SCOTTISH STATUTORY INSTRUMENTS

# 2014 No. 148

# NATIONAL HEALTH SERVICE

## The National Health Service (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014

| | |
|---|---|
| *Made - - - -* | *28th May 2014* |
| *Laid before the Scottish Parliament - - - -* | *30th May 2014* |
| *Coming into force - -* | *28th June 2014* |

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 2(5), 17E(1), 17N(1), 27, 28(2), 105(7) and 106 of the National Health Service (Scotland) Act 1978(**1**) and all other powers enabling them to do so.

### Citation, commencement and interpretation

**1.** (1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014 and come into force on 28th June 2014.

(2) In these Regulations "the 2009 Regulations" means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(**2**).

### Amendment of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

**2.** The 2009 Regulations are amended in accordance with regulations 3 to 9.

(**1**) 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), section 66(1) and Schedule 9, paragraph 19(1). Section 17E was inserted by the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"), section 22(2). Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1), section 4. Section 27 was amended by the Health Services Act 1980 (c.53) ("the 1980 Act"), section 20(2); the National Health Service (Amendment) Act 1986 (c.66) ("the 1986 Act"), section 3(3); the 1990 Act, section 66(1) and Schedule 9, paragraph 19(7); the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 3; the 1997 Act, Schedule 2, paragraph 44; the Health and Social Care Act 2001 (c.15), section 44(2) and (3); the Health and Social Care Act 2012 (c.7), section 213(7)(c) and section 220(2); and S.I. 1987/2202, S.I. 2003/1590, S.I. 2004/1771, S.I. 2005/2011, S.I. 2007/289 and S.I. 2010/231. Section 28(2) was amended by the 1986 Act, section 3(4); the 1990 Act, section 66(1) and Schedule 9, paragraph 19(8); and the 1997 Act, Schedule 2, paragraph 45. Section 105(7) was amended by the 1980 Act, Schedule 6, paragraph 5 and Schedule 7; the Health and Social Services and Social Security Adjudications Act 1983 (c.41), section 29(1) and Schedule 9, paragraph 24; and the Health Act 1999 (c.8), Schedule 4, paragraph 60. Section 108(1) contains a definition of "prescribed" relevant to the exercise of the statutory powers under which these Regulations are made. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

(**2**) S.S.I. 2009/183; amended by S.I. 2010/231, S.I. 2012/1479, S.I. 2012/1916, S.I. 2013/235, S.I. 2013/2042, S.S.I. 2009/209, S.S.I. 2010/128, S.S.I. 2011/32, S.S.I. 2011/55, S.S.I. 2012/36 and S.S.I. 2014/73.

**Amendment to regulation 2**

**3.** In regulation 2 (interpretation and application), in the appropriate place, insert—

""controlled locality" is to be construed in accordance with paragraph 1A of Schedule 3;";

""NHS funded services" means—

(a) primary medical services provided by a person under arrangements with a Health Board for the purpose of meeting that Health Board's duty to provide or secure the provision of primary medical services as respects their area; and

(b) pharmaceutical services provided by a person on a Board's pharmaceutical or provisional pharmaceutical list;"; and

""nominated community representative" means a person nominated by one or more Community Councils from amongst their elected members for the purpose of making representations in accordance with the procedures set out in Schedule 3;".

**Amendment to regulation 5**

**4.** In regulation 5 (pharmaceutical list)(**3**)—

(a) in paragraph (2), for "a consultation in accordance with paragraph (2A)" substitute "a pre-application and joint consultation in accordance with regulation 5A";

(b) omit paragraph (2A);

(c) omit sub-paragraph (h) of paragraph (2C);

(d) after sub-paragraph (i) of paragraph (2C) insert—

"(j) "(j) (where the provisions of paragraph (10B) apply) evidence of the significant change that has occurred (which evidence will be of sufficient detail so as to assist the Board to make a determination) that means in the applicant's view that the granting of the application will now not prejudice the provision of NHS funded services in the controlled locality.";

(e) for paragraph (10) substitute—

"(10) An application made in any case other than one to which paragraph (3) or (4) applies shall be assessed in accordance with the procedures set out in Schedule 3, and shall be granted by the Board—

(a) only if it is satisfied that the provision of pharmaceutical services at the premises named in the application is necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood in which the premises are located by persons whose names are included in the pharmaceutical list; and

(b) if the boundaries of the neighbourhood within which the applicant intends to provide pharmaceutical services falls within any part of a controlled locality, only if it is satisfied that the granting of such an application, in its opinion, would not prejudice the provision of NHS funded services in the controlled locality."; and

(f) after paragraph (10A) insert—

"(10B) The provisions of this paragraph apply where—

(a) an application for the provision of pharmaceutical services to which regulation 5(10)(b) applies was refused by—

(**3**) Relevantly amended by S.S.I. 2011/32.

(i) the Board (and not overturned by the National Appeal Panel); or

(ii) the National Appeal Panel,

in the previous 3 years;

(b) that application was in relation to a neighbourhood that encompassed the same, or substantially the same, area encompassed by the neighbourhood to which the application that is now being submitted relates; and

(c) in the case of a refusal by the Board, the refusal of the application was not under paragraph (2B).".

**Pre-application and joint consultation**

**5.** After regulation 5 insert—

"**Pre-application and joint consultation**

**5A.** (1) A person who intends to make an application under regulation 5(2) (except in the instance of an application to which paragraph (3) or (4) of regulation 5 applies) must, prior to making that application—

(a) consult with the Board to which their intended application relates to discuss the case for the proposed pharmacy, having regard to the Board's pharmaceutical care services plan, for the purpose of determining the scope of the application; and

(b) agree the approach to completing a joint consultation in accordance with paragraphs (2) and (3).

(2) The joint consultation must be undertaken jointly with the Board to which the intended application relates and be for the purpose of—

(a) assessing whether the neighbourhood to which the application relates has adequate provision, by persons on the pharmaceutical list, of some or all of the pharmaceutical services that the applicant intends to provide; and

(b) establishing the level of support of residents in the neighbourhood to which the application relates.

(3) The joint consultation must—

(a) be completed within the period of 90 days immediately prior to the making of the application;

(b) seek views on—

(i) the pharmaceutical services to be provided by the applicant;

(ii) gaps in existing pharmaceutical service provision;

(iii) the relationship and integration of the pharmaceutical services to be provided by the applicant with other NHS funded services;

(iv) the potential for the pharmaceutical services to be provided by the applicant to impact on other NHS funded services;

(v) the neighbourhood to which the application relates; and

(vi) the location and proposed opening hours of the premises to which the application relates;

(c) be undertaken in such a way as to reach, as far as possible, the majority of residents in the neighbourhood to which the application relates, including publication on social media used by the Board and advertisement of the joint consultation—

(i) (where the application is to relocate) through display in a prominent place where the applicant currently provides pharmaceutical services; or

(ii) (where the application is to open additional premises or to be included in the pharmaceutical list) through advertisement in a newspaper most likely to have the largest circulation in the neighbourhood to which the application relates; and

(d) be for a continuous period of not less than 90 working days from the date of advertisement under sub-paragraph (c).

(4) Following the completion of the joint consultation, the Board and applicant must agree upon and produce a consultation analysis report which details—

(a) the methods of engagement used to undertake consultation activity;

(b) the list of consultation questions and responses;

(c) the number and category of respondents; and

(d) the level of support of residents in the neighbourhood to which the application relates for the issues consulted upon.

(5) The Board and applicant must complete the consultation analysis report as soon as reasonably practicable, following which the Board must submit that report to the Chair of the Pharmacy Practices Committee prior to any determination of the application under Schedule 3.".

**Amendment to regulation 15**

**6.** In paragraph (1) of regulation 15 (publication of particulars)(**4**)—

(a) in sub-paragraph (d) omit "and" in the last place it occurs;

(b) in sub-paragraph (e) insert "; and" after "regulation 12(2)"; and

(c) after sub-paragraph (e) insert—

"(f) "(f) details of any controlled locality identified by the Board under paragraph 1A of Schedule 3.".

**Amendment to Schedule 2**

**7.** In Schedule 2 (forms), for Form A(1) (application for inclusion in the pharmaceutical list to provide pharmaceutical services)(**5**) substitute the form set out in the Schedule to these Regulations.

**Amendment to Schedule 3**

**8.** (1) Schedule 3 (the Board) is amended as follows.

(2) In paragraph 1 (receipt and notification of applications)(**6**) for sub-paragraph (1) substitute—

"(1) Upon receipt of an application to which regulation 5(10) applies, or receiving further information submitted under regulation 5(2E), the Board shall—

(a) assess whether the boundaries of the neighbourhood within which the applicant intends to provide pharmaceutical services, or any part of it, falls within a controlled locality; and

(**4**) Relevantly amended by S.S.I. 2009/209.
(**5**) Form A(1) was substituted by S.S.I. 2011/32.
(**6**) Relevantly amended by S.S.I. 2011/32.

(b) within 10 working days of an assessment being made, give written notice of the application and any assessment that it is within a controlled locality to—

(i) the Area Pharmaceutical Committee;

(ii) the Area Medical Committee;

(iii) any person whose name is included in the pharmaceutical list or the provisional pharmaceutical list and whose interests may, in the opinion of the Board, be significantly affected if the application were granted;

(iv) any Board whose boundary is within two kilometres of the proposed premises; and

(v) any nominated community representative that covers the neighbourhood within which the applicant intends to provide pharmaceutical services, or any part of it,

and any person or body so notified may, within 30 days from the date on which the notification was sent to such person or body, make written representations about the application to the Board.".

(3) After paragraph 1 insert—

"**Applications relating to areas of a prescribed description**

**1A.** (1) For the purpose of section 27(4)(d) of the Act, a controlled locality is an area within a Health Board, which is remote or rural in character, and which is served by a dispensing doctor.

(2) The boundary of a controlled locality area is that of the dispensing doctor's practice area under sub-paragraph (1) on the day before the day on which the application under regulation 5(2) is made.

(3) Upon identifying any areas which are a controlled locality in accordance with this paragraph, the Board must, as soon as reasonably practicable—

(a) give written notice to the dispensing doctor serving that controlled locality and to the person or body listed at paragraph 1 informing them of the identification of the controlled locality;

(b) delineate the boundaries of the controlled locality on a map; and

(c) record that controlled locality in its pharmaceutical care services plan.

**Review of controlled locality**

**1B.** (1) The Board shall, subject to sub-paragraph (2) and regulation 5(10B), no earlier than 3 years from the date of notification of a controlled locality in accordance with paragraph 1A, review that controlled locality designation.

(2) If the Board is satisfied that within that 3 year period there has been a substantial change in circumstances in relation to the controlled locality area then it may reconsider the controlled locality designation.

(3) Following a review, prior to a decision to keep or change the controlled locality designation, the Board must, as soon as practicable, give written notice to the dispensing doctor serving that controlled locality and to the persons or body mentioned in paragraph 1 informing them of—

(a) the proposal and the reasons for it; and

(b) their right, within 30 days from the date on which the notification was sent, to make written representations about that change to the Board containing a statement of reasons why that proposal should be reconsidered.

(4) Following consideration of any representations received in accordance with sub-paragraph (3) the Board must make their final decision and where applicable—

(a) delineate on a map the new boundaries of the controlled locality; or

(b) remove from the map, the delineated boundary of an area that has ceased to be a controlled locality.".

(4) Omit paragraph 2 (public consultation).

(5) For paragraph 3 (determination of applications)(**7**) substitute—

"**Determination of applications**

**3.** (1) In considering an application to which regulation 5(10)(a) applies, the Board shall have regard to—

(a) the pharmaceutical services already provided in the neighbourhood of the premises named in the application by persons whose names are included in a pharmaceutical list;

(b) pharmaceutical services to be provided in the neighbourhood at these premises by any person whose name is included in the provisional pharmaceutical list;

(c) any representations received by the Board under paragraph 1;

(d) any information available to the Board which, in its opinion, is relevant to consideration of the application;

(e) the consultation analysis report submitted in accordance with regulation 5A;

(f) the pharmaceutical care services plan; and

(g) the likely long term sustainability of the pharmaceutical services to be provided by the applicant.

(2) The Board may, if it considers that oral representations are unnecessary, determine the application without hearing oral representations.

(3) In any case in which the Board decides to hear oral representations, the Board must—

(a) give the applicant and any person from whom it received representations under paragraph 1 reasonable notice of the meeting at which such representations are to be heard;

(b) permit the applicant and any person making representations at the hearing to be assisted by another person;

(c) permit the applicant or any person making representations at the hearing either to—

(i) speak to their own representations; or

(ii) nominate the person assisting them to speak on their behalf; and

(d) confirm that any person assisting the applicant or any person making representations at the hearing is not appearing in the capacity of counsel, solicitor or paid advocate.

(4) The Board shall, subject to sub-paragraph (5), make a determination on the application within 6 weeks of the date that they received the consultation analysis report under regulation 5A.

(**7**) Relevantly amended by S.S.I. 2011/32.

(5) A 6 week determination period under sub-paragraph (4) may be extended in exceptional circumstances and in such an event the Board must inform the applicant and any person or body notified under paragraph 1 or 2A, of the extended time period and the reasons for it.

(6) The Board's determination of an application must include—

(a) a summary of the consultation analysis report submitted in accordance with regulation 5A;

(b) an explanation of how the consultation analysis report was taken into account in arriving at the decision, with regard to the tests under regulation 5(10), as applicable; and

(c) the reasons for its decision.

(7) The functions of the Board under this paragraph shall be exercised on its behalf by the Pharmacy Practices Committee in accordance with Part I of Schedule 4.".

(6) In paragraph 4 (notification of decisions), for "and the reasons for it" where those words occur substitute "and the information required under paragraph 3(6)".

(7) After sub-paragraph (7) of paragraph 5 (appeals)(**8**) insert—

"(7A) The National Appeal Panel shall, subject to sub-paragraph (7B), make a decision under sub-paragraph (5) or a determination under sub-paragraph (6) within 3 months of the date of receipt of a notice of appeal under sub-paragraph (4).

(7B) The 3 month period in sub-paragraph (7A) may be extended in exceptional circumstances and in such an event the National Appeal Panel must inform the interested parties of the extended time period and the reasons for it.

(7C) In this paragraph "interested parties" means the appellant, the applicant and any person mentioned in paragraph 1 who makes written representations to the Board about the application.".

(8) In sub-paragraph (6) of paragraph 6 (form of appeal)(**9**) after "any person" insert "or body".

**Amendment to Schedule 4**

**9.** In Schedule 4 (pharmacy practices committee)—

(a) after paragraph 5 (quorum) insert—

"**Independent legal assessor**

**5A.** (1) The Board may appoint an independent legal assessor to assist them in their deliberations, including voting.

(2) The independent legal assessor's role is to provide legal and technical advice and support."; and

(b) in sub-paragraph (5) of paragraph 6 (voting) for "of it" to "decision" substitute "to the Board of that decision and the information required under paragraph 3(6) of Schedule 3".

**Amendment of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004**

**10.** The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(**10**) are amended as follows.

(**8**) Relevantly amended by S.S.I. 2011/32.
(**9**) Inserted by S.S.I. 2011/32.
(**10**) S.S.I. 2004/115 to which there are no relevant amendments.

**11.** After paragraph 44(3) (provision of dispensing services) of Schedule 5 (other contractual terms) insert—

"(3A) A contractor must receive the support of an appropriately qualified pharmacist independent prescriber provided by the Health Board, where the Health Board considers that the health outcomes of patients are likely to be improved by the contractor and pharmacist working together with the aim of ensuring that the patient gets the best clinical benefit from their prescribed medicines.".

**Amendment of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004**

**12.** The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004(**11**) are amended as follows.

**13.** After paragraph 15(3) (provision of dispensing services) of Schedule 1 (content of agreements) insert—

"(3A) A provider must receive the support of an appropriately qualified pharmacist independent prescriber provided by the Health Board, where the Health Board considers that the health outcomes of patients are likely to be improved by the provider and pharmacist working together with the aim of ensuring that the patient gets the best clinical benefit from their prescribed medicines.".

**Transitional and saving provision**

**14.** (1) In this regulation—

(a) "the coming into force date" means the day on which these Regulations come into force; and

(b) "the transitional period" means the period of three months beginning with the coming into force date.

(2) Any application commenced prior to the coming into force date is subject to the 2009 Regulations as they had effect immediately before the coming into force date.

(3) Where, on or after the coming into force date, any person intends to make an application in accordance with regulation 5A(1) of the 2009 Regulations, the obligation to consult imposed by regulation 5A(2) may only be performed after the transitional period.

(4) In paragraph (2) "commenced" includes commencement of consultation under regulation 5(2A) of the 2009 Regulations as they had effect immediately before the coming into force date.

St Andrew's House,Edinburgh
28th May 2014

*ALEX NEIL*
A member of the Scottish Government

(**11**) S.S.I. 2004/116 to which there are no relevant amendments.

SCHEDULE Regulation 7

# FORM A (1)

# Application for Inclusion in the Pha Pharmaceutical Services – Reloca

(Please delete words/sections

TO .....

## 1. Applicant's details

I am/we are applying as an Individual/ a Pharmacist/ a Corporate Body please also provide Superintendent Ph

I/We (name of person making application)

of (correspondence address and name of company if re

(ii) already in our possession (lease or ownership)

**(iii) registered by the General Pharmaceutical Cou

If the answer to (iii) is yes, state reference number.

If the answer to (iii) is no, give date of application for r

***(c) If applicable the Responsible Pharmacist at the s

Name

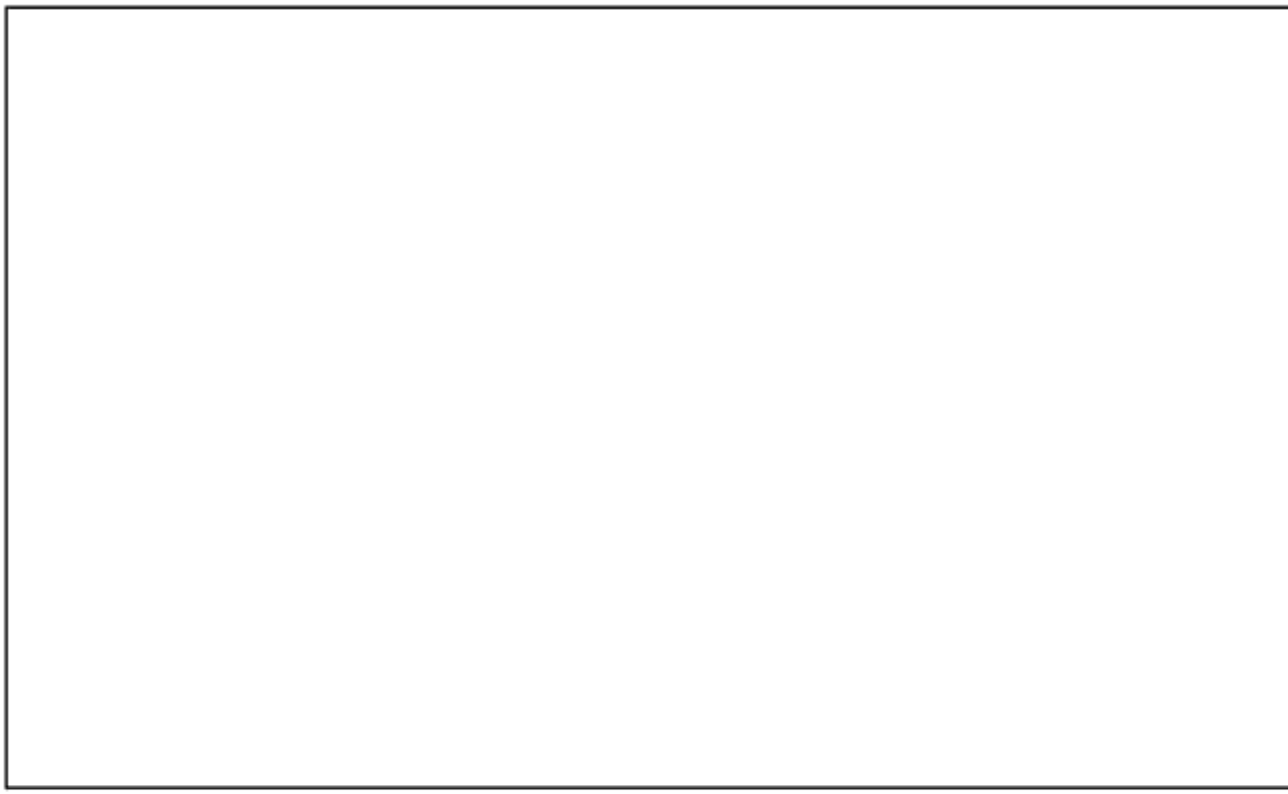
GPhC Registration No.

**If the application is for a relocation please proceed t 4(b)**

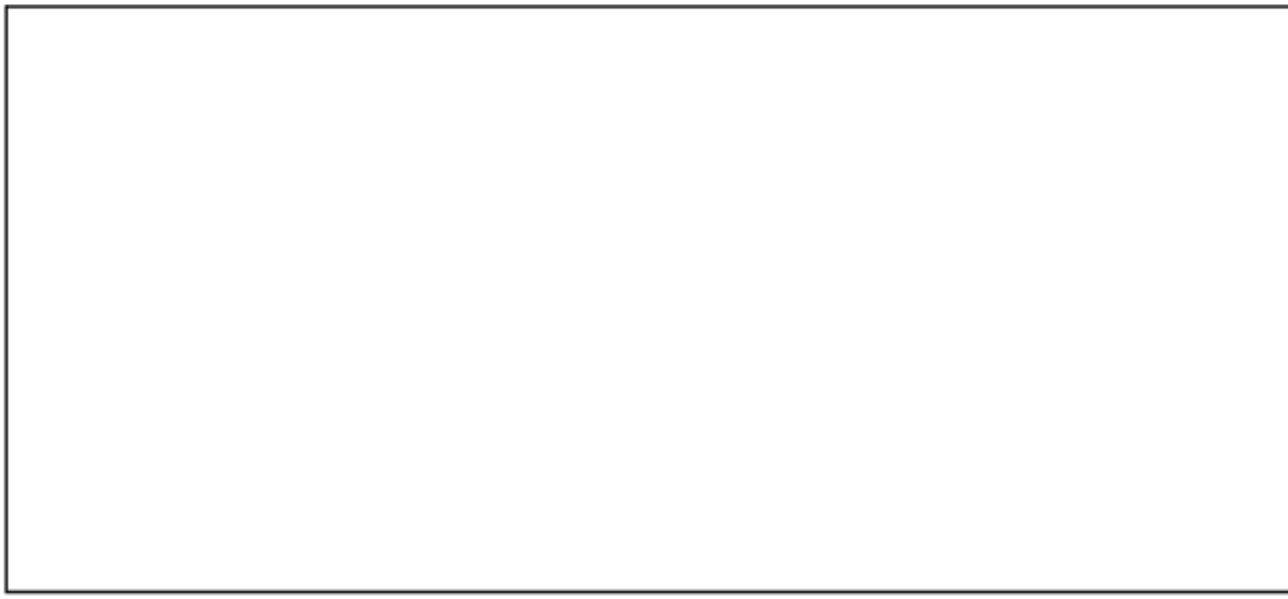
## 3. Relocation Details

**(a) To be completed only by persons whose names applying under Part 1(a)**

I/We consider the relocation fulfils the criteria for minc



It is preferred that services will be continuous however state why and for what period below.



(iii) Please provide a description of the pharmaceutic
to provide, along with detail of any further services you
successful.

(iv) Please provide the date you intend to commence
if relocation is successful.

(v) Please detail the hours in each day that you curren
services, alongside any intention to extend hours (takin
Service Scheme.)

(iii) Describe the boundaries of the neighbourhood, w
services, which your application proposes to cover.

(iv) Provide an assessment of the current provision, i
you believe there not to be adequate provision and evid

(v) Describe the pharmaceutical services you will pro

(vii) State the hours in each day that you intend to pro
Board's Hours of Service Scheme.)

(viii) Has there been an application to provide pharma
encompasses the same or substantially the same area en
at 4(ii) above within the previous 12 months?

Yes ☐ No ☐

If yes, please provide evidence of the significant chang
that either, it is now necessary or desirable that an appl
adequate provision of pharmaceutical services in the ne
relates, or that the granting of the application will now
services in the controlled locality (as applicable). **If the**

(3) ***Premises need only be registered with the Gener is to dispense medicines from the premises.*

(4) ****Responsible Pharmacist details should be prov being provided.*

(5) *Payment cannot be made for NHS services provide pharmaceutical list recorded in Form C as issued by the*

---

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations principally make amendments to the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 ("the 2009 Regulations").

Regulation 3 adds new definitions to regulation 2 of the 2009 Regulations.

Regulation 4 makes amendments to regulation 5 of the 2009 Regulations to reflect changes to the application process, including the introduction of a pre-application and joint consultation stage and a new process for applications relating to a controlled locality.

Regulation 5 inserts regulation 5A which sets out provision on the new pre-application and joint consultation stage.

Regulation 6 amends regulation 15 of the 2009 Regulations, adding a controlled locality to the list of particulars that a Health Board must publish and make available at its offices for inspection.

Regulation 7 makes an amendment to Schedule 2 to the 2009 Regulations by replacing Form A(1) (application for inclusion in the pharmaceutical list to provide pharmaceutical services) with the form set out in the Schedule to these Regulations.

Regulation 8 makes amendments to Schedule 3 of the 2009 Regulations reflecting changes to the application procedure including: the introduction of a requirement to notify a community representative of an application; making provision on controlled localities and arrangements for their review by a Health Board; updating rules on assistance at an application hearing; and requiring the Pharmacy Practices Committee to submit more detailed information with the determination of an

application. In addition, the Pharmacy Practices Committee and National Appeal Panel must make determinations within a 3 month period.

Regulation 9 makes amendments to Part I of Schedule 4 of the 2009 Regulations concerning the Pharmacy Practices Committee and introduces a right for the Pharmacy Practices Committee to appoint an independent legal assessor to assist them.

Regulations 11 and 13 make corresponding amendments to the provision in The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 and The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 that permits medical practitioners to provide dispensing services. The amendments provide that such dispensing practitioners must receive support from a pharmacist independent practitioner where the Health Board considers it appropriate to improve patient health outcomes.

Regulation 14 makes transitional and saving provision.

A Business Regulatory Impact Assessment has been prepared and placed in the Scottish Parliament Information Centre. Copies can be obtained from the Scottish Government Pharmacies and Medicines Division, St Andrew's House, Regent Road, Edinburgh, EH1 3DG.