# STATUTORY INSTRUMENTS

# 2007 No. 3101

# The European Qualifications (Health and Social Care Professions) Regulations 2007

# PART 5

# PHARMACISTS AND PHARMACY TECHNICIANS: THE PHARMACISTS AND PHARMACY TECHNICIANS ORDER 2007

# Amendment of the Pharmacists and Pharmacy Technicians Order 2007

**71.** The Pharmacists and Pharmacy Technicians Order 2007(1) is amended in accordance with this Part.

#### Amendment of article 3

- **72.** In article 3 (interpretation)—
  - (a) after the definition of "the Charter" insert—

""competent authority" means any authority or body of a relevant European State designated by that State for the purposes of the Directive as competent to—

- (a) receive or issue evidence of qualifications or other information or documents,
- (b) receive applications and take the decisions referred to in the Directive,

in connection with practice as a pharmacist or a pharmacy technician;";

- (b) after the definition of "the Council" insert—
  - ""the Directive" means Directive 2005/36/EC of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications(2), and references in this Order to the Directive, or to any provision of the Directive, are references to the Directive, or to that provision of the Directive, as amended from time to time;";
- (c) in the definition of "exempt person"—
  - (i) in paragraph (b), after "access to" insert ", or is pursuing,", and
  - (ii) in paragraph (c), after "access to" insert "and pursuit of";
- (d) after the definition of "fitness to practise committee" insert—
  - ""General Systems Regulations" means the European Communities (Recognition of Professional Qualifications) Regulations 2007(3);";
- (e) omit the definition of "the Pharmacy Qualifications Directive";

<sup>(1)</sup> S.I. 2007/289

<sup>(2)</sup> OJNo. L255, 30.09.2005, p.22, as amended by Council Directive 2006/100/EC of 20th November 2006, OJ No. L363 of 20.12.2006, p.141.

<sup>(</sup>**3**) S.I. 2007/2781.

- (f) omit the definition of "the Second General System Directive"; and
- (g) omit the definition of "the Second General System Regulations".

- 73. In article 10 (the Register of Pharmacists), for paragraph (2)(b) substitute—
  - "(b) shall be divided into three parts, and—
    - (i) the first part shall be known as "Part 1 Practising Pharmacists",
    - (ii) the second part shall be known as "Part 2 Non-practising Pharmacists", and
    - (iii) the third part shall be known as "Part 3 Visiting Pharmacists from relevant European States"."

# **Amendment of article 11**

- 74. In article 11 (entitlement to registration in the Register of Pharmacists)—
  - (a) in paragraph (1)(a)(i), after "article 12(1)" insert "and (1A)"; and
  - (b) in paragraphs (1), (2) and (3)(b), for "the Register of Pharmacists" substitute "Part 1 or 2 of the Register of Pharmacists".

#### Amendment of article 12

- **75.** In article 12 (preregistration requirements for pharmacists in respect of qualifications and additional education, training or experience)—
  - (a) in paragraph (1)—
    - (i) in sub-paragraph (b), for "the Register of Pharmacists; or" substitute "Part 1 or 2 of the Register of Pharmacists;",
    - (ii) after sub-paragraph (b) insert—
      - "(ba) he is an exempt person—
        - (i) whose case falls within regulation 3(9)(a) or (e) of the General Systems Regulations,
        - (ii) to whom regulations 20 to 26 of those Regulations apply by reason of the operation of regulation 3(4) of those Regulations, and
        - (iii) who is permitted to pursue the profession of pharmacist in the United Kingdom by virtue of Part 3 of those Regulations (having, in particular, successfully completed any adaptation period, or passed any aptitude test, that he may be required to undertake pursuant to that Part of those Regulations); or", and
    - (iii) in sub-paragraph (c)—
      - (aa) at the beginning insert "subject to paragraph (1A),", and
      - (bb) in paragraph (ii)(aa), after "referred to in sub-paragraph (b)," insert "and to whom sub-paragraph (ba) does not apply,";
  - (b) after paragraph (1) insert—
    - "(1A) For the purposes of article 11(1)(a)(i), an exempt person who holds a qualification in pharmacy which—
      - (a) was granted otherwise than in a relevant European State, and

(b) has not previously been accepted by a relevant European State as qualifying him to practise as a pharmacist in that State,

is "appropriately qualified" only if his qualification is evidence of training in pharmacy that meets, or under article 22(a) of the Directive (part-time training) is to be treated as meeting, the requirements of article 44 of the Directive (training as a pharmacist)."; and

- (c) in paragraph (3)—
  - (i) after "paragraph (1)(b)" insert ", (ba)", and
  - (ii) for "the Pharmacy Qualifications Directive" substitute "the Directive".

#### Amendment of article 14

- **76.** In article 14 (specific obligations of the Society in respect of pharmacists' and prospective pharmacists' education, training and the acquisition of experience), in paragraph (h)(4)—
  - (a) after "article 11(1)(a)(iii) and (iv)," insert "for the purposes of rules under article 39(1),"; and
  - (b) in sub-paragraph (v), after "Part 2" insert "or Part 3".

#### **Amendment of article 16**

- 77. In article 16 (supplemental matters in connection with articles 14 and 15), for paragraph (5) substitute—
  - "(5) In making, varying, suspending or revoking any determination mentioned in this article, or granting, refusing, suspending or withdrawing any accreditation or approval mentioned in this article, the Society—
    - (a) shall ensure that the relevant requirements of the Treaties are met, and
    - (b) shall ensure that the relevant requirements of the Directive are met, and in particular shall ensure that the requirements of article 44 of the Directive (training as a pharmacist) are met, or under article 22(a) of the Directive (part-time training) are to be treated as being met,

and shall act in a manner which is consistent with those requirements.".

#### Amendment of article 17

- **78.** In article 17 (form, manner and content of applications for registration in the Register of Pharmacists or retention in that register)—
  - (a) in paragraph (1)—
    - (i) for "registration in the Register of Pharmacists, or for retention in that register," substitute "registration in Part 1 or 2 of the Register of Pharmacists, or for retention in those parts of that register,", and
    - (ii) after sub-paragraph (b)(i) insert—
      - "(ia) where the applicant is an exempt person, proof that he is a national of a relevant European State or (where he is not a national of a relevant European State) proof of the Community right by virtue of which he is an exempt person,"; and
  - (b) for paragraphs (4) to (6) substitute—
    - "(4) Paragraphs (5) to (8) apply in relation to an exempt person ("E")—

<sup>(4)</sup> Paragraph (h) of article 14 is partly in force.

- (a) to whom article 12(1)(b) or (ba) applies; and
- (b) who is making an application for entry in Part 1 or 2 of the Register of Pharmacists.
- (5) For the purpose of determining whether E's fitness to practise is impaired, the Registrar shall accept as sufficient evidence of E's good health a certificate which—
  - (a) attests to E's good physical and mental health; and
  - (b) is required of a person who wishes to practise as a pharmacist in E's attesting State
- (6) If no such certificate is required of persons who wish to practise as a pharmacist in E's attesting State, for the purpose of determining whether E's fitness to practise is impaired, the Registrar shall accept as sufficient evidence of E's good health a certificate which—
  - (a) attests to E's good physical and mental health; and
  - (b) is issued by a competent authority in E's attesting State.
- (7) For the purpose of determining whether E's fitness to practise is impaired, the Registrar shall accept as sufficient evidence of E's good character a certificate which—
  - (a) attests to E's good character or good repute; and
  - (b) is issued by a competent authority in E's attesting State.
- (8) If no such certificate is issued by a competent authority in E's attesting State, for the purpose of determining whether E's fitness to practise is impaired, the Registrar shall accept as sufficient evidence of E's good character a certificate—
  - (a) attesting to the authenticity of a declaration on oath made by E—
    - (i) before a competent judicial or administrative authority, notary or qualified professional body of E's attesting State, and
    - (ii) attesting to E's good character; and
- (b) issued by the authority, notary or body referred to in sub-paragraph (a)(i). In this paragraph, "declaration on oath" includes a solemn declaration.
  - (9) In paragraphs (5) to (8) the "attesting State", in relation to E, is—
    - (a) the relevant European State in which E obtained his qualification in pharmacy; or
    - (b) (if different) the relevant European State from which E comes to Great Britain.
- (10) The Registrar shall not accept any certificate referred to in paragraph (5), (6), (7) or (8) if it is presented more than three months after the date on which it was issued."

# **Substitution of article 18**

**79.** For article 18 substitute—

# "Notification of results of application

- **18.**—(1) This article applies where a person ("A") applies to have his name registered in Part 1 or 2 of the Register of Pharmacists.
- (2) The Registrar, within the period of one month beginning with the date of receipt of the application, must—
  - (a) acknowledge receipt of the application; and

- (b) inform A of any missing document required for the purposes of the application.
- (3) The Registrar must, within the specified period, notify A—
  - (a) of the result of the application; and
  - (b) if the Registrar refuses the application, of the reasons for the decision, and of any right of appeal A has to the Registration Appeals Committee.
- (4) In paragraph (3) "the specified period"—
  - (a) except in a case specified in sub-paragraph (b), means the period of three months beginning with the relevant date;
  - (b) if A's application is made on the grounds that he is appropriately qualified by virtue of article 12(1)(ba), means the period of four months beginning with the relevant date.
- (5) The "relevant date", in relation to an application, is—
  - (a) the date when the Registrar receives the application; or
  - (b) if any document required for the purposes of the application, or the relevant fee, is missing when the Registrar receives the application, the date on which the Registrar first has all the documents required for those purposes together with the relevant fee.".

#### Insertion of article 18A

**80.** After article 18 insert—

# "Visiting pharmacists from relevant European States

**18A.** Schedule A1 (visiting pharmacists from relevant European States) shall have effect.".

# **Amendment of article 21**

- 81. In article 21(5) (the Register of Pharmacy Technicians), for paragraph (2)(b) substitute—
  - "(b) shall be divided into three parts, and—
    - (i) the first part shall be known as "Part 1 Practising Pharmacy Technicians",
    - (ii) the second part shall be known as "Part 2 Non-practising Pharmacy Technicians", and
    - (iii) the third part shall be known as "Part 3 Visiting Pharmacy Technicians from relevant European States"."

# **Amendment of article 22**

**82.** In article 22(6) (entitlement to registration in the Register of Pharmacy Technicians), in paragraphs (1) and (2), for "the Register of Pharmacy Technicians" substitute "Part 1 or 2 of the Register of Pharmacy Technicians".

<sup>(5)</sup> Article 21 has not yet been brought into force.

<sup>(6)</sup> Article 22 has not yet been brought into force.

- **83.** In article 23(7) (preregistration requirements for pharmacy technicians in respect of qualifications and additional education, training or experience)—
  - (a) in paragraph (1)—
    - (i) for sub-paragraph (b) substitute—
      - "(b) he is an exempt person and is permitted to pursue the profession of pharmacy technician in Great Britain by virtue of Part 3 of the General Systems Regulations (having, in particular, successfully completed any adaptation period, or passed any aptitude test, that he may be required to undertake pursuant to that Part of those Regulations); or", and
    - (ii) in sub-paragraph (c), omit "having successfully completed any adaptation period or aptitude test that he may be required to complete pursuant to the Second General Systems Regulations"; and
  - (b) in paragraph (2)(b), for "the Second General Systems Directive" substitute "the Directive".

# Amendment of article 25

- **84.** In article 25(8) (specific obligations of the Society in respect of pharmacy technicians' and prospective pharmacy technicians' education, training and the acquisition of experience), in paragraph (f)—
  - (a) after "article 22(1)(a)(iii) and (iv)," insert "for the purposes of rules under article 39(1),"; and
  - (b) in sub-paragraph (v), after "Part 2" insert "or Part 3".

# Amendment of article 27

**85.** In article 27(9) (supplemental matters in connection with articles 25 and 26), in paragraph (5) (b), for "Second General System Directive" substitute "Directive".

#### Amendment of article 28

- **86.** In article 28(10) (form, manner and content of applications for registration in the Register of Pharmacy Technicians or retention in that register), in paragraph (1)—
  - (a) for "registration in the Register of Pharmacy Technicians, or for retention in that register," substitute "registration in Part 1 or 2 of the Register of Pharmacy Technicians, or for retention in those parts of that register,"; and
  - (b) after sub-paragraph (b)(i) insert—
    - "(ia) where the applicant is an exempt person, proof that he is a national of a relevant European State or (where he is not a national of a relevant European State) proof of the Community right by virtue of which he is an exempt person,".

# Insertion of articles 28A and 28B

87. After article 28 insert—

<sup>(7)</sup> Article 23 has not yet been brought into force.

<sup>(8)</sup> Article 25 has not yet been brought into force.

<sup>(9)</sup> Article 27 has been brought into force for the purpose only of the exercise of the power to make rules.

<sup>(10)</sup> Article 28 has been brought into force for the purpose only of the exercise of the power to make rules.

# "Notification of results of application

- **28A.**—(1) This article applies where an exempt person ("E") applies to have his name registered in Part 1 or 2 of the Register of Pharmacy Technicians.
- (2) The Registrar, within the period of one month beginning with the date of receipt of the application, must—
  - (a) acknowledge receipt of the application; and
  - (b) inform E of any missing document required for the purposes of the application.
- (3) The Registrar must, within the period of four months beginning with the relevant date, notify E—
  - (a) of the result of the application; and
  - (b) if the Registrar refuses the application, of the reasons for the decision, and of any right of appeal E has to the Registration Appeals Committee.
  - (4) The "relevant date", in relation to an application, is—
    - (a) the date when the Registrar receives the application; or
    - (b) if any document required for the purposes of the application, or the relevant fee, is missing when the Registrar receives the application, the date on which the Registrar first has all the documents required for those purposes together with the relevant fee.

# Visiting pharmacy technicians from relevant European States

- **28B.**—(1) This article applies to an exempt person ("V") who is lawfully established as a pharmacy technician in a relevant European State other than the United Kingdom ("State A").
- (2) Paragraph (3) applies if V has the benefit of regulation 8 of the General Systems Regulations in connection with the provision by V of services as a pharmacy technician in Great Britain on a temporary and occasional basis (V having complied with any requirements imposed under Part 2 of those Regulations in connection with the provision by V of services as a pharmacy technician).
- (3) V is entitled to be registered in Part 3 of the Register of Pharmacy Technicians; and the Registrar shall give effect to the entitlement.
- (4) If V is entitled under paragraph (3) to be registered in Part 3 of the Register of Pharmacy Technicians but is not registered in that part of that register, V shall be treated as being registered in that part of that register.
- (5) V's entitlement under paragraph (3) ceases if V ceases, whether as a result of the operation of regulation 17 of the General Systems Regulations or otherwise, to have the benefit of regulation 8 of those Regulations in connection with the provision by V of services as a pharmacy technician in Great Britain on a temporary and occasional basis.
  - (6) If—
    - (a) V's entitlement under paragraph (3) ceases by reason of the operation of paragraph (5), and
    - (b) V is registered in Part 3 of the Register of Pharmacy Technicians,

the Registrar may remove V from that part of that register.

- (7) Paragraph (8) applies if—
  - (a) V's establishment in State A is subject to a condition relating to V's practice as a pharmacy technician;

- (b) V's name is registered in Part 3 of the Register of Pharmacy Technicians; and
- (c) for any of the purposes of this Order it falls to be decided whether V's fitness to practise is or may be impaired on the ground of misconduct.
- (8) The matters that may be counted as misconduct include (in particular) any act or omission by V during the course of the provision by V of services as a pharmacy technician in Great Britain on a temporary and occasional basis that is, or would be if the condition applied in relation to practice as a pharmacy technician outside State A, a breach of the condition.
  - (9) In paragraphs (7) and (8) "condition" includes limitation.
- (10) Paragraphs (1) to (6) are not to be taken to prejudice the application, in relation to persons registered in Part 3 of the Register of Pharmacy Technicians, of any other provision of this Order under which a registered pharmacy technician's name may be removed from the Register of Pharmacy Technicians or under which a registered pharmacy technician's registration in that register may be suspended."

- **88.** In article 33 (registrants' duties with regard to their registration entries)—
  - (a) in paragraph (2)(a), at the end of paragraph (ii) insert—
    "or
    - (iii) has changed his name,"; and
  - (b) in paragraph (3), for "registrant" substitute "person registered in Part 1 or 2 of one of the Society's registers".

# Amendment of article 35

- **89.** In article 35 (fitness to practise matters before registration)—
  - (a) in paragraph (1)—
    - (i) for sub-paragraph (a) substitute—
      - "(a) the fitness to practise of a person who is registered in Part 1 or 2 of one of the Society's registers was impaired at the time of his registration as a result of serious, specific circumstances or because of a problem with his physical or mental health; and", and
    - (ii) in sub-paragraph (b), for "that matter or problem" substitute "those circumstances or that problem";
  - (b) in paragraph (2)—
    - (i) for "registrant" substitute "person registered in Part 1 or 2 of one of the Society's registers", and
    - (ii) for "because of his involvement in a serious matter or a problem" substitute "as a result of serious, specific circumstances or because of a problem"; and
  - (c) in paragraph (3), for "registrant" substitute "person".

# Amendment of article 36

**90.** In article 36 (moving between different parts of a register), in paragraph (1)(c), after "Part 2" insert "or Part 3".

- 91. In article 39(11) (continuing professional development)—
  - (a) in paragraph (1), after "Part 1" insert "or 3"; and
  - (b) after paragraph (2) insert—
    - "(2A) Paragraphs (1) and (2)(c), so far as relating to a person ("P") who is a registrant only as a result of being registered in Part 3 of one of the Society's registers, have effect subject to, respectively, paragraphs (2B) and (2C).
      - (2B) Rules under paragraph (1)—
        - (a) may not impose requirements on P if P is required to undertake, in P's home State, continuing professional development in relation to the profession of pharmacy or pharmacy technician (as the case may be); and
        - (b) where they impose requirements on P—
          - (i) shall take account of the fact that P is fully qualified to pursue that profession in P's home State, and
          - (ii) shall specify that continuing professional development which P is required to undertake by the requirements may be undertaken outside Great Britain.
    - (2C) Where rules make provision such as is mentioned in subsection (2)(c), the rules must secure that any sanction imposed in relation to P by or under that provision is appropriate and proportionate in view of P's continued lawful establishment in P's home State as a pharmacist or pharmacy technician (as the case may be).
    - (2D) In paragraphs (2B) and (2C) "home State", in relation to P, means the relevant European State in which P is lawfully established as a pharmacist or pharmacy technician (as the case may be)."

# Amendment of article 40

- **92.** In article 40 (fees in connection with registration)—
  - (a) in paragraph (1), for "The Council" substitute "Subject to paragraph (1A), the Council"; and
  - (b) after paragraph (1) insert—
    - "(1A) Rules under paragraph (1) shall not provide for fees in respect of registration in Part 3 of one of the Society's registers.".

# Amendment of article 42

- 93. In article 42 (appealable registration decisions), in paragraph (1)—
  - (a) before sub-paragraph (a) insert—
    - "(za) a decision under Part 3 of the General Systems Regulations to require an exempt person to whom article 12(1)(ba)(i) and (ii) applies to complete an adaptation period, or pass an aptitude test, before deciding whether he is "appropriately qualified" for the purposes of article 11(1)(a)(i);";
  - (b) in sub-paragraph (a), for "the Register of Pharmacists" substitute "Part 1 or 2 of the Register of Pharmacists";
  - (c) after sub-paragraph (a) insert—

- "(aa) a decision to refuse to register a person in Part 3 of the Register of Pharmacists under Schedule A1 (visiting pharmacists from relevant European States);";
- (d) in sub-paragraph (c), for "article 18(1)" substitute "article 18(3)(a)";
- (e) for sub-paragraph (d)(12) substitute—
  - "(d) a decision under Part 3 of the General Systems Regulations to require an exempt person to complete an adaptation period, or pass an aptitude test, before deciding whether he is "appropriately qualified" for the purposes of article 22(1) (a)(i);";
- (f) in sub-paragraph (e)(13), for "the Register of Pharmacy Technicians" substitute "Part 1 or 2 of the Register of Pharmacy Technicians";
- (g) after sub-paragraph (e) insert—
  - "(ea) a decision to refuse to register a person in Part 3 of the Register of Pharmacy Technicians under article 28B (visiting pharmacy technicians from relevant European States);"; and
- (h) after sub-paragraph (f)(14) insert—
  - "(fa) a failure to give any notice required by article 28A(3)(a) within the specified period;".

- 94. In article 43 (appeals to the Registration Appeals Committee), in paragraph (1)(b)—
  - (a) for "article 18(1)" substitute "article 18(3)(a)"; and
  - (b) after "18(3)(a)" insert "or 28A(3)(a)".

# **Insertion of article 64A**

95. After article 64 insert—

# "The Directive: designation of competent authority etc.

- **64A.**—(1) The Society is designated as the competent authority in Great Britain(15) for the purposes of the Directive so far as relating to the profession of pharmacist.
- (2) Accordingly, the Society shall in Great Britain carry out (in particular) the functions specified in Schedule A2.
- (3) The Society is designated as the competent authority in Great Britain for the award of evidence of formal qualifications in pharmacy listed in relation to the United Kingdom in Annex V, point 5.6.2 of the Directive.
- (4) Subject to paragraph (5), the Secretary of State may give directions to the Society in connection with its functions specified in Schedule A2, and it shall be the duty of the Society to comply with any such directions.
  - (5) Directions given under paragraph (4) may be as to matters of administration only.
  - (6) In Schedule A2—

<sup>(12)</sup> Sub-paragraph (d) of article 42(1) has not yet been brought into force.

<sup>(13)</sup> Sub-paragraph (e) of article 42(1) has not yet been brought into force.

<sup>(14)</sup> Sub-paragraph (f) of article 42(1) has not yet been brought into force.

<sup>(15)</sup> In Northern Ireland, the competent authority for the purposes of the Directive so far as relating to the profession of pharmacist is the Pharmaceutical Society of Northern Ireland.

"non-UK pharmacy qualification" means a qualification in pharmacy that is awarded to a person by a competent authority of a relevant European State other than the United Kingdom;

"GB pharmacy qualification" means a qualification in pharmacy that is awarded to a person by a competent authority in Great Britain.".

#### **Amendment of article 66**

**96.** In article 66 (rules), in paragraph (2), for "the Treaties, the Pharmacy Qualifications Directive and the Second General System Directive" substitute "the Treaties and the Directive".

#### Insertion of Schedules A1 and A2

97. Before Schedule 1 insert—

#### "SCHEDULE A1

Article 18A

#### VISITING PHARMACISTS FROM RELEVANT EUROPEAN STATES

# **Application and interpretation**

- **1.** This Schedule applies to an exempt person who is lawfully established as a pharmacist in a relevant European State other than the United Kingdom.
  - 2. In this Schedule—
    - (a) a "visiting practitioner" means an exempt person to whom this Schedule applies;
    - (b) the "home State", in relation to a visiting practitioner, means the relevant European State in which the practitioner is lawfully established as a pharmacist; and
    - (c) a reference to the provision of occasional pharmacy services is a reference to the provision of services as a pharmacist in Great Britain on a temporary and occasional basis.

# Registration in respect of provision of occasional pharmacy services

- **3.**—(1) A visiting practitioner is entitled to be registered in Part 3 of the Register of Pharmacists if the practitioner is entitled under paragraph 4 or 7 to provide occasional pharmacy services; and the Registrar shall give effect to the entitlement.
- (2) A visiting practitioner who is entitled under sub-paragraph (1) to be registered in Part 3 of the Register of Pharmacists, but who is not registered in that part of that register, shall be treated as registered in that part of that register.
- (3) Sub-paragraph (4) applies where a person's entitlement under sub-paragraph (1) to be registered in Part 3 of the Register of Pharmacists ceases because, by reason of the operation of paragraph 8(1), (2) or (5), the person ceases to be entitled under this Schedule to provide occasional pharmacy services.
- (4) If the person's name is registered in Part 3 of the Register of Pharmacists, the Registrar may remove the person's name from that part of that register.
- (5) Sub-paragraphs (1) to (4) are not to be taken to prejudice the application, in relation to persons registered in the Register of Pharmacists on the basis of entitlement under sub-paragraph (1), of any other provision of this Order under which a registered pharmacist's name may be removed from the Register of Pharmacists or under which a registered pharmacist's registration in that register may be suspended.

# Entitlement to provide occasional pharmacy services: first year

- **4.** A visiting practitioner is entitled to provide occasional pharmacy services if—
  - (a) the practitioner has complied with the requirements of paragraph 5, and
  - (b) where the practitioner's case falls within regulation 3(9)(a) or (e) of the General Systems Regulations, the provision by the practitioner of occasional pharmacy services is in accordance with regulations 14 to 16 of those Regulations (the practitioner having, in particular, successfully completed any adaptation period, or passed any aptitude test, that the practitioner may be required to undertake pursuant to Part 2 of those Regulations),

but paragraph 8 contains provision about the duration of entitlement under this paragraph.

# First provision of services: required documents

- **5.**—(1) A visiting practitioner who proposes to provide occasional pharmacy services for the first time must, before providing any such services, send or produce to the Registrar the required documents.
  - (2) The required documents are—
    - (a) a written declaration that—
      - (i) states the practitioner's wish to provide occasional pharmacy services, and
      - (ii) contains details of the insurance cover, or other means of personal or collective protection, that the practitioner has with regard to professional liability;
    - (b) if the practitioner is a national of a relevant European State, proof of nationality;
    - (c) if the practitioner is not a national of a relevant European State, proof of the Community right by virtue of which the practitioner is an exempt person;
    - (d) evidence of qualifications in pharmacy (see paragraph 6); and
    - (e) a certificate (or certificates) issued by a competent authority in the practitioner's home State confirming—
      - (i) that the practitioner is lawfully established as a pharmacist in that State, and
      - (ii) that the practitioner is not prohibited (whether on a permanent or temporary basis) from practising as a pharmacist there.
  - (3) A declaration under sub-paragraph (2)(a) may be supplied by any means.
- **6.**—(1) Subject to sub-paragraph (3), the evidence referred to in paragraph 5(2)(d) is evidence of the European-recognised qualifications which entitle the visiting practitioner to provide, in the practitioner's home State, the pharmacy services that the practitioner proposes to provide in Great Britain on a temporary and occasional basis.
- (2) This sub-paragraph applies to a visiting practitioner whose case falls within regulation 3(9) (a) or (e) of the General Systems Regulations (with the result that the practitioner is not entitled to provide occasional pharmacy services unless their provision by the practitioner is in accordance with regulations 14 to 16 of those Regulations).
- (3) If sub-paragraph (2) applies to a visiting practitioner, the evidence referred to in paragraph 5(2)(d) of the practitioner's qualifications in pharmacy is evidence of the qualifications which entitle the practitioner to practise as a pharmacist in his home State.
- (4) In this paragraph, "European-recognised qualifications" means qualifications which relevant European States are required by the Directive to recognise.

# Entitlement to provide occasional pharmacy services after first year: renewals

- 7.—(1) Sub-paragraph (2) applies where the Registrar receives the required renewal documents from a visiting practitioner who is entitled under this Schedule to provide occasional pharmacy services.
- (2) The visiting practitioner is entitled to continue to provide occasional pharmacy services, but paragraph 8 contains provision about the duration of entitlement continued under this subparagraph.
- (3) Sub-paragraph (4) applies where the Registrar receives the required renewal documents from a visiting practitioner—
  - (a) who is not entitled under this Schedule to provide occasional pharmacy services;
  - (b) who has been previously entitled under this Schedule to provide occasional pharmacy services; and
  - (c) whose registration in Part 3 of the Register of Pharmacists is not suspended.
- (4) The visiting practitioner is once again entitled to provide occasional pharmacy services but, in a case where the practitioner's name is not in Part 3 of the Register of Pharmacists as a result of removal otherwise than under paragraph 3(4), only if the Registrar decides, after having regard (in particular) to the fact of that removal and the reasons for it, that the entitlement should be renewed.

Paragraph 8 contains provision about the duration of entitlement under this sub-paragraph.

- (5) In relation to a visiting practitioner "the required renewal documents" are—
  - (a) a renewal declaration; and
  - (b) each evidence of change document (if any).
- (6) In this paragraph "renewal declaration", in relation to a visiting practitioner, means a written declaration that—
  - (a) states the practitioner's wish to provide occasional pharmacy services in a further year; and
  - (b) contains details of the insurance cover, or other means of personal or collective protection, that the practitioner has with regard to professional liability.
  - (7) Where a document—
    - (a) is, in relation to a visiting practitioner, one of the required documents for the purposes of paragraph 5,
    - (b) is not a declaration under paragraph 5(2)(a), and
    - (c) substantiates a matter as respects which there has been a material change since the practitioner last (whether under paragraph 5 or this paragraph) supplied the then-current version of the document to the registrar,

the version of the document current when under this paragraph the practitioner supplies a renewal declaration to the registrar is an "evidence of change document" for the purposes of subparagraph (5)(b).

(8) A renewal declaration supplied under this paragraph may be supplied by any means.

# Duration of entitlement to provide occasional pharmacy services

**8.**—(1) Unless an entitlement under paragraph 4 or 7(4) is continued (or further continued) by paragraph 7(2), the entitlement ceases at the end of the year that begins with the end of the day on which the Registrar received the documents whose receipt gave rise to the entitlement.

- (2) Where an entitlement under paragraph 4 or 7(4) is continued (or further continued) by paragraph 7(2), the entitlement is extended so as to cease at the end of the year that begins with the end of the relevant day.
  - (3) For the purposes of sub-paragraph (2)—
    - (a) if the day on which the Registrar receives the documents whose receipt gives rise to the continuation (or further continuation) is an anniversary of the start day, "the relevant day" means the day on which the Registrar receives those documents;
    - (b) otherwise, "the relevant day" means the anniversary of the start day that is the first such anniversary to occur after the Registrar receives the documents whose receipt gives rise to the continuation (or further continuation).
- (4) In sub-paragraph (3) "the start day", in relation to an entitlement under paragraph 4 or 7(4), means the day on which the Registrar receives the documents whose receipt gives rise to the entitlement.
  - (5) An entitlement under this Schedule to provide occasional pharmacy services ceases if—
    - (a) the visiting practitioner concerned becomes established as a pharmacist in the United Kingdom; or
    - (b) a disqualifying decision is made against the visiting practitioner concerned.
- (6) In sub-paragraph (5) "disqualifying decision", in relation to a visiting practitioner, means a decision made by a competent or judicial authority in the practitioner's home State that has the effect that the practitioner—
  - (a) ceases in that State to be registered or otherwise officially recognised as a pharmacist; or
  - (b) is prohibited (whether on a permanent or temporary basis) from practising as a pharmacist in that State.
  - (7) If in the case of a visiting practitioner—
    - (a) the practitioner's registration in Part 3 of the Register of Pharmacists is suspended or the practitioner's name is removed from that part of that register, and
    - (b) immediately before the time when the suspension or (as the case may be) removal takes effect, the practitioner is entitled under this Schedule to provide occasional pharmacy services.

that entitlement ceases at that time.

#### **Conditions**

- 9.—(1) Paragraph (2) applies if—
  - (a) the establishment of a visiting practitioner in the practitioner's home State is subject to a condition relating to the practitioner's practice as a pharmacist;
  - (b) the practitioner's name is registered in Part 3 of the Register of Pharmacists; and
  - (c) for any of the purposes of this Order it falls to be decided whether the practitioner's fitness to practise is or may be impaired on the ground of misconduct.
- (2) The matters that may be counted as misconduct include (in particular) any act or omission by the visiting practitioner during the course of the provision by the practitioner of occasional pharmacy services that is, or would be if the condition applied in relation to practice as a pharmacist outside the practitioner's home State, a breach of the condition.
  - (3) In paragraphs (1) and (2) "condition" includes limitation.

SCHEDULE A2 Article 64A
DIRECTIVE 2005/36: FUNCTIONS OF THE SOCIETY UNDER ARTICLE 64A(2)

Provision of Directive	Function of Society		
Article 7(2)(b)	Issuing certificates containing attestations in relation to persons established as pharmacists in Great Britain.		
Article 8(1)	Receiving information from, or providing information to other competent authorities in relation to—		
	(a)	the legality of a person's establishment as a pharmacist;	
	(b)	the good conduct of such a person;	
	(c)	the absence of any disciplinary or criminal sanctions of a professional nature against such a person.	
Article 8(2)	Receiving information from, or providing information to, other competent authorities in connection with the investigation of complaints made against persons providing services as a pharmacist.		
Article 23(1)	Issuing certificates of effective and lawful practice in Great Britain to pharmacists.		
Article 23(6)	Issuing certificates stating that GB pharmacy qualifications, which do not correspond to the titles set out in respect of the United Kingdom at point 5.6.2 of Annex V to the Directive, certify successful completion of training in pharmacy that is in accordance with article 44 of the Directive or that under article 22(a) of the Directive (part-time training) is to be treated as in accordance with article 44 of the Directive.		
Article 50(1) and paragraph 1(b) of Annex VII	Providing information to other competent authorities concerning the training in Great Britain of a pharmacist to whom Chapter 1 of Part 3 of the General Systems Regulations applies.		
Article 50(1) and paragraph 1(d) of Annex VII	Issuing, in respect of practice as a pharmacist, the certificates of current professional status referred to in sub-paragraph (d) of paragraph 1 of Annex VII to the Directive within the time limits set by that sub-paragraph.		
Article 50(1) and paragraph 2 of Annex VII	Issuing certificates stating that evidence of GB pharmacy qualifications is that covered by the Directive.		
Article 50(2)	In cases of justified doubts—		
	(a)	requiring confirmation of the authenticity of non-UK pharmacy qualifications;	
	(b)	requiring confirmation that holders of non-UK pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or under article 22(a) of the Directive are to be treated as satisfying those conditions;	

Provision of Directive		Function of Society	
	(c)	providing confirmation to competent authorities of other relevant European States of the authenticity of any person's GB pharmacy qualifications;	
	(d)	providing confirmation that holders of GB pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or under article 22(a) of the Directive are to be treated as satisfying those conditions.	
Article 50(3)	In cas	In cases of justified doubts—	
	(a)	verifying information provided in connection with non-UK pharmacy qualifications awarded following training in a relevant European State other than the State in which the qualification was awarded;	
	(b)	providing information in connection with a person's GB pharmacy qualifications awarded following training in another relevant European State.	
Article 56(1)		Ensuring the confidentiality of information exchanged with other competent authorities.	
Article 56(2)	Receiving information from, or providing information to, other competent authorities regarding disciplinary action, criminal sanctions or other serious circumstances likely to have consequences for the practice of the profession of pharmacist.		
	Where such information is received by the Society—		
	(a)	examining the veracity of the circumstances;	
	(b)	deciding the nature and scope of any investigations that need to be carried out;	
	(c)	informing other competent authorities of the Society's conclusions."	