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WELSH STATUTORY INSTRUMENTS

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**2013 No. 898**

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013

**PART 6**

Fitness grounds and inclusion in and removal from pharmaceutical lists

**Deferral of applications on fitness grounds**

- 31.**—(1) This regulation applies to applications made under—
- (a) regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 12(5); and
  - (b) regulation 12 (applications for preliminary consent and effect of preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.
- (2) A Local Health Board may defer consideration or determination of an application where—
- (a) there are criminal proceedings in the United Kingdom or proceedings elsewhere in the world relating to conduct which in the United Kingdom would constitute a criminal offence in respect of—
    - (i) the applicant (and where the applicant is a body corporate, in respect of the applicant or a director or superintendent of the applicant), or
    - (ii) 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,which, if they resulted in a conviction or the equivalent of a conviction, would be likely to lead to the applicant's removal from the Local Health Board's pharmaceutical list, if the applicant had been included in it;
  - (b) 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) licensing or regulatory body or any other investigation (including one by another Local Health Board or equivalent body) relating to the applicant's professional capacity, that if the outcome of which was adverse would be likely to lead to the removal of the applicant from the Local Health Board's pharmaceutical list, if the applicant had been included in it;
  - (c) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is suspended from a relevant list;
  - (d) 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 a relevant list;

- (e) the Tribunal is considering an appeal by the applicant (or where the applicant is a body corporate, any director or superintendent of the applicant) against a decision of a Local Health Board or an equivalent body—
    - (i) to refuse an application by the applicant for inclusion in a relevant list,
    - (ii) to conditionally include or remove or contingently remove the applicant from a relevant list, or
    - (iii) to refuse an application from the applicant for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body,and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if he or she were to be included in it;
  - (f) the Tribunal 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 Local Health Board or equivalent body—
    - (i) to refuse an application by that body corporate for inclusion in a relevant list;
    - (ii) to refuse an application by that corporate body for preliminary consent to be included in a pharmaceutical list held by a Local Health Board or an equivalent body; or
    - (iii) to conditionally include it in, or to remove or contingently remove it from any relevant list,and if that appeal were to be unsuccessful the Local Health Board would be likely to remove the applicant from the pharmaceutical list if he or she were to be included in it;
  - (g) the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) is being investigated in relation to any fraud, where the outcome, if adverse, would be likely to lead to the removal of the applicant from the pharmaceutical list if the applicant had been included in it;
  - (h) 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 in relation to fraud, where the outcome if adverse would be likely to lead to the removal of the applicant from the pharmaceutical list if the body corporate had been included in it; or
  - (i) the Tribunal is considering an application from a Local Health Board or equivalent body for a national disqualification of the applicant (and where the applicant is a body corporate, any director or superintendent of the applicant) or 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;
  - (j) a Local Health Board or equivalent body, for a reason relating to fraud, unsuitability 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 the applicant from a relevant list but that decision has yet to take effect .
- (3) A Local Health Board may only defer a decision under paragraph (2) until the proceedings, investigations or applications mentioned in that paragraph are concluded or the reason for the deferral no longer exists.
- (4) A Local Health Board must, as soon as is practicable, notify the applicant in writing of a decision to defer consideration or determination of the application, and the reasons for this.

(5) Once the proceedings, investigations or applications mentioned in paragraph (2) are concluded, the Local Health Board must notify the applicant that he or she within 30 days of the date of the notification (or such longer period as it may agree)—

- (a) must confirm in writing that the applicant wishes to proceed with the application; and
- (b) may update the application if the applicant wishes.

(6) If the applicant fails to confirm that he or she wishes to proceed in accordance with paragraph (5), the Local Health Board must deem the application as having been withdrawn by the applicant.

### **Refusal of applications on fitness grounds**

**32.**—(1) This regulation applies to applications made under—

- (a) regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the application is made by a person who has a valid preliminary consent in accordance with regulation 12(5); and
- (b) regulation 12 (applications for preliminary consent and effect of preliminary consent) where the applicant is not already included in that Local Health Board's pharmaceutical list.

(2) A Local Health Board may refuse to grant an application where—

- (a) having considered the information and undertakings required by Part 2 of Schedule 1 and any other information in its possession in relation to the application, the Local Health Board considers that the applicant is unsuitable to be included in its pharmaceutical list;
- (b) having contacted the referees nominated by the applicant in accordance with Part 2 of Schedule 1, it is not satisfied with the references given;
- (c) having checked with the NHS Business Services Authority 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;
- (d) having checked with the Welsh Ministers for any facts that they consider 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 that these justify such a refusal; or
- (e) it considers that admitting the applicant to the list would be prejudicial to the efficiency of the service which he or she would undertake to provide.

(3) A Local Health Board must refuse to grant an application where—

- (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; or

- (d) on appeal the Tribunal determines that the applicant may be included in the pharmaceutical list subject to conditions but the applicant has not, within 30 days of that decision notified the Local Health Board that he or she agrees to the imposition of conditions.

(4) Where the Local Health Board is considering a 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)(a), (c) and (d)—

- (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 public finances;
- (f) whether any offence was a sexual offence to which Part 2 of the Sexual Offences Act 2003(1) 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 Local Health Board 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 Local Health Board or equivalent body in each case.

(5) When the Local Health Board takes into account the matters set out in paragraph (4), it must consider the overall effect of the matters being considered.

(6) If a Local Health Board refuses an application to which this regulation applies under grounds in paragraph (2) or (3), the Local Health Board 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 Tribunal; and
- (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.

### **Conditional inclusion relating to fitness grounds**

**33.—**(1) A Local Health Board that receives an application from a person—

- (a) under regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list), except where the application is made by a person who has been

(1) 2003 c. 42.

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

granted preliminary consent under regulation 12 (applications for preliminary consent and effect of preliminary consent) and which is valid in accordance with regulation 12(5); or

- (b) under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list,

may determine that the person, whilst he or she is included in the pharmaceutical list or whilst his or her preliminary consent is valid, is to be subject to the imposition of conditions having regard to the requirements of section 104 (conditional inclusion in ophthalmic and pharmaceutical lists) of the 2006 Act.

(2) A Local Health Board may vary the terms of service on which a person is included in the pharmaceutical list for the purpose of paragraph (1).

(3) A condition imposed under paragraph (1) must be a condition imposed with a view to—

- (a) preventing any prejudice to the efficiency of the services, or any of the services, which the person has undertaken to provide; or
- (b) preventing any act or omission within section 107(3)(a) of the 2006 Act (disqualification of practitioners).

(4) If a Local Health Board decides to grant an application subject to a condition imposed under paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—

- (a) the reasons for the decision;
- (b) the person's right of appeal against its decision to the Tribunal;
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, 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 the person, in accordance with regulation 17(2), provides a notice of commencement before the Tribunal has determined an appeal against a condition imposed under paragraph (1), that person is to be included in the pharmaceutical list subject to the condition, but only until 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 Local Health Board to impose the condition; and
- (b) if the person 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 that person for the purpose of or in connection with the imposition of the condition.

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

- (a) the Tribunal confirms the decision of the Local Health Board; or
- (b) imposes a different condition,

the person must, within 30 days of being notified of the Tribunal's decision, notify the Local Health Board as to whether or not the person wishes to withdraw his or her application.

(8) If the person fails, in the circumstances described in paragraph (7), to notify the Local Health Board within that 30 days that he or she does not wish to withdraw his or her application, the grant of that person's application lapses.

(9) Where a person wishes to withdraw from a pharmaceutical list, that person must notify the Local Health Board at least 30 days in advance of that date, if—

- (a) a condition is imposed under paragraph (1);

- (b) the person appeals that condition to the Tribunal;
- (c) on appeal, the Tribunal confirms the imposition of that condition or imposes another condition; and
- (d) within 30 days of being informed of the decision of the Tribunal the person notifies the Local Health Board that he or she wishes to withdraw from its pharmaceutical list,

unless it is impracticable for the person to do so in which case the person must notify the Local Health Board as soon as it is practicable to do so.

**Removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act**

**34.**—(1) Where a Local Health Board is considering—

- (a) removing a person’s name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act, other than in cases specified in regulation 35 (removal from a pharmaceutical list for other reasons);
- (b) contingently removing a person’s name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act;
- (c) removing a person’s name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act;
- (d) imposing any particular condition under section 108 of the 2006 Act, or varying any condition or imposing a different condition under that section, or varying a person’s terms of service under section 108(4) of the 2006 Act; or
- (e) removing a person’s name from the pharmaceutical list for breach of a condition under regulation 33 (conditional inclusion relating to fitness grounds),

on fitness grounds, it must follow the procedure set out in this regulation.

(2) Before taking an action specified in paragraph (1), the Local Health Board must give the person—

- (a) notice of any allegation against him or her;
- (b) notice of what action the Local Health Board is considering and on what grounds;
- (c) the opportunity to make written representations within 30 days beginning on the date on which the notification is given under this paragraph; and
- (d) the opportunity to put the person’s case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(3) If the Local Health Board 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) Once the Local Health Board has reached a decision it must notify the person of that decision and it must include with that notification an explanation of—

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

(5) Where the Local Health Board has decided to impose a contingent removal, it must inform the person of their right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(6) The Local Health Board must not remove a person's name from the pharmaceutical list, or impose a contingent removal, until the time for bringing an appeal has expired or, where an appeal is made, it has been determined by the Tribunal.

(7) Where a Local Health Board is notified by the Tribunal that it has considered—

- (a) an appeal by a person against a contingent removal and the Tribunal has decided to remove the person from the pharmaceutical list instead; or
- (b) an appeal by a person who is subject to conditions under regulation 33 and the Tribunal has decided not to include the person in that pharmaceutical list,

the Local Health Board must remove the person from its pharmaceutical list and must notify the person immediately that it has done so.

### **Removal from a pharmaceutical list for other reasons**

**35.**—(1) Subject to paragraph (2), a Local Health Board must remove a person from a pharmaceutical list that it maintains where it becomes aware that the person (and where the person is a body corporate, any director or superintendent of that body)—

- (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 a Local Health Board is considering removing a person from its pharmaceutical list under grounds contained in paragraph (1), the Local Health Board must, before reaching its decision—

- (a) notify the person of the action that it is considering taking and the grounds for considering taking that action; and
- (b) as part of that notification—
  - (i) inform the person of any allegation made against him or her; and
  - (ii) advise the person that he or she may make—
    - (aa) written representations to the Local Health Board with regard to that action provided such representations are received by the Local Health Board within 30 days beginning with the date of notification by the Local Health Board; and
    - (bb) oral representations to the Local Health Board with regard to that action, provided the person notifies the Local Health Board of his or her wish to make oral representations within 30 days beginning with the date of the notification by the Local Health Board and the person (or a representative) attends the hearing that the Local Health Board arranges for the purposes of hearing those representations; and
- (c) in a case to which paragraph (1)(a) or (b) applies, if the person is a body corporate, advise the person that the Local Health Board will not remove the body corporate from its pharmaceutical list as a consequence of paragraph (1)(a) or (b) (without prejudice to any other action that it may take), provided that—
  - (i) the director or superintendent concerned ceases to be a director or superintendent of the body corporate within the period of 30 days commencing with the date of the notice; and

- (ii) within that period, the body corporate notifies the Local Health Board of the date on which the director or superintendent has ceased or is to cease to be a director or superintendent of the body corporate.
- (3) A Local Health Board must remove a person from a pharmaceutical list—
- (a) if the person has not, in the preceding six months, provided pharmaceutical services from the premises in respect of which the person is included in the pharmaceutical list (but a period during which the person has been suspended does not count towards calculating the six month period); or
  - (b) if the person has died, but not if that person's business is carried on after his or her death by a representative under section 72 of the Medicines Act 1968 (representative of pharmacist in case of death or disability) so long as the business is carried on by the representative in accordance with the provisions of that Act, and the representative agrees to be bound by the terms of service; or
  - (c) if the person is no longer a registered pharmacist.
- (4) Before removing a person from a pharmaceutical list under paragraph (3) the Local Health Board must—
- (a) give the person or the person's representative mentioned under paragraph (3)(b) 30 days notice of its intention to remove the person from the pharmaceutical list;
  - (b) give the person or the person's representative mentioned under paragraph (3)(b) the opportunity to make representations in writing or, if he or she so desires, in person, during that period; and
  - (c) consult the Local Pharmaceutical Committee.
- (5) Once the Local Health Board has taken a decision to remove the person from the pharmaceutical list on grounds contained in paragraph (1), it must notify the person of that decision and it must include with the notification an explanation of—
- (a) the reasons for the decision;
  - (b) the person's right of appeal against its decision to the Tribunal; and
  - (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.
- (6) The Local Health Board must notify the person immediately in writing of its decision under paragraph (3) to remove the person from the pharmaceutical list and of the person's right of appeal under paragraph (7).
- (7) A person notified under paragraph (6) may, within 30 days of receiving the notice appeal the decision by notice in writing to the Welsh Ministers setting out the grounds of appeal.
- (8) Upon receipt of an appeal under paragraph (7) the Welsh Ministers must notify the Local Health Board that an appeal has been received.
- (9) The Welsh Ministers may determine the appeal in respect of which a valid notice of appeal has been given in accordance with paragraph (7) in such manner (including with regard to procedures) as the Welsh Ministers think fit.
- (10) On determining an appeal under paragraph (9), the Welsh Ministers may—
- (a) confirm the decision of the Local Health Board; or
  - (b) substitute for that decision any decision that the Local Health Board could have taken when it took that decision.
- (11) A Local Health Board must not remove the person's name from the pharmaceutical list until—



- (a) if no appeal is made, the period for bringing an appeal against the decision has elapsed; or
- (b) if an appeal is made, the appeal is determined.

(12) Where an appeal is upheld, the Local Health Board must not remove the person's name from the pharmaceutical list.

### **Suspension from a pharmaceutical list**

**36.**—(1) Before making a decision under section 110(1) (suspension) or section 111(2) (suspension pending appeal) of the 2006 Act, the Local Health Board must give the person—

- (a) notice of any allegation against him or her;
- (b) notice of the action the Local Health Board is considering and on what grounds;
- (c) the opportunity to make written representations within 30 days beginning with the date the notification is given under this paragraph; and
- (d) the opportunity to make representations at an oral hearing before the Local Health Board, provided the person notifies the Local Health Board that he or she wishes to make representations within a specified period (of not less than 24 hours).

(2) The Local Health Board must take into account any representations made by the person before it reaches its decision.

(3) Once the Local Health Board has reached a decision it must as soon as is reasonable practicable notify the person in writing of its decision and the reasons for it (including any facts relied upon).

(4) Where the Local Health Board has suspended a person from the pharmaceutical list, it must inform the person of the reasons for the decision and, in the case of a suspension under section 110(1) of the 2006 Act, of his or her right to have the decision reviewed in accordance with section 113 (review of decisions) of the 2006 Act.

(5) The Local Health Board may at any time revoke the suspension and notify the person of its decision.

### **Notification of decision to impose conditions**

**37.**—(1) Where a Local Health Board decides to—

- (a) refuse to grant an application from a person under regulation 32;
- (b) impose conditions on a person under regulation 33;
- (c) remove a person from its pharmaceutical list under regulation 34 or 35;
- (d) suspend a person from its pharmaceutical list under regulation 36,
- (e) impose or vary a condition under regulation 38; or
- (f) impose or vary a condition under regulation 39

it must notify the persons and bodies specified in paragraph (2) and additionally notify those specified in paragraph (3), if requested to do so by those persons or bodies in writing (including electronically), of the matters set out in paragraph (4).

(2) The persons to be notified are—

- (a) the Welsh Ministers;
- (b) any other Local Health Board or equivalent body that to the knowledge of the notifying Local Health Board has the applicant included in a relevant list;
- (c) the Scottish Ministers;
- (d) the Secretary of State;

- (e) the Northern Ireland Executive;
  - (f) the General Pharmaceutical Council, the Pharmaceutical Society of Northern Ireland or any other appropriate regulatory body;
  - (g) the Local Pharmaceutical Committee for the Local Health Board's area;
  - (h) the National Health Service Commissioning Board; and
  - (i) in the case of fraud, the NHS Business Services Authority.
- (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 person, are using or have used his or her services (or where the person is a body corporate, have used the services of any director or superintendent of that body corporate) in a professional capacity, or
    - (ii) are considering employing or using the services of the person (or where the person is a body corporate, using the services of any director or superintendent of that body corporate) 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 person is or was a member of the partnership or that it is considering inviting the person to become a member.
- (4) The matters referred to in paragraph (1) are—
- (a) where the person is an individual or a partnership—
    - (i) the person's, or each member of the partnership's name, address and date of birth;
    - (ii) the person's or each member of the partnership's, professional registration number;
    - (iii) the date and copy of the decision of the Local Health Board; and
    - (iv) a contact name of a person in the Local Health Board for further enquiries.
  - (b) where the person is a body corporate—
    - (i) the body corporate's name, company registration number and the address of the registered office;
    - (ii) the professional registration number of body corporate's superintendent and of any director of the body corporate who is a registered pharmacist;
    - (iii) the date and copy of the decision of the Local Health Board; and
    - (iv) a contact name of a person in the Local Health Board for further enquiries.
- (5) The Local Health Board must send to the person a copy of any information about him or her 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 Local Health Board 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 person .
- (7) Where a Local Health Board is notified by the Tribunal that it has imposed a national disqualification on a person whom the Local Health Board has removed from its pharmaceutical list, the Local Health Board must 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 Local Health Board must 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.

**Review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act**

**38.**—(1) Where in accordance with section 113 (review of decisions) of the 2006 Act, a Local Health Board must review its decision to contingently remove a person from the pharmaceutical list or suspend a person from the pharmaceutical list under section 110 (suspension) of the 2006 Act, or where it decides to review such a decision, it must give that person—

- (a) notice that it intends to review its decision;
- (b) notice of the decision that it is minded to take upon review, and the reasons for it;
- (c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a); and
- (d) the opportunity to put the person’s case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

(2) On such a review the Local Health Board may—

- (a) confirm the contingent removal or suspension;
- (b) in the case of a suspension terminate it;
- (c) in the case of a contingent removal, vary the conditions, impose different conditions, revoke the contingent removal, or remove the practitioner from the list.

(3) A person who has been suspended from a pharmaceutical list under section 110 of the 2006 Act or contingently removed from a pharmaceutical list under section 108 of the 2006 Act cannot request a review until the expiry of—

- (a) three months beginning with the date of the decision of the Local Health Board to contingently remove; or
- (b) six months beginning with the date of the decision on the previous review.

(4) If the Local Health Board 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 oral hearing, as the case may be, before reaching its decision.

(5) Once the Local Health Board has made a decision under section 113(3) of the 2006 Act, it must notify the person of its decision and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision;
- (b) if the person has a right of appeal in relation to the decision—
  - (i) the right of appeal that the person has in relation to that decision under section 114 of the 2006 Act (appeals)(3), and
  - (ii) the time limit within which, in accordance with the Tribunal Procedure (First Tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought; and
- (c) if the person has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 113(1) of the 2006 Act.

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(3) Note there is no right of appeal to the Tribunal against a decision to suspend a practitioner or to review a decision on suspension. However, there is a right of appeal to the Tribunal against any decision of a Local Health Board on a review of a contingent removal under section 113 of the 2006 Act. See section 114 of the 2006 Act.

**Review of a decision to impose conditions**

**39.**—(1) Where a Local Health Board has made a decision to impose conditions in accordance with regulation 33, 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 Local Health Board's decision until the expiry of a three month period beginning with the date the Local Health Board—

- (a) includes the person's name on its pharmaceutical list; or
- (b) grants the person preliminary consent,

and cannot request a review within six months of a decision on a previous review.

(3) A Local Health Board must give the person whose application has been granted subject to conditions—

- (a) notice that it intends to review its decision;
- (b) notice of the decision that it is minded to take upon review, and the reasons for it.
- (c) the opportunity to make written representations to the Local Health Board within the period of 30 days beginning with the date of notification under sub-paragraph (a); and
- (d) the opportunity to put the person's case at an oral hearing before the Local Health Board, if the person so requests within the 30 day period mentioned in sub-paragraph (c).

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

(5) Upon review the Local Health Board may—

- (a) maintain the current conditions;
- (b) impose new conditions;
- (c) vary the person's terms of service;
- (d) vary the conditions; or
- (e) where the person has breached a condition, remove the person from the pharmaceutical list.

(6) As soon as practicable after reaching a decision, the Local Health Board must notify the person of its decision, and it must include with the notification of its decision an explanation of—

- (a) the reasons for the decision;
- (b) the right of appeal that the person has to the Tribunal; and
- (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.

**Appeals**

**40.**—(1) A person, other than a person notified under regulation 37, who has been notified by a Local Health Board of its decision that it—

- (a) intends to—
  - (i) refuse to grant an application to which regulation 32 (refusal of applications on fitness grounds) applies under grounds contained in paragraph (2) or (3) of that regulation;

- (ii) impose conditions on the person by virtue of regulation 33 (conditional inclusion relating to fitness grounds), or vary the person's terms of service pursuant to that regulation;
- (iii) in accordance with regulation 34 (removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act)—
  - (aa) remove the person's name from the pharmaceutical list under section 107 (disqualification of practitioners) of the 2006 Act;
  - (bb) contingently remove the person's name from the pharmaceutical list under section 108 (contingent removal) of the 2006 Act;
  - (cc) remove the person's name from the pharmaceutical list for breach of a condition imposed under section 108 of the 2006 Act;
  - (dd) impose any particular condition under section 108 of the 2006 Act, vary any condition, impose a different condition or vary the person's terms of service under that section;
  - (ee) remove the person's name from the pharmaceutical list for breach of a condition imposed under regulation 33; or
- (iv) remove the person from the pharmaceutical list on grounds contained in regulation 35(1); or
- (b) has reviewed a decision to impose conditions under regulation 39 (review of a decision to impose conditions) and has decided to take any of the actions in regulation 39(5); or
- (c) has reviewed a decision to contingently remove the person from a pharmaceutical list by virtue of regulation 38 (review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act) and has—
  - (i) confirmed the contingent removal;
  - (ii) varied the conditions attached to the contingent removal or imposed different conditions; or
  - (iii) has removed the person from the pharmaceutical list,may appeal that decision to the Tribunal.
- (2) An appeal under paragraph (1) must be made in writing, setting out the grounds on which the appeal is made and must be submitted to the Tribunal within the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008, the application notice must be sent to the Tribunal if an appeal is to be brought.
- (3) The Tribunal, on determining an appeal, may make any decision that the Local Health Board could make under this Part.