
WELSH STATUTORY INSTRUMENTS

2013 No. 898

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

PART 4

Applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to pharmaceutical lists

Applications to be included in or for amendment to a pharmaceutical list

- 8.—**(1) A person may submit an application to a Local Health Board where that person—
- (a) wishes to be included in a pharmaceutical list maintained by the Local Health Board;
 - (b) is already included in a pharmaceutical list maintained by the Local Health Board but wishes, within the Board's area, to—
 - (i) open additional premises from which to provide the same or different pharmaceutical services;
 - (ii) relocate to different premises, and at those premises to provide the same or different pharmaceutical services; or
 - (iii) provide from the listed premises pharmaceutical services that are of a different description to those services already listed in relation to that person; or
 - (c) is already included in a pharmaceutical list maintained by a neighbouring Local Health Board but wishes to relocate to different premises in the area of the Local Health Board to which the application is made, and at those premises to provide the same pharmaceutical services.
- (2) An application to a Local Health Board made under this regulation must be made in writing and must provide the information set out in Part 1 of Schedule 1.
- (3) Subject to regulation 46 (home Local Health Board), a person making an application under paragraph (1)(a) must provide the information and undertakings specified in Part 2 of Schedule 1.
- (4) A Local Health Board must return an application if it does not contain all of the information required under paragraphs (2) and (3).
- (5) An application to be included in a pharmaceutical list by a person not already included must be refused if the applicant is an individual who qualified as a pharmacist in Switzerland or an EEA state other than the United Kingdom, unless that individual satisfies the Local Health Board that he or she has the level of knowledge of English which, in the interests of that individual and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the Local Health Board.
- (6) All applications made under regulation 8(1) will be determined under regulation 9 (determination of applications to be included in or for amendment to a pharmaceutical list) except for applications to which—

- (a) regulation 13 (applications involving minor relocation within a Local Health Board's area);
- (b) regulation 14 (applications involving minor relocation between neighbouring Local Health Board areas);
- (c) regulation 15 (applications involving temporary relocation); or
- (d) regulation 16 (applications involving a change of ownership),

applies and which are determined under those regulations.

(7) Parts 1 and 3 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining applications made under this Part.

Determination of applications to be included in or for amendment to a pharmaceutical list

9.—(1) Subject to regulation 10 (determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations), where the premises specified in an application are not in a controlled locality, the Local Health Board must grant the application only if it is satisfied that it is necessary or expedient to do so in order to secure in the neighbourhood in which the premises are located the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application (the “necessary or expedient test”).

(2) Subject to regulation 10, where the premises specified in an application are in a controlled locality but not in a reserved location (as defined in regulation 11(4)) the Local Health Board—

- (a) must refuse the application where it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in the controlled locality within which the premises specified in the application are situated (the “prejudice test”); and
- (b) must, where the application has not been refused under the prejudice test, grant the application only if it is satisfied that it is necessary or expedient to do so to secure in the neighbourhood in which the premises are located the adequate provision, by persons included in a pharmaceutical list, of the services, or some of the services, specified in the application (the “necessary or expedient test”).

(3) The prejudice test does not apply to the Local Health Board's determination of an application where the premises specified in an application are situated in a reserved location.

(4) A Local Health Board must refuse an application in which the applicant does not offer to provide all of the essential services but may grant an application in respect of all or some only of the directed services specified in it.

(5) In determining an application under this regulation which has been made under regulation 8(1) (a), (except where the application is made by a person who has been granted preliminary consent under regulation 12 which is valid in accordance with regulation 12(5)); or under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations

10. Where in determining an earlier application for inclusion in or amendment to a pharmaceutical list the necessary or expedient test under regulation 9 was considered in relation to the neighbourhood in which the Local Health Board is satisfied the premises specified in the application under consideration are located and it was decided that it was not necessary or expedient to grant the earlier application to secure in the neighbourhood the adequate provision of pharmaceutical services, the necessary or expedient test must not be considered again in relation to that neighbourhood—

- (a) for three years, beginning on the date on which the earlier application was determined by the Local Health Board or, if that determination was appealed, the date of the decision on the appeal; unless
- (b) the Local Health Board is satisfied that there has been a substantial change of circumstances in relation to the neighbourhood since the necessary or expedient test was last considered.

Locations in controlled localities that are reserved locations

11.—(1) A Local Health Board must determine whether premises specified in an application submitted to it under regulation 8 (applications to be included in or for amendment to a pharmaceutical list) or premises or the relevant location from which the applicant wishes to provide pharmaceutical services, specified in an application submitted to it under regulation 12 (applications for preliminary consent and effect of preliminary consent) that are in a controlled locality are also in a reserved location.

(2) Where it has been determined by the Local Health Board, or on appeal the Welsh Ministers (under paragraph (1) and Schedule 3 respectively) or pursuant to regulation 11ZA or 13 of the 1992 Regulations, in relation to premises or a relevant location, from which pharmaceutical services are to be or are being provided, that those premises are or the relevant location is in a reserved location, the person included in the pharmaceutical list in relation to those premises, or that relevant location, may make an application in writing to the Local Health Board to make a further determination as to whether, on the date of the application, those premises are, or that relevant location is, in a reserved location.

(3) For the purposes of this regulation the “relevant location” (*“lleoliad perthnasol”*) means, where the location of the premises from which the pharmaceutical services are to be provided, is specified in writing by the applicant before the Local Health Board makes its determination, that location, and where that location is not so specified, the best estimate the Local Health Board is able to make of where those premises may be

(4) Subject to paragraph (5), a reserved location is a location in a controlled locality in respect of which the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location of the premises is less than 2,750 persons.

(5) A location is not a reserved location under paragraph (4) if the Local Health Board considers that if a pharmacy were to operate from the location the extent to which it would be used would be similar to or greater than might be expected if the number of individuals on the patient lists for the area within 1.6 kilometres of the premises or the location were equal to or more than 2,750 persons.

(6) Where in making a further determination applied for in accordance with paragraph (2) the Local Health Board determines that those premises are, or the relevant location is, not in a reserved location, or there is an appeal against a determination by the Local Health Board and it is determined on appeal that the premises are not, or that the relevant location is not, in a reserved location—

- (a) the Local Health Board may determine that the premises are, or the relevant location is to be treated for the purposes of these Regulations as if they were in a reserved location,

where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Local Health Board itself), dispensing services or pharmaceutical services in any controlled locality; or

- (b) if the Local Health Board considers that the provision of primary medical services by a provider of primary medical services (other than one employed by the Local Health Board), pharmaceutical services by a NHS pharmacist or NHS appliance contractor, local pharmaceutical services provided under a pilot scheme or pharmaceutical services provided by a doctor is likely to be adversely affected by a determination that the premises are not in a reserved location, it may make such determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients.

Applications for preliminary consent and effect of preliminary consent

12.—(1) A person who wishes to be granted the right to be included in a pharmaceutical list maintained by the Local Health Board on a subsequent application under regulation 8(1)(a) or 8(1)(b)(i) (applications to be included in or for amendment to a pharmaceutical list) may submit an application to a Local Health Board for preliminary consent under this regulation.

(2) An application made under this regulation must be made in writing and must provide the information and undertakings set out in—

- (a) Part 1 of Schedule 1; and
- (b) subject to regulation 46, Part 2 of Schedule 1.

(3) A Local Health Board must return an application if it does not contain all of the information required under paragraph (2).

(4) A Local Health Board must determine an application for preliminary consent as if it were an application made under regulation 8(1)(a) or 8(1)(b)(i).

(5) A preliminary consent will be valid for a period of six months from the date on which it is granted, which is the later of either—

- (a) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 2; or
- (b) where an appeal is made against the decision of the Local Health Board, the date on which the Welsh Ministers give notice of their decision on the appeal under paragraph 8 of Schedule 3.

(6) A Local Health Board must grant a subsequent application made under regulation 8(1)(a) or 8(1)(b)(i) by a person who has been granted preliminary consent if—

- (a) the date on which the application was received by the Local Health Board is within the period specified in paragraph (5);
- (b) the services specified in the application are the same as those that were specified in the application for preliminary consent; and
- (c) the premises specified in the application are in the same location as the premises or the locality of the premises specified in the application for preliminary consent.

(7) Where sub-paragraphs (a) and (b) of paragraph (6) are satisfied but the premises specified in the application have a different location from that in respect of which preliminary consent was granted, the Local Health Board must treat the application as though it were an application under regulation 8(1)(b)(ii).

(8) The grant of an application under paragraph (6) must be subject to any conditions that were imposed by the Local Health Board, or the Welsh Ministers on appeal, in relation to the final grant of the corresponding preliminary consent.

(9) In determining an application under this regulation from a person who is not already included in the Local Health Board's pharmaceutical list (apart from an application from a person who has a valid preliminary consent in accordance with paragraph (5)), a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Applications involving minor relocation within a Local Health Board's area

13.—(1) A person who has made an application under regulation 8(1)(a) (applications to be included in or for amendment to a pharmaceutical list) may at any time after making the application but before the end of the relevant period (as defined in regulation 17(3)(b) (procedure following grant of an application)) notify the Local Health Board that he or she wishes to change the premises from which he or she intends to provide the pharmaceutical services specified in the application and the Local Health Board may amend the premises specified in the original application if it is satisfied that—

- (a) the change is a minor relocation;
- (b) the pharmaceutical services specified in the application that would have been provided at the premises specified in the original application will be provided at the new premises; and
- (c) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible.

(2) A Local Health Board must grant an application made by a person under regulation 8(1)(b) (ii) to relocate from listed premises to new premises at which the person intends to provide the same pharmaceutical services if it is satisfied that—

- (a) the change is a minor relocation;
- (b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (c) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises;
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow); and
- (e) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 15 (applications involving temporary relocation).

(3) A person who has had an application granted under this regulation may not, within twelve months of the date of the grant of the application (as defined in regulation 17(3)(a)) submit another application for determination under this regulation or under regulation 14.

Applications involving minor relocation between neighbouring Local Health Board areas

14.—(1) A Local Health Board must grant an application made by a person under regulation 8(1) (c) (applications to be included in or for amendment to a pharmaceutical list) to relocate from listed

premises in the area of a neighbouring Local Health Board to new premises in the area of the Local Health Board to which the application is made, and at those premises the person intends to provide the same pharmaceutical services, if—

- (a) the Local Health Board to which the application is made is satisfied that—
 - (i) the change is a minor relocation,
 - (ii) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible,
 - (iii) the same pharmaceutical services will be provided at the new premises as are provided at the listed premises,
 - (iv) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow),
 - (v) the premises specified in the application from which the person wishes to relocate are not premises to which the person has temporarily relocated under regulation 15 (applications involving temporary relocation); and
- (b) the person consents to the removal of his or her name from the pharmaceutical list maintained by the Local Health Board in whose area the current listed premises are located with effect from the date on which the provision of pharmaceutical services from the new premises commences.

(2) A person who has had an application granted under this regulation may not, within twelve months of the date of the grant of the application (as defined in regulation 17(3)(a)) submit another application for determination under this regulation or under regulation 13.

Applications involving temporary relocation

15.—(1) A Local Health Board may make a temporary amendment to an entry in a pharmaceutical list by granting an application made by a person under regulation 8(1)(b)(ii) (applications to be included in or for amendment to a pharmaceutical list) to relocate to different premises on a temporary basis if it is satisfied that—

- (a) the circumstances in which the application is made require the flexible provision of pharmaceutical services;
- (b) for the patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the temporary premises is not significantly less accessible;
- (c) the same pharmaceutical services will be provided at the temporary premises as are provided at the listed premises; and
- (d) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) A temporary amendment to an entry in the pharmaceutical list will have effect from the date on which the Local Health Board approved the application made to it and will be valid for such period of up to six months and any further periods of up to three months each that the Local Health Board considers necessary.

(3) A person may revert to the overridden entry in the pharmaceutical list maintained by the Local Health Board before the end of the period determined by the Local Health Board under paragraph (2) on giving the Local Health Board at least 7 days notice in writing.

(4) Where, in accordance with this regulation, an entry in a pharmaceutical list is overridden by a temporary amendment any proceedings with regard to the overridden arrangements are unaffected by that overriding (although they may need to be stayed for other reasons), and if, as a result of those proceedings the overridden arrangements require amendment before the end of the temporary

amendment, the reversion to the overridden arrangements is to be to the original overridden amendments as amended as a result of those proceedings.

Applications involving a change of ownership

16.—(1) A Local Health Board must grant an application made by a person under regulation 8(1) (a), (b)(i) or (ii) (applications to be included in or for amendment to a pharmaceutical list) who intends to provide pharmaceutical services at premises from which those services are, at the time of the application, provided by another person who is included in a pharmaceutical list maintained by the Local Health Board under regulation 3 (preparation and maintenance of pharmaceutical lists) if the Local Health Board is satisfied that—

- (a) the premises are already included in a pharmaceutical list maintained by the Local Health Board;
- (b) the same pharmaceutical services will continue to be provided from the premises; and
- (c) the provision of pharmaceutical services will not be interrupted (except for such period as the Local Health Board may for good cause allow).

(2) In determining an application under this regulation which has been made under regulation 8(1) (a) (except where the application has been made by a person who has been granted preliminary consent under regulation 12 which is valid in accordance with regulation 12(5)), or under regulation 12 where the applicant is not already included in that Local Health Board's pharmaceutical list a Local Health Board may—

- (a) defer consideration of the application on fitness grounds under regulation 31 (deferral of applications on fitness grounds);
- (b) refuse the application on fitness grounds under regulation 32 (refusal of applications on fitness grounds); or
- (c) impose conditions on the grant of the application under regulation 33 (conditional inclusion relating to fitness grounds).

Procedure following grant of an application

17.—(1) Following the date of the grant of an application made under regulation 8 (applications to be included in or for amendment to a pharmaceutical list), a Local Health Board must not include a person in a pharmaceutical list or amend a pharmaceutical list unless—

- (a) the condition in paragraph (2) is satisfied; and
- (b) the requirements of regulation 33 (conditional inclusion relating to fitness grounds), if any, are met as regards the imposition of conditions on any person.

(2) A person will be included in the relevant pharmaceutical list or the relevant pharmaceutical list will be amended as appropriate if, not less than 14 days before the end of the relevant period, he or she notifies the Local Health Board in writing, providing the information specified in Part 3 of Schedule 1, that he or she will within the next 14 days commence the provision at the premises of the services that were specified in the application.

(3) For the purposes of this regulation and, where relevant, regulation 18—

- (a) “the date of the grant of an application” (“*y dyddiad y caniateir cais*”) is the date which is the later of either—
 - (i) 30 days after notice of the Local Health Board's decision on the application was sent by the Local Health Board in accordance with paragraph 14 of Schedule 2; or
 - (ii) the date of the determination of any appeal that is brought against the decision of the Local Health Board,

- and “granted” (“*caniatawyd*”) is to be construed accordingly; and
- (b) “the relevant period” (“*cyfnod perthnasol*”) is—
- (i) the period of six months from the date an application is granted; or
 - (ii) such further period in addition to that specified in sub-paragraph (a) not exceeding three months that the Local Health Board may for good cause allow.

Application to extend the relevant period

18.—(1) Before the expiry of the relevant period, a person may make an application to the Local Health Board to extend the relevant period.

(2) In accordance with regulation 17(3)(b)(ii) the person may apply for an extension of up to three months.

(3) An application to the Local Health Board under this regulation must be in writing and must set out in full why an extension of the relevant period is sought.

(4) Parts 1 and 3 of Schedule 2 specify the procedures to be followed by a Local Health Board when determining applications made under this regulation.

(5) For the purposes of this regulation, “person” (“*person*”) means the person who would be entitled to provide notification to a Local Health Board in accordance with regulation 17(2) of commencement of provision of pharmaceutical services.

Appeals

19.—(1) Schedule 3 makes provision for appeals to the Welsh Ministers in respect of decisions of Local Health Boards made under this Part.

(2) There is no right of appeal under these Regulations in respect of a decision of a Local Health Board to make or not to make, or to extend a temporary amendment to a pharmaceutical list under regulation 15 (applications involving temporary relocation).