
STATUTORY INSTRUMENTS

2012 No. 1909

**The National Health Service
(Pharmaceutical Services) Regulations 2012**

PART 6

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

Refusal of applications for inclusion in a pharmaceutical list on fitness grounds

33.—(1) An application for inclusion in a pharmaceutical list by a person (A) who is not already included in it must be refused if the Primary Care Trust is satisfied that—

- (a) A (or where A is a body corporate, any director or superintendent of A) has been convicted in the United Kingdom of murder;
- (b) A (or where A is a body corporate, any director or superintendent of A) has been convicted in the United Kingdom of a criminal offence, other than murder—
 - (i) which was committed after 1st April 2005, and
 - (ii) has been sentenced to a term of imprisonment of over 6 months;
- (c) A is the subject of a national disqualification; or
- (d) where, on appeal, the First-tier Tribunal determines A may be included in the pharmaceutical list subject to conditions, A has not within 30 days of that decision notified the Primary Care Trust that A agrees to the imposition of the conditions.

(2) An application for inclusion in a pharmaceutical list by a person who is not already included may be refused if the Primary Care Trust—

- (a) having contacted the referees mentioned in paragraph 3(8) of Schedule 2, is not satisfied with the references given;
- (b) considers that A is unsuitable to be included in the list;
- (c) having—
 - (i) checked with the NHS BSA for any facts that it considers relevant relating to past or current fraud investigations involving or related to A (and where A is a body corporate, any director or superintendent of A), and
 - (ii) considered these and any other facts in its possession relating to fraud involving or relating to A (and where A is a body corporate, any director or superintendent of A), considers the outcome of these enquiries justify such refusal;
- (d) having—
 - (i) checked with the Secretary of State for any facts considered by the Secretary of State to be relevant relating to past or current investigations or proceedings involving or relating to A (and where A is a body corporate, any director or superintendent of A), and

- (ii) considered these and any other facts in its possession involving or relating to A (and where A is a body corporate, any director or superintendent of A), considers the outcome of these enquiries justify such refusal; or
 - (e) considers that granting the application would be prejudicial to the efficiency of the service which A has undertaken to provide.
- (3) Where the Primary Care Trust is considering refusal of an application under paragraph (2), it must consider all facts which appear to it to be relevant and must in particular take into consideration in relation to paragraph (2)(b) to (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 A 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(1) (sexual offences) applies, or if it had been committed in England and Wales, would have applied;
 - (g) whether A (and where A is a body corporate, any director or superintendent of A) has been refused inclusion in, conditionally included in, removed, contingently removed or is currently suspended from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, the facts relating to the matter which led to such action and the reasons given by the Primary Care Trust or other primary care organisation for such action; or
 - (h) whether A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been—
 - (i) a director or superintendent of a body corporate which has been refused inclusion in, conditionally included in, removed or contingently removed from a relevant list, or
 - (ii) is currently suspended from a relevant list,
 for a reason relating to unsuitability, fraud or efficiency of service provision, and if so, what the facts were in each such case and the reasons given by the Primary Care Trust or other primary care organisation in each case.
- (4) When the Primary Care Trust takes into consideration the matters set out in paragraph (3), it must consider the overall effect of all the matters being considered.
- (5) If an application for inclusion in a pharmaceutical list by a person who is not already included in it is refused under paragraph (1) or (2), the Primary Care Trust must notify the applicant of that decision and it must include with the notification an explanation of—
 - (a) the reasons for the decision;
 - (b) the applicant's right of appeal against the decision to the First-tier Tribunal, which must be exercised within 30 days of the date on which the applicant was notified of the decision.

Deferral of consideration of applications for inclusion in a pharmaceutical list on fitness grounds

34.—(1) An application for inclusion in a pharmaceutical list by a person (A) who is not already included in it may be deferred if the Primary Care Trust is satisfied that—

(a) there are, in respect of A (or where A is a body corporate, in respect of A or a director or superintendent of A)—

(i) criminal proceedings in the United Kingdom, or

(ii) proceedings elsewhere relating to conduct, which, if it had occurred in the United Kingdom, would constitute a criminal offence,

which, if they result in a conviction, or the equivalent of a conviction, would be likely to lead to A's removal from its pharmaceutical list, if A were to be included in it;

(b) in respect of a body corporate of which A is, or has in the preceding 6 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 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 A's removal from its pharmaceutical list, if A were to be included in it;

(c) there is an investigation anywhere in the world—

(i) by A's (or where A is a body corporate, any director or superintendent of A's) licensing or regulatory body, or

(ii) relating to A (or where A is a body corporate, any director or superintendent of A) in A's professional capacity (including one by another Primary Care Trust or another primary care organisation),

which, if the outcome were adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;

(d) A (and where A is a body corporate, any director or superintendent of A) is suspended from a relevant list;

(e) a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is suspended from a relevant list;

(f) the First-tier Tribunal is considering an appeal by A (or where A is a body corporate, by A or any director or superintendent of A) against a decision of a Primary Care Trust or another primary care organisation—

(i) to refuse an application for inclusion in a relevant list, or

(ii) to include A conditionally in, or to remove or contingently remove A from, a relevant list,

and if that appeal were to be unsuccessful, the Primary Care Trust would be likely to remove A from the pharmaceutical list if A were to be included in it;

(g) the First-tier Tribunal is considering an appeal by a body corporate of which A (or where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, or has in the preceding 6 months been, a director or superintendent, against a decision of a Primary Care Trust or another primary care organisation—

(i) to refuse an application by that body corporate for inclusion in its list,

- (ii) to include A conditionally in, or to remove or contingently remove A from, a relevant list,
 - and if that appeal were to be unsuccessful the Primary Care Trust would be likely to remove A from the pharmaceutical list if A were to be included in it;
- (h) A (and where A is a body corporate, any director or superintendent of A) is being investigated by the NHS BSA in relation to any fraud, where the result, if adverse, would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
- (i) a body corporate, of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent, is being investigated by the NHS BSA in relation to any fraud, where the result if adverse would be likely to lead to the removal of A from the pharmaceutical list if A were to be included in it;
- (j) the First-tier Tribunal is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of A (and where A is a body corporate, any director or superintendent of A);
- (k) the First-tier Tribunal is considering an application from a Primary Care Trust or Local Health Board for a national disqualification of a body corporate of which A (and where A is a body corporate, any director or superintendent of A) was, at the time of the originating events, a director or superintendent; or
- (l) a Primary Care Trust or other primary care organisation, for a reason relating to unsuitability, fraud or efficiency of service provision—
 - (i) is considering removal (other than voluntary removal) or contingent removal of the applicant from a relevant list, or
 - (ii) has taken a decision to remove (other than voluntary removal) or contingently remove A from a relevant list but that decision has yet to take effect.
- (2) A Primary Care Trust may only defer a decision under paragraph (1) until—
 - (a) the outcome of the cause for the deferral is known; or
 - (b) the reason for the deferral no longer exists.

Granting applications for inclusion in a pharmaceutical list subject to efficiency conditions and conditions to combat fraud

35.—(1) An application for inclusion in a pharmaceutical list by a person (P) who is not already included may be granted subject to a condition of a type mentioned in paragraph (3), which is determined by the Primary Care Trust and which the Primary Care Trust decides to impose with regard to P.

(2) The Primary Care Trust may vary the terms of service of an NHS chemist for the purpose of or in connection with the imposition of the condition.

- (3) A condition imposed under paragraph (1) must be a condition with a view to—
 - (a) preventing any prejudice to the efficiency of the services, or any of the services, which P has undertaken to provide; or
 - (b) preventing any act or omission within section 151(3)(a) of the 2006 Act (disqualification of practitioners).

(4) If a Primary Care Trust decides to grant an application subject to a condition imposed under paragraph (1), it must notify P of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) P's right of appeal against its decision to the First-tier Tribunal;
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008⁽²⁾, the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (d) the effect of paragraph (5).

(5) If P issues a notice of commencement before the First-tier Tribunal has determined an appeal against a condition imposed under paragraph (1), P is to be included in the pharmaceutical list subject to the condition, but only pending the outcome of the appeal if the appeal is successful.

(6) The appeal is to be by way of redetermination of—

- (a) the decision of the Primary Care Trust to impose the condition; and
- (b) if P has, at the time the appeal is determined, been included in the pharmaceutical list, any decision under paragraph (2) to vary the terms of service of P for the purpose of or in connection with the imposition of the condition.

(7) If at the time the appeal is determined, P has not been included in the pharmaceutical list, and—

- (a) the First-tier Tribunal confirms the decision of the Primary Care Trust; or
- (b) imposes a different condition,

P must, within 30 days of P being notified of the First-tier Tribunal's decision, notify the Primary Care Trust as to whether or not P wishes to withdraw P's application

(8) If P fails, in the circumstances described in paragraph (7), to notify the Primary Care Trust within that 30 days that P does not wish to withdraw P's application, the grant of P's application lapses.

(2) S.I. 2008/2699 (L 16); see rule 19 of those Rules.