

## SCHEDULE 3

Regs 10(8), 45(3), 63(6), 77(4), 98(9)

### Appeals to the Secretary of State

## PART 1

### Preliminary matters

#### Determination of third party appeal rights in certain cases

1.—(1) If the Secretary of State has received a notification under paragraph 30(6) of Schedule 2 from a person (P1), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P1 is to have third party appeal rights on the basis that—

- (a) P1 is a person to whom paragraph 30(3)(a) and (b) of Schedule 2 applies; and
- (b) in relation to P1, [<sup>F1</sup>NHS England] should have been satisfied as mentioned in paragraph 30(3)(c) of Schedule 2.

(2) If the Secretary of State has received a notification under regulation 63(5) from a person (P2), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P2 is to have third party appeal rights on the basis that—

- (a) P2 is a person to whom regulation 63(3)(a) and (b) applies; and
- (b) in relation to P2, [<sup>F1</sup>NHS England] should have been satisfied as mentioned in regulation 63(3)(c).

(3) Once the Secretary of State has made a determination under paragraph (1) or (2), the Secretary of State must notify [<sup>F1</sup>NHS England] and P1 or P2 of that determination and the reasons for it.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

#### Misconceived appeals

2. If the Secretary of State, after considering a valid notice of appeal under regulation 45, 63 or 77, or paragraph 30, 32(5) or 36 of Schedule 2 against a decision, is of the opinion that the notice—

- (a) contains no valid grounds of appeal (for example, because it amounts to a challenge to the legality or reasonableness of a HWB's or Primary Care Trust's pharmaceutical needs assessment, or to the fairness of the process by which the HWB or a Primary Care Trust undertook that assessment); or
- (b) contains no reasonable grounds for appeal (for example, where it is vexatious or frivolous),

the Secretary of State may determine the appeal by dismissing it (without proceeding to notify the appeal under Part 2).

## PART 2

### Notification of appeals

#### Notification of appeals notices under paragraph 30, 32(5) or 36 of Schedule 2

3.—(1) Unless the Secretary of State determines the appeal under paragraph 2, or the appeal relates to an application pursuant to regulation 23, the Secretary of State must send a copy of a valid notice of appeal sent under paragraph 30, 32(5) or 36 of Schedule 2 to—

- (a) [<sup>F1</sup>NHS England];
- (b) in the case of an appeal against the grant of an application, any person who was entitled to receive notification of the decision by virtue of paragraph 28(5) of Schedule 2;
- (c) in the case of an appeal in relation to a notifiable application, including against decisions as mentioned in paragraphs 32(4) and 36(1)(b) to (f) of Schedule 2—
  - (i) the applicant (unless they are the person bringing the appeal),
  - (ii) any person who was notified in relation to that application under paragraph 19 of Schedule 2 who made representations in writing about the application under paragraph 19(4) of that Schedule (unless they are also the person bringing the appeal), and
- (d) in the case of an appeal in relation to an application pursuant to regulation 26(1), 27 or 28 (including against decisions as mentioned in paragraph 36(1)(d) to (f) of Schedule 2), any person notified in relation to the decision on that application under paragraph 28(3) (c) or (4).

(2) Any person to whom a notice of appeal is sent under sub-paragraph (1) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they are sent the notice of appeal by the Secretary of State.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), [Sch. para. 1](#)

#### Notification of appeals relating to notices under regulation 45

4.—(1) A valid notice of appeal under regulation 45(1)(b) does not need to be notified to others.

(2) The Secretary of State must send a valid notice of appeal—

- (a) against a determination under regulation 36(2) to the persons given notice of the proposed determination under regulation 38(1) or (2); or
- (b) against a determination under regulation 41(2) or 42(1) to—
  - (i) the person making the routine application to which the determination relates, and
  - (ii) any person given notice of the determination who is mentioned in regulation 43(1) (b)(ii),

unless they are the person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

### Notification of appeals relating to decisions under Part 8 of these Regulations

- 5.—(1) A valid notice of appeal under regulation 63(1)(a) does not need to be notified to others.
- (2) The Secretary of State must send a valid notice of appeal against—
- (a) a decision mentioned in regulation 63(1)(b) to the persons, other than the appellant, given notice of the decision under [<sup>F2</sup>regulation 50(7)]; or
  - (b) a decision or determination mentioned in regulation 63(1)(c) to (f) to—
    - (i) the person who made the original application for outline consent or premises approval,
    - (ii) any person who was notified in relation to that application under regulation 52(1) to (3) who made representations in writing about the application under regulation 52(4), and
    - (iii) if the appeal is against a refusal to grant temporary premises approval, the applicant who made the relevant outstanding pharmacy application,unless they are person bringing the appeal.
- (3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

#### Textual Amendments

- F2** Words in Sch. 3 para. 5(2)(a) substituted (1.3.2015) by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015 (S.I. 2015/58), regs. 1(1), 7 (with reg. 10)

### Non notification of appeals relating to notices under regulation 77 or 98

6. A valid notice of appeal under regulation 77 or 98 does not need to be notified to others.

## PART 3

### Determination of appeals

#### Flexibility with regard to the manner of determining appeals

7.—(1) Except in so far as these Regulations provide to the contrary, the Secretary of State is to determine the appeal to which a valid notice of appeal under regulation 45, 63 or 77, or under paragraph 30, 32(5) or 36 of Schedule 2, relates in such manner (including with regard to procedures) as the Secretary of State sees fit.

(2) The Secretary of State may determine the appeal without hearing any oral representations, if the Secretary of State considers that oral representations are unnecessary.

(3) Where appropriate, the Secretary of State may, if the Secretary of State thinks fit, consider 2 or more appeals together and in relation to each other, but where the Secretary of State does so, the Secretary of State must give notice of the Secretary of State's intention to do so to—

- (a) [<sup>F1</sup>NHS England];
- (b) the appellants; and
- (c) any other person notified in relation to the appeals under Part 2.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, SCHEDULE 3. (See end of Document for details)

[<sup>F3</sup>(4) Where an application for inclusion in a pharmaceutical list has been updated in accordance with paragraph 5A of Schedule 2, the Secretary of State may, on an application from NHS England, defer the Secretary of State’s decision in relation to the application on any ground that NHS England could have relied on for deferring the application pursuant to regulation 34 until—

- (a) the reason for the deferral no longer exists; or
- (b) the outcome of the cause of the deferral is known and NHS England has—
  - (i) decided, in the light of that outcome, whether or not to redetermine the application, and
  - (ii) redetermined the application, if it is to be redetermined.

(5) Where NHS England redetermines an application in accordance with paragraph 5A(2) of Schedule 2 and refuses it, the Secretary of State may direct that the proceedings relating to the appeal are to be brought to an end without a determination of the matter under paragraph 9.]

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F3** [Sch. 3 para. 7\(4\)\(5\)](#) inserted (1.10.2022) by [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment\) Regulations 2022 \(S.I. 2022/930\)](#), regs. 1(2), 7

#### Oral hearings

**8.—(1)** If the Secretary of State does decide to hear oral representations, the Secretary of State must give not less than 14 days notice of the time and place at which the oral representations are to be heard to—

- (a) [<sup>F1</sup>NHS England];
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that applicant is bringing the appeal, the person bringing the appeal;
- (d) any Local Pharmaceutical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates;
- (e) any Local Medical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates; and
- (f) any additional presenters,

and they (or their duly authorised representatives) are to be the only persons entitled to make oral representations at the hearing.

(2) For these purposes, a person (P) is an “additional presenter” if—

- (a) P was notified of the appeal under Part 2 and has made written representations in accordance with paragraph 3(2), 4(3) or 5(3) <sup>F4</sup> ...; and
- (b) the Secretary of State is satisfied that P made a reasonable attempt to express P’s views on the appeal adequately in P’s written representations.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

**F4** Words in Sch. 3 para. 8(2)(a) omitted (26.11.2018) by virtue of [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2018 \(S.I. 2018/1114\)](#), regs. 1(1), **6(2)**

## Decisions of the Secretary of State

**9.**—(1) On determining an appeal relating to a valid notice under paragraph 30 or 36, the Secretary of State may—

- (a) if the appeal is an appeal to which paragraph 30 or 36(1)(a) of Schedule 2 applies (that is, against a decision to grant or refuse a routine or excepted application)—
  - (i) confirm the decision of [F1NHS England],
  - (ii) quash the decision and redetermine the application, or
  - (iii) quash the decision and remit the matter to [F1NHS England] for it to redetermine the application, where the Secretary of State considers that there should be a (further) notification under paragraph 19 of Schedule 2, subject to such directions as the Secretary of State considers appropriate; or
- (b) if the appeal is an appeal to which paragraph 32(5) or 36(1)(b) to (f) applies—
  - (i) confirm the decision of [F1NHS England], or
  - (ii) substitute for that decision any decision that [F1NHS England] could have taken when it took that decision.

(2) If the Secretary of State grants or confirms the grant of a routine application, the Secretary of State may direct [F1NHS England]—

- (a) to impose a condition under paragraph 33, in circumstances where [F1NHS England] could have imposed such a decision if it had granted the application; or
- (b) to take such action under regulation 50(4) or (5) as the Secretary of State thinks fit.

(3) On determining an appeal relating to a valid notice under regulation 45, the Secretary of State may—

- (a) confirm the decision or determination of [F1NHS England];
- (b) substitute for that decision or determination any decision or determination that [F1NHS England] could have taken when it took that decision or made that determination; or
- (c) quash the decision or determination of [F1NHS England] and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate.

(4) On determining an appeal relating to a valid notice under regulation 63, the Secretary of State may—

- (a) in the case of decision or determination mentioned in regulation 63(1)(a), (b), (e) or (f)—
  - (i) confirm the decision or determination of [F1NHS England],
  - (ii) substitute for that decision or determination any decision or determination that [F1NHS England] could have taken when it took that decision or made that determination, or
  - (iii) quash the decision or determination of [F1NHS England] and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate; or

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- (b) if the appeal is against a decision to grant or refuse an application for outline consent or premises approval—
  - (i) confirm the decision of [F1NHS England],
  - (ii) quash the decision of [F1NHS England] and redetermine the application, or
  - (iii) quash the decision of [F1NHS England] and remit the matter to it for it to redetermine the application, subject to such directions as the Secretary of State considers appropriate.
- (5) On determining an appeal relating to a valid notice under regulation 77, the Secretary of State may—
  - (a) confirm the decision of [F1NHS England]; or
  - (b) substitute for that decision any decision that [F1NHS England] could have taken when it took that decision.
- (6) If the Secretary of State grants or confirms the grant of an application for—
  - (a) outline consent, the Secretary of State may direct [F1NHS England] to take such action under regulation 53(3) as the Secretary of State thinks fit; or
  - (b) premises approval, the Secretary of State may direct [F1NHS England] to take such action under regulation 57 as the Secretary of State thinks fit.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

#### Notification of decisions and subsequent action by [F1NHS England]

**10.**—(1) Once the Secretary of State has determined the appeal, the Secretary of State must notify the following—

- (a) [F1NHS England];
- (b) the person who made the original application to which the appeal relates;
- (c) if a person other than that person brought the appeal, the person who brought the appeal; and
- (d) any person who made written representations relating to the application pursuant to the notification under Part 2,

and must include with that notification a statement of the reasons for the Secretary of State's decision and the Secretary of State's findings of fact.

[F5(1A) If the Secretary of State has—

- (a) granted or confirmed the grant of a consolidation application; or
- (b) allowed or refused an appeal against a decision as mentioned in paragraph 36(1)(b) in respect of an extension period under paragraph 34A(4)(b)(i),

the Secretary of State must notify the relevant HWB (under this sub-paragraph or sub-paragraph (1)(d)), and must include with that notification a statement of the reasons for the Secretary of State's decision and the Secretary of State's findings of fact.]

(2) If the Secretary of State has granted or confirmed the grant of a routine or excepted application—

- (a) [F1NHS England] must send to the applicant a template of the notice of commencement referred to in paragraph 29 [F6 or a notice of consolidation referred to in paragraph 29A]; and
  - (b) the time periods in paragraphs 31, 32[F7, 34 and 34A] thereafter apply as if the references to the applicant being sent notices of [F1NHS England's] decision were reference to the applicant being notified by the Secretary of State under [F7 sub-paragraph (1)].
- (3) If the Secretary of State has granted or confirmed the grant of—
- (a) a routine application, [F1NHS England] must proceed as soon as is practicable to take such action under regulation 50(4) or (5) as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(2)(b);
  - (b) an application for outline consent, [F1NHS England] must proceed as soon as is practicable to make a determination under regulation 53(3), subject to any directions of the Secretary of State under paragraph 9(6)(a); or
  - (c) an application for premises approval, [F1NHS England] must proceed as soon as is practicable take such action under regulation 57 as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(6)(b).

**Textual Amendments**

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F5** Sch. 3 para. 10(1A) inserted (5.12.2016) by [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2016 \(S.I. 2016/1077\)](#), regs. 1(1), **20(a)**
- F6** Words in Sch. 3 para. 10(2)(a) inserted (5.12.2016) by [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2016 \(S.I. 2016/1077\)](#), regs. 1(1), **20(b)(i)**
- F7** Words in Sch. 3 para. 10(2)(b) substituted (5.12.2016) by [The National Health Service \(Pharmaceutical Services, Charges and Prescribing\) \(Amendment\) Regulations 2016 \(S.I. 2016/1077\)](#), regs. 1(1), **20(b)(ii)**

**Effect of decisions by the Secretary of State**

**11.** For the purposes of these Regulations, the Secretary of State's decision becomes [F1NHS England's] decision on the matter (but no further appeal to the Secretary of State on that decision is possible), unless the Secretary of State's decision is overruled by a court.

**Textual Amendments**

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

**Changes to legislation:**

There are currently no known outstanding effects for the The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, SCHEDULE 3.