

SCHEDULE 2

Regulations 6, 8 and 24

Procedures to be followed by Local Health Boards to determine applications under the Regulations

PART 1

Preliminary matters

General principles

1.—(1) Except in so far as these Regulations provide to the contrary, a Local Health Board may determine an application submitted to it in such manner as it thinks fit.

(2) A Local Health Board must return an application submitted to it if the application does not contain all of the information that an applicant is required to provide in accordance with Schedule 1.

(3) A Local Health Board may if it thinks fit consider two or more applications together and in relation to each other but where it intends to do so it must give notice of that intention in writing to—

- (a) the respective applicants; and
- (b) where the application is one in respect of which notice must be given under paragraph 8, any other person that must be given notice of that application.

(4) Where in accordance with subparagraph (3) a Local Health Board considers two or more applications to which regulation 9(2) applies together and in relation to each other, it may refuse an application (notwithstanding the fact that it would if determining the application in isolation grant it) where the number of applications is such, or the circumstances in which they are made are such, that to grant all of them or more than one of them, would prejudice the proper provision of primary medical services, pharmaceutical services or dispensing services in the controlled locality within which the premises specified in the application are situated.

Timetable for determining applications

2. A Local Health Board must endeavour to determine an application as soon as is practicable after its receipt.

Persons prohibited from taking part in decision-making on applications

3.—(1) No person is to take part in determining an application if he or she—

- (a) is a person who is included in the pharmaceutical list or dispensing doctor list maintained by the Local Health Board, or is an employee of such a person;
- (b) is a shareholder, director or company secretary of a company which runs a retail pharmacy business in the area of the Local Health Board;
- (c) is a provider of primary medical services in the area of the Local Health Board;
- (d) is an APMS contractor in the area of the Local Health Board, or is an officer, trustee or other person concerned with the management of a company, society or voluntary organisation or other body which is an APMS contractor, or is employed or engaged by such an APMS contractor; or
- (e) is employed or engaged by the Local Health Board for the purposes of providing primary medical services within an LHBMS practice.

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(2) No other person is to take part in determining an application if, because of an interest or an association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

PART 2

Determination of controlled localities

Notice of proposed determination in respect of controlled localities

4.—(1) If a Local Health Board decides that an application by a Local Medical Committee or a Local Pharmaceutical Committee cannot be considered by virtue of regulation 6(3) (areas that are controlled localities), the Local Health Board must take no action in relation to that application other than to notify the applicant of that fact and of its right of appeal against that decision under regulation 7 (appeals).

(2) In all other cases, before making a determination under regulation 6(2) a Local Health Board must give a written notice of proposed determination to—

- (a) the Local Medical Committee in its area;
- (b) the Local Pharmaceutical Committee in its area;
- (c) the Community Health Council for the area; and
- (d) any person included in a pharmaceutical list maintained by the Local Health Board and any provider of local pharmaceutical services under a pilot scheme or any provider of primary medical services in the area for which the Local Health Board is established who, in the opinion of the Local Health Board, may be affected by the determination.

(3) A notice of proposed determination must inform the person notified of their right to make representations (or in the case of a Local Medical Committee or Local Pharmaceutical Committee being notified that applied for the determination any further representations) in writing on the proposed determination within 30 days of the date on which the notice was sent to them.

Deferral of applications

5. Where a Local Health Board has issued a notice of proposed determination it must defer consideration of any application submitted under Part 4 or Part 5 of these Regulations but not determined by it if the application could be affected by the proposed determination until—

- (a) it has determined whether or not the locality is or is part of a controlled locality and the period for bringing an appeal relating to that determination has ended; or
- (b) the date of the determination of any such appeal.

Imposition of conditions

6. Where a Local Health Board determines whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it—

- (a) must consider whether the provision of—
 - (i) primary medical services by a provider of such services (other than itself),
 - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
 - (iii) local pharmaceutical services provided under a pilot scheme, or
 - (iv) pharmaceutical services by a doctor,

- is likely to be adversely affected as a consequence of that determination; and
- (b) may, where it is of the opinion that any of those services are likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision under the GMS Regulations for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

Notification of determinations and action following determinations

7.—(1) Once a Local Health Board has determined the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality it must—

- (a) as soon as practicable after reaching a determination give notice in writing to those notified under paragraph 4(2) informing them of—
 - (i) the determination and the reasons for it,
 - (ii) any conditions that it has imposed under paragraph 6, and
 - (iii) any rights of appeal under Schedule 3; and
 - (b) as soon as practicable after the relevant date—
 - (i) delineate precisely on a map the boundaries of the controlled locality or remove the delineated boundary of a locality that has ceased to be a controlled locality;
 - (ii) give a doctor that is affected reasonable notice of any conditions that have been imposed under paragraph 6 as a result of the determination; and
 - (iii) proceed to determine any applications that have been deferred under paragraph 5.
- (2) For the purposes of this paragraph, the “relevant date” (“*dyddiad perthnasol*”) is the later of—
- (a) the date on which the period for bringing an appeal relating to the determination ends; or
 - (b) the date of the determination of any such appeal.

PART 3

Applications for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

Notice of certain applications

- 8.—(1) This paragraph applies to applications for—
- (a) inclusion in or amendment to a—
 - (i) pharmaceutical list made under Part 4 of these Regulations, except for applications under regulation 16 (applications involving a change of ownership); and
 - (ii) dispensing doctor list made under Part 5 of these Regulations;
 - (b) an extension of the relevant period under regulation 18; and
 - (c) a further determination as to whether premises are or a relevant location is in a reserved location under regulation 11(2).
- (2) Where a Local Health Board has determined that an application falling within—

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- (a) sub-paragraph (1)(a)(i) cannot be considered because of regulation 10 (determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations); or
 - (b) sub-paragraph (1)(a)(ii) cannot be considered because of regulation 24(7),
the Local Health Board must take no action in relation to that application other than to notify the applicant of that fact and of any right of appeal under Schedule 3.
- (3) In all other cases, notice in writing of the application must be given in accordance with paragraph 9.
- (4) Those notified of an application may within 30 days of the date on which the notification was sent to them, make representations on the application in writing to the Local Health Board to which the application was submitted.

Persons and bodies to be notified

- 9.—(1) The persons and bodies that must be notified by a Local Health Board are—
- (a) the Local Pharmaceutical Committee;
 - (b) the Local Medical Committee;
 - (c) any person—
 - (i) included in a pharmaceutical list maintained by it, or
 - (ii) who has been granted preliminary consent for inclusion in a pharmaceutical list, whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;
 - (d) any provider of local pharmaceutical services under a pilot scheme in the area for which the Local Health Board is established whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;
 - (e) any Community Health Council serving the area of the Local Health Board;
 - (f) any patient group, consumer group or community group in the area of the Local Health Board that it considers has a significant interest in the provision of pharmaceutical services in the area;
 - (g) where the premises specified in the application are in a controlled locality, any person (except itself) who is a provider of primary medical services within the Local Health Board's area or who is included in the dispensing doctor list maintained by the Local Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application is granted;
 - (h) any Local Health Board or equivalent body any part of whose area is within two kilometres of the premises or the location of the premises specified in the application; and
 - (i) in the case of an application made under regulation 14 (applications involving minor relocation between neighbouring Local Health Board areas), the Local Health Board from whose area the applicant wishes to relocate.
- (2) A Local Health Board notified under sub-paragraph (1)(h) must—
- (a) within 14 days of receiving the notification give notice in writing to the persons and bodies specified in sub-paragraph (1)(a) to (g) that are within or that serve the area for which the Local Health Board is established; and
 - (b) notify the Local Health Board that provided the notification under sub-paragraph (1) that it has provided the notification required by sub-paragraph (2)(a).

(3) An equivalent body notified under sub-paragraph (1)(h) may request the Local Health Board to give notification to such persons in the area for which the equivalent body is established whose interests might in the opinion of the equivalent body, be significantly affected if the application is granted and the Local Health Board must comply with any such request.

Content of notifications

- 10.** A notification of an application under paragraph 8 must—
- (a) inform the person or body notified—
 - (i) of their right to make representations on the application under paragraph 8(4);
 - (ii) of the circumstances in which the Local Health Board may require an oral hearing to be held under paragraph 11; and
 - (iii) if the Local Health Board intends to consider the application together with and in relation to any other application, of that intention;
 - (b) provide a copy of the application submitted by the applicant to enable the person or body notified to make informed representations with regard to whether or not the application should be granted; and
 - (c) where regulation 11(1) applies to an application under paragraph 8(1)(a) inform the person or body notified that the Local Health Board will be determining whether the premises or relevant location specified in the application that are in a controlled locality are also in a reserved location.

Oral hearings

11.—(1) In the case of an application falling within paragraph 8, a Local Health Board may require an oral hearing to be held if it considers it is necessary to hear oral representations before determining such an application.

- (2) If the Local Health Board does decide to hold an oral hearing it must—
- (a) give not less than 14 days notice of the time and place of the hearing to—
 - (i) the applicant; and
 - (ii) any person who has made representations on the application under paragraph 8(4);
 - (b) advise the applicant who has been given notice of the hearing; and
 - (c) advise those notified that they may make oral representations relating to the application at the hearing.
- (3) Any person mentioned in sub-paragraph (2) wishing to make oral representations at the hearing may be assisted in the presentation of their representations by another person and may be represented by that other person at the hearing, including where the person notified under sub-paragraph (2) is unable to attend the hearing in person.
- (4) A Local Health Board may determine the procedure to be followed at the oral hearing.
- (5) A Local Health Board is not bound by any recommendations arising from an oral hearing.

Information to which a Local Health Board must have regard

12. In determining an application falling within paragraph 8 a Local Health Board must have regard, in particular, to—

- (a) any representations received by the Local Health Board under paragraph 8(4);
- (b) any recommendations arising from an oral hearing, if one is held under paragraph 11; and

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- (c) any other information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application.

Imposition of conditions

13.—(1) This sub-paragraph applies where a Local Health Board decides to grant an application falling within—

- (a) paragraph 8(1)(a)(i) where the premises specified in the application are in a controlled locality; or
 - (b) paragraph 8(1)(a)(ii).
- (2) Where sub-paragraph (1) applies, a Local Health Board —
- (a) must consider whether the provision of—
 - (i) primary medical services by a provider of such services (other than itself),
 - (ii) pharmaceutical services by an NHS pharmacist or NHS appliance contractor,
 - (iii) local pharmaceutical services provided under a pilot scheme; or
 - (iv) pharmaceutical services by a doctor,is likely to be adversely affected as a consequence of its decision to grant the application; and
 - (b) may, where it is of the opinion that the provision of any of those services is likely to be adversely affected, impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (arrangements for the provision of pharmaceutical services by doctors) or equivalent provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant list.

Notification of decisions: applications for inclusion in or amendment to pharmaceutical lists

14.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(i), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13 and the determination of reserved location under regulation 11(1))—

- (a) in the case of an application to which paragraph 8(2)(a) applies, to the applicant; and
 - (b) in the case of all other applications falling within paragraph 8(1)(a)(i) to—
 - (i) the applicant, and
 - (ii) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).
- (2) In the case of an application which is determined under regulation 16 (applications involving a change of ownership), a Local Health Board must as soon as practicable after reaching a decision give notice in writing in accordance with paragraph 9.
- (3) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists

15.—(1) A Local Health Board must, as soon as is practicable after reaching a decision on an application falling within paragraph 8(1)(a)(ii), give notice in writing of its decision (including the question of the imposition of conditions under paragraph 13)—

- (a) in the case of an application to which paragraph 8(2)(b) applies, to the applicant; and
- (b) in the case of all other applications falling within paragraph 8(1)(a)(ii) to—
 - (i) the applicant, and
 - (ii) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications under regulation 18 for extension of the relevant period

16.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(b), give notice in writing of its decision to—

- (a) the applicant, and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Notification of decisions: applications under regulation 11(2)

17.—(1) A Local Health Board must, as soon as practicable after reaching a decision on an application falling within paragraph 8(1)(c), give notice in writing of its decision to—

- (a) the applicant; and
- (b) any person who made representations on the application to the Local Health Board in accordance with paragraph 8(4).

(2) A notification of a decision under this paragraph must include a statement of the reasons for the decision and of any rights of appeal.

Action following determination in respect of reserved locations

18.—(1) After determining an application falling under regulation 11(2) or making a determination in accordance with regulation 11(1), as soon as practicable after the relevant date the Local Health Board must delineate precisely on a map the boundaries of any reserved location that it has determined or remove the delineated boundary of a location that has ceased to be a reserved location, as the case may be.

(2) For the purposes of this paragraph, the “relevant date” (“*dyddiad perthnasol*”) is the later of—

- (a) the date on which the period for bringing an appeal relating to the determination ends; or
- (b) the date of the determination of any such appeal.