

SCHEDULE 2

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

PART 4

Determination and deferral of applications

Flexibility with regard to determining or deferring applications

22.—(1) Except in so far as these Regulations provide to the contrary, the NHSCB is to determine or defer routine and excepted applications in such manner (including with regard to procedures) as it sees fit.

(2) The NHSCB may determine a routine or excepted application without hearing any oral representations, if it considers that oral representations are unnecessary.

(3) Where appropriate, the NHSCB may if it thinks fit consider 2 or more applications together and in relation to each other, but where it does so, it must give notice to the applicants of its intention to do so (if it has not already done so under Part 3).

Additional matters for consideration in relation to applications for inclusion in a pharmaceutical list

23.—(1) In the case of a routine or excepted application by a person (A) for inclusion in a pharmaceutical list who is not already included in it, the NHSCB must, prior to determining the application—

- (a) check with the NHS BSA whether A, and if A is a body corporate whether any director or superintendent of A, has any record of, or is under investigation for, fraud;
- (b) check with the Secretary of State whether the Secretary of State holds any information about A, and if A is a body corporate about any director or superintendent of A, that is relevant to its consideration of whether—
 - (i) the application should be refused or deferred under regulations 33 or 34, or
 - (ii) conditions should be imposed under regulation 35;
- (c) take up references from, and check the references provided by, the referees whose details A is required to provide pursuant to paragraph 3(8).

(2) In such a case, having considered whether—

- (a) the application should be refused or deferred under regulations 33 or 34; or
- (b) conditions should be imposed under regulation 35,

if it is minded to impose conditions under regulation 35, it must notify A at least 7 days in advance of determining that it is to impose such conditions and consider any representations (which may be at an oral hearing) that A makes prior to the determination with regard to the notification.

Action following deferrals

24.—(1) Where the NHSCB receives a routine or excepted application, consideration or determination of which may be deferred, if it does decide to defer consideration or determination of that application (whether before or after the application is notified, in the case of a notifiable application), it must—

- (a) notify the applicant (A) of its decision and the reasons for it; and

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- (b) where possible, notify A of the period for which the application is being deferred (if necessary by reference to a future event rather than a period of time).
- (2) If the application is—
- (a) a routine application, consideration of which may be deferred under regulation 14(1)(a), 16(1)(a), 19(2)(a) or 21(1)(a), it must proceed as soon as is practicable to invite other applications under regulation 14(1)(b), 16(1)(b), 19(2)(b) or 21(1)(b), in such manner as it sees fit;
 - (b) a routine application, consideration of which may be deferred under regulation 14(2), 16(3), 19(3) or 21(3), it must make arrangements that enable it to consider the other applications at the same time as A’s application, as soon as is practicable;
 - (c) a routine application, consideration of which may be deferred under regulation 14(3), 16(4), 19(4) or 21(4), it must, once the appeal relating to the other application has reached its final outcome, notify A of that outcome and that A must within a specified period (of not less than 30 days)—
 - (i) update A’s application, and
 - (ii) notify the NHSCB as to whether or not A still wishes to proceed with the application;
 - (d) a routine application, consideration of which may be deferred under regulation 16(2) or 21(2), it must keep under regular review the issue of whether the future circumstances that gave rise to the deferral have arisen;
 - (e) a routine application, consideration of which may be deferred under regulation 32, it must—
 - (i) send A a copy of the designation that led to the decision,
 - (ii) review that decision once the designation that led to the decision has been cancelled or is varied in a manner which means the application may no longer be deferred under regulation 32,
 - (iii) notify A of the cancellation or variation, and
 - (iv) require A within a specified period (of not less than 30 days)—
 - (aa) to update A’s application, and
 - (bb) to notify the NHSCB as to whether or not A still wishes to proceed with the application;
 - (f) a routine or excepted application, consideration of which may be deferred under regulation 34, once the outcome of the cause for the deferral is known, the NHSCB must notify A that A must within a specified period (of not less than 30 days)—
 - (i) update A’s application, and
 - (ii) notify the NHSCB as to whether or not A still wishes to proceed with the application; and
 - (g) a routine application, consideration of which must be deferred under regulation 38(4), it must proceed, as soon as is practicable, with the determination of whether the relevant area is or is not to be part of a controlled locality.
- (3) If A informs the NHSCB within the period specified under sub-paragraph (2)(c), (e)(iv) or (f) that A does not wish to proceed with the application, or fails to respond in the required manner to the notification within the specified period, the application is to be treated as withdrawn.

Oral hearings

- 25.—**(1) If the NHSCB does decide to hear oral representations, it must—

- (a) give the applicant and any additional presenters not less than 14 days notice of the time and place at which the oral representations are to be heard; and
 - (b) in the case of the applicant, advise the applicant of who apart from the applicant (including other applicants, where the hearing relates to more than one application), has been invited to make representations at the hearing.
- (2) For these purposes, a person (P) is an “additional presenter” if—
- (a) the application to which the oral hearing relates is a notifiable application;
 - (b) P was given notice of the application under Part 3 and made representations about the application in accordance with paragraph 19(4), which—
 - (i) indicated that, if there were to be an oral hearing in relation to the application, P would wish to make oral representations at that hearing, and
 - (ii) identified a matter about which the NHSCB considers it would be desirable to hear further evidence from P at the oral hearing; and
 - (c) the NHSCB is satisfied that P made a reasonable attempt to express P’s views on the application adequately in P’s written representations.
- (3) If the NHSCB decides at or after an oral hearing that an application is to be deferred, it may (but need not) hold a further oral hearing once the period for which the application is deferred expires.

Persons barred from taking part in decision making on routine and excepted applications

26.—(1) No person is to take part in determining or deferring any routine or excepted application who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining or deferring a particular routine or excepted application if because of an interest or 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.

Timetable for determining applications

27. As regards any routine or excepted application—

- (a) the NHSCB must endeavour to determine it as soon as is practicable; and
- (b) unless consideration of it is deferred in accordance with these Regulations or there is other good cause for delay, in the case of—

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- (i) a notifiable application, the NHSCB must determine it within 4 months of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it, or
- (ii) an application which is not a notifiable application, the NHSCB must determine it within 30 days of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it.