
STATUTORY INSTRUMENTS

2005 No. 641

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

PART 3

Conditional inclusion, suspension and removal from pharmaceutical lists

Review of decision to impose conditions

42.—(1) Where a Primary Care Trust has made a decision to impose conditions in accordance with regulation 21, it may review such a decision, either of its own volition or at the request of the person whose application has been granted subject to conditions.

(2) A person whose application has been granted subject to conditions may not request a review of a Primary Care Trust's decision until the expiry of a three month period beginning with the date the Primary Care Trust—

- (a) includes his name on its pharmaceutical list; or
- (b) grants him preliminary consent,

as the case may be.

(3) A Primary Care Trust must afford to the person whose application has been granted subject to conditions an opportunity to make written representations to the Primary Care Trust or to put his case at an oral hearing before the Primary Care Trust, and it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision upon review.

(4) Upon review, the Primary Care Trust may vary the conditions, impose different conditions or, where the chemist has breached a condition, remove him from its pharmaceutical list.

(5) A Primary Care Trust shall inform the chemist of its decision upon review, the reasons for it (including any facts relied upon), and his right of appeal to the FHSAA.

(6) After a review has taken place at his request, the person whose application has been granted subject to conditions cannot request another review before the expiry of six months from the date of the decision on the previous review.

Appeals following a review

43. A person whose application has been granted subject to conditions under regulation 21(2) may appeal to the FHSAA against any decision of the Primary Care Trust under regulation 42—

- (a) to vary a condition;
- (b) to vary his terms of service; or
- (c) on any review of an earlier such decision of the Primary Care Trust,

and the appeal shall be by way of redetermination of the Primary Care Trust's decision.

Removal for breach of conditions

44. If a chemist fails to comply with a condition which has been imposed under regulation 21, 30, 42 or 43, the Primary Care Trust may remove him from its pharmaceutical list, in accordance with regulation 48.

Removal from pharmaceutical lists

45.—(1) This regulation does not apply to any case to which regulation 44 or 48 applies.

(2) Where a Primary Care Trust determines that a person included in its pharmaceutical list—

(a) has died; or

(b) is no longer a chemist,

the Primary Care Trust shall, subject to paragraph (4), remove his name from that list.

(3) Where a chemist provides local pharmaceutical services under a pharmacy pilot scheme, and no longer provides pharmaceutical services, the Primary Care Trust shall remove his name from its pharmaceutical list.

(4) The name of any pharmacist whose business is carried on by representatives in accordance with the provisions of section 72 of the Medicines Act 1968 shall not be removed from the pharmaceutical list under paragraph (2) so long as the business is carried on by them in accordance with the provisions of that Act, and the representatives agree to be bound by the terms of service.

(5) Where a Primary Care Trust receives a notice under regulation 39(12), it shall remove the name of the chemist from its pharmaceutical list in respect of the existing premises with immediate effect from the date specified in the notice as the date for commencing the provision of pharmaceutical services from the new premises.

(6) Where a chemist who had been suspended has resumed the provision of pharmaceutical services from premises other than those from which he had provided services prior to his suspension, the Primary Care Trust shall remove his name from its pharmaceutical list in respect of the premises from which he no longer provides pharmaceutical services.

(7) Where a Primary Care Trust determines that a chemist, whose name has been included for the preceding six months in a pharmaceutical list, has not during that period provided pharmaceutical services at particular premises, it may remove the chemist's name from the list in respect of those premises.

(8) Where a Primary Care Trust determines that a chemist has breached a condition imposed by—

(a) regulation 13(2)(a), it shall, subject to regulation 13(2)(b), remove that chemist from the list in respect of the premises to which that condition relates; or

(b) regulation 13(4), it shall remove that chemist from the list in respect of the premises to which that condition relates.

(9) A period during which the chemist provided no pharmaceutical services by reason only that he was suspended from the pharmaceutical list does not count towards the period of six months referred to in paragraph (7).

(10) Before making any determination under paragraph (7) or (8), the Primary Care Trust shall—

(a) give the chemist 28 days' notice of its intention;

(b) afford the chemist an opportunity of making representations to the Primary Care Trust in writing or, if he so desires, in person; and

(c) consult the Local Pharmaceutical Committee.

(11) Where under paragraph (7) or (8) the Primary Care Trust decides to remove a chemist's name from its pharmaceutical list, it shall give notice in writing of its decision to the chemist.

(12) A chemist to whom a notice has been given under paragraph (11) may, within 30 days of receiving the notice, appeal to the Secretary of State against the decision of the Primary Care Trust and the Primary Care Trust shall not remove the chemist's name from the pharmaceutical list until—

- (a) if no appeal is made, the expiration of that period of 30 days; or
- (b) if an appeal is made, the appeal is determined.

(13) An appeal under paragraph (12) shall be in writing and shall set out the grounds of appeal.

(14) Where the Secretary of State allows the appeal, he shall direct the Primary Care Trust not to remove the chemist's name from the pharmaceutical list.

(15) Nothing in this regulation shall—

- (a) prejudice the right of a chemist to be included again in a pharmaceutical list; or
- (b) affect a chemist who is performing a period of relevant service within the meaning of paragraph (16), and no removal under paragraph (7) shall be effected in respect of any such chemist until six months after he has completed that service.

(16) In paragraph (15), "relevant service" means—

- (a) whole-time service in the armed forces of the Crown in a national emergency, whether as a volunteer or otherwise;
- (b) compulsory whole-time service in those forces, including service resulting from any reserve liability; or
- (c) any equivalent service by a person liable for compulsory whole-time service in those forces.

Criteria for decisions on removal

46.—(1) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(4)(1) of the Act (an unsuitability case), it shall—

- (a) consider the information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or paragraphs 16 and 17 of Schedule 3,
- (b) consider any information held by the Secretary of State as to any record about past or current investigations or proceedings involving him or related to him; and
- (c) in reaching its decision take into consideration the matters set out in paragraph (2).

(2) The matters referred to in paragraph (1) are—

- (a) the nature of any offence, investigation or incident;
- (b) the length of time since any such offence, incident, conviction or investigation;
- (c) whether there are other offences, incidents or investigations to be considered;
- (d) the 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 chemist 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 applies, or if it had been committed in England and Wales, would have applied;
- (g) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) has been refused admittance to, conditionally included in,

(1) Section 49F was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part 1, paragraphs 1 and 21 and by the 2003 Act, section 196 and Schedule 14, Part 4.

removed, contingently removed or is currently suspended from, any list or any 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;

- (h) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed from, any of a Primary Care Trust's lists or from equivalent lists, 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; and
- (i) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any of a Primary Care Trust's lists or from equivalent lists, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(3) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(3) of the Act (a fraud case), it shall consider—

- (a) any information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or 16 and 17 of Schedule 3;
- (b) any information held by the Secretary of State as to any record about past or current investigations or proceedings involving or related to the chemist; and
- (c) the matters set out in paragraph (4).

(4) The matters referred to in paragraph (3)(c) are—

- (a) the nature of the incidents of fraud;
- (b) the length of time since the last incident of fraud occurred, and since any investigation into that incident of fraud was concluded;
- (c) whether there are other incidents of fraud or other criminal offences to be considered;
- (d) any action taken by any licensing or regulatory or other body, the police or the courts as a result of any such incident or offence;
- (e) the relevance of any investigation into the incident of fraud to the provision by the chemist of pharmaceutical services, and any likely risk to users of pharmaceutical services or to public finances;
- (f) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) 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;
- (g) whether the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed 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; and
- (h) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any list or

equivalent list, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(5) Where a Primary Care Trust is considering removal of a chemist's name from its pharmaceutical list under section 49F(2) of the Act (an efficiency case), it shall—

- (a) consider the information from the chemist supplied under paragraphs 29 and 30 of Schedule 1 or 16 and 17 of Schedule 3;
- (b) consider any information held by the Secretary of State as to any record about past or current investigations or proceedings involving or related to the chemist; and
- (c) in reaching its decision, take into consideration the matters set out in paragraph (6).

(6) The matters referred to in paragraph (5)(c) are—

- (a) the nature of any incident which was prejudicial to the efficiency of the pharmaceutical services provided by the chemist;
- (b) the length of time since the last such incident occurred, and since any investigation into that incident was concluded;
- (c) any action taken by any licensing, regulatory or other body, the police or the courts as a result of any such incident;
- (d) the nature of any incident and whether there is a likely risk to users of pharmaceutical services;
- (e) whether the chemist has previously failed to supply information, make a declaration or comply with an undertaking required by these Regulations;
- (f) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) 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;
- (g) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which has been refused admittance to, conditionally included in, removed or contingently removed 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; and
- (h) whether the chemist (and, where the chemist is a body corporate, any director or superintendent of the chemist) was a director or superintendent, at the time of the originating events, of a body corporate which is currently suspended from any list or equivalent list, and if so, the facts relating to the matter which led to the suspension and the reasons given by the Primary Care Trust or equivalent body for the suspension.

(7) In making any decision under section 49F of the Act, the Primary Care Trust shall take into account the effect of all relevant incidents and offences relating to the chemist of which it is aware, whichever condition it relies on.

(8) When making a decision on any condition in section 49F of the Act, the Primary Care Trust shall state in its decision on which condition (or conditions) in section 49F of the Act it relies.

Cases where the Primary Care Trust must remove a chemist

47.—(1) Subject to paragraph (2), a Primary Care Trust must remove a chemist's name from its pharmaceutical list where it becomes aware that the chemist (and where the chemist is a body corporate, any director or superintendent of the chemist)—

- (a) has been convicted in the United Kingdom of murder;

- (b) has been convicted in the United Kingdom of a criminal offence 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; or
- (c) is subject to a national disqualification.

(2) Where the ground for removal under paragraph (1) is that a director of a body corporate has been convicted of a criminal offence (other than murder), the Primary Care Trust shall notify the body corporate that unless—

- (a) the director concerned ceases to be a director of the body corporate within the period of 28 days commencing with the date of the notice; and
- (b) the body corporate notifies the Primary Care Trust of this fact within that period,

it shall remove the name of the body corporate from its pharmaceutical list under paragraph (1).

(3) The Primary Care Trust shall notify the chemist immediately that his name has been removed from the pharmaceutical list.

Procedure on removal

48.—(1) Where a Primary Care Trust is considering—

- (a) removing a chemist's name from the pharmaceutical list under section 49F (disqualification of practitioners) of the Act (other than in cases specified in regulation 47);
- (b) contingently removing a chemist's name from the pharmaceutical list under section 49G(2) (contingent removal) of the Act;
- (c) removing a chemist's name from the pharmaceutical list for breach of a condition imposed under section 49G of the Act; or
- (d) removing a chemist's name from the pharmaceutical list for breach of a condition under regulation 44,

on fitness to practise grounds, it shall follow the procedure set out in this regulation.

(2) Before reaching a decision of the kind mentioned in paragraph (1), the Primary Care Trust shall give the chemist—

- (a) notice in writing of any allegation against him;
- (b) notice of what action the Primary Care Trust is considering and on what grounds;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (b); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(3) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (2)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(4) The Primary Care Trust shall inform the chemist of its decision, the reasons for it (including any facts relied upon), and, if the decision is adverse, that he has a right of appeal to the FHSAA.

(5) Where the Primary Care Trust has decided to impose a contingent removal, it shall also inform the chemist of his right to have the decision reviewed in accordance with section 49L(3) (review of decisions) of the Act.

(2) Section 49G was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 21.

(3) Section 49L was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 23.

(6) The Primary Care Trust shall inform the chemist that if he wishes to appeal, he must do so within the period of 28 days beginning with the date on which the Primary Care Trust informs him of its decision, and shall tell him how to proceed with making his appeal.

(7) The Primary Care Trust shall not remove a chemist's name from the pharmaceutical list, or impose a contingent removal, until the determination by the FHSAA of any appeal against the Primary Care Trust's decision or any time for appeal has expired.

(8) Where a Primary Care Trust is notified by the FHSAA that it has considered—

- (a) an appeal by a chemist against a contingent removal by the Primary Care Trust, and the FHSAA has decided to remove him instead; or
- (b) an appeal by a chemist under regulation 30 where he has been included in a pharmaceutical list pursuant to regulation 21(8), and the FHSAA has decided not to include him in that list,

the Primary Care Trust shall remove the chemist from its list and shall notify the chemist immediately that it has done so.

Supplementary matters relating to removal

49. In addition to the services covered by the definition of “health scheme” in section 49F(8) (disqualification of practitioners) of the Act, the following shall also be health schemes—

- (a) health services, including medical and surgical treatment, provided by Her Majesty's Forces;
- (b) services provided by Port Health Authorities constituted under the Public Health (Control of Disease) Act 1984(4);
- (c) health services provided to a prisoner in the care of the medical officer or any other officer of a prison appointed for the purposes of section 7 (prison officers) of the Prison Act 1952(5); and
- (d) publicly-funded health services provided by or on behalf of any organisation anywhere in the world.

Procedure on suspension

50.—(1) Before reaching a decision to suspend a chemist under section 49I(6) (suspension) or 49J(7) (suspension pending appeal) of the Act, the Primary Care Trust shall give the chemist—

- (a) notice in writing of any allegation against him;
- (b) notice of what action the Primary Care Trust is considering and on what grounds;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (b); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(2) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(4) 1984 c. 22.

(5) 1952 c. 52.

(6) Section 49I was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 21.

(7) Section 49J was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 22.

(3) The Primary Care Trust may suspend a chemist with immediate effect once it has reached a decision to suspend him.

(4) The Primary Care Trust shall inform the chemist of its decision and the reasons for it (including any facts relied upon).

(5) Where the Primary Care Trust has decided to suspend a chemist under section 49I (suspension) of the Act, it shall also inform the chemist of his right to have the decision reviewed in accordance with section 49L (review of decisions) of the Act.

Procedure on review of Primary Care Trust decision

51.—(1) Where, in accordance with section 49L (review of decisions) of the Act, a Primary Care Trust must review its decision to contingently remove a chemist from the pharmaceutical list or suspend a chemist from the pharmaceutical list under section 49I (suspension) of the Act, or where it decides to review such a decision, it shall give the chemist—

- (a) notice in writing that it intends to review its decision;
- (b) notice of the decision it is minded to take upon review, and the reasons for it;
- (c) the opportunity to make written representations to the Primary Care Trust within the period of 28 days beginning with the date of the notification under sub-paragraph (a); and
- (d) the opportunity to put his case at an oral hearing before the Primary Care Trust, if he so requests within the 28 day period mentioned in sub-paragraph (c).

(2) If the Primary Care Trust receives representations or a request for an oral hearing within the period specified in paragraph (1)(c), it must take the representations into account, or hold the hearing, as the case may be, before reaching its decision.

(3) The Primary Care Trust shall inform the chemist of its decision, the reasons for it (including any facts relied upon), and any right of appeal to the FHSAA.

(4) The Primary Care Trust shall inform the chemist 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 the Primary Care Trust informs him of its decision, and shall tell him how to proceed with making his appeal.

(5) The Primary Care Trust shall also notify the chemist of his right to have the decision further reviewed in accordance with section 49L of the Act.

Review periods on national disqualification

52. The period for review of a national disqualification shall be the period specified below instead of that in section 49N(8)(8) (national disqualification) of the Act where the circumstances are that—

- (a) on making a decision to impose a national disqualification, the FHSAA states that it is of the opinion that the criminal or professional conduct of the disqualified person is such that there is no realistic prospect of a further review being successful if held within the period specified in section 49N(8)(a) of the Act, in which case the reference to “two years” in that provision shall be a reference to five years;
- (b) on the last review by the FHSAA of a national disqualification the disqualified person was unsuccessful and the FHSAA states that it is of the opinion that there is no realistic prospect of a further review being successful if held within a period of three years beginning with the date of its decision on that review, in which case the reference to “one year” in section 49N(8)(b) of the Act shall be a reference to three years;

(8) Section 49N was inserted by the 2001 Act, section 25 and amended by the 2002 Act, section 2(5) and Schedule 2, Part I, paragraphs 1 and 25 and by the 2003 Act, section 184 and Schedule 11, paragraphs 7 and 24.

- (c) the FHSAA states that it is of the opinion that because a criminal conviction considered by the FHSAA in reaching its decision has been quashed or the penalty reduced on appeal, there is a need for an immediate review, in which case the reference to “two years” or “one year” in section 49N(8) of the Act shall be a reference to the period that has already elapsed; or
- (d) the FHSAA is of the opinion that because the decision of a licensing or regulatory body has been quashed or the penalty reduced on appeal, there is a need for an immediate review, in which case the reference to “two years” or “one year” in section 49N(8) of the Act shall be a reference to the period that has already elapsed.

Withdrawals from the list

53.—(1) Subject to paragraphs (2) to (4), the Primary Care Trust shall, on receiving any notice from any chemist pursuant to paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3, so amend its pharmaceutical list either—

- (a) on the date notified by him in accordance with paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3; or
- (b) on the date from which it has agreed that the withdrawal shall take effect,

whichever is the earlier.

(2) Where a Primary Care Trust is investigating a chemist—

- (a) for the purpose of deciding whether or not to exercise its powers under section 49F (disqualification of practitioners), 49G (contingent removal) or 49I (suspension) of the Act;
- (b) in order to see whether the chemist has failed to comply with a condition imposed on his inclusion under regulation 21, 30, 42 or 43 so as to justify his removal from the pharmaceutical list; or
- (c) who has been suspended under section 49I(1)(a) of the Act,

the chemist may not withdraw from any lists in which he is included, except where the Secretary of State has given his consent, until the matter has been finally determined by the Primary Care Trust.

(3) A chemist may withdraw a notice given pursuant to paragraph 35 of Schedule 1 or paragraph 22 of Schedule 3 at any time before the Primary Care Trust removes his name from its pharmaceutical list.

(4) Where a Primary Care Trust has decided to remove a chemist from its pharmaceutical list under section 49F or 49G of the Act, or contingently remove him under section 49G of the Act, or remove him for breach of a condition imposed on inclusion under regulation 44, but has not yet given effect to its decision, the chemist may not withdraw from any list in which he is included, except where the Secretary of State has given his consent.

(5) Where a Primary Care Trust has suspended a chemist under section 49I(1)(b) of the Act, the chemist may not withdraw from any of a Primary Care Trust’s lists in which he is included, except where the Secretary of State has given his consent, until the decision of the relevant court or body is known and the matter has been considered and finally determined by the Primary Care Trust.

Temporary provision of services during a period of suspension

54.—(1) A chemist who has been suspended, except a temporary chemist who has been suspended, may nominate to the Primary Care Trust a person or persons to provide pharmaceutical services in his place, for the period of his suspension.

(2) A nominated person may apply to the Primary Care Trust, in accordance with this regulation—

- (a) for temporary inclusion in that Primary Care Trust's pharmaceutical list; or
 - (b) if he is already included in that Primary Care Trust's pharmaceutical list, for temporary inclusion in respect of the premises from which the suspended chemist had undertaken to provide pharmaceutical services, or in respect of the pharmaceutical services which the suspended chemist had undertaken to provide.
- (3) An application shall be in writing and shall include—
- (a) the name and address of the applicant and the suspended chemist;
 - (b) a statement as to whether the applicant is a registered pharmacist, a person lawfully conducting a retail pharmacy business in accordance with section 69 (general provisions) of the Medicines Act 1968⁽⁹⁾, or a supplier of appliances;
 - (c) the address of the premises from which the applicant undertakes to provide pharmaceutical services;
 - (d) a statement to the effect that the applicant is applying to provide pharmaceutical services from the specified premises, only for the period of the suspended chemist's suspension and for so long as the suspended chemist consents; and
 - (e) the information and undertakings specified in Part 3 of Schedule 4.
- (4) Where the applicant is not already on the Primary Care Trust's pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraphs (6), (7), (8), (10), (11) and (15) and regulations 19, 21 and 26.
- (5) Where the applicant is already on the Primary Care Trust's pharmaceutical list, the Primary Care Trust shall grant the application, subject to paragraphs (10), (11) and (15) and regulation 26.
- (6) An application made under this regulation by a person who qualified to have his name registered under the Pharmacy Act 1954⁽¹⁰⁾ by virtue of section 4A⁽¹¹⁾ (qualification by appropriate European diploma for registration) of that Act 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.
- (7) Subject to paragraph (8), an application to a Primary Care Trust in whose pharmaceutical list the applicant is not already included shall not be granted unless the Primary Care Trust has—
- (a) checked as far as practicable the references and information provided by the applicant in accordance with Part 3 of Schedule 4;
 - (b) checked 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 a fraud case; and
 - (c) considered whether there are grounds—
 - (i) for refusing the application under regulation 19, or
 - (ii) for imposing conditions in accordance with regulation 21.
- (8) Where a person is urgently needed as a temporary chemist in order to secure the adequate provision of pharmaceutical services in the neighbourhood in which the premises from which the applicant intends to provide pharmaceutical services are located, and it is not practicable for the Primary Care Trust to comply with paragraph (7) before granting his application, the Primary Care Trust may grant his application, provided that it complies with paragraph (7) as soon as practicable after that grant.

⁽⁹⁾ 1968 c. 67.

⁽¹⁰⁾ 1954 c. 61.

⁽¹¹⁾ Section 4A was inserted by S.I. 1987/2202, article 2(4), and amended by S.I. 1996/1405, regulation 2, S.I. 2003/3148, regulation 8 and S.I. 2004/1947, regulation 13.

(9) For the purpose of determining the adequacy of the provision of pharmaceutical services pursuant to paragraph (8), a Primary Care Trust shall treat any local pharmaceutical services being provided in the neighbourhood in which the premises named in the application are located as if they were pharmaceutical services, and shall not take into account any pharmaceutical services provided by a distance selling chemist in that neighbourhood.

(10) A Primary Care Trust must refuse an application if—

- (a) the suspended chemist is a body corporate and the applicant—
 - (i) is an employee of the body corporate,
 - (ii) is, or was at the time a suspension was imposed, or at the time of the originating events, a director or superintendent of the suspended chemist,
 - (iii) is a body corporate in which—
 - (aa) the suspended chemist; or
 - (bb) any person who is, or was at the time a suspension was imposed, or at the time of the originating events, a director or superintendent of the suspended chemist,is a majority shareholder,
- (iv) is a body corporate which has a director or superintendent who is an employee of the suspended chemist, or
- (v) is a body corporate which has a director or superintendent who is, or was at the time a suspension was imposed, or was at the time of the originating events, a director or superintendent of the suspended chemist; or
- (b) the suspended chemist is an individual and the applicant—
 - (i) is an employee of the suspended chemist, or
 - (ii) is a body corporate, of which the suspended chemist or his employee is a director or superintendent or the majority shareholder.

(11) A Primary Care Trust may refuse an application if—

- (a) the suspended chemist is a body corporate and the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is in a relationship (including a family relationship) with the suspended chemist, or with any person who is, or was at the time a suspension was imposed, or was at the time of the originating events, a director or superintendent of the suspended chemist, the nature of which makes it unlikely that the applicant will be able to exercise an appropriate degree of autonomy; or
- (b) the suspended chemist is an individual and the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) is in a relationship (including a family relationship) with the suspended chemist, the nature of which makes it unlikely that the applicant will be able to exercise an appropriate degree of autonomy.

(12) Where a Primary Care Trust receives an application to which it considers that paragraph (11) applies—

- (a) before determining the application, it shall invite the applicant and the suspended chemist to make representations to it in writing or, if they so desire, in person, before the end of the period of 14 days beginning on the day on which the Primary Care Trust invited representations; and
- (b) it shall make a decision on the application before the end of the period of 14 days beginning on the day on which it receives or hears the applicant's or the suspended chemist's representations, whichever is the later of the two, or, where no representations are made, the day on which the time for making such representations expires.

(13) Before the end of the period of 14 days beginning with the day on which it has received both a nomination under paragraph (1) and an application under paragraph (2), a Primary Care Trust shall—

- (a) determine the application;
- (b) where it considers that paragraph (11) applies, invite representations in accordance with paragraph (12)(a); or
- (c) where it considers that there are grounds for deferring consideration or determination of the application under regulation 26, notify the applicant in writing to that effect.

(14) A Primary Care Trust shall, as soon as is practicable, give notice in writing of its decision on an application to—

- (a) the applicant;
- (b) the suspended chemist; and
- (c) where it decides to grant the application, the Local Pharmaceutical Committee and the Local Medical Committee established for the Primary Care Trust's area.

(15) Where an applicant is already included in the Primary Care Trust's pharmaceutical list, or has been granted preliminary consent to be included in that list, and in either case is subject to conditions imposed in accordance with regulations 21, 30, 42 or 43, a grant of his application under this regulation shall be subject to those same conditions.

(16) Where a Primary Care Trust grants an application under this regulation, it shall include the applicant in its pharmaceutical list or, where the applicant is already included in that list, include him in relation to the premises or services specified in the application.

(17) The suspended chemist may at any time during the period of his suspension notify the Primary Care Trust in writing that—

- (a) he no longer consents to the provision of pharmaceutical services by the temporary chemist; and
- (b) he requires that the temporary chemist should cease the provision of pharmaceutical services with effect from a specified date.

(18) A suspended chemist must give the Primary Care Trust at least two working days' notice of the date specified in paragraph (17)(b); and in this paragraph, "working day" means any day other than Saturday, Sunday, Christmas Day, Good Friday or a bank holiday.

(19) Where the Primary Care Trust receives notification from the suspended chemist in accordance with paragraphs (17) and (18), it shall, as soon as practicable, notify the temporary chemist in writing that he is to cease the provision of pharmaceutical services with effect from the specified date, and shall remove his name from the pharmaceutical list with effect from that date.

(20) Subject to paragraph (21), a Primary Care Trust may at any time remove a temporary chemist's name from the pharmaceutical list if the temporary chemist is in a relationship with the suspended chemist which makes it unlikely that he will be able to exercise an appropriate degree of autonomy.

(21) Where a Primary Care Trust is minded to remove a temporary chemist's name from the pharmaceutical list in accordance with paragraph (20), it shall—

- (a) as soon as practicable, notify the suspended chemist and the temporary chemist that it is so minded, giving a brief statement of its reasons;
- (b) afford to the suspended chemist and the temporary chemist an opportunity to make representations to it in writing or, if they so desire, in person, before the end of the period of 14 days beginning on the day on which the notification is given;

- (c) make a decision as to removal from the pharmaceutical list before the end of the period of 14 days beginning on the day on which it receives or hears the applicant's or the suspended chemist's representations, whichever is the later of the two, or, where no representations are made, the day on which the time for making such representations expires; and
- (d) as soon as practicable, give notice in writing of its decision to the suspended chemist and the temporary chemist.

(22) On and after the date on which the period of suspension of the suspended chemist ends (whether the suspended chemist's name is removed from the pharmaceutical list or whether he is reinstated as a chemist), the temporary chemist may no longer provide the pharmaceutical services that he had previously provided in the place of the chemist who had been suspended; and the Primary Care Trust shall remove the temporary chemist's name from its pharmaceutical list with effect from that date.

(23) In this regulation, references to removing a temporary chemist's name from a pharmaceutical list shall be construed as removing his name in respect of the premises from which he has provided pharmaceutical services under this regulation (or in respect of the pharmaceutical services he has provided under this regulation).

(24) Where a Primary Care Trust has refused a person's application to be a temporary chemist that person may appeal to the Secretary of State in accordance with regulation 29.

Notifications

55.—(1) Where a Primary Care Trust—

- (a) removes a chemist's name from the pharmaceutical list under section 49F of the Act;
- (b) contingently removes a chemist's name from the pharmaceutical list under section 49G of the Act;
- (c) suspends a chemist from the pharmaceutical list;
- (d) removes a chemist's name from the pharmaceutical list for breach of a condition under regulation 44; or
- (e) removes a chemist's name from the pharmaceutical list for breach of a condition imposed under section 49G of the Act,

it shall notify the persons and bodies specified in regulation 28(2), and shall additionally notify those specified in regulation 28(3) if so requested by those persons or bodies in writing (including electronically), of the matters set out in regulation 28(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 that regulation.

(2) Regulation 28(5) to (8) shall apply to notifications given under this regulation as they apply to notifications given under regulation 28(1).