demonstrate that P has the level of knowledge of English which, in the interests of P and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the Primary Care Trust.

#### **Fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list**

4.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list by a body corporate (C1)—

- (a) as regards C1; or
- (b) as regards any other body corporate (C2) of which a director or superintendent of C1—
  - (i) is a director or superintendent or has been a director or superintendent in the 6 months prior to the date of the application, or
  - (ii) has been a director or superintendent for more than 6 months prior to the date of the application, where they were a director or superintendent of C2 at the time of the originating events to which the information relates.

(2) Details of any convictions that C1 or C2 has for offences committed in the United Kingdom that are not spent convictions.

(3) Details of whether C1 or C2 (being corporate bodies registered within the United Kingdom) has at any time been convicted of an offence elsewhere than in the United Kingdom where the

originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

- (4) Details of any criminal proceedings to which C1 or C2 is currently subject—
  - (a) in the United Kingdom; or
  - (b) elsewhere than in the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.
- (5) Details of any investigation to which C1 or C2—
  - (a) is, to its knowledge, subject by the General Pharmaceutical Council in relation to an entry in Part 3 of the GPhC register; or
  - (b) has been subject by the General Pharmaceutical Council, the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland in relation to an entry in the register required to be kept under section 75 of the 1968 Act<sup>(4)</sup> (registration of premises), the outcome of which was averse.
- (6) If C1 or C2, to its knowledge, is or has been subject to any investigation or proceedings that could lead or could have led to its removal from a relevant list, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.
- (7) If C1 or C2 is, to its knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.
- (8) If C1 or C2 has been refused inclusion in, or conditionally included in (other than by reason of a condition imposed under Part 9), a relevant list, details of that refusal or conditional inclusion.
- (9) If C1 or C2 is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—
  - (a) any deferment of that application; or
  - (b) any refusal or conditional inclusion, where the refusal or conditional inclusion has not yet reached its final outcome.

### **Providing fitness information instead to a home Primary Care Trust**

- 5.—(1) Where an applicant is a body corporate with a registered office in England—
  - (a) it may provide any information that it is required to include in a routine or excepted application (“the current application”) pursuant to paragraph 3 or 4 to its home Primary Care Trust instead of to the Primary Care Trust to which it is making the current application (PCT1), if different; and
  - (b) if it has already provided information to its home Primary Care Trust on a previous occasion, it need not provide that information again to its home Primary Care Trust in relation to the current application.
- (2) An applicant relying on paragraph (1) must, when making its application—
  - (a) confirm to PCT1 that A’s home Primary Care Trust already has all the information required under paragraphs 3 and 4; or
  - (b) undertake to provide any missing information required under those paragraphs to its home Primary Care Trust and confirm to PCT1 when that has taken place.

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(4) Amended by [S.I. 1968/1699](#) and [2010/231](#).

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### **Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises**

6. If, as regards a routine or excepted application—
- (a) for inclusion in a pharmaceutical list by a person not already included; or
  - (b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person,

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.

### **Additional information to be included with routine applications**

7.—(1) If an applicant (A) is making a routine application and is seeking to satisfy a Primary Care Trust that granting that application would meet a need for pharmaceutical services, or secure improvements to or better access to pharmaceutical services, in circumstances where—

- (a) that need, those improvements or that better access has or have been identified in the Primary Care Trust's pharmaceutical needs assessment, A must include in that application details that explain how A intends to meet that need, or secure those improvements or that better access (in whole or in part); or
- (b) that need, those improvements or that better access has or have not been identified in the Primary Care Trust's pharmaceutical needs assessment, A must include in that application, details that explain A's belief that regulation 18(1)(b) is satisfied in relation to that application.

(2) Where an applicant includes information in an application pursuant to paragraph (a) but not paragraph (b) of sub-paragraph (1), the Primary Care Trust must not consider whether regulation 18(1)(b) applies in relation to that application when it determines that application.

### **Additional information to be included with excepted applications**

8. If the applicant (A) is making an excepted application, A must include in that application details that explain—

- (a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act<sup>(5)</sup> (regulations as to pharmaceutical services) are not to apply in relation to that application; and
- (b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

### **Undertakings**

9. An applicant (A) must provide the following undertakings—
- (a) an undertaking to notify the Primary Care Trust within 7 days of any material changes to the information provided in the application that occur before—
    - (i) the application is withdrawn,
    - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or

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(5) Section 129(2A) and (2B) were inserted by the Health Act 2006 (c. 21), section 26(3).

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- (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;
- (b) an undertaking to notify the Primary Care Trust if A is included, or applies to be included, in any other relevant list before—
  - (i) the application is withdrawn,
  - (ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
  - (iii) if the application is granted, A commences the provision of the services to which the application relates,whichever is the latest of these events to take place;
- (c) if A is seeking inclusion in a pharmaceutical list or (if A is already listed in that list) the listing of premises in relation to A that are not already listed in relation to A, an undertaking—
  - (i) to comply with all the obligations that are to be their terms of service under regulation 11 if the application is granted, and
  - (ii) in particular, in relation to any proposed pharmacy premises, to provide all the services and perform all the activities at those premises that are required under the terms of service to be provided or performed as or in connection with essential services; and
- (d) if A is seeking to provide directed services an undertaking—
  - (i) that A will provide the directed services mentioned in the application, if the Primary Care Trust does commission the services from A within 3 years of the date 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,
  - (ii) if the services are commissioned by the Primary Care Trust, that A will provide the services in accordance with an agreed service specification, and
  - (iii) A's agreement to a service specification will not be unreasonably withheld.

### **Nature of details to be supplied**

**10.** Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy the Primary Care Trust in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Primary Care Trust may need to make of the information or documentation when carrying out its functions.

## **PART 2**

### **Preliminary matters**

#### **Relevant information or documentation**

**11.—(1)** As regards any routine or excepted application, if the Primary Care Trust to which the application is made considers that relevant information or documentation is missing—

- (a) it may request the missing relevant information or documentation from the applicant; and

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- (b) the applicant must, within the period reasonably specified by the Primary Care Trust in the request under paragraph (a)—
  - (i) provide any information or documentation reasonably requested,
  - (ii) notify the Primary Care Trust that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or
  - (iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the Primary Care Trust of that and seek a review by the Primary Care Trust of the reasonableness of the request.
- (2) If an applicant refuses to comply with a request under sub-paragraph (1)(a)—
  - (a) within the period—
    - (i) reasonably specified by the Primary Care Trust under paragraph (1)(b), or
    - (ii) ending on the date specified by the applicant in accordance with paragraph (1)(b)(ii), if the Primary Care Trust is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,unless paragraph (b) applies, the application is to be treated as withdrawn;
  - (b) in circumstances where the applicant has, in accordance with sub-paragraph (1)(b)(iii), sought a review by the Primary Care Trust of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—
    - (i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the Primary Care Trust for the provision of that information or documentation,
    - (ii) need not be provided by the applicant, the request of the Primary Care Trust is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.
- (3) A Primary Care Trust may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application, but it must consider whether or not it needs to request information or documentation under this paragraph prior to notifying an application (where it is required to do so) under Part 3.

### **Failure to provide undertakings**

**12.**—(1) If, when an applicant (A) submits an application, A fails to provide with the application the undertakings referred to in paragraph 9 that are relevant to the application, the Primary Care Trust must, prior to notifying the application under Part 3, request that A provide the relevant undertakings within a specified period.

(2) If A fails to comply with a request under sub-paragraph (1) within a period reasonably specified by the Primary Care Trust under that sub-paragraph, the application is to be treated as withdrawn.

### **Functions of a home Primary Care Trust in relation to certain applications**

**13.**—(1) Where an applicant (A) is relying on paragraph 5(1), the Primary Care Trust to which A's application is made (PCT1) must notify A's home Primary Care Trust (PCT2) of the application and seek a recommendation from it as to whether the application should be refused or deferred under regulation 33 or 34.

(2) Where it receives a notification under sub-paragraph (1), PCT2 must consider whether the application should be refused or deferred under regulation 33 or 34, and having done so, it must make a recommendation to PCT1 within 30 days of having received the notification.

(3) The recommendation must—

- (a) set out all the relevant facts and be fully reasoned; and
- (b) if it is that the application be refused or deferred, be sent by PCT1 as soon as is practicable to A, and PCT1 must at the same time seek the views of A on the accuracy of the facts set out by PCT2.

#### **Deferral of notifiable applications prior to notification**

**14.**—(1) A Primary Care Trust that receives—

(a) a routine application, consideration of which may or must be deferred under regulation 14(1) to (3), 16(1) to (4), 19(1) to (4), 21(1) to (4) or 38(4); or

(b) a notifiable application, consideration of which may be deferred under regulation 32 or 34, must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not to defer consideration of that application under those provisions.

(2) If consideration of the application is deferred prior to notification, once the Primary Care Trust no longer has grounds for deferring the application, it must proceed as soon as is practicable with the notification of the application, unless the application has been withdrawn or the Primary Care Trust is required to treat it as withdrawn.

(3) Notification must not be delayed because of a deferral under regulation 34 in a case where the applicant is relying on paragraph 5(1), unless prior to the decision to defer the applicant's home Primary Care Trust has provided PCT1 with its recommendation under paragraph 13(2).

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

**15.** A Primary Care Trust that receives a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list may, without notifying that application under Part 3 (or if no notification is required, as soon as is practicable), decide to refuse that application under regulation 30.

#### **Refusal of notifiable applications on fitness grounds prior to notification**

**16.** A Primary Care Trust that receives a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list may, without notifying that application under Part 3, decide to refuse that application under regulation 33(1).

#### **Proposed new pharmacy premises in controlled localities: refusal of routine applications because of preliminary matters prior to notification**

**17.** A Primary Care Trust that receives a routine application where the applicant is seeking the listing of pharmacy premises must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not the application needs to be refused under regulation 40(2).

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## PART 3

### Notification of certain applications

#### Applications requiring notifications

**18.** An application is a “notifiable application” for the purposes of this Schedule if—

- (a) it is a routine application; or
- (b) it is an excepted application pursuant to regulation 24, 25 or 26(2),

and the Primary Care Trust to whom the application was made has not decided to dispense with the notification pursuant to paragraphs 15 to 17.

#### Notification procedure for notifiable applications

**19.—**(1) As soon as is practicable (having regard to its functions under Part 2), the Primary Care Trust (PCT1) must give notice of a notifiable application to—

- (a) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (b) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
- (c) any person—
  - (i) included in its pharmaceutical list, or
  - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;

- (d) any LPS chemist—
  - (i) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
  - (ii) whose interests might, in the opinion of PCT1, be significantly affected if the application were granted;
- (e) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (f) if the applicant is seeking to locate premises in, or within 1.6 kilometres of, a controlled locality in its area—
  - (i) any provider of primary medical services, or
  - (ii) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services); andwho, in the opinion of PCT1, has a significant interest in the outcome of the application;
- (g) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the proposed listed chemist premises to which the application relates.

(2) PCT1 may also give notice of the notifiable application to any other person who, in the opinion of PCT1, has a significant interest in the outcome of the application.

(3) A Primary Care Trust notified under sub-paragraph (1)(g) (PCT2) must, within 14 days of receiving the notification—

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- (a) give notice of the application to—
    - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
    - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the application,
    - (iii) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included, whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
    - (iv) any LPS chemist—
      - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT2, be significantly affected if the application were granted,
    - (v) any relevant local involvement network, and any other patient, consumer or community group in its area which, in the opinion of PCT2, has a significant interest in the outcome of the application, and
    - (vi) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in its area—
      - (aa) any provider of primary medical services, or
      - (bb) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services), who, in the opinion of PCT2, has a significant interest in the outcome of the application; and
  - (b) notify PCT1 of the action that it has taken under sub-paragraph (a).
- (4) Those notified under sub-paragraphs (1) to (3)(a) may make representations in writing about the application that is the subject of the notification to PCT1, provided they do so—
- (a) within 45 days of the date on which notice of the application was given to them; or
  - (b) in the case of notifications under sub-paragraph (2) or (3), within such longer period as PCT1 may specify.

### **Parallel notifications**

**20.**—(1) If the Primary Care Trust is considering, as a consequence of a notifiable application, making (including revising) a determination as to whether or not an area is or is not to be part of a controlled locality, it must give notice under this Part at the same time that it gives notice under regulation 38(1).

(2) If, as a consequence of a notifiable application, a Primary Care Trust is required, by virtue of regulation 41 to determine whether or not an area is a reserved location, the Primary Care Trust must consider giving notice under this Part at the same time that it gives notice under regulation 41(4).

### **Content of notifications**

**21.**—(1) A person notified under paragraph 19 (P)—

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- (a) must be informed—
    - (i) of P’s right to make representations under paragraph 19(4);
    - (ii) of the circumstances in which notified persons would be permitted, pursuant to paragraph 25, to make oral representations at any oral hearing relating to the application, and
    - (iii) if the Primary Care Trust intends to consider the application together and in relation to any other application, of that intention;
  - (b) need not be given the same information as other persons notified under paragraph 19 but, subject to sub-paragraphs (2) to (4), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P’s interest in the matter.
- (2) P need not be provided with any information that is published as part of the Primary Care Trust’s pharmaceutical needs assessment.
- (3) P must not be provided with—
- (a) information supplied by the applicant (A), or where applicable A’s home Primary Care Trust, under paragraphs 2 to 5 or 13; and
  - (b) any private addresses, private telephone numbers or dates of birth supplied by A.
- (4) If A advises the Primary Care Trust that—
- (a) information supplied by A is considered by A to be confidential to A; and
  - (b) A does not consent to the information being disclosed as part of the notification,
- the Primary Care Trust must withhold that information from P if it considers that the full disclosure principle does not require it to provide that information to P.
- (5) The “full disclosure principle” is 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, unless it is fair and proper for that information to be withheld from that individual.
- (6) If information is being withheld from P under paragraph (4), P must be informed of the nature of the information that is being withheld from P.

## PART 4

### Determination and deferral of applications

#### **Flexibility with regard to determining or deferring applications**

**22.**—(1) Except in so far as these Regulations provide to the contrary, a Primary Care Trust is to determine or defer routine and excepted applications in such manner (including with regard to procedures) as it sees fit.

(2) A Primary Care Trust may determine a routine or excepted application without hearing any oral representations, if it considers that oral representations are unnecessary.

(3) Where appropriate, a Primary Care Trust may if it thinks fit consider 2 or more applications together and in relation to each other, but where it does so, it must give notice to the applicants of its intention to do so (if it has not already done so under Part 3).

### **Additional matters for consideration in relation to applications for inclusion in a pharmaceutical list**

**23.**—(1) In the case of a routine or excepted application by a person (A) for inclusion in a pharmaceutical list who is not already included in it, a Primary Care Trust must, prior to determining the application—

- (a) check with the NHS BSA whether A, and if A is a body corporate whether any director or superintendent of A, has any record of, or is under investigation for, fraud;
  - (b) check with the Secretary of State whether the Secretary of State holds any information about A, and if A is a body corporate about any director or superintendent of A, that is relevant to its consideration of whether—
    - (i) the application should be refused or deferred under regulations 33 or 34, or
    - (ii) conditions should be imposed under regulation 35;
  - (c) take up references from, and check the references provided by, the referees whose details A is required to provide pursuant to paragraph 3(8).
- (2) In such a case, having considered whether—
- (a) the application should be refused or deferred under regulations 33 or 34; or
  - (b) conditions should be imposed under regulation 35,

if it is minded to impose conditions under regulation 35, it must notify A at least 7 days in advance of determining that it is to impose such conditions and consider any representations (which may be at an oral hearing) that A makes prior to the determination with regard to the notification.

### **Action following deferrals**

**24.**—(1) Where a Primary Care Trust (PCT1) receives a routine or excepted application, consideration or determination of which may be deferred, if it does decide to defer consideration or determination of that application (whether before or after the application is notified, in the case of a notifiable application), it must—

- (a) notify the applicant (A) of its decision and the reasons for it; and
  - (b) where possible, notify A of the period for which the application is being deferred (if necessary by reference to a future event rather than a period of time).
- (2) If the application is—
- (a) a routine application, consideration of which may be deferred under regulation 14(1)(a), 16(1)(a), 19(2)(a) or 21(1)(a), it must proceed as soon as is practicable to invite other applications under regulation 14(1)(b), 16(1)(b), 19(2)(b) or 21(1)(b), in such manner as it sees fit;
  - (b) a routine application, consideration of which may be deferred under regulation 14(2), 16(3), 19(3) or 21(3), it must make arrangements that enable it to consider the other applications at the same time as A's application, as soon as is practicable;
  - (c) a routine application, consideration of which may be deferred under regulation 14(3), 16(4), 19(4) or 21(4), it must, once the appeal relating to the other application has reached its final outcome, notify A of that outcome and that A must within a specified period (of not less than 30 days)—
    - (i) update A's application, and
    - (ii) notify PCT1 as to whether or not A still wishes to proceed with the application;

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- (d) a routine application, consideration of which may be deferred under regulation 16(2) or 21(2), it must keep under regular review the issue of whether the future circumstances that gave rise to the deferral have arisen;
  - (e) a routine application, consideration of which may be deferred under regulation 32, it must—
    - (i) send A a copy of the designation that led to the decision,
    - (ii) review that decision once the designation that led to the decision has been cancelled or is varied in a manner which means the application may no longer be deferred under regulation 32,
    - (iii) notify A of the cancellation or variation, and
    - (iv) require A within a specified period (of not less than 30 days)—
      - (aa) to update A's application, and
      - (bb) to notify PCT1 as to whether or not A still wishes to proceed with the application;
  - (f) a routine or excepted application, consideration of which may be deferred under regulation 34, once the outcome of the cause for the deferral is known, PCT1 must notify A that A must within a specified period (of not less than 30 days)—
    - (i) update A's application; and
    - (ii) notify PCT1 as to whether or not A still wishes to proceed with the application; and
  - (g) a routine application, consideration of which must be deferred under regulation 38(4), it must proceed, as soon as is practicable, with the determination of whether the relevant area is or is not to be part of a controlled locality.
- (3) If A informs the Primary Care Trust within the period specified under sub-paragraph (2)(c), (e)(iv) or (f) that A does not wish to proceed with the application, or fails to respond in the required manner to the notification within the specified period, the application is to be treated as withdrawn.

### **Oral hearings**

- 25.—**(1) If the Primary Care Trust does decide to hear oral representations, it must—
- (a) give the applicant and any additional presenters not less than 14 days notice of the time and place at which the oral representations are to be heard; and
  - (b) in the case of the applicant, advise the applicant of who apart from the applicant (including other applicants, where the hearing relates to more than one application), has been invited to make representations at the hearing.
- (2) For these purposes, a person (P) is an “additional presenter” if—
- (a) the application to which the oral hearing relates is a notifiable application;
  - (b) P was given notice of the application under Part 3 and made representations about the application in accordance with paragraph 19(4), which—
    - (i) indicated that, if there were to be an oral hearing in relation to the application, P would wish to make oral representations at that hearing, and
    - (ii) identified a matter about which the Primary Care Trust considers it would be desirable to hear further evidence from P at the oral hearing; and
  - (c) the Primary Care Trust is satisfied that P made a reasonable attempt to express P's views on the application adequately in P's written representations.

(3) If the Primary Care Trust decides at or after an oral hearing that an application is to be deferred, it may (but need not) hold a further oral hearing once the period for which the application is deferred expires.

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

**26.**—(1) No person is to take part in determining or deferring any routine or excepted application who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider or a PCTMS practice; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining or deferring a particular routine or excepted application if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

### **Timetable for determining applications**

**27.** As regards any routine or excepted application—

- (a) the Primary Care Trust must endeavour to determine it as soon as is practicable; and
- (b) unless consideration of it is deferred in accordance with these Regulations or there is other good cause for delay, in the case of—
  - (i) a notifiable application, the Primary Care Trust must determine it within 4 months of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it, or
  - (ii) an application which is not a notifiable application, the Primary Care Trust must determine it within 30 days of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it.

## **PART 5**

Notification, taking effect of decisions and rights of appeal to the Secretary of State

### **Notification of decisions on routine and excepted applications**

**28.**—(1) As regards any routine application, once it has determined the application, a Primary Care Trust (PCT1) must, as soon as is practicable, give notice of its decision to—

- (a) the applicant;

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- (b) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
  - (c) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts);
  - (d) any person—
    - (i) included in its pharmaceutical list, or
    - (ii) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT1, be significantly affected by the decision;
  - (e) any LPS chemist—
    - (i) with whom the Primary Care Trust has made arrangements for the provision of any local pharmaceutical services, and
    - (ii) whose interests might, in the opinion of PCT1, be significantly affected by the decision;
  - (f) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has a significant interest in the decision;
  - (g) if the applicant is seeking to locate premises in or within 1.6 kilometres of a controlled locality in its area—
    - (i) any provider of primary medical services, or
    - (ii) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services),who, in the opinion of PCT1, has a significant interest in the decision;
  - (h) any person—
    - (i) whom PCT1 notified under paragraph 19(2), and
    - (ii) who made representations in writing about the application under paragraph 19(4); and
  - (i) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates.
- (2) A Primary Care Trust notified under paragraph (1)(i) (PCT2) must, as soon as is practicable—
- (a) give notice of the decision to—
    - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (iii) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT2, be significantly affected by the decision;
    - (iv) any LPS chemist—
      - (aa) with whom PCT2 has made arrangements for the provision of any local pharmaceutical services, and

- (bb) whose interests might, in the opinion of PCT2, be significantly affected by the decision,
  - (v) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT2 has a significant interest in the decision, and
  - (vi) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in its area—
    - (aa) any provider of primary medical services, or
    - (bb) any other person on its dispensing doctors list if it has one (being a performer but not a provider of primary medical services),who, in the opinion of PCT2, has a significant interest in the decision, and
  - (b) notify the Primary Care Trust that gave it notice under sub-paragraph (1)(i) of the action that it has taken under paragraph (a).
- (3) As regards any excepted application, once it has determined the application, PCT1 must, as soon as is practicable, give notice of its decision to—
  - (a) in the case of an application pursuant to regulation 23, the applicant;
  - (b) in the case of an application pursuant to regulation 24, 25 or 26(2)—
    - (i) the applicant,
    - (ii) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts), and
    - (iv) any person whom a Primary Care Trust (not necessarily PCT1) notified under paragraph 19 and who made representations in writing about the application under paragraph 19(4);
  - (c) in the case of an application pursuant to regulation 26(1) or 27 to 29—
    - (i) the applicant,
    - (ii) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts),
    - (iv) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT1, be significantly affected by the decision;
    - (v) any LPS chemist—
      - (aa) with whom PCT1 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT1, be significantly affected by the decision,

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- (vi) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT1 has a significant interest in the decision, and
  - (vii) any other Primary Care Trust or Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates.
- (4) A Primary Care Trust notified under sub-paragraph (3)(c)(vii) (PCT3) must as soon as is practicable—
- (a) give notice of the decision to—
    - (i) any Local Pharmaceutical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (ii) any Local Medical Committee for its area (including one for its area and that of one or more other Primary Care Trusts) not already given notice of the decision,
    - (iii) any person—
      - (aa) included in its pharmaceutical list, or
      - (bb) who is entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of PCT3, be significantly affected by the decision;
    - (iv) any LPS chemist—
      - (aa) with whom PCT3 has made arrangements for the provision of any local pharmaceutical services, and
      - (bb) whose interests might, in the opinion of PCT3, be significantly affected by the decision,
    - (v) any relevant local involvement network, and any other patient, consumer or community group in its area which in the opinion of PCT3 has a significant interest in the decision, and
  - (b) notify the Primary Care Trust that gave it notice under sub-paragraph (3)(c)(vii) of the action that it has taken under paragraph (a).
- (5) Where a Primary Care Trust has decided to consider 2 or more applications together pursuant to paragraph 22(3), it must give notice to each applicant of the decision taken with regard to each other application considered together with their application.
- (6) Each notification of a decision under this paragraph must include a statement by PCT1 of the reasons for the decision.

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

**29.** A Primary Care Trust must send with a notice of decision under paragraph 28 in respect of the grant of an application a template of a notice of commencement, for the applicant to send to it under paragraph 34, in which the applicant is to provide the following information (some of which the Primary Care Trust may have included in the template that it sends)—

- (a) the address of the premises to which the application relates;
- (b) the services that are to be provided from those premises;
- (c) the date of the grant of the application;
- (d) a declaration with regard to when the applicant intends to commence the provision of those services at those premises;

- (e) in the case of pharmacy premises, the registration number for those premises with the General Pharmaceutical Council; and
- (f) a signature on behalf of the applicant and the date of the notice.

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

**30.**—(1) A person with third party rights (as provided for in this paragraph) may appeal to the Secretary of State against a decision of a Primary Care Trust (PCT1) to grant a notifiable application, or an application to which regulation 26(1), 27 or 28 applies, provided that the person notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which that person was notified of PCT1's decision under paragraph 28.

- (2) For the purposes of this Schedule, a person (P1) is a person with third party rights if—
  - (a) P1 is a person to whom sub-paragraph (3) applies; or
  - (b) P1 was entitled to receive notification of the decision to grant the application by virtue of paragraph 28(5).
- (3) P1 is a person to whom this sub-paragraph applies if—
  - (a) P1 was a person whom a Primary Care Trust (not necessarily PCT1) was required to notify about the decision on the application by virtue of P1 being—
    - (i) included in its pharmaceutical list, or
    - (ii) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,and a person whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision;
  - (b) in the case of a notifiable application, P1 made representations in writing about the application under paragraph 19(4); and
  - (c) in the case of a notifiable application but subject to sub-paragraph (6), PCT1 is satisfied, having regard to those representations in writing and any oral representations made in accordance with paragraph 25, that P1—
    - (i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and
    - (ii) has grounds for opposing the application, which—
      - (aa) do not amount to a challenge to the legality or reasonableness of PCT1's pharmaceutical needs assessment, or to the fairness of the process by which PCT1 undertook that assessment, and
      - (bb) are not vexatious or frivolous.

(4) If PCT1 considers that a person notified under paragraph 28 is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of the determination.

(5) A notice of appeal under sub-paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(6) A person to whom sub-paragraph (3)(a) and (b) applies (P2) who is not notified by the Primary Care Trust that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D1) by the Primary Care Trust that it is not satisfied as mentioned in sub-paragraph (3)(c), provided that P2—

- (a) notifies the Secretary of State within 30 days of the date on which that person was notified of PCT1's decision under paragraph 28 (D2) that P2 wishes to appeal against D1 and D2; and

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- (b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

and if the appeal against D1 is successful, P2 is a person with third party appeal rights in relation to D2 for the purposes of this Schedule.

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

**31.**—(1) As regards any routine application, sub-paragraph (2) applies where—

- (a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and
- (b) prior to the determination of the application, A was only able to provide a best estimate of where the proposed listed chemist premises would be (not the address of those premises).

(2) Where this sub-paragraph applies, it is a condition of the grant of that application that A notifies to the Primary Care Trust that granted the application the address of the premises to be listed within 6 months of—

- (a) the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3);
- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, the date on which the appeal is determined by the Secretary of State; or
- (c) in a case of an application which is subject to a condition imposed by virtue of paragraph 33(2), the date on which that condition becomes spent,

whichever is the latest.

(3) A notification under sub-paragraph (2) is only valid if the Primary Care Trust is satisfied that the premises are at a location that is within the range of possible locations covered by the estimate referred to in sub-paragraph (1)(b).

(4) If a Primary Care Trust receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

- (a) notify A of whether or not it is satisfied that it is a valid notification;
- (b) if it is satisfied that it is a valid notification, notify the address to the persons notified of the decision to grant the application; and
- (c) if the Primary Care Trust is not satisfied that it is a valid notification, it must include with that notification—
  - (i) the reasons for its decision, and
  - (ii) an explanation of how A's rights of appeal under paragraph 36(1)(b) may be exercised.

(5) A Primary Care Trust may not vary or remove a condition imposed by virtue of this paragraph.

(6) If A breaches a condition imposed by virtue of this paragraph, the grant of the application lapses.

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

**32.**—(1) As regards any routine application, sub-paragraph (2) applies where—

- (a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and
- (b) prior to the determination of the application, A provided the address of where the proposed listed chemist premises would be.

(2) Where this sub-paragraph applies, A may notify to the Primary Care Trust (PCT1) that granted the application a different address (“new address”) as the address to which the application relates within—

- (a) 4 months of the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3); or
- (b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, 4 months of the date on which the appeal is determined by the Secretary of State.

(3) A notification under sub-paragraph (2) is only valid if PCT1 is satisfied that accepting the notification as valid would neither—

- (a) result in a significant change to the arrangements that are in place (having regard to the grant of A’s application) for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of its area, or
  - (ii) in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the new address; nor
- (b) cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area.

(4) If PCT1 receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

- (a) notify A of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;
- (b) if PCT1 is not satisfied that it is a valid notification, it must include with that notification—
  - (i) the reasons for its decision, and
  - (ii) an explanation of how A’s rights of appeal under paragraph 36(1)(b) may be exercised.
- (c) 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 must include with that notification—
  - (i) the reasons for its decision, and
  - (ii) if the person has a right of appeal under sub-paragraph (5), an explanation of how that right of appeal may be exercised.

(5) A person (X) who—

- (a) is notified under sub-paragraph (4)(c); and
  - (b) was entitled to be notified of the decision to grant the application—
    - (i) by virtue of paragraph 28(5), or
    - (ii) as a person whom a Primary Care Trust (not necessarily PCT1) was required to notify about the application by virtue of X being—
      - (aa) included in its pharmaceutical list, or
      - (bb) entitled to be included in its pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
- and a person whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision;

may appeal against a decision by PCT1 to accept the purported notification as a valid notification, provided X notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which X was notified under sub-paragraph (4)(c).

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(6) A notice of appeal under sub-paragraph (5) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

**Conditional grant in cases relating to future needs or future improvements or better access**

**33.**—(1) Where a Primary Care Trust (PCT1) grants a routine application because doing so—

- (a) will meet a future need for pharmaceutical services, or pharmaceutical services of a specified type in its area; or
- (b) will secure future improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type, in its area,

sub-paragraph (2) applies.

(2) Where this sub-paragraph applies, PCT1 may grant the application subject to a condition that pharmaceutical services are not provided at the listed chemist premises to which the application relates (or at any premises to which the business relocates) until—

- (a) some or all of the future circumstances, as a consequence of which the application was granted, have arisen; or
- (b) a specified date (having regard to when some or all of the future circumstances, as a consequence of which the application was granted, are likely to arise).

(3) PCT1 may vary or remove a condition imposed by virtue of sub-paragraph (2), but if it varies the condition, the revised condition (which becomes a condition imposed by virtue of sub-paragraph (2)) must be a condition that it also meets the requirements of that paragraph.

(4) The condition imposed by virtue of sub-paragraph (2) becomes spent once—

- (a) where a date has been specified, that date passes; or
- (b) where the condition relates to future circumstances arising, PCT1 notifies the successful applicant (P) that the future circumstances have arisen.

(5) P may by a notice request a determination from PCT1 as to whether the future circumstances have arisen at any time (but only once in any 60 days), and PCT1 must give notice of that determination within 30 days of that request.

**Taking effect of listing decisions: general**

**34.**—(1) As regards any application—

- (a) for inclusion in a pharmaceutical list of a Primary Care Trust (PCT1) by a person who is not already included in it; or
- (b) by a person who is included in a PCT1's pharmaceutical list and who is seeking—
  - (i) to open, within the area of PCT1, additional premises from which to provide the same or different pharmaceutical services;
  - (ii) to relocate to different premises in the area of PCT1, and at those premises to provide the same or different pharmaceutical services;
  - (iii) to provide, from the person's listed chemist premises within the area of PCT1, services that are in addition to those already listed in relation to that person,

if the application is granted, paragraph (2) applies.

(2) Subject to paragraph 35, PCT1 may only change its pharmaceutical list to give effect to that decision if the successful applicant (P) gives PCT1 a valid notice of commencement, in the correct form, informing PCT1 that P is to commence the provision of the services in respect of which the application was made and at the premises to which the application related in the next 14 days.

(3) A notice of commencement is in the correct form if it—

- (a) includes the information required under paragraph 29; and
  - (b) is in the same format as the version of the notice sent by the Primary Care Trust with the notice of decision under paragraph 28.
- (4) A notice of commencement is invalid unless it is sent to PCT1 within—
- (a) if, prior to PCT1 determining the application—
    - (i) P undertook to commence the provision of the services in respect of which the application was made within a period of less than 6 months, and
    - (ii) that undertaking was not withdrawn,  
that period;
  - (b) 6 months of—
    - (i) unless paragraph (a) applies, the date on which P was sent the notice of PCT1's decision under paragraph 28 granting the application,
    - (ii) if the grant was appealed by a person with third party appeal rights, the date on which that appeal is determined by the Secretary of State,
    - (iii) if, in the course of granting the application, a decision is taken to impose a condition in accordance with regulation 35 and that condition is appealed by P, the date on which that appeal is determined by the First-tier Tribunal (unless regulation 35(8) applies),
    - (iv) if the grant of the application was subject to a condition imposed by virtue of paragraph 31, the date on which—
      - (aa) P validly notifies to PCT1 under a condition imposed by virtue of paragraph 31 of the address of the premises, or
      - (bb) if P appeals successfully against a decision of PCT1 that a notification under a condition imposed by virtue of paragraph 31 is invalid, that appeal is determined by the Secretary of State,
    - (v) if P, pursuant to paragraph 32—
      - (aa) notifies PCT1 of a new address,
      - (bb) PCT1 does not accept the validity of the notification, and
      - (cc) P appeals successfully against that decision,  
the date on which that appeal is determined by the Secretary of State, or
    - (vi) if the grant of the application was subject to a condition imposed by virtue of paragraph 33, the date on which the condition imposed by virtue of that paragraph becomes spent or is removed on appeal, orwhichever is the latest; or
  - (c) such longer period—
    - (i) not exceeding a further 3 months as PCT1 may allow, or
    - (ii) if—
      - (aa) the grant is appealed by a person with third party appeal rights,
      - (bb) a decision to accept a notification pursuant to paragraph 32 is appealed by a third party,
      - (cc) P appeals successfully against a notice under paragraph 35, or
      - (dd) if P appeals successfully against a decision not to allow a longer period under sub-paragraph (i),

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as the Secretary of State may allow when the appeal is determined, and so once a valid notice of commencement can no longer be sent in relation to an application (having regard also to paragraph 10(2) of Schedule 3), the grant of that application lapses.

(5) A notice of commencement ceases to have effect if the Secretary of State receives a valid notice of appeal—

- (a) from a person with third party appeal rights relating to the grant to which the notice of commencement relates; or
- (b) from a third party, in a case to which sub-paragraph (4)(c)(ii)(bb) applies.

### **Notice requiring the commencement of pharmaceutical services**

**35.**—(1) A Primary Care Trust that has granted a routine application—

- (a) for inclusion in a pharmaceutical list by a person (P) not already included; or
- (b) if P is already included in that list, for inclusion also in relation to premises not already listed in relation to P,

may, if the grant has not lapsed and is not under appeal to the Secretary of State, give notice to P requiring P to commence the provision of pharmaceutical services by a date specified in the notice.

(2) If a Primary Care Trust gives notice under sub-paragraph (1) but afterwards a valid notice of appeal is given against the grant, the notice under sub-paragraph (1) lapses.

(3) A notice under sub-paragraph (1) may not specify a date that is—

- (a) earlier than 30 days from the date of the notice under that paragraph; or
- (b) later than 9 months after the date on which the grant of the application was notified to P.

(4) The Primary Care Trust may change its pharmaceutical list to give effect to that notice—

- (a) on the specified date, unless the decision to give notice under sub-paragraph (1) is appealed; or
- (b) if the notice under paragraph (1) is appealed and the appeal is unsuccessful or discontinued—
  - (i) if the appeal is discontinued, 30 days after P discontinues the appeal,
  - (ii) if the appeal is unsuccessful, 30 days after the appeal is determined, or
  - (iii) on the specified date,

whichever is the latest.

### **Appeals to the Secretary of State by the applicant**

**36.**—(1) As regards any routine or excepted application, other than an application pursuant to regulation 29, the applicant (A) may appeal to the Secretary of State against a decision by a Primary Care Trust—

- (a) to refuse the application on grounds set out in Parts 3 to 5 or 7 of these Regulations;
- (b) that a notification pursuant to a condition imposed by virtue of paragraph 31 is invalid;
- (c) to refuse to accept that a notification under paragraph 32(2) is a valid notification;
- (d) to impose or vary a condition imposed pursuant to paragraph 33;
- (e) to refuse to allow A an extension period under paragraph 34(4)(c)(i); or
- (f) to give notice under paragraph 35,

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provided A notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which A was notified of the decision that is being appealed.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.