

SCHEDULE 2

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

PART 5

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

Notification of decisions on routine and excepted applications

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

- (a) the applicant;
- (b) any Local Pharmaceutical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;
- (c) any Local Medical Committee—
 - (i) whose area includes the premises or location to which the application relates, or
 - (ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;
- (d) any person—
 - (i) included in a pharmaceutical list for the area of the relevant HWB, or
 - (ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
- (e) any LPS chemist—
 - (i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and
 - (ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
- (f) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision;
- (g) if the applicant is seeking to locate premises in or within 1.6 kilometres of a controlled locality in the area of the relevant HWB—
 - (i) any provider of primary medical services, or
 - (ii) any other person on the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services),who, in the opinion of the NHSCB, has a significant interest in the decision;
- (h) any person—
 - (i) whom the NHSCB notified under paragraph 19(2), and
 - (ii) who made representations in writing about the application under paragraph 19(4);

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- (i) any Local Health Board any part of whose area is within 2 kilometres of the premises or location to which the decision relates; and
 - (j) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.
- (2) If any part (PA) of the area of a notified HWB (HWB2) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—
- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(b);
 - (b) any Local Medical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (1)(c);
 - (c) any person—
 - (i) included in a pharmaceutical list for the area of HWB2, or
 - (ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
 - (d) any LPS chemist—
 - (i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB2, and
 - (ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
 - (e) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision; and
 - (f) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in the area of HWB2—
 - (aa) any provider of primary medical services, or
 - (bb) any other person on the dispensing doctors list for the area of HWB2 if there is one (being a performer but not a provider of primary medical services),who, in the opinion of the NHSCB, has a significant interest in the decision.
- (3) As regards any excepted application, once it has determined the application, the NHSCB must, as soon as is practicable, give notice of its decision to—
- (a) in the case of an application pursuant to regulation 23, the applicant;
 - (b) in the case of an application pursuant to regulation 24, 25 or 26(2)—
 - (i) the applicant,
 - (ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,
 - (iii) any Local Medical Committee whose area includes the premises or location to which the application relates,
 - (iv) the relevant HWB, and if the applicant is relocating to different premises in the area of another HWB, the other HWB, and

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- (v) any (other) person whom the NHSCB notified under paragraph 19 and who made representations in writing about the application under paragraph 19(4);
- (c) in the case of an application pursuant to regulation 26(1) or 27 to 29—
 - (i) the applicant,
 - (ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,
 - (iii) any Local Medical Committee whose area includes the premises or location to which the application relates,
 - (iv) any person—
 - (aa) included in a pharmaceutical list for the area of the relevant HWB, or
 - (bb) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
 - (v) any LPS chemist—
 - (aa) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and
 - (bb) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision,
 - (vi) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision,
 - (vii) any Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates, and
 - (viii) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.

(4) If, in the case of an application pursuant to regulation 26(1) or 27 to 29, any part (PA) of the area of a HWB (HWB3) notified under sub-paragraph (3)(c) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—

- (a) any Local Pharmaceutical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (3)(c)(ii);
- (b) any Local Medical Committee—
 - (i) whose area includes PA, and
 - (ii) that is not given notice of the application under paragraph (3)(c)(iii);
- (c) any person—
 - (i) included in a pharmaceutical list for the area of HWB3, or
 - (ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
- (d) any LPS chemist—

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- (i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB3, and
 - (ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision; and
- (e) any Local Healthwatch organisation for the area of HWB3, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision.
- (5) Where the NHSCB has decided to consider 2 or more applications together pursuant to paragraph 22(3), it must give notice to each applicant of the decision taken with regard to each other application considered together with their application.
- (6) Each notification of a decision under this paragraph must include a statement by the NHSCB of the reasons for the decision.

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

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

- (a) the address of the premises to which the application relates;
- (b) the services that are to be provided from those premises;
- (c) the date of the grant of the application;
- (d) a declaration with regard to when the applicant intends to commence the provision of those services at those premises;
- (e) in the case of pharmacy premises, the registration number for those premises with the General Pharmaceutical Council; and
- (f) a signature on behalf of the applicant and the date of the notice.

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

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

- (2) For the purposes of this Schedule, a person (P1) is a person with third party rights if—
- (a) P1 is a person to whom sub-paragraph (3) applies; or
 - (b) P1 was entitled to receive notification of the decision to grant the application by virtue of paragraph 28(5).
- (3) P1 is a person to whom this sub-paragraph applies if—
- (a) P1 was a person whom the NHSCB was required to notify about the decision on the application by virtue of P1 being a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision, and also being—
 - (i) included in a pharmaceutical list,
 - (ii) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,
 - (iii) an LPS chemist, or

(iv) either—

(aa) a provider of primary medical services, or

(bb) another person on the dispensing doctor list for the area of the relevant HWB if there is one (P1 being a performer but not a provider of primary medical services),

but only if the application is in respect of premises in a controlled locality and it was granted partly on the basis that, having regard to regulation 44(3), in the opinion of the NHSCB granting the application would not prejudice the proper provision of relevant NHS services in the area of the relevant HWB or of a neighbouring HWB of the relevant HWB;

(b) in the case of a notifiable application, P1 made representations in writing about the application under paragraph 19(4); and

(c) in the case of a notifiable application but subject to sub-paragraph (6), the NHSCB is satisfied, having regard to those representations in writing and any oral representations made in accordance with paragraph 25, that P1—

(i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and

(ii) has grounds for opposing the application, which—

(aa) do not amount to a challenge to the legality or reasonableness of a pharmaceutical needs assessment, or to the fairness of the process by which a HWB or Primary Care Trust undertook that assessment, and

(bb) are not vexatious or frivolous.

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

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

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

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

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

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

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

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

(a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and

(b) prior to the determination of the application, A was only able to provide a best estimate of where the proposed listed chemist premises would be (not the address of those premises).

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

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

whichever is the latest.

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

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

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

(5) The NHSCB may not vary or remove a condition imposed by virtue of this paragraph.

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

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

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

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

(2) Where this sub-paragraph applies, A may notify to the NHSCB a different address (“new address”) as the address to which the application relates within—

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

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

- (a) result in a significant change to the arrangements that are in place (having regard to the grant of A's application) for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
 - (i) in any part of the area of the relevant HWB, or

- (ii) in a controlled locality that is part of the area of a neighbouring HWB of the relevant HWB, where that controlled locality is within 1.6 kilometres of the new address; nor
 - (b) cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB.
 - (4) If the NHSCB receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—
 - (a) notify A of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;
 - (b) if the NHSCB is not satisfied that it is a valid notification, it must include with that notification—
 - (i) the reasons for its decision, and
 - (ii) an explanation of how A's rights of appeal under paragraph 36(1)(b) may be exercised.
 - (c) if it is satisfied that it is a valid notification, notify the new address to the persons notified of the decision to grant the application, and must include with that notification—
 - (i) the reasons for its decision, and
 - (ii) if the person has a right of appeal under sub-paragraph (5), an explanation of how that right of appeal may be exercised.
 - (5) A person (X) who—
 - (a) is notified under sub-paragraph (4)(c); and
 - (b) was entitled to be notified of the decision to grant the application—
 - (i) by virtue of paragraph 28(5), or
 - (ii) as a person whom the NHSCB was required to notify about the application by virtue of X being—
 - (aa) an LPS chemist,
 - (bb) included in a pharmaceutical list, or
 - (cc) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,and a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;
- may appeal against a decision by the NHSCB to accept the purported notification as a valid notification, provided X notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which X was notified under sub-paragraph (4)(c).
- (6) A notice of appeal under sub-paragraph (5) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

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

- 33.**—(1) Where the NHSCB grants a routine application because doing so—
- (a) will meet a future need for pharmaceutical services, or pharmaceutical services of a specified type in its area; or
 - (b) will secure future improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type, in its area,
- sub-paragraph (2) applies.

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

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

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

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

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

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

Taking effect of listing decisions: general

34.—(1) As regards any application—

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

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

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

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

- (a) includes the information required under paragraph 29; and
- (b) is in the same format as the version of the notice sent by the NHSCB with the notice of decision under paragraph 28.

(4) A notice of commencement is invalid unless it is sent to the NHSCB within—

- (a) if, prior to the NHSCB determining the application—
 - (i) P undertook to commence the provision of the services in respect of which the application was made within a period of less than 6 months, and
 - (ii) that undertaking was not withdrawn,
- that period;

- (b) 6 months of—
- (i) unless paragraph (a) applies, the date on which P was sent the notice of the NHSCB's decision under paragraph 28 granting the application,
 - (ii) if the grant was appealed by a person with third party appeal rights, the date on which that appeal is determined by the Secretary of State,
 - (iii) if, in the course of granting the application, a decision is taken to impose a condition in accordance with regulation 35 and that condition is appealed by P, the date on which that appeal is determined by the First-tier Tribunal (unless regulation 35(8) applies),
 - (iv) if the grant of the application was subject to a condition imposed by virtue of paragraph 31, the date on which—
 - (aa) P validly notifies to the NHSCB under a condition imposed by virtue of paragraph 31 of the address of the premises, or
 - (bb) if P appeals successfully against a decision of the NHSCB that a notification under a condition imposed by virtue of paragraph 31 is invalid, that appeal is determined by the Secretary of State,
 - (v) if P, pursuant to paragraph 32—
 - (aa) notifies the NHSCB of a new address,
 - (bb) the NHSCB does not accept the validity of the notification, and
 - (cc) P appeals successfully against that decision,the date on which that appeal is determined by the Secretary of State, or
 - (vi) if the grant of the application was subject to a condition imposed by virtue of paragraph 33, the date on which the condition imposed by virtue of that paragraph becomes spent or is removed on appeal, or
- whichever is the latest; or
- (c) such longer period—
- (i) not exceeding a further 3 months as the NHSCB may allow, or
 - (ii) if—
 - (aa) the grant is appealed by a person with third party appeal rights,
 - (bb) a decision to accept a notification pursuant to paragraph 32 is appealed by a third party,
 - (cc) P appeals successfully against a notice under paragraph 35, or
 - (dd) if P appeals successfully against a decision not to allow a longer period under sub-paragraph (i),as the Secretary of State may allow when the appeal is determined,

and so once a valid notice of commencement can no longer be sent in relation to an application (having regard also to paragraph 10(2) of Schedule 3), the grant of that application lapses.

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

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

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Notice requiring the commencement of pharmaceutical services

35.—(1) The NHSCB, having granted a routine application—

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

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

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

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

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

(4) The NHSCB may change its pharmaceutical list to give effect to that notice—

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

whichever is the latest.

Appeals to the Secretary of State by the applicant

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

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

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

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

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