
STATUTORY INSTRUMENTS

2005 No. 641

**The National Health Service
(Pharmaceutical Services) Regulations 2005**

PART 2

Pharmaceutical Lists and Applications for Admission to a Pharmaceutical List

Preparation of lists

4.—(1) A Primary Care Trust shall prepare and publish lists, to be called pharmaceutical lists, of the persons, other than doctors and dentists—

- (a) whose applications to be included in a pharmaceutical list have been granted by the Primary Care Trust, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the Primary Care Trust's area, in particular, by way of the provision of drugs; and
- (b) whose applications to be included in a pharmaceutical list have been granted by the Primary Care Trust, subject to and in accordance with the provisions of these Regulations, and who accordingly undertake to provide pharmaceutical services from premises in the Primary Care Trust's area by way of the provision of appliances.

(2) Each such list shall contain—

- (a) the addresses of premises in the Primary Care Trust's area from which those services are provided;
- (b) the days on which and times at which pharmaceutical services are provided at that address (including times at which those services are provided when the person is not obliged to do so); and
- (c) in the case of a list referred to in paragraph (1)(a), shall indicate whether or not the chemist has undertaken to provide directed services, and if he has, which services.

(3) The pharmaceutical lists shall be available for public inspection.

Applications for inclusion in or amendment to a pharmaceutical list

5.—(1) Subject to paragraph (4), a person, other than a doctor or dentist—

- (a) who wishes to be included in a pharmaceutical list for the provision of pharmaceutical services from premises in a Primary Care Trust's area;
- (b) who is already included in a pharmaceutical list but wishes—
 - (i) to open, within a Primary Care Trust's area, additional premises from which to provide the same or different pharmaceutical services,
 - (ii) to change the premises from which he provides pharmaceutical services to other premises within that area from which he wishes to provide the same or different pharmaceutical services, or

- (iii) to provide from his existing premises in that area pharmaceutical services other than those already listed in relation to him; or
- (c) who is already included in a pharmaceutical list of a neighbouring Primary Care Trust but wishes to change the premises within the neighbourhood from which he provides pharmaceutical services to other premises in the area of the Primary Care Trust to which he makes an application under this Regulation and—
 - (i) the change is a minor relocation, and
 - (ii) the same pharmaceutical services will be provided,

shall apply, in accordance with this regulation, to the Primary Care Trust, providing the information set out in Part 1 of Schedule 4.

(2) A person applying in accordance with paragraph (1)(a) shall provide the information and undertakings specified in Part 3 of Schedule 4.

(3) A person who wishes to be included in a Primary Care Trust's pharmaceutical list—

- (a) pursuant to a determination made by the Secretary of State under regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002⁽¹⁾; or
- (b) as a temporary chemist,

shall apply under regulation 10 or 54 (as the case may be), and not under this regulation.

(4) In this Part and in regulation 54 and Schedule 4 and unless the context otherwise requires, “applicant” and “application” shall be construed accordingly.

(5) Where an application has been granted under regulation 6 or 7, no further application may be granted under regulation 6 or 7 in relation to those new premises for a period of 12 months beginning with the date on which the applicant commenced the provision of pharmaceutical services from the new premises unless the Primary Care Trust for good cause allows him to make an application before the end of that period.

Applications involving a minor relocation within a Primary Care Trust's area

6.—(1) In the case of an application under regulation 5(1)(b), where the applicant intends to change within the neighbourhood the premises from which he provides pharmaceutical services, being the same services as he intends to provide from the new premises, and the Primary Care Trust is satisfied that—

- (a) the change is a minor relocation; and
- (b) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow),

the Primary Care Trust shall grant the application, subject to regulations 9(2) and 21(10) (and accordingly regulations 11 to 20 shall not apply).

(2) Except where paragraph (3) applies, a Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in, regulations 23, 24(1) and (3) to (6), 25, 26, 27 and 29.

(3) Where the minor relocation is to premises which are less than 500 metres by the most practicable route by foot from the applicant's existing premises (“a minor relocation of less than 500 metres”), the Primary Care Trust shall—

- (a) determine the application without giving notice of the application under regulation 23 or hearing any oral representations under regulation 24; and

(1) S.I. 2002/2016, as amended by S.I. 2002/2469.

(b) grant the application,

unless, within the period of 30 days beginning with the date of receipt of the application it notifies the applicant that it considers that it is desirable that the application be determined as if it were a minor relocation to premises which are 500 metres or more by the most practicable route by foot from the applicant's existing premises ("a minor relocation of 500 metres or more").

(4) Where the Primary Care Trust determines under paragraph (3) that an application for a minor relocation of less than 500 metres should be determined as if it were a minor relocation of 500 metres or more, it shall send the applicant a statement in writing setting out—

- (a) its decision and its reasons for it; and
- (b) the applicant's right of appeal under paragraph (5).

(5) The applicant may within the period of 30 days beginning with the date of receipt of the notification under paragraph (4), appeal in writing to the Secretary of State against the decision notified to him under that paragraph.

(6) A notice of appeal under paragraph (5) shall contain a concise statement of the grounds of appeal.

(7) The Secretary of State may, when determining the appeal under paragraph (5)—

- (a) confirm the decision of the Primary Care Trust;
- (b) grant the appeal; or
- (c) grant the application.

(8) The Secretary of State shall notify the applicant and the Primary Care Trust in writing of his determination and shall include with the notification a written statement of the reasons for his determination.

(9) Where the determination of the Secretary of State is to grant the appeal, the Primary Care Trust shall within the period of 30 days beginning with the date of receipt of the notification under paragraph (8) determine the application in accordance with paragraph (3)(a).

Applications involving a minor relocation between neighbouring Primary Care Trusts

7.—(1) In the case of an application under regulation 5(1)(c), where—

- (a) the Primary Care Trust is satisfied that—
 - (i) the change is a minor relocation, and
 - (ii) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow); and
- (b) the applicant consents to the removal of his name from the pharmaceutical list of the Primary Care Trust in which his existing premises are located in respect of those premises with effect from the date on which he commences to provide pharmaceutical services from his new premises,

the Primary Care Trust shall grant the application, subject to regulations 9(2) and 21(10) (and accordingly regulations 11 to 20 shall not apply).

(2) Subject to paragraph (3), a Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in, regulations 23, 24(1) and (3) to (6), 25, 26, 27 and 29.

(3) Where the minor relocation is to premises which are less than 500 metres by the most practicable route by foot from the applicant's existing premises ("a minor relocation of less than 500 metres"), the Primary Care Trust shall—

- (a) determine the application without giving notice of the application under regulation 23 or hearing any oral representations under regulation 24; and
- (b) grant the application,

unless within the period of 30 days beginning with the date of receipt of the application it notifies the applicant that it considers that it is desirable that the application be determined as if it were a minor relocation to premises which are 500 metres or more by the most practicable route by foot from the applicant's existing premises ("a minor relocation of 500 metres or more").

(4) Where the Primary Care Trust determines under paragraph (3) that an application for a minor relocation of less than 500 metres should be determined as if it were a minor relocation of 500 metres or more, it shall send the applicant a statement in writing setting out—

- (a) its decision and its reasons for it; and
- (b) the applicant's right of appeal under paragraph (5).

(5) The applicant may within the period of 30 days beginning with the date of receipt of the notification under paragraph (4), appeal in writing to the Secretary of State against the decision notified to him under that paragraph.

(6) A notice of appeal under paragraph (5) shall contain a concise statement of the grounds of appeal.

(7) The Secretary of State may, when determining the appeal under paragraph (5)—

- (a) confirm the decision of the Primary Care Trust;
- (b) grant the appeal; or
- (c) grant the application.

(8) The Secretary of State shall notify the applicant and the Primary Care Trust in writing of his determination and shall include with the notification a written statement of the reasons for his determination.

(9) Where the determination of the Secretary of State is to grant the appeal, the Primary Care Trust shall within the period of 30 days beginning with the date of receipt of the notification under paragraph (8) determine the application in accordance with paragraph (3)(a).

Applications involving a change of ownership

8.—(1) Where the applicant intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by a person who is included in a pharmaceutical list, and the Primary Care Trust is satisfied that—

- (a) the same services will be provided from those premises; and
- (b) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow),

the Primary Care Trust shall grant the application, subject to—

- (i) where the applicant is not already on that Primary Care Trust's pharmaceutical list, paragraph (2) and regulations 11, 19 and 21 (and accordingly regulations 12 to 18 and 20 shall not apply), or
- (ii) where the applicant is already on that Primary Care Trust's pharmaceutical list, paragraph (2) (and accordingly regulations 11 to 21 shall not apply).

(2) Where a temporary chemist wishes to make an application under regulation 5(1)(b) on behalf of the suspended chemist in whose place he is providing pharmaceutical services, and that application is to relate to his provision of those services as a temporary chemist, and the application is one falling within paragraph (1), he must, before making the application, obtain the written consent of the Primary Care Trust to the application.

(3) A Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in regulations 24(1) and (3) to (7), 26, 27, 28 and 29 and where paragraph (1)(i) applies, in addition regulation 24(2).

Applications following suspension from the list

9.—(1) Where—

- (a) the applicant intends to provide pharmaceutical services (otherwise than as a temporary chemist) from premises from which, at the time of the application, no services are being provided because the person who had undertaken to provide services from those premises is suspended from the pharmaceutical list; and
- (b) the Primary Care Trust is satisfied that the applicant will provide the same services as were provided by that person prior to his suspension,

the Primary Care Trust shall grant the application, subject to—

- (i) where the applicant is not already on that Primary Care Trust's pharmaceutical list, regulations 11, 19 and 21 (and accordingly regulations 12 to 18 and 20 shall not apply), or
- (ii) where the applicant is already on that Primary Care Trust's pharmaceutical list, regulation 11(2) (and accordingly regulations 11(1) and 12 to 21 shall not apply).

(2) A Primary Care Trust shall determine an application to which paragraph (1) relates in accordance with the procedures set out in regulations 24(1) and (3) to (7), 26, 27, 28 and 29 and where paragraph (1)(i) applies, in addition regulation 24(2).

(3) Where a temporary chemist wishes to make an application under regulation 5(1)(b) on behalf of the suspended chemist in whose place he is providing pharmaceutical services, that application shall be dealt with as if the application had been made by the suspended chemist whilst not suspended from the pharmaceutical list (except that regulation 8(2) shall also apply in the case of an application falling within regulation 8(1)).

Right of return to pharmaceutical lists

10.—(1) This regulation applies if the Secretary of State makes a determination under regulation 4 of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002 that a person is to be given a right of return to a Primary Care Trust's pharmaceutical list on making an application for his name to be included in that list after ceasing to provide local pharmaceutical services under a pharmacy pilot scheme, and the conditions mentioned in paragraph (2) are satisfied.

(2) The conditions are that—

- (a) the period of time between the cessation of provision of local pharmaceutical services by the applicant and the commencement of provision of pharmaceutical services by the applicant will be such that the provision of such services will be continuous (except for such period as the Primary Care Trust may for good cause allow); and
- (b) the determination or determinations relevant to the application have not been invalidated by any subsequent determination, and that any conditions specified in the determination or determinations are satisfied.

(3) A person making an application under this regulation for inclusion of his name in a pharmaceutical list must apply to the Primary Care Trust giving the information set out in Part 1 of Schedule 4 while he is still providing local pharmaceutical services under a pharmacy pilot scheme, and in addition he must—

- (a) make clear that the application is made by virtue of this regulation; and
- (b) attach copies of all determinations relevant to the application.

(4) A person who meets the conditions specified in paragraph (7) must, in addition to the requirements of paragraph (3), provide the information, declarations and undertakings specified in Part 3 of Schedule 4.

(5) If a person has made an application in the manner described in paragraph (3) and (if applicable) (4) to a Primary Care Trust for his name to be included in its pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraph (6) and regulation 11(2).

(6) Notwithstanding the determination relevant to his application, if an applicant meets the conditions specified in paragraph (7), the provisions of regulations 19, 21, 26, 28 and 30 apply to his application under this regulation.

(7) The conditions referred to in paragraphs (4) and (6) are that—

- (a) the applicant is not, at the time of his application to a Primary Care Trust, already included in that Primary Care Trust's pharmaceutical list; and
- (b) the applicant was not, immediately before the date on which he commenced the provision of local pharmaceutical services, included in that Primary Care Trust's pharmaceutical list.

(8) Any conditions imposed by a Primary Care Trust under regulation 20 or by the Secretary of State under regulation 29(18)(b), 32(10)(b) or 38(14)(b) which are still in force by virtue of regulation 20(3) shall be unaffected by the grant of an application under this regulation.

(9) A Primary Care Trust must, as soon as is practicable, and in any event within the period of four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing of its decision on an application under this regulation to those persons or bodies listed in regulation 27(1)(a).

(10) Where a Primary Care Trust grants an application under this regulation, the applicant must be included in the relevant pharmaceutical list or lists only if, not less than 14 days before the expiry of six months after the date on which the grant was notified to him by the Primary Care Trust in accordance with paragraph (9), he notifies the Primary Care Trust, in the form set out in Part 2 of Schedule 4, that he will, within the next 14 days, commence the provision of services in respect of which the application was made at the premises to which the application related.

(11) Where, at any time after making an application under this regulation, but before the expiry of the six months referred to in paragraph (10), the applicant notifies the Primary Care Trust that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the Primary Care Trust is satisfied that the change is a minor relocation, it may amend the premises named in the original application.

(12) For the purposes of paragraph (10), the date of the notification of a grant of an application is the day after the expiry of the period of 30 days beginning on the date on which notice of that decision is given under paragraph (9).

(13) Except as specified in paragraphs (6) and (8), regulations 5 to 9, 11(1) and 12 to 28 and 30 to 42 do not apply to an application under this regulation.

Refusal: general provisions

11.—(1) An application, other than one to which regulation 6, 7, 8(1)(b)(ii) or 9(3) applies, which is made by a person who qualified to have his name registered under the Pharmacy Act 1954⁽²⁾ by virtue of section 4A⁽³⁾ of that Act (qualification by European diploma) shall not be granted unless the applicant satisfies the Primary Care Trust that he has the knowledge of English which, in the interests of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Primary Care Trust's area.

(2) 1954 c. 61.

(3) Section 4A was inserted by S.I. 1987/2202.

(2) A Primary Care Trust shall refuse an application in which a pharmacist does not offer to provide all of the essential services.

Necessary or desirable test

12.—(1) Subject to regulations 13, 19, 21, 25 and 26, an application shall be granted by the Primary Care Trust only if it is satisfied that it is necessary or desirable to grant the application in order to secure, in the neighbourhood in which the premises from which the applicant intends to provide the services are located, the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application (“the necessary or desirable test”).

(2) Subject to regulations 25 and 26 and paragraph (4), in considering whether the necessary or desirable test is satisfied, a Primary Care Trust shall have regard in particular to—

- (a) whether or not any of the following services are already provided by persons in the neighbourhood in which the premises named in the application are located—
 - (i) any pharmaceutical services specified in the application provided by persons included in a pharmaceutical list, or any directed services the applicant agrees to provide if his name is included in the pharmaceutical list, or
 - (ii) any local pharmaceutical services provided under a pharmacy pilot scheme which are of the same description as any pharmaceutical services specified in the application;
- (b) whether the recipients of pharmaceutical services already have a reasonable choice with regard to—
 - (i) the pharmaceutical services provided in the neighbourhood in which the premises named in the application are located, by persons included in a pharmaceutical list, and
 - (ii) the persons included in a pharmaceutical list from whom such recipients may obtain pharmaceutical services in the neighbourhood in which the premises named in the application are located;
- (c) any other information available to the Primary Care Trust which, in its opinion, is relevant to the consideration of the application; and
- (d) any representations received by the Primary Care Trust—
 - (i) under regulation 23(2) or (3), or
 - (ii) where the application is in respect of premises in a controlled locality, under regulation 33(4) from a person mentioned in regulation 33(2)(a) to (d) or (f) to (j) or (3)(a) to (d), (f) or (g).

(3) In considering whether the necessary or desirable test is satisfied, a Primary Care Trust may also have regard to any pharmaceutical services that the applicant proposes to provide in that neighbourhood in circumstances where he is not obliged to provide those services.

(4) The Primary Care Trust shall not take into account pharmaceutical services provided from premises at which pharmaceutical services are provided by a distance selling chemist when considering the pharmaceutical services already provided in the neighbourhood.

Exemption from the necessary or desirable test

13.—(1) Unless the applicant requests otherwise, or the premises to which his application relates are in a neighbourhood in which local pharmaceutical services are or are to be provided, regulation 12 shall not apply to an application in respect of—

- (a) premises which are in an approved retail area (within the meaning of regulation 15);

- (b) premises which the applicant is willing to keep open for at least 100 hours per week for the provision of pharmaceutical services;
 - (c) premises which are in a new one-stop primary care centre (within the meaning of regulation 16); or
 - (d) premises at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises (“distance selling premises”).
- (2) As regards an application to which paragraph (1)(b) applies, if the application is granted—
- (a) it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that the premises to which the application relates are kept open for at least 100 hours per week for the provision of pharmaceutical services, and the Primary Care Trust may not vary or remove that condition; and
 - (b) the Primary Care Trust may only remove a person from the pharmaceutical list for breach of that condition if—
 - (i) that person has repeatedly breached the condition, or is likely to breach the condition repeatedly, without good cause, or
 - (ii) the breach is, in all the circumstances, a serious breach and as a consequence of it the safety of a patient has been or may be put at serious risk.
- (3) As regards an application to which paragraph (1)(a), (b) or (c) applies—
- (a) the application may only be granted if the applicant agrees to a condition of his inclusion in the pharmaceutical list that he will provide, where requested to do so by the Primary Care Trust, and at the premises to which the application relates, such directed services as the Primary Care Trust may specify; and
 - (b) if the application is granted, it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that he provides, where requested to do so by the Primary Care Trust and at the premises to which the application relates, the directed services specified by the Primary Care Trust for the purposes of this paragraph (read with regulation 14).
- (4) As regards an application to which paragraph (1)(d) applies, if the application is granted it is a condition of the applicant’s inclusion in a pharmaceutical list (and so a term of service) that—
- (a) he does not offer to provide pharmaceutical services to persons who are present at the premises to which the application relates; and
 - (b) the means by which he provides pharmaceutical services are such that the person receiving them does so otherwise than at the premises to which the application relates,
- and the Primary Care Trust may not vary or remove those conditions.

Variation of directed services in respect of exempted premises

- 14.—(1) A person in respect of whom a condition is imposed by virtue of regulation 13(3)(b) may apply to a Primary Care Trust for it to vary the directed services that it has specified as regards him for the purposes of that condition, but he may only do so after at least three years have elapsed—
- (a) since the condition was imposed in respect of him; or
 - (b) during which the Primary Care Trust has not required him to provide the directed services.
- (2) An application under paragraph (1) shall include the applicant’s reasons for asking the Primary Care Trust to vary the condition concerned.
- (3) The Primary Care Trust shall determine an application under paragraph (1) within 60 days of receiving it.
- (4) In determining an application under paragraph (1), the Primary Care Trust shall—

- (a) specify, as regards the applicant, different or no directed services for the purposes of the condition imposed by virtue of regulation 13(3)(b) in respect of the premises to which the application relates, if this has the effect of either granting the application under paragraph (1) or granting it only in part; or
 - (b) confirm that, as regards the applicant, the directed services that it has previously specified for the purposes of the condition imposed by virtue of regulation 13(3)(b) in respect of the premises to which the application relates are to remain unchanged.
- (5) Where the Primary Care Trust is considering taking action under paragraph (4)(a), it shall consult the Local Pharmaceutical Committee before determining the application.
- (6) A Primary Care Trust shall notify the applicant in writing of any action taken under paragraph (4), and where this has the effect of refusing an application under paragraph (1) or granting it in part, it shall send the applicant a statement in writing setting out—
- (a) the reasons for the refusal or, as the case may be, for granting the application only in part; and
 - (b) the applicant’s right of appeal under paragraph (7).
- (7) The applicant may, within 30 days of receiving a notification pursuant to paragraph (6), appeal in writing to the Secretary of State against any action under paragraph (4) which has the effect of refusing an application under paragraph (1) or granting it only in part.
- (8) A notice of appeal under paragraph (7) shall contain a concise statement of the grounds of appeal.
- (9) The Secretary of State may, when determining an appeal, either confirm the action taken by the Primary Care Trust or take any action that the Primary Care Trust could have taken under paragraph (4).
- (10) The Secretary of State shall notify the applicant in writing of his determination and shall in every case include with the notification a written statement of the reasons for the determination.

Approved retail areas

15.—(1) For the purposes of these Regulations, premises are in an approved retail area if they are in a retail area that has been approved by the Secretary of State under this paragraph for the purposes of the exemption in regulation 13(1)(a).

(2) Approval of an area under paragraph(1) shall only be granted if the Secretary of State is satisfied that it is in respect of—

- (a) an area—
 - (i) which comprises a discrete site or building which is a shopping centre, a retail park or retail premises, or
 - (ii) for which is planned a discrete site or building which, if the permitted development is carried out (and it may, at the time of the approval, be part carried out), will be a shopping centre, a retail park or retail premises,and such an area, for the purposes of these Regulations, is a “retail area”;
- (b) a retail area which is not or will not be part of—
 - (i) a primary shopping area which is or is part of—
 - (aa) a city, metropolitan or town centre; or
 - (bb) a district centre which performs the role of a city, metropolitan or town centre, or
 - (ii) an edge of centre location which relates to—

(aa) a city, metropolitan or town centre; or

(bb) a district centre which performs the role of a city, metropolitan or town centre,

and in determining whether or not an area is a “primary shopping area” or an “edge of centre” location for the purposes of this sub-paragraph, regard shall be had to any relevant national planning policy guidance; and

(c) a retail area which exceeds or will exceed the minimum size,

but approval under paragraph (1) shall otherwise be granted by the Secretary of State as he sees fit.

(3) For the purposes of paragraph (2)(c) a retail area exceeds or will exceed the minimum size if—

(a) in the case of a shopping centre or retail premises, it is or will be, or incorporates or will incorporate, leasehold retail premises the gross floor space of which exceeds or will exceed 15,000 square metres; or

(b) in the case of a retail park, it, together with any adjacent retail area, incorporates or will incorporate leasehold retail premises the gross floor space of which exceeds or will exceed 15,000 square metres.

(4) The Secretary of State shall publish, in such manner and at such intervals as he sees fit, a list of retail areas which are for the time being approved by him under paragraph (1).

(5) The Secretary of State may withdraw his approval under paragraph (1) of a retail area in appropriate circumstances.

New one-stop primary care centres

16.—(1) For the purposes of these Regulations, premises are in a new one-stop primary care centre if they are in a one-stop primary care centre which a Primary Care Trust on or after 1st April 2005 has for the first time included in its strategic service development plan (or if it has no such plan, in a written plan that achieves the same purpose as a strategic service development plan), at which on or after 1st April 2005—

(a) the services of health care professionals will be provided for the first time; or

(b) as a consequence of substantial new development or redevelopment, the services of a broad range of health care professionals will be provided for the first time.

(2) For the purposes of these Regulations, premises are a “one-stop primary care centre” if they are in a discrete site or building—

(a) at which the services of a broad range of health care professionals is, or will be, regularly and frequently provided (together, where appropriate, with other health or social services);

(b) at which there is, or will be, a provider of primary medical services with a patient list which comprises at least 18,000 patients; and

(c) which is under the management or control of a consortium, and for these purposes a “consortium” is an association of persons or undertakings carrying on a business together with—

(i) a single management and equity structure, and

(ii) agreed written articles of association which commit them to running a one-stop primary care centre.

(3) In determining whether the requirements of paragraph (2)(a) are met, a Primary Care Trust shall have regard to the range and number of health care professionals (apart from those who are, or who are engaged or employed by, other chemists) who are available to provide services within its area.

Refusal: distance selling premises

17. A Primary Care Trust shall not grant an application to which regulation 13(1)(d) applies if the premises to which the application relates are on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

Refusal: premises which are in a controlled locality but not in a reserved location

18.—(1) Paragraph (2) applies where the application is in respect of premises in a controlled locality and—

- (a) the Primary Care Trust has determined under regulation 35; or
- (b) on appeal it is determined,

that the premises from which the applicant wishes to provide pharmaceutical services are not in a reserved location.

(2) Subject to regulations 25 and 26 the Primary Care Trust—

- (a) shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality;
- (b) shall refuse an application under regulation 61 in relation to any part of the area specified in the application—
 - (i) which is not in a controlled locality, or
 - (ii) which is within 1.6 kilometres of any pharmacy;
- (c) shall refuse an application under regulation 61 in relation to any premises from which the doctor wishes to be authorised to dispense and which are within 1.6 kilometres of any pharmacy; and
- (d) may refuse an application in a case to which regulation 36(9) applies (notwithstanding that it would, if determining that application in isolation, grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality,

and any refusal of such an application may relate to all or any part of the area within the controlled locality.

Refusal: fitness to practise grounds

19.—(1) This regulation applies to an application to a Primary Care Trust—

- (a) under regulation 5, 40 or 54, where the applicant is not already on that Primary Care Trust's pharmaceutical list; and
- (b) under regulation 10, where the applicant meets the conditions specified in paragraph (7) of that regulation.

(2) A Primary Care Trust may refuse to grant an application to which this regulation applies if—

- (a) having considered the undertakings and declarations required by paragraphs 1, 2 and 3 of Part 3 of Schedule 4 and any other information in its possession in relation to the application, it considers that the applicant is unsuitable to be included in the list;
- (b) having checked the information provided by the applicant in accordance with paragraphs 4, 5 and 6 of Part 3 of Schedule 4, and any further information provided pursuant to the

- undertaking given in accordance with paragraph 12 of Part 3 of Schedule 4, it considers the applicant is unsuitable to be included in the list;
- (c) having contacted the referees nominated by the applicant in accordance with paragraph 7 of Part 3 of Schedule 4, it is not satisfied with the references given;
 - (d) having checked with the National Health Service Counter Fraud and Security Management Service for any facts that it considers relevant relating to past or current fraud investigations involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), and having considered these and any other facts in its possession relating to fraud involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal;
 - (e) having checked with the Secretary of State for any facts that he considers relevant relating to past or current investigations or proceedings involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) and, having considered these and any other facts in its possession involving or relating to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant), it considers these justify such refusal; or
 - (f) it considers that admitting the applicant to the list would be prejudicial to the efficiency of the service which he would undertake to provide.
- (3) A Primary Care Trust must refuse to grant an application to which this regulation applies if—
- (a) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of murder;
 - (b) the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) has been convicted in the United Kingdom of a criminal offence, other than murder, which was committed after the date on which these Regulations come into force and has been sentenced to a term of imprisonment of over six months;
 - (c) the applicant is the subject of a national disqualification;
 - (d) the applicant has not updated his application in accordance with regulation 26(4); or
 - (e) in a case to which regulation 30 applies, he does not notify the Primary Care Trust under regulation 30(4) that he wishes to be included in its pharmaceutical list subject to the specified conditions.
- (4) Where the Primary Care Trust is considering refusal of an application under paragraph (2), it shall consider all facts which appear to it to be relevant and shall in particular take into consideration in relation to paragraph (2)(a), (b), (d) and (e)—
- (a) the nature of any offence, investigation or incident;
 - (b) the length of time since any offence, incident, conviction or investigation;
 - (c) whether there are other offences, incidents or investigations to be considered;
 - (d) any action taken or penalty imposed by any licensing or regulatory body, the police or the courts as a result of any such offence, incident or investigation;
 - (e) the relevance of any offence, investigation or incident to the provision by the applicant of pharmaceutical services and any likely risk to users of pharmaceutical services or to public finances;
 - (f) whether any offence was a sexual offence to which Part 1 of the Sexual Offences Act 2003(4) applies, or if it had been committed in England and Wales, would have applied;

(g) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has been refused admittance to, conditionally included in, removed, contingently removed or is currently suspended from any list or equivalent list on fitness to practise grounds, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or equivalent body for such action; or

(h) whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from any list or equivalent list, or is currently suspended from any such list, on fitness to practise grounds, and if so, what the facts were in each such case and the reasons given by the Primary Care Trust or equivalent body in each case.

(5) When the Primary Care Trust takes into consideration the matters set out in paragraph (4), it shall consider the overall effect of all the matters being considered.

(6) An applicant may appeal to the FHSAA against a decision of the Primary Care Trust to refuse to grant his application—

(a) to be included in the pharmaceutical list (including an application to be included as a temporary chemist); or

(b) for preliminary consent to be included in that list,

on grounds specified in paragraph (2).

(7) An appeal must be made within the period of 28 days beginning with the date on which the Primary Care Trust notified the applicant of the decision under regulation 10(9), 27(1), 37(1) or 54(14) (as the case may be), and such an appeal shall be by way of redetermination of the Primary Care Trust's decision.

Imposition of conditions

20.—(1) Subject to regulations 22(4), 25 and 26 where—

(a) the premises specified in an application under regulation 5(1) are in a controlled locality, or are not in a controlled locality but are within 1.6 kilometres of any part of any controlled locality in which reside patients for whom a doctor provides pharmaceutical services or for whom a GMS contractor or PMS contractor provides dispensing services; and

(b) the granting of the application would, in the view of the Primary Care Trust, result in a significant change in the arrangements for the provision of pharmaceutical services, local pharmaceutical services or dispensing services in any part of a controlled locality,

the Primary Care Trust shall, where it grants the application, consider the conditions (if any) which are to be imposed in relation to that grant under paragraph (2), and pending the final determination of such conditions, shall not in consequence of the grant give notice to any doctor to discontinue the provision of pharmaceutical services or dispensing services to any patient.

(2) Where the Primary Care Trust considers that the provision of primary medical services by any provider of such services (other than itself) or pharmaceutical services by any chemist or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of a grant under paragraph (1), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulation or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

(3) Where a Primary Care Trust has imposed any conditions under paragraph (2), or the Secretary of State has imposed any conditions under regulation 29(18)(b), 32(10)(b) or 38(14)(b), those

conditions shall be unaffected by the commencement or continuation of a pharmacy pilot scheme for the provision of local pharmaceutical services by the person whose application was granted subject to such conditions (or by a successor to that person who likewise provides local pharmaceutical services under that scheme).

Conditional inclusion relating to fitness to practise matters

21.—(1) This regulation applies to an application to a Primary Care Trust—

- (a) under regulation 5(1)(a), except an application in respect of which preliminary consent has previously been granted, where the premises specified in the application have the same location as that in respect of which preliminary consent has previously been granted;
- (b) under regulation 40 or 54, where the applicant is not already included in that Primary Care Trust's pharmaceutical list; or
- (c) under regulation 10, where the applicant meets the conditions specified in paragraph (7) of that regulation.

(2) Where a person makes an application to which this regulation applies, a Primary Care Trust may determine that, while he remains included in the pharmaceutical list, or while his preliminary consent has effect, he is to be subject to the imposition of conditions, having regard to the requirements in section 43ZA (conditional inclusion in medical, dental, ophthalmic and pharmaceutical lists) of the Act.

(3) A Primary Care Trust may vary the terms of service in relation to an applicant for the purpose of, or in connection with, the imposition of those conditions.

(4) A Primary Care Trust shall notify the applicant in writing as soon as is practicable of any conditions it intends to impose.

(5) When the Primary Care Trust notifies the applicant of any decision under this regulation, it shall inform him that if he wishes to exercise a right of appeal he must do so within the period of 28 days beginning with the date on which it gave him the notice informing him of its decision, and shall tell him how to make an appeal.

(6) A Primary Care Trust shall require the applicant to notify it, within 28 days of the date of the notification under paragraph (4)—

- (a) whether he agrees to the imposition of the conditions; or
- (b) whether he is appealing against that imposition of conditions under regulation 30.

(7) Paragraph (8) applies where—

- (a) a Primary Care Trust has granted an application for inclusion in its pharmaceutical list but imposed conditions on that grant; and
- (b) the applicant is considering whether to appeal, or has notified the Primary Care Trust that he wishes to appeal, but wishes to be included in the pharmaceutical list during the period until the time for appeal has expired or the appeal is decided.

(8) A Primary Care Trust shall include the applicant in its pharmaceutical list if—

- (a) it has received notification from him that he agrees to the imposition of the conditions during the period until the time for appeal has expired or the appeal is decided; and
- (b) the requirements of regulation 39 are satisfied.

(9) Where no notification is received from the applicant in accordance with paragraph (5), the Primary Care Trust shall deem him to have withdrawn his application.

(10) In the case of an application under regulation 5(1)(b) or (c), where an applicant is subject to conditions imposed in accordance with this regulation, or regulation 30, 42 or 43 a grant of his application shall be subject to those same conditions.

Relevant procedures for applications

22.—(1) An application which—

- (a) does not concern a controlled locality, or does concern a controlled locality but falls within paragraph (2); and
- (b) does not fall within regulations 6 to 10 or 54 (the procedures for which are referred to in regulation 6(2), 7(2), 8(3), 9(2), 10 and 54),

shall be dealt with in accordance with the procedures set out in paragraph (4) and regulations 12(2) to (4), 23 to 30.

(2) An application falls within this paragraph—

- (a) where the application is made under regulation 5(1)(b)(iii) except where the additional services which the person wishes to be able to provide include the provision of drugs; or
- (b) where—
 - (i) the applicant is seeking only to change within a controlled locality the premises at which he provides pharmaceutical services; and
 - (ii) the granting of the application would not, in the opinion of the Primary Care Trust, result in a significant change in the arrangements for the provision of pharmaceutical services (including by a person on the dispensing doctor list) or of local pharmaceutical services in any part of the locality.

(3) An application which—

- (a) concerns a controlled locality; and
- (b) does not fall within regulations 6 to 10 or 54 (the procedures for which are referred to in regulation 6(2), 7(2), 8(3), 9(2), 10 and 54), shall, unless it falls within paragraph (2), be dealt with in accordance with the procedures set out in—
 - (i) paragraph (4) and regulations 12(2) to (4), 25, 26, 28 and 30, and
 - (ii) regulations 31 to 38.

(4) Subject to regulations 25 and 26, where the premises specified in an application under regulation 5(1) are within 1.6 kilometres of the locality of another Primary Care Trust, the Primary Care Trust shall make enquiries as to controlled localities in that locality in order to determine—

- (a) whether the application is of the description specified in regulation 20(1); and
- (b) which controlled localities are to be considered for the purposes of paragraph (2)(b)(ii) or regulation 20(1)(b),

and where it is satisfied that there is a relevant controlled locality in that locality, it shall consult that other Primary Care Trust before forming a view for the purposes of paragraph (2)(b)(ii) or regulation 20(1)(b).

Notification of applications

23.—(1) This regulation applies where a Primary Care Trust receives an application which falls to be dealt with as mentioned in regulation 6, 7 or 22(1).

(2) Subject to regulations 25 and 26, the Primary Care Trust shall, as soon as is practicable, give notice in writing of the application to—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;
- (c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

- (d) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (e) any Primary Care Trust or Local Health Board any part of whose area is within two kilometres of the premises;
- (f) any Patients' Forum serving the area of the Primary Care Trust; and
- (g) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and any person so notified may, within 45 days from the date on which the notification was sent, or such longer period as the Primary Care Trust may allow in its notification, make representations in writing to the Primary Care Trust.

(3) A Primary Care Trust or Local Health Board which is notified under paragraph (2)(e) shall, as soon as is practicable, give notice in writing of the application to—

- (a) the Local Pharmaceutical Committee for its area;
- (b) the Local Medical Committee for its area;
- (c) any person whose name is included in a pharmaceutical list and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted;
- (e) any Patients' Forum or Community Health Council serving its area; and
- (f) any other patient, consumer or community groups in the area that the Primary Care Trust or Local Health Board considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and any person so notified may, within 45 days from the date on which the notification was sent, make representations in writing to the Primary Care Trust to which the application was made.

(4) Any notice given under paragraph (2) or (3) shall include a notification of the right to make representations in accordance with that paragraph.

Determination of applications

24.—(1) Subject to the following paragraphs and regulations 25 and 26, the Primary Care Trust may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.

(2) Subject to regulations 25 and 26, in considering any application from an applicant who is not already included in that Primary Care Trust's pharmaceutical list (except an applicant who has applied under regulation 5(1)(c)), a Primary Care Trust shall—

- (a) check as far as reasonably practicable the information provided by the applicant, particularly that provided in accordance with paragraphs 1 to 6 of Part 3 of Schedule 4;
- (b) check with the National Health Service Counter Fraud and Security Management Service whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has any record of fraud;
- (c) check with the Secretary of State as to any information held by him as to any record about past or current investigations or proceedings involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (d) take up and check the references provided under paragraph 7 of Part 3 of Schedule 4; and
- (e) consider whether there are grounds—

- (i) for refusing the application under regulation 19, or
- (ii) for imposing conditions in accordance with regulation 21.

(3) In any case where the Primary Care Trust decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under regulation 23(2) or 23(3) not less than 14 days notice of the time and place at which the oral representations are to be heard.

(4) The applicant and any person mentioned in paragraph (3) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(5) The procedure by which representations are heard shall be such as the Primary Care Trust may determine.

(6) No person—

- (a) who provides or assists in providing pharmaceutical services under Part 2 of the Act;
- (b) who is an LPS chemist;
- (c) who holds a GMS contract, or is a legal and beneficial shareholder in, or director or company secretary of, a company which holds a GMS contract, or is employed or engaged by a GMS contractor;
- (d) who is a PMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a party to a PMS agreement, or is employed or engaged by a PMS contractor;
- (e) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;
- (f) who is employed or engaged by a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice; or
- (g) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or an officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.

(7) Subject to regulations 25 and 26, the Primary Care Trust may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it shall give notice in writing to the applicants and any persons to whom copies of the application were sent under regulation 23(2).

Deferral of consideration of certain applications

25.—(1) Subject to paragraph (2), this regulation applies to—

- (a) an application under regulation 5(1);
- (b) such an application where the applicant has previously been granted preliminary consent, but where regulation 41(2) applies;
- (c) an application for preliminary consent under regulation 40; or
- (d) a notification under regulation 39(8),

relating to the provision of pharmaceutical services from premises or, in the case of a notification under sub-paragraph (d) above, the changed premises which are specified or described in a designation, or located within a neighbourhood specified in a designation.

(2) This regulation does not apply to—

- (a) an application under regulation 5(1) and to which regulation 8, 9 or 10 applies;

- (b) an application under regulation 5(1) where the applicant has previously been granted preliminary consent, and where all the conditions specified in regulation 41(1) are satisfied;
- (c) an application under regulation 40 and to which, by virtue of regulation 40(3), regulation 8 or 9 applies;
- (d) an application or notification in respect of which a determination by the Primary Care Trust has been made, where that determination is the subject of an appeal under regulation 29 or 38; or
- (e) an application or notification which was received by the Primary Care Trust more than 30 days before the date of the designation mentioned in paragraph (1).

(3) A Primary Care Trust may defer consideration or determination of an application or notification to which this regulation applies; but, subject to any power to defer contained in regulation 26, may no longer do so when the designation mentioned in paragraph (1) is cancelled, or varied in such a way that it no longer specifies or includes the premises in question.

(4) A Primary Care Trust must, as soon as is practicable, notify the applicant of a decision to defer consideration or determination of his application or notification, and send him a copy of the designation mentioned in paragraph (1).

(5) In this regulation, “designation” means a designation made by a Primary Care Trust under regulation 3(1) of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(5).

Deferral of consideration of applications on fitness to practise grounds

26.—(1) A Primary Care Trust may defer consideration or determination of an application under regulation 5, 40 or 54, or an application under regulation 10 where the applicant meets the conditions specified in paragraph (7) of that regulation where—

- (a) there are, in respect of the applicant (and where the applicant is a body corporate, in respect of the applicant or a director or superintendent of the applicant)—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere in the world relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence, which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to his removal from its pharmaceutical list, if he were to be included in it;
- (b) in respect of a body corporate of which the applicant is, or has in the preceding six months been, or was at the time of the originating events, a director or superintendent, there are—
 - (i) criminal proceedings in the United Kingdom, or
 - (ii) proceedings elsewhere in the world relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence, which, if they resulted in a conviction, or the equivalent of a conviction, would be likely to lead to his removal from its pharmaceutical list, if he were to be included in it;
- (c) there is an investigation anywhere in the world by the applicant’s (or where the applicant is a body corporate, any director or superintendent of the applicant’s) licensing or regulatory body or any other investigation (including one by another Primary Care Trust or equivalent body) relating to him in his professional capacity, that if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if he were to be included in it;

- (d) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is suspended from any list or equivalent list;
- (e) a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is suspended from any list or equivalent list;
- (f) the FHSAA is considering an appeal by the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) against a decision of a Primary Care Trust or an equivalent body—
 - (i) to refuse an application by him for inclusion in any list or equivalent list,
 - (ii) to refuse an application by him for preliminary consent to be included in a pharmaceutical list held by a Primary Care Trust or equivalent body, or
 - (iii) to conditionally include him in, or to remove or contingently remove him from, any list kept by a Primary Care Trust,and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove the applicant from the pharmaceutical list if he were to be included in it;
- (g) the FHSAA is considering an appeal by a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, or has in the preceding six months been, a director or superintendent, against a decision of a Primary Care Trust or an equivalent body—
 - (i) to refuse an application by that body corporate for inclusion in its list,
 - (ii) to refuse an application by that body corporate for preliminary consent to be included in a pharmaceutical list held by a Primary Care Trust or equivalent body, or
 - (iii) to conditionally include it in, or to remove or contingently remove it from, any list kept by a Primary Care Trust or equivalent body,and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove the applicant from the pharmaceutical list if it were to be included in it;
- (h) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is being investigated by the National Health Service Counter Fraud and Security Management Service in relation to any fraud, where the result, if adverse, would be likely to lead to the removal of the applicant from the pharmaceutical list if he were to be included in it;
- (i) a body corporate, of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent, is being investigated by the National Health Service Counter Fraud and Security Management Service in relation to any fraud case, where the result if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if he had been included in it;
- (j) the FHSAA is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (k) the FHSAA is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of a body corporate of which the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) was, at the time of the originating events, a director or superintendent; or
- (l) in the case of an application under regulation 5(1)(b) or (c), a Primary Care Trust or equivalent body is considering removal or contingent removal of the applicant from any of its lists or equivalent lists on fitness to practise grounds, or the Primary Care Trust or

equivalent body has taken a decision to remove or contingently remove the applicant from any of its lists or equivalent lists on fitness to practise grounds but that decision has yet to take effect.

(2) Subject to any power to defer consideration or determination of an application under regulation 25, a Primary Care Trust may only defer a decision under paragraph (1) until the outcome of the relevant event mentioned in that paragraph is known.

(3) A Primary Care Trust must, as soon as is practicable, notify the applicant in writing of a decision to defer consideration or determination of his application, and the reasons for this.

(4) Subject to regulation 25, once the outcome of the relevant event mentioned in paragraph (1) is known the Primary Care Trust shall notify the applicant that he must within 28 days of the date of the notification (or such longer period as it may agree)—

- (a) update his application; and
- (b) confirm in writing that he wishes to proceed with his application.

(5) If the applicant fails to update his application or confirm that he wishes to proceed in accordance with paragraph (4), the Primary Care Trust shall deem him to have withdrawn his application.

(6) Provided any additional information has been received within the 28 days or the time agreed, the Primary Care Trust shall notify the applicant as soon as possible—

- (a) that his application to be included has been successful; or
- (b) that it has decided to refuse the application or decided to impose conditions on his inclusion, and the reasons for that (including any facts relied upon), and of any right of appeal under regulation 19(6), 29 and 30.

Notification of decision

27.—(1) Subject to paragraph (2), a Primary Care Trust shall, as soon as practicable, and in any event within the period of four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing of its decision on an application under regulation 5(1), or of its decision whether or not to amend the premises named in the original application as mentioned in regulation 39(8)—

- (a) in the case of an application to which regulation 6, 7, 8, 9, 10 or 39(8) applies, to—
 - (i) the applicant,
 - (ii) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision,
 - (iii) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected by the decision,
 - (iv) the Local Pharmaceutical Committee,
 - (v) the Local Medical Committee,
 - (vi) any Primary Care Trust or Local Health Board any part of whose locality is within two kilometres of the premises, and
 - (vii) any Patients' Forum serving the locality of the Primary Care Trust, and
 - (viii) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood; and
- (b) in the case of an application to which regulation 12 applies, or would apply but for an exemption under regulation 13 to—

- (i) the applicant, and
- (ii) any person who has made representations to the Primary Care Trust in accordance with regulation 23(2) or (3),

and shall include with the notice a statement of the reasons for the decision and of any rights of appeal arising under regulation 29.

(2) In the case of an application that involves a change of ownership and falls to be dealt with under regulation 8(1), for the period of four months specified in paragraph (1) there shall be substituted a period of 30 days.

(3) Any Primary Care Trust or Local Health Board which is notified under paragraph (1)(a)(vi) shall, as soon as practicable, give notice in writing of the decision and reasons to—

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;
- (c) any person whose name is included in the pharmaceutical list and whose interests might in the opinion of that Primary Care Trust or Local Health Board be significantly affected by the decision;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected by the decision;
- (e) any Patient’s Forum or Community Health Council notified under regulation 23(3)(e); and
- (f) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood,

and shall notify them of any rights of appeal arising under regulation 29.

(4) In this regulation, “decision” includes a decision to grant an application subject to conditions, where the applicant has agreed to the imposition of the conditions pursuant to regulation 21(6)(a).

Notifications by Primary Care Trusts to other persons

28.—(1) Where a Primary Care Trust—

- (a) refuses to grant an application on grounds specified in regulation 19; or
- (b) imposes conditions under regulation 21, 30, 42 or 43,

it shall notify the persons and bodies specified in paragraph (2), and shall additionally notify those specified in paragraph (3) if so requested by those persons or bodies in writing (including electronically), of the matters set out in paragraph (4); and the applicant or chemist in relation to whom such a decision has been taken under this paragraph is called a “pharmaceutical practitioner” in this regulation.

(2) Where paragraph (1) applies, a Primary Care Trust shall notify—

- (a) the Secretary of State;
- (b) any Primary Care Trust or equivalent body that has on any of its lists or equivalent lists—
 - (i) the pharmaceutical practitioner, or
 - (ii) a body corporate of which the pharmaceutical practitioner is a director or superintendent,

or any Primary Care Trust or equivalent body that is considering an application for inclusion in, or for preliminary consent to be included in, any of its lists or equivalent lists from such a practitioner, director, superintendent or body corporate;

- (c) the Scottish Executive;

- (d) the National Assembly for Wales;
 - (e) the Northern Ireland Executive;
 - (f) the Royal Pharmaceutical Society of Great Britain, the Pharmaceutical Society of Northern Ireland or any other appropriate regulatory body;
 - (g) the Local Pharmaceutical Committee for the Primary Care Trust's area;
 - (h) the National Patient Safety Agency⁽⁶⁾; and
 - (i) where it is a fraud case, the National Health Service Counter Fraud and Security Management Service.
- (3) The persons or bodies who may request to be additionally notified in accordance with paragraph (1) are—
- (a) persons or bodies that can establish that they—
 - (i) are or were employing the pharmaceutical practitioner, are using or have used his services (or where the pharmaceutical practitioner is a body corporate, any director or superintendent of that practitioner) in a professional capacity, or
 - (ii) are considering employing or using the services of the pharmaceutical practitioner (or where the pharmaceutical practitioner is a body corporate, any director or superintendent of that practitioner) in a professional capacity; and
 - (b) a partnership any of whose members provide or assist in the provision of pharmaceutical services and can establish that the pharmaceutical practitioner is or was a member of the partnership, or that it is considering inviting him to become such a member.
- (4) The matters referred to in paragraph (1) are—
- (a) the name, address and date of birth of the pharmaceutical practitioner;
 - (b) where the pharmaceutical practitioner is a body corporate, the name and registered office of the body corporate;
 - (c) any professional registration number of the pharmaceutical practitioner;
 - (d) the date and a copy of the decision of the Primary Care Trust; and
 - (e) a contact name of a person in the Primary Care Trust for further enquiries.
- (5) The Primary Care Trust shall send to the pharmaceutical practitioner concerned a copy of any information about him provided to the persons or bodies specified in paragraphs (2) and (3) and any correspondence with those persons or bodies relating to that information.
- (6) Where the Primary Care Trust has notified any of the persons or bodies specified in paragraph (2) or (3) of the matters set out in paragraph (4), it may in addition, if so requested by that person or body, notify that person or body of any evidence that was considered, including representations made by the pharmaceutical practitioner.
- (7) Where a Primary Care Trust is notified by the FHSAA that it has imposed a national disqualification on a pharmaceutical practitioner whom the Primary Care Trust has removed from its list, it shall notify the persons or bodies specified in paragraph (2)(b), (g), (h) and (i) and paragraph (3).
- (8) Where a decision is changed on review or appeal, or a suspension lapses, the Primary Care Trust shall notify any person or body that was notified of the original decision of the later decision, or of the fact that the suspension has lapsed.

⁽⁶⁾ The National Patient Safety Agency is established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001 (S.I. 2001/1743).

Appeals

29.—(1) This regulation shall not apply to any right of appeal specified—

- (a) in regulation 6(5) or 7(5);
- (b) in regulation 19(6); or
- (c) in regulation 30.

(2) Where a Primary Care Trust—

- (a) has determined an application to which regulation 6(1), 7(1), 8, 9 and 10 applied; or
- (b) made a decision whether or not to amend the premises named in the original application as mentioned in regulation 39(8),

the applicant and any person who has been notified of the decision under regulation 27(1)(a)(ii) or (iii) or regulation 27(3)(c) or (d) may appeal to the Secretary of State.

(3) Where a Primary Care Trust has determined an application to which regulation 12 applied, or would apply but for an exemption under regulation 13, the persons who may appeal to the Secretary of State are—

- (a) the applicant; and
- (b) except in the case of an application to which regulation 13(1) applies, any person who—
 - (i) was given notice of the application under regulation 23(2)(c) or (d) or regulation 23(3)(c) or (d), and
 - (ii) made representations to the Primary Care Trust in accordance with regulation 23(2) or (3).

(4) Where a Primary Care Trust refuses to allow an extension to the period within which an applicant is to notify the Primary Care Trust that he will commence provision of the services, as mentioned in regulation 39(2), the applicant may appeal to the Secretary of State.

(5) Where a Primary Care Trust has notified an applicant that he is required to commence provision of the services, as mentioned in regulation 39(3), the applicant may appeal to the Secretary of State.

(6) Any appeal under this regulation shall be made by sending to the Secretary of State a notice of appeal in writing—

- (a) within 30 days from the date on which the Primary Care Trust sent its decision to the appellant; or
- (b) in the case of an appeal against a determination to which regulation 6, 7, 8, 9 and 10 applied, or a decision pursuant to regulation 39(8), such longer period as the Secretary of State may for reasonable cause allow.

(7) Where in determining an application, a Primary Care Trust has, pursuant to regulation 24(7), considered that application together with one or more other applications, any of the applicants and any of the persons mentioned in paragraph (2) or (3) may appeal against the determination of any of the applications, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(8) The Secretary of State may consider together two or more appeals against a Primary Care Trust provided that those appeals relate to an application within the same neighbourhood which fell to be granted under regulation 6(1), 7(1) or 8(1).

(9) Any notice of appeal made under this regulation shall contain a concise statement of the grounds of appeal.

(10) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(11) Unless paragraph (10) applies, the Secretary of State shall send a copy of the notice of appeal to the Primary Care Trust whose determination is appealed against and—

- (a) in the case of an appeal to which paragraph (2) or (4) relates, to the persons mentioned in regulation 27(1)(a);
- (b) in the case of an appeal to which paragraph (3) relates, to the persons mentioned in regulation 27(1)(b); or
- (c) in the case of an appeal to which regulation 9(1) or (3) or 54(24) relates, to the applicant and to the suspended chemist.

(12) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (11) may, within 30 days from the date on which the notice was sent to him, make representations in writing to the Secretary of State on appeal.

(13) The Secretary of State may require an oral hearing before he determines the appeal.

(14) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(15) The procedure of any oral hearing shall be determined by the person or persons hearing the appeal.

(16) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (11).

(17) The appellant and any person to whom a notice of the hearing is sent under paragraph (16) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(18) On determining an appeal under this regulation, the Secretary of State shall either—

- (a) allow the appeal;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination;
- (d) confirm the decision of the Primary Care Trust; or
- (e) where paragraph (5) applies, specify a date for the commencement of pharmaceutical services by the appellant.

(19) The Secretary of State shall, as soon as practicable, send to the appellant and to any person to whom a copy of the notice of appeal was sent pursuant to paragraph (11) and who made representations under paragraph (12), notice in writing of his decision on the appeal and shall include in the notice a statement of his reasons for the decision and of his findings of fact.

Appeals against imposition of conditions and related decisions

30.—(1) An applicant (or a person whose application has been granted subject to conditions, as the case may be) may appeal to the FHSAA against any decision of the Primary Care Trust to impose conditions, or any particular condition, on him in accordance with regulation 21(2); and the appeal shall be by way of redetermination of the Primary Care Trust’s decision.

(2) An appeal under this regulation must be made within 28 days of the notification of the decision being appealed against.

(3) On appeal the FHSAA may make any decision which the Primary Care Trust could have made, and shall notify the appellant and the Primary Care Trust in writing as soon as is practicable of the decision.

(4) Where the decision of the FHSAA on appeal is that conditions be imposed on the appellant, whether or not those conditions are identical with the conditions imposed by the Primary Care Trust, the Primary Care Trust shall require the appellant to notify it, within 28 days of the date of the notification to him under paragraph (3), as to whether he agrees to the imposition of the conditions.

(5) Where no notification is received from the appellant in accordance with paragraph (4), or the appellant notifies the Primary Care Trust that he does not agree to the imposition of the conditions, the Primary Care Trust shall deem him to have withdrawn his application and shall remove his name from its pharmaceutical list if his name was included pursuant to regulation 21(8).

(6) Subject to regulation 21(8), any decision of the Primary Care Trust that may be the subject of an appeal under this regulation shall not have effect until the FHSAA has determined any appeal against it or any time for appeal has expired.

Determination that an area is a controlled locality

31.—(1) Where, before the coming into force of these Regulations, an area was a controlled locality for the purposes of the 1992 Regulations, subject to the provisions of this regulation, that area shall continue to be a controlled locality.

(2) Subject to paragraph (10), a Primary Care Trust may at any time consider and determine whether or not an area is rural in character, and paragraphs (7) and (8)(b) and (c) shall apply as they apply to an application under paragraph (3).

(3) A Local Medical Committee or a Local Pharmaceutical Committee may at any time apply in writing to a Primary Care Trust to consider and determine whether or not an area specified in the application is rural in character.

(4) On receiving an application under paragraph (3), the Primary Care Trust shall, subject to paragraph (10), consider and determine whether or not the area specified in the application or any part of such area, is rural in character.

(5) The Primary Care Trust shall, before making a determination under this regulation, give notice in writing to the Local Medical Committee, the Local Pharmaceutical Committee and any provider of primary medical services or chemist, or LPS chemist who, in the opinion of the Primary Care Trust, may be affected by the determination, and shall inform them that they may make representations in writing within 30 days from the date on which the notice was sent.

(6) Where the Primary Care Trust determines that any area or part of an area is or is not rural in character, it shall consider whether the provision of primary medical services by any provider of primary medical services (except itself), or pharmaceutical services by any chemist (other than a distance selling chemist), or local pharmaceutical services by any LPS chemist, is likely to be adversely affected in consequence of that determination.

(7) The Primary Care Trust shall determine the boundaries of any area, or part of an area, referred to in the application which it determines to be rural in character, and—

- (a) any area determined to be rural in character by the Primary Care Trust or, on appeal under regulation 32, by the Secretary of State, shall be a controlled locality; and
- (b) the Primary Care Trust shall delineate precisely the boundaries of any controlled locality on a map, and shall publish the map.

(8) Any area forming part of an area referred to in an application under paragraph (3) which is determined not to be rural in character shall not be or, as the case may require, shall cease to be, a controlled locality.

(9) The Primary Care Trust shall not in consequence of a determination under paragraph (4)—

- (a) include any particulars in a pharmaceutical list;
- (b) give notice to a doctor pursuant to regulation 60(7);
- (c) give notice to a GMS contractor or PMS contractor pursuant to an equivalent provision to regulation 60(7) under the GMS Regulations or PMS Regulations; or
- (d) determine an application under regulation 36,

during the period for bringing an appeal or pending the determination of any such appeal.

(10) Subject to paragraph (11), where the question whether or not an area is rural in character has been determined—

- (a) by a Primary Care Trust under this regulation; or
- (b) on appeal under regulation 32,

that question shall not again be considered in relation to that area or any part of it during the period of five years immediately following the date of the determination.

(11) A question to which paragraph (10) applies may be considered by a Primary Care Trust during the period referred to in that paragraph only where it is satisfied, whether on an application under paragraph (3) or otherwise, that there has been a substantial change in circumstances in relation to the area in question, or the relevant part of it, since the question was last determined.

(12) The Primary Care Trust shall, upon any determination by it under this regulation, give to the persons mentioned in paragraph (5) notice in writing of its determination and of the reasons for it, and shall inform them that they may appeal to the Secretary of State in accordance with regulation 32.

Appeals relating to rurality of an area

32.—(1) Where a Primary Care Trust—

- (a) has determined, pursuant to regulation 31, that an area is, or is not, rural in character;
- (b) has refused to consider that question on the ground that it is not satisfied as mentioned in paragraph (11) of that regulation; or
- (c) has determined under these Regulations that it should, or should not, postpone the making or termination of arrangements, as mentioned in regulation 20(2),

the Local Medical Committee, the Local Pharmaceutical Committee or a provider of primary medical services under Part 1 of the Act, chemist or LPS chemist who is required to be given notice by the Primary Care Trust under regulation 31(5) may appeal to the Secretary of State against any such determination or, as the case may be, refusal, by giving notice of appeal in accordance with paragraph (2).

(2) Any notice of appeal under paragraph (1) shall be sent to the Secretary of State, within 30 days of the date on which the decision of the Primary Care Trust was sent to the person making the appeal, and shall contain a concise statement of the grounds of appeal.

(3) The Secretary of State shall, on receipt of any notice of appeal under this regulation, send copies thereof to the Primary Care Trust and to all the persons to whom it has given notice of its determination under regulation 31 (12).

(4) The Primary Care Trust and the persons to whom the notice of appeal was sent under paragraph (3) may, within 30 days from the date on which the Secretary of State sent copies to them of the notice of appeal under this regulation, make representations in writing to him on the appeal.

(5) The Secretary of State may require an oral hearing before he determines an appeal under this regulation.

(6) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal and to report to him on it.

(7) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(8) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person to whom a copy of the notice of appeal was sent under paragraph (3).

(9) The appellant and any person to whom a notice of the hearing is sent under paragraph (8) may attend the hearing and be heard in person or by counsel, solicitor or other representative, and the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(10) On determining an appeal under this regulation, the Secretary of State—

- (a) shall, where he allows an appeal against a refusal mentioned in paragraph (1)(b), also determine the question whether or not the relevant area is rural in character;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients, himself postpone, for such a period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination.

(11) The Secretary of State shall, upon the determination by him of an appeal under this regulation, give notice of the decision in writing, together with his reasons for it, to all the persons to whom the notice of appeal was sent under paragraph (3).

Notification of an application in respect of premises in a controlled locality

33.—(1) This regulation applies where a Primary Care Trust receives an application which falls to be dealt with as mentioned in regulation 22 (3) or 35(7)(b).

(2) Subject to regulations 25 and 26, the Primary Care Trust shall send a notice of the application and a copy of the application to—

- (a) the Local Pharmaceutical Committee;
- (b) the Local Medical Committee;
- (c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;

- (e) any person (except itself) who is a provider of primary medical services within the area of the Primary Care Trust, or whose name is included in the dispensing doctor list of the Primary Care Trust, who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted;
 - (f) any Primary Care Trust or Local Health Board any part of whose area is within two kilometres of the premises;
 - (g) any Patients' Forum serving the locality of the Primary Care Trust;
 - (h) any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood;
 - (i) any other Primary Care Trust part of whose area is or might form part of a reserved location; and
 - (j) where the determination is required to be made by regulation 61, any other Primary Care Trust part of whose area is within 1.6 kilometres of the premises from which the doctor wishes to dispense.
- (3) Subject to regulations 25, and 26 where a Primary Care Trust or Local Health Board is sent a copy of an application under paragraph (2)(f) it shall, as soon as practicable, send a copy to—
- (a) the Local Pharmaceutical Committee for its locality;
 - (b) the Local Medical Committee for its locality;
 - (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
 - (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted;
 - (e) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted; and
 - (f) any Patients' Forum or Community Health Council serving its area;
 - (g) and any other patient, consumer or community groups in the area of the Primary Care Trust that the Primary Care Trust considers has an interest in the provision of pharmaceutical services in the neighbourhood.
- (4) Any person to whom a Primary Care Trust or Local Health Board has sent a copy of the application may, within 30 days of the date on which that copy was sent to him make representations in writing to the Primary Care Trust to which the application was made.
- (5) Any other person who considers that he might be affected by the decision may, within such reasonable period as the Primary Care Trust to whom the application was made may allow, make representations in writing to it.

Decision not to consider an application in respect of premises in a controlled locality

- 34.—(1) Subject to paragraph (2), a Primary Care Trust shall not consider under regulation 36—
- (a) any application for outline consent under regulation 61 where, during the relevant period, an application made under that regulation or any corresponding provision of directions relating to dispensing services in respect of the same area has been finally refused;
 - (b) any application to which regulation 40 applies, where the location of the premises at which the pharmacist intends to provide pharmaceutical services is in a controlled locality and—

- (i) is in an area in respect of which an application under regulation 61 or any corresponding provision of directions relating to dispensing services was finally granted during the relevant period, or
- (ii) is within 1.6 kilometres of the location of premises in respect of which an application to which regulation 22(1) or (3) applies was finally refused during the relevant period;
- (c) any request by a chemist under regulation 35(5) for a determination as to whether premises are in a reserved location, where the application in relation to the premises was refused by the operation of regulation 18(2) during the relevant period; or
- (d) any application by a doctor for outline consent or premises approval for premises—
 - (i) in respect of which outline consent or premises approval has been refused by the operation of regulation 18(2) during the relevant period, or
 - (ii) which are within 1.6 kilometres of such premises.

(2) A Primary Care Trust may at any time consider an application to which paragraph (1) applies where it is satisfied that, since the date of the refusal or, as the case may be, grant referred to in paragraph (1)(a) or (b), or, where there has been more than one such refusal or grant during the relevant period, the last such refusal or grant, there has been a substantial change of circumstances affecting the controlled locality.

(3) In this regulation, “relevant period” means the period of 5 years immediately preceding the making of the application.

Pharmaceutical services in reserved locations

35.—(1) Subject to regulation 34, the Primary Care Trust shall, when the period for representations has expired under regulation 33 determine whether the premises, or relevant location, from which the applicant wishes to provide pharmaceutical services, at the date of the receipt of the application by the Primary Care Trust, are in a reserved location.

(2) In this regulation—

- (a) subject to paragraph (3), a “reserved location” means that the number of individuals on all of the patient lists for the area which is within 1.6 kilometres of the premises, or from the relevant location, as the case may be, is less than 2750; and
- (b) the “relevant location” means, where the location of the premises from which the pharmaceutical services are to be provided is specified in writing by the applicant before the Primary Care Trust make its determination, that location, and where that location is not so specified, the best estimate the Primary Care Trust is able to make of where those premises may be.

(3) Premises, or a relevant location, are not in a reserved location where the Primary Care Trust considers that there are circumstances, including but not limited to the age or degree of infirmity of the individuals referred to in paragraph (2), why the extent of use of pharmaceutical services if a pharmacy were to operate from the premises or from the relevant location would be similar to or greater than might be expected if the number of individuals mentioned in paragraph (1)(a) were 2750 or more.

(4) Before reaching its opinion under paragraph (3) the Primary Care Trust shall invite and consider representations as to whether paragraph (3) may apply from those persons mentioned in regulation 33(2).

(5) Subject to regulation 34(1)(c), where it has been determined by the Primary Care Trust or on appeal by the Secretary of State, in relation to premises, or a relevant location, from which pharmaceutical services are to be, or are being, provided, that those premises are in a reserved

location, the chemist in relation to those premises, or that relevant location, may make an application in writing for the Primary Care Trust to make a further determination as to whether, on the date the request is made, that is, the date stated on it, those premises are, or that the relevant location is, in a reserved location.

(6) Where, in making a further determination applied for in accordance with paragraph (5) the Primary Care Trust would determine that those premises are, or that relevant location is, not in a reserved location, or there is an appeal against a determination by the Primary Care Trust and it is determined on the appeal that premises are not, or that relevant location is not, in a reserved location—

- (a) the Primary Care Trust shall determine that the premises are, or the relevant location is, to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Primary Care Trust itself), dispensing services or pharmaceutical services in any locality; or
- (b) if the Primary Care Trust considers that the provision of primary medical services by a provider of primary medical services (other than one employed by the Primary Care Trust), or pharmaceutical services by any chemist, is likely to be adversely affected by a determination that the premises are not in a reserved location, it shall make such a determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or a GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients.

(7) A determination required by—

- (a) paragraph (1) shall be made in accordance with this regulation, and with regulations 34, 36 and 37; and
- (b) paragraph (5) shall be made in accordance with this regulation and regulations 33, 34, 36 and 37.

(8) Where—

- (a) there is an appeal against a determination made by the Primary Care Trust that premises are, or a relevant location is, in a reserved location; and
- (b) it is determined by the appeal that the premises are not, or relevant location is not, in a reserved location,

the Primary Care Trust shall redetermine the application.

(9) The Primary Care Trust shall delineate precisely the boundaries of any reserved location it has determined under paragraph (1) or (5) on a map, and shall publish the map.

Determination of applications in respect of controlled localities

36.—(1) Subject to regulations 25 and 26, the Primary Care Trust may make a determination in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, make the determination without hearing any oral representations.

(2) When determining an application, the Primary Care Trust shall consider whether the provision of primary medical services by any provider of such services (except itself) or pharmaceutical services by any chemist or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of that grant, and whether any conditions should be imposed in accordance with regulation 20(2).

(3) Subject to regulations 25 and 26, in considering any application made under regulation 5 from an applicant who is not already included in that Primary Care Trust's pharmaceutical list, a Primary Care Trust shall—

- (a) check as far as practicable the information provided by the applicant, particularly that provided in accordance with paragraphs 1 to 6 of Part 3 of Schedule 4;
- (b) check with the National Health Service Counter Fraud and Security Management Service whether the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) has any record of fraud;
- (c) check with the Secretary of State as to any information held by him as to any record about past or current investigations or proceedings involving or related to the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant);
- (d) take up and check any references provided under paragraph 7 of Part 3 of Schedule 4; and
- (e) consider whether there are grounds—
 - (i) for refusing the application under regulation 19, or
 - (ii) for imposing conditions in accordance with regulation 21.

(4) In any case where the Primary Care Trust decides to hear oral representations, it shall give the applicant and any person from whom it has received representations under regulation 33(4) or (5) not less than 14 days notice of the time and place at which the representations are to be heard.

(5) The Primary Care Trust may invite any other person to give oral evidence as it thinks fit.

(6) The applicant and any person mentioned in paragraph (4) may be assisted at any such hearing in the presentation of his representations by some other person, but no person shall be entitled to be heard in the capacity of counsel or solicitor.

(7) The procedure by which representations are heard shall be such as the Primary Care Trust may determine.

(8) No person—

- (a) who provides or assists in providing pharmaceutical services under Part 2 of the Act;
- (b) who is a LPS chemist;
- (c) who is a GMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a GMS contractor, or is employed or engaged by a GMS contractor;
- (d) who is a PMS contractor, or is a legal and beneficial shareholder in, or director or company secretary of, a company which is a PMS contractor, or is employed or engaged by a PMS contractor;
- (e) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;
- (f) is employed or engaged by a Primary Care Trust for the purposes of providing primary medical services within a PCTMS practice; or
- (g) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or a director, officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.

(9) Subject to regulations 25 and 26, the Primary Care Trust may, where it thinks fit, where two or more determinations fall to be made which relate to each other, make those determinations together, and, where it proposes to do so, it shall so inform the applicants and the persons to whom copies of the applications were sent under regulation 33.

Notification of decision in respect of applications in controlled localities

37.—(1) The Primary Care Trust shall, as soon as practicable after making the determination and in any event within four months beginning with the date of receipt of the application unless the Primary Care Trust has good cause to require a longer period, give notice in writing—

- (a) of its decision and the reasons for that decision to—
 - (i) the applicant,
 - (ii) the Local Pharmaceutical Committee,
 - (iii) the Local Medical Committee,
 - (iv) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (v) any LPS chemist whose interests might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (vi) any person (except itself) who is a provider of primary medical services within the area of the Primary Care Trust or whose name is included in the dispensing doctor list of the Primary Care Trust, who might, in the opinion of the Primary Care Trust, be significantly affected if the application were granted,
 - (vii) any other Primary Care Trust or Local Health Board to which notice was sent pursuant to regulation 33(2)(f), (i) or (j), and
 - (viii) any other person who has made representations under the provisions of regulation 33(4) or (5); and
- (b) of the rights of appeal arising under regulation 38 to—
 - (i) the applicant, and
 - (ii) any person who made representations under the provisions of regulation 33(4), other than a Local Pharmaceutical Committee or a Local Medical Committee.

(2) In the case of an application that involves a change of ownership and falls to be dealt with under regulation 8(1), for the period of four months specified in paragraph (1) there shall be substituted the period of 30 days.

(3) Any Primary Care Trust or Local Health Board which is notified under paragraph (1)(a)(vii) shall, as soon as practicable, give notice in writing of the decision and reasons for it to—

- (a) the Local Pharmaceutical Committee for its locality;
- (b) the Local Medical Committee for its locality;
- (c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted;
- (d) any LPS chemist whose interests might, in the opinion of that Primary Care Trust, be significantly affected if the application were granted; and
- (e) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Primary Care Trust or Local Health Board, be significantly affected if the application were granted.

(4) In paragraph (1), “making the determination” includes granting an application subject to conditions, where the applicant has agreed to the imposition of the conditions pursuant to regulation 21(6)(a).

Appeals in connection with determinations in respect of controlled localities etc

- 38.**—(1) This regulation shall not apply to any right of appeal specified—
- (a) in regulation 19(6); or
 - (b) in regulation 30.
- (2) Where a Primary Care Trust—
- (a) has determined an application or a question raised by an application under regulations 33 to 36;
 - (b) has refused to consider an application under those regulations on the ground that it is not satisfied as mentioned in regulation 34(2);
 - (c) has determined that it should, or should not, postpone the making or termination of arrangements under regulation 60, as mentioned in regulation 20(2) or 35(6)(b); or
 - (d) has refused to consider an application for preliminary consent under regulation 40(1) in accordance with the procedures set out in regulations 33 to 36;
 - (e) has determined that—
 - (i) the provisional date shall be extended under regulation 62(8),
 - (ii) the application for outline consent shall be refused under paragraph (13)(a) of that regulation or,
 - (iii) outline consent shall lapse under paragraph (13)(b) of that regulation;
 - (f) has determined an application for premises approval for new premises under regulation 64(1);
 - (g) has determined an application for premises approval for additional or new premises under regulation 65(1) or (3);
 - (h) has determined an application for premises approval in relation to a practice amalgamation under regulation 66(3);
 - (i) has refused to grant temporary premises approval under regulation 65(9) or 66(4); or
 - (j) has determined whether or not to grant premises approval to relevant premises under regulation 67,

an appeal to the Secretary of State may be made, in accordance with paragraph (5), against that determination or, as the case may be, against that refusal, by any person specified in paragraph (3).

- (3) The persons who may make an appeal under this regulation are—
- (a) in the case of an appeal mentioned in paragraph (2)(a), (c), (d), (g), (h) and (j)—
 - (i) the applicant,
 - (ii) any person who—
 - (aa) provides primary medical services within the area of the Primary Care Trust (except itself), or any other Primary Care Trust to which a copy of the application was sent under regulation 33(2)(f), (h) or (i), or
 - (bb) whose name is included in the pharmaceutical list or dispensing doctor list of the Primary Care Trust, or any other Primary Care Trust or Local Health Board to which a copy of the application was sent under regulation 33(2)(f), (h) or (i), or
 - (iii) any person who provides local pharmaceutical services under a pharmacy pilot scheme entered into by the Primary Care Trust or any other Primary Care Trust to which a copy of the application was sent under regulation 33(2)(f),

but in the case of a person specified in paragraph (ii) or (iii), that person may make an appeal only if he has made representations pursuant to regulation 33(4) in connection with the application; and

(b) in the case of an appeal mentioned in paragraph (2)(b), (e), (f) and (i), the applicant.

(4) Where, in determining any application or question raised by an application, a Primary Care Trust has, pursuant to regulation 36(9), considered that application or question together with one or more other applications or questions, any of the applicants and any of the persons mentioned in paragraph (3)(a) may appeal against the determination of any of the applications, or against any determination of a question raised by an application, and where the Secretary of State receives appeals against two or more of the determinations, those appeals shall be considered together.

(5) An appeal shall be made in writing within 30 days from the date on which notice of the decision was sent to the appellant and shall contain a concise statement of the grounds of appeal on which the appellant intends to rely.

(6) If the Secretary of State, after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, he may determine the appeal by dismissing it.

(7) Unless paragraph (6) applies, the Secretary of State shall send a copy of the notice of appeal to the Primary Care Trust whose determination is appealed against, to those persons mentioned in paragraph (3)(a) and to any Local Medical Committee and Local Pharmaceutical Committee to which a copy of the application was required to be sent under regulation 33(2) or (3).

(8) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (7) may, within 30 days from the date the copy was sent to him, make representations in writing on the appeal to the Secretary of State.

(9) The Secretary of State may require an oral hearing of an appeal before he determines it.

(10) The Secretary of State shall, where he requires an oral hearing, appoint one or more persons to hear the appeal who shall report to him on it with recommendations as to the relevant findings of fact and their conclusions.

(11) The procedure at any oral hearing shall be determined by the person or persons hearing the appeal.

(12) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to—

- (a) the appellant;
- (b) the Primary Care Trust;
- (c) the Local Medical Committee;
- (d) the Local Pharmaceutical Committee; and
- (e) any other person who made representations to the Primary Care Trust in connection with the application.

(13) The appellant and any of the persons to whom notice of the hearing is required to be sent under paragraph (12) may attend and be heard in person or by counsel, solicitor or other representative, and the Primary Care Trust may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(14) On an appeal under this regulation, the Secretary of State—

- (a) may allow the appeal;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations

- or PMS Regulations) for the provision by a doctor or GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination;
 - (d) shall, where he allows an appeal against a refusal of the Primary Care Trust as mentioned in paragraph (2)(b), remit the application to the Primary Care Trust and direct that regulation 34(1) shall not apply; or
 - (e) may dismiss the appeal.
- (15) The decision of the Secretary of State shall be given in writing and shall—
- (a) include a statement of his reasons for the decision and of his findings of fact; and
 - (b) as soon as practicable, be sent to the persons mentioned in paragraph (12).

Procedure after grant of application

39.—(1) Subject to regulation 21(8), a Primary Care Trust shall not include an applicant in its pharmaceutical list, or include him in respect of different premises or services, before—

- (a) the date specified in paragraph (10); and
- (b) the satisfaction of the condition specified in paragraph (2).

(2) Where an application is granted by the Primary Care Trust (or, on appeal, by the Secretary of State or the FHSAA), the applicant shall be included in the Primary Care Trust's pharmaceutical list, or included in respect of different premises or services, only if, not less than 14 days before—

- (a) the expiry of six months after the date on which the grant was notified to him by the Primary Care Trust in accordance with regulation 27(1) or regulation 37(1); or
- (b) the expiry of such further period or periods, not in all exceeding nine months from the date of notification of the grant, as it, or on appeal the Secretary of State, may for good cause allow,

he notifies the Primary Care Trust, in the form set out in Part 2 of Schedule 4, that he will within the next 14 days commence the provision of the services in respect of which the application was made at the premises to which the application related.

(3) The Primary Care Trust may give written notice to an applicant whose application under regulation 5(1)(a) has been granted requiring him to commence the provision of pharmaceutical services by a date specified in its notice.

- (4) The Primary Care Trust may not specify in the notice to be given under paragraph (3) a date—
- (a) earlier than the date specified in paragraph (10);
 - (b) subject to sub-paragraph (d), within the period of 28 days beginning with the date of its notice;
 - (c) subject to sub-paragraph (d) ending later than the period of 3 months beginning with the date of its notice; or
 - (d) ending later than nine months from the date of notification of the grant.

(5) A notice under paragraph (3) shall inform the applicant of his right to appeal against the notice under regulation 29(5) and shall tell him how to make such an appeal.

(6) Where the Primary Care Trust has given a notice under paragraph (3), it shall include the applicant in its pharmaceutical list from the date specified unless the Primary Care Trust—

- (a) the Primary Care Trust for good cause determines that the applicant shall commence the provision of pharmaceutical services from a different date (being a date not later than nine months from the date of notification of the grant), in which case the applicant shall be included in the pharmaceutical list from that date;
 - (b) the Primary Care Trust withdraws its notice;
 - (c) the applicant appeals under regulation 29(5), in which case where the appeal is unsuccessful the applicant shall be included in the Primary Care Trust's pharmaceutical list in accordance with the Secretary of State's determination of the appeal.
- (7) Where—
- (a) the Primary Care Trust has granted an application made under regulation 5(1)(b) or (c); and
 - (b) the applicant is suspended from the Primary Care Trust's pharmaceutical list,
- before giving the notification required under paragraph (2), a temporary chemist whose application to provide pharmaceutical services in his place has been granted may give that notification in accordance with paragraph (2); and (on satisfaction of the requirements in paragraph (1)) the Primary Care Trust shall include the temporary chemist in its pharmaceutical list.
- (8) Where, at any time after making the application, but before—
- (a) the expiry of the six months referred to in paragraph (2), or of any further period allowed by the Primary Care Trust or, on appeal, by the Secretary of State, in accordance with that paragraph; or
 - (b) the date specified by the Primary Care Trust in its notice under paragraph (3),
- the applicant notifies the Primary Care Trust that he intends to change within the neighbourhood the premises from which he intends to provide pharmaceutical services, being the same services as those named in the application, and the Primary Care Trust is satisfied that the change is a minor relocation, it may, subject to regulations 25 and 26, amend the premises named in the original application.
- (9) The date specified in paragraph (10) is—
- (a) the date before which an applicant may not be included in the pharmaceutical list (or included in respect of different premises or services) for the purposes of paragraph (1); and
 - (b) the date of the notification of a grant of an application for the purposes of paragraphs (2) and (4).
- (10) The date referred to in paragraph (9) is whichever of the dates mentioned in sub-paragraphs (a) or (b) is the later—
- (a) the day after the expiry of the period of 30 days beginning on the date on which notice of the Primary Care Trust's decision is given under regulation 27(1) or (as the case may be) regulation 37(1); or
 - (b) where an appeal or appeals relating to an application are made under these Regulations, the date on which the Secretary of State or the FHSAA, as the case may be, gives notice of his decision or its decision on the last such appeal to be decided.
- (11) Where an application is one which falls to be determined in accordance with regulation 22(3), the Primary Care Trust shall not include the applicant in the relevant pharmaceutical list or alter such a list unless the application is finally granted within the meaning of paragraph (14).
- (12) In the case of a grant of an application under regulation 5(1)(c), the Primary Care Trust shall within the period of 14 days beginning with the date of receipt of the notice set out in Part 2 of Schedule 4 notify the Primary Care Trust in whose list the applicant's existing premises are located of the applicant's intention to commence the provision of pharmaceutical services from his new premises.
- (13) Where—

- (a) an application made by a temporary chemist under regulation 5(1)(b) has been granted;
- (b) the temporary chemist is included in the pharmaceutical list in respect of the premises or services specified in the application; and
- (c) the suspension of the suspended chemist in whose place the temporary chemist is providing pharmaceutical services is terminated (and has not been followed by removal of the suspended chemist's name from the pharmaceutical list),

the temporary chemist's name shall be removed from the pharmaceutical list in respect of the premises or services in question, and the name of the chemist who had previously been suspended shall be included in the pharmaceutical list in respect of those premises or services in the place of the temporary chemist.

(14) An application granted in accordance with the provisions of regulations 33 to 36 shall not be treated as finally granted for the purposes of these Regulations until the end of the period for bringing an appeal under regulation 38 or until the determination of any such appeal, whichever is the later, and "final grant" shall be construed accordingly.

Preliminary consent to be included in a pharmaceutical list

40.—(1) A person to whom regulation 5(1) applies may apply to a Primary Care Trust for consent (in these Regulations referred to as "preliminary consent").

(2) An application for preliminary consent shall be in writing and shall—

- (a) specify the premises or the location of the premises from which the applicant intends to provide pharmaceutical services if his application is granted;
- (b) specify the pharmaceutical services which it is proposed to provide; and
- (c) provide the information set out in Parts 1 and 3 of Schedule 4.

(3) An application for preliminary consent shall be determined as if it were an application made under regulation 5(1).

(4) A preliminary consent shall have effect for a period of six months from its final grant.

(5) In this regulation and in regulation 41, an application for preliminary consent shall not be treated as finally granted until the end of the period for bringing an appeal relating to that application under any provision of these Regulations or until the determination of any such appeal, whichever is the later, and "final grant" shall be construed accordingly.

Effect of preliminary consent

41.—(1) Subject to paragraph (2) and regulations 19, 25 and 26, where the applicant has been finally granted preliminary consent, the Primary Care Trust shall grant an application made under regulation 5(1) provided that—

- (a) the date of the application under regulation 5(1), being the date on which the application was received by the Primary Care Trust, falls within the period referred to in regulation 40(4);
- (b) the pharmaceutical services which it is proposed to provide are the same as those specified in the application for preliminary consent; and
- (c) the premises specified in the application are within the location in respect of which the preliminary consent was granted.

(2) Where sub-paragraphs (a) and (b) of paragraph (1) are satisfied, but the premises specified in the application are in a different location from that in respect of which preliminary consent was granted, the Primary Care Trust shall treat the application as though it were an application

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under regulation 5(1)(b)(ii) to change the location of the premises, and the determination of such an application shall be subject to regulations 19, 21, 25 and 26.

(3) The grant of an application under this regulation shall be subject to any conditions imposed under regulation 20, 21, 29, 30 or 38 in relation to the final grant of the corresponding preliminary consent, except where different conditions are imposed under regulation 42 or 43 in relation to the application in which case it shall be subject to those different conditions.