STATUTORY INSTRUMENTS

2007 No. 3101

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

PART 6

PHARMACISTS AND PHARMACY TECHNICIANS: OTHER LEGISLATION

Amendment of the Medicines Act 1968

98. In the Medicines Act 1968(**1**)—

(a) in section 69(**2**) (general provisions), after subsection (1) insert—

"(1ZA) In subsection (1)(a) "pharmacist" does not include a person registered in Part 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007(**3**) (visiting pharmacists from relevant European States).";

(b) in section 70(**4**) (business carried on by individual pharmacist or by partners), in the second sentence of subsection (2), in the substituted paragraph (a), for "pharmacists" substitute "persons registered in Part 1 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007";

(c) in section 71(**5**) (bodies corporate), after subsection (2) add—

"(3) In subsection (2)(a) "pharmacist" does not include a person registered in Part 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007 (visiting pharmacists from relevant European States).";
and

(d) in section 132 (general interpretation provisions), in subsection (1), in the definition of "pharmacist"(**6**), after "Part 1" insert "or 3".

Amendment of the National Health Service (Scotland) Act 1978

99. In the National Health Service (Scotland) Act 1978(**7**), in section 108 (interpretation and construction), in subsection (1), in the definition of "registered pharmacist", after "Part 1" insert "or 3".

(**1**) 1968 c.67.
(**2**) Section 69 was amended by the Statute Law (Repeals) Act 1993 (c.50), Schedule 1, Part 12, and by S.I. 1976/1213 and 2007/289.
(**3**) S.I. 2007/289.
(**4**) Section 70 was amended by S.I. 2007/289 and is to be substituted by section 27 of the Health Act 2006 (c.28) on a date to be appointed.
(**5**) Section 71 was amended by S.I. 2007/289 and is to be substituted by section 28 of the Health Act 2006 on a date to be appointed.
(**6**) The definition of "pharmacist" was amended by S.I. 1976/1213 and 2007/289.
(**7**) 1978 c.29.

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

100. In the Medicines for Human Use (Clinical Trials) Regulations 2004(**8**), in regulation 2 (interpretation), in paragraph (1), in paragraph (a) of the definition of "pharmacist", after "Part 1" insert "or 3".

Amendment of the Gender Recognition (Disclosure of Information) (England, Wales and Northern Ireland) (No. 2) Order 2005

101. In the Gender Recognition (Disclosure of Information) (England, Wales and Northern Ireland) (No. 2) Order 2005(**9**), in article 5 (disclosure for medical purposes), in paragraph (3)(c), after "Part 1" insert "or 3".

Amendment of the Gender Recognition (Disclosure of Information) (Scotland) Order 2005

102. In the Gender Recognition (Disclosure of Information) (Scotland) Order 2005(**10**), in article 5 (disclosure for medical purposes), in paragraph (2)(b)(iii), after "Part 1" insert "or 3".

Amendment of the Health Act 2006

103. In the Health Act 2006(**11**)—

(a) in section 27(1), in the substituted section 70 of the Medicines Act 1968, in subsection (4)(b), for "pharmacist" substitute "person registered in Part 1 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007"; and

(b) in section 28(1), in the substituted section 71 of the Medicines Act 1968, after subsection (6) add—

"(7) In subsection (6)(a) "pharmacist" does not include a person registered in Part 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007 (visiting pharmacists from relevant European States).".

Amendment of the National Health Service Act 2006

104. In the National Health Service Act 2006(**12**), in section 275 (interpretation), in subsection (1), in the definition of "registered pharmacist"(**13**), after "Part 1" insert "or 3".

Amendment of the National Health Service (Wales) Act 2006

105. In the National Health Service (Wales) Act 2006(**14**), in section 206 (interpretation), in subsection (1), in the definition of "registered pharmacist"(**15**), after "Part 1" insert "or 3".

(**8**) S.I. 2004/1031; the definition of "pharmacist" was amended by S.I. 2007/289.
(**9**) S.I. 2005/916; article 5(3)(c) was amended by S.I. 2007/289.
(**10**) S.S.I. 2005/125; article 5(2)(b)(iii) was amended by S.I. 2007/289.
(**11**) 2006 c.28.
(**12**) 2006 c.41.
(**13**) The definition of "registered pharmacist" was substituted by S.I. 2007/289.
(**14**) 2006 c.42.
(**15**) The definition of "registered pharmacist" was substituted by S.I. 2007/289.

Amendment of the Controlled Drugs (Supervision of Management and Use) Regulations 2006

106. In the Controlled Drugs (Supervision of Management and Use) Regulations 2006(**16**), in regulation 2 (interpretation), in paragraph (1), for the definition of "registered pharmacist" substitute—

> ""registered pharmacist" means a person registered in Part 1 or 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007(**17**);".

Amendment of the Royal Pharmaceutical Society of Great Britain (Registration) Rules 2007

107.—(1) The Royal Pharmaceutical Society of Great Britain (Registration) Rules 2007(**18**) are amended as follows.

(2) In rule 6 (application for registration in the Register of Pharmacists)—

(a) in paragraph (1), after "applicants for registration in" insert "Part 1 or 2 of"; and

(b) in paragraph (3)—

(i) after "applying for registration" insert "in Part 1 or 2 of the Register of Pharmacists",

(ii) after sub-paragraph (c) insert—

"(ca) where the applicant is an exempt person—

(i) evidence that he is a national of a relevant European State(**19**), or

(ii) (where he is not a national of a relevant European State) evidence of the Community right by virtue of which he is an exempt person, which, in a case where sub-paragraph (d) applies, must be the evidence set out in that sub-paragraph;",

(iii) for sub-paragraph (e) substitute—

"(e) sufficient evidence (in the opinion of the Registrar) that he is appropriately qualified, and if the applicant ("A")—

(i) is appropriately qualified by virtue of article 12(1)(b) of the Order,

(ii) holds a diploma listed in Annex V, point 5.6.2 of the Directive (evidence of formal qualifications of pharmacists), and

(iii) has successfully completed training as a pharmacist 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),

A must also provide a certificate which must be issued by a competent authority in A's attesting State(**20**) and which must certify that the evidence of qualification provided by A is a diploma listed in relation to that State in Annex V, point 5.6.2 of the Directive;",

(iv) in sub-paragraph (f)(i), for "17(4)(a)" substitute "17(5) or (6)", and

(v) in sub-paragraph (g)(i), for "17(4)(b)" substitute "17(7) or (8)".

(3) In rule 7 (retention in the Register of Pharmacists), after paragraph (8) add—

(**16**) S.I. 2006/3148.
(**17**) S.I. 2007/289.
(**18**) Scheduled to S.I. 2007/441.
(**19**) "Relevant European State" is defined in the Pharmacists and Pharmacy Technicians Order 2007 as meaning an EEA State or Switzerland.
(**20**) "Attesting State" is defined in article 17(9) of the Pharmacists and Pharmacy Technicians Order 2007.

"(9) This rule does not apply in relation to a person who is registered in Part 3 of the Register of Pharmacists.".

(4) In rule 8 (applications to move to a different part of the register), after paragraph (4) add—

"(5) This rule does not apply in relation to a person wishing to move from Part 3 to Part 1 of the register.".

(5) In rule 9 (applications for annotations to denote that a registered pharmacist is a supplementary prescriber or an independent prescriber), in paragraph (1), for "registered pharmacist" substitute "person registered in Part 1 of the Register of Pharmacists".

(6) In rule 12 (applications for restoration within twelve months of specified removals from the register), after paragraph (4) add—

"(5) This rule does not apply in relation to a person who has been removed from Part 3 of the register under rule 10(6).".

(7) In rule 15 (notice of intention to remove: stage one), for paragraph (1) substitute—

"(1) Where the Registrar has reasonable grounds for believing—

(a) that a registrant's entry in the register may have been fraudulently procured or incorrectly made; or

(b) that the fitness to practise of a person who is registered in Part 1 or 2 of the register was impaired at the time of his registration and he had not informed the Registrar of the relevant matter (that is, serious, specific circumstances or a problem with his physical or mental health for the purposes of article 35(1)(a) of the Order) before his registration,

paragraph (2) applies."

Amendment of the Approved European Pharmacy Qualifications Order of Council 2007

108.—(1) The Approved European Pharmacy Qualifications Order of Council 2007(**21**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation)—

(a) in paragraph (2)—

(i) for the definition of "competent authorities" substitute—

""competent authorities"means any authority or body of a relevant European State designated by that State for the purposes of the Directive(**22**) 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 the practice of pharmacy;,",

(ii) omit the definition of "the Pharmacy Training Directive", and

(iii) for the definition of "reference date" substitute—

""reference date", in relation to a relevant European State, means the date specified in relation to that State in the column entitled "Reference date" in Annex V, point 5.6.2 of the Directive."; and

(b) after paragraph (2) add—

(**21**) S.I. 2007/564.

(**22**) "The Directive" is defined in the Pharmacists and Pharmacy Technicians Order as meaning Directive 2005/36/EC of the European Parliament and of the Council of 7th September 2005.

"(3) References in this Order to any provision of the Directive are references to that provision of the Directive as amended from time to time.".

(3) In article 2 (appropriate European diplomas)—

(a) in paragraph (1), after "registration in" insert "Part 1 or 2 of"; and

(b) in paragraph (2)—

(i) for sub-paragraph (a) substitute—

"(a) a diploma listed in Annex V, point 5.6.2 of the Directive which has been granted in a relevant European State after its reference date and which is evidence of training commenced after that date, provided that that diploma is accompanied, where appropriate, by the certificate listed in relation to that State in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma"; or", and

(ii) in sub-paragraph (b)—

(aa) omit "(where appropriate, duly authenticated)", and

(bb) in paragraph (iv), for "not specified in Schedule 2" substitute "not listed in Annex V, point 5.6.2 of the Directive".

(4) Article 3 (conditions relating to a specified diploma awarded in Italy) is revoked.

(5) For article 4 substitute—

"**Conditions relating to diplomas, whether listed or not, awarded in respect of training before a relevant European State's reference date**

4. A diploma to which article 2(2)(b)(i) applies is only an appropriate European diploma if—

(a) in the case of a diploma which is listed in Annex V, point 5.6.2 of the Directive—

(i) the Registrar is satisfied (by means of a certificate from the relevant competent authorities or otherwise) that the diploma guarantees that the holder's training satisfies the requirements of article 44 of the Directive (requirements for pharmacists' training), and

(ii) the diploma is accompanied, where appropriate, by the certificate listed in relation to the relevant European State in which the diploma was awarded in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma";

(b) in the case of a diploma which is not listed in Annex V, point 5.6.2 of the Directive, the diploma is accompanied by a certificate from the competent authorities of the relevant European State in which the diploma was awarded which attests that the diploma—

(i) is evidence of training which satisfies the requirements of article 44 of the Directive, and

(ii) is treated by the competent authorities of the relevant European State in which it was awarded as equivalent to a diploma listed in relation to that State in Annex V, point 5.6.2 of the Directive,

and the certificate is made available to the Registrar; or

(c) whether or not the diploma is listed in Annex V, point 5.6.2 of the Directive, the competent authorities of a relevant European State have certified that the holder has, in a relevant European State, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years

during the five years preceding the date of the certificate, and the certificate is made available to the Registrar.".

(6) In article 5 (conditions relating to old diplomas granted in respect of training commenced in the former Czechoslovakia, the former Soviet Union or the former Yugoslavia)—

(a) in paragraph (a), for "specified in Schedule 2" substitute "listed in Annex V, point 5.6.2 of the Directive"; and

(b) for paragraph (b) substitute—

"(b) those competent authorities have also certified that the holder of the diploma has, in the relevant European State specified in the appropriate row of column (c) of the table in Schedule 3, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years during the five years preceding the date of that certificate; and".

(7) In article 6 (conditions relating to old diplomas granted in respect of training commenced in the former German Democratic Republic)—

(a) in paragraph (a), for "specified in Schedule 2" substitute "listed in Annex V, point 5.6.2 of the Directive"; and

(b) for paragraph (b) substitute—

"(b) the competent authorities in Germany have certified that the holder of the diploma has been effectively and lawfully engaged in Germany in the practice of an activity open to pharmacists in Germany for at least three consecutive years during the five years preceding the date of that certificate, and the certificate is made available to the Registrar.".

(8) In article 7 (conditions relating to new diplomas), in paragraph (a)—

(a) for sub-paragraph (i) substitute—

"(i) is evidence of training which satisfies the requirements of article 44 of the Directive, and"; and

(b) in sub-paragraph (ii), for "specified in Schedule 2" substitute "listed in Annex V, point 5.6.2 of the Directive".

(9) For article 8 substitute—

"**Justified doubts**

8. A diploma is only an appropriate European diploma if—

(a) in a case where the Society (including its Registrar) has justified doubts about the authenticity of the evidence of the diploma made available to the Society and has required of the relevant competent authorities confirmation of the authenticity of the evidence, the relevant competent authorities have confirmed the authenticity of the evidence;

(b) in a case where the Society (including its Registrar) has justified doubts about whether the holder of the diploma has completed training which satisfies the requirements of article 44 of the Directive, and has required of the relevant competent authorities confirmation of completion of such training, the relevant competent authorities have confirmed completion of such training;

(c) in a case where the Society (including its Registrar) has justified doubts concerning training received in a relevant European State other than that in which the diploma was awarded, and has required confirmation of the relevant competent authorities in accordance with article 50(3) of the Directive, the relevant competent authorities have provided confirmation in accordance with that article.".

(10) Schedules 1 (reference dates) and 2 (specified pharmacy qualifications) are revoked.