STATUTORY RULES OF NORTHERN IRELAND

2008 No. 192

PHARMACY

The European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008

Made - - - -	*29th April 2008*
Coming into operation	*22nd May 2008*

The Department of Health, Social Services and Public Safety (**1**), being a Department designated (**2**) for the purposes of section 2(2) of the European Communities Act 1972(**3**) in relation to measures in respect of the conditions of, and the recognition of qualifications for, access to and pursuit of activities in the field of pharmacy, makes the following regulations in exercise of the powers conferred by section 2(2) of, as read with paragraph 1A of Schedule 2(**4**) to, the European Communities Act 1972.

These regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Department of Health, Social Services and Public Safety that it is expedient for the references to Directive 2005/36/EC of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications(**5**), or to a provision of that Directive, to be construed as references to that Directive, or to that provision of the Directive, as amended from time to time.

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008.

(2) These regulations shall come into operation on 22nd May 2008.

(3) In these regulations "the Order" means the Pharmacy (Northern Ireland) Order 1976(**6**).

(4) The Interpretation Act (Northern Ireland) 1954 shall apply to these regulations as it applies to an Act of the Assembly(**7**).

(**1**) See S.I. 1999/283 (N.I. 1) Article 3(6)
(**2**) S.I. 1996/1912
(**3**) 1972 c.68
(**4**) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51)
(**5**) 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 *[and instruments by which EEA States and Switzerland adopt 2005/36]*
(**6**) S.I. 1976/1213 (N.I. 22) as amended by 1981 c.45 & c.55; 1983 c.54; S.I. 1984/703 (N.I.3); S.R.1987 No.457; S.I.1994/429(N.I.2); S.R. 1996 No.393; 2004 c.33; S.R. 2004 No. 78
(**7**) 1954 c.33 (N.I.)

PART 1

AMENDMENT OF THE PHARMACY (NORTHERN IRELAND) ORDER 1976

Amendment of the Order

2. The Order is amended in accordance with the following regulations.

Amendment of Article 2 of the Order

3. In Article 2 of the Order (Interpretation)—

(a) after the definition of "certificate of registration" insert—

" "competent authorities" 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 qualification or other information or documents,

(b) receive applications and take decisions referred to in the Directive in connection with the practice of pharmacy;";

(b) after the definition of "the Department" 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 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) after the definition of "enactment" insert—

" "exempt person" means

(a) a national of a relevant European State other than the United Kingdom;

(b) a national of the United Kingdom who is seeking access to, or is pursuing, the profession of pharmacy by virtue of an enforceable Community right; or

(c) a person who is not a national of a relevant European State but who is, by virtue of an enforceable Community right, entitled to be treated, for the purposes of access to, and pursuit of, the profession of pharmacy, no less favourably than a national of a relevant European State;

"General Systems Regulations" means the European Communities (Recognition of Professional Qualification) Regulations 2007(**8**);" "

(d) in the definition of "national" for "member State" substitute "relevant European State";

(e) in the definition of "registered" after "pharmaceutical chemist," insert "visiting pharmaceutical chemist from a relevant European State";

(f) in the definition of "registered person" after "pharmaceutical chemist" insert ",visiting pharmaceutical chemist from a relevant European State"; and

(g) after the definition of "the registrar" insert—

" "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;

"relevant European State" means an EEA State or Switzerland;" "

(**8**) S.I.2007/2781

Amendment of Article 5 of the Order

4. In Article 5 of the Order(**9**) (Regulations) after paragraph (1)insert—

"(1A) Regulations made by the Council under this Article may not make provision for the payment of fees in connection with registration as a visiting pharmaceutical chemist from a relevant European State.".

Amendment of Article 6 of the Order

5. In Article 6 of the Order (The registers), for paragraph (1) substitute—

"(1) In relation to the registers mentioned in sub-paragraphs (a), (b) and (c) there shall continue to be kept, and in relation to the register mentioned in sub-paragraph (d) there shall be kept, in accordance with the succeeding provisions of this Order,—

(a) a register of pharmaceutical chemists;

(b) a register of druggists;

(c) a register of students; and

(d) a register of visiting pharmaceutical chemists from a relevant European State.".

Amendment of Article 8 of the Order

6. For Article 8(2)(c) of the Order (Qualifications for registration) substitute—

"(c) every exempt person—

(i) who holds an appropriate European diploma; or

(ii) (aa) whose case falls within regulation 3(9)(a) or (e) of the General Systems Regulations,

(bb) to whom regulations 20 to 26 of those regulations apply by reason of the operation of regulation 3(4) of those regulations, and

(cc) who is permitted to pursue the profession of pharmacy 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).".

Amendment of Article 8 A of the Order

7. Article 8A of the Order(**10**) (Registration by virtue of appropriate European diploma) shall be amended as follows—

(1) Omit paragraph (1A).

(2) For paragraphs (2) to (7) substitute the following paragraphs—

"(2) Subject to paragraph (8) the following diplomas are appropriate European diplomas for the purposes of article 8(2)(c)(i), namely—

(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 the diploma is accompanied, where appropriate, by the certificate listed in relation to that State in the column

(**9**) Article 5(1)(a) is amended by S.R. 2004 No. 78
(**10**) Article 8A was inserted by S.R. 1987 No.457

of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma"; or

(b) any diploma which—

(i) subject to paragraph (3), has been granted in a relevant European State before its reference date or which is evidence of training commenced before that date but completed on or after that date,

(ii) subject to paragraph (4), was awarded by the competent authorities of, or which is evidence of training started in, the territory specified in column (b) of the table in Schedule 2A before the date specified in the corresponding entry in column (a) of that table,

(iii) subject to paragraph (5), is evidence of training commenced before 3rd October 1990 and undertaken in the territory of the former German Democratic Republic, or

(iv) subject to paragraph (6), does not fall within heads (i) to (iii) and is not listed in Annex V, point 5.6.2 of the Directive but which is a diploma in pharmacy granted in a relevant European State on or after its reference date.

(3) A diploma to which paragraph (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.

(4) A diploma to which paragraph (2)(b)(ii) applies is only an appropriate European diploma if—

(a) the competent authorities of the relevant European State specified in the appropriate row of column (c) of the table in Schedule 2A have certified that

the diploma has, in its territory, the same legal validity as regards access to the practice of pharmacy as the diploma listed in Annex V, point 5.6.2 of the Directive in respect of their State;

(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 2A, 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

(c) the certificates are made available to the registrar.

(5) A diploma to which paragraph (2)(b)(iii) applies is only an appropriate European diploma if —

(a) the diploma entitles its holder to practice pharmacy throughout the territory of Germany on the same conditions as those that apply to the holder of the diploma listed in Annex V, point 5.6.2 of the Directive in respect of Germany; and

(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

(c) the certificate is made available to the registrar.

(6) A diploma to which (2)(b)(iv) applies is only an appropriate European diploma if—

(a) the competent authorities of the European State that awarded it have certified that the diploma—

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

(ii) is treated by them as equivalent to a diploma listed in Annex V, point 5.6.2 of the Directive in respect of their State; and

(b) the certificates are made available to the registrar.

(7) A diploma is only an appropriate European diploma if—

(a) in a case where the registrar or the Council has justified doubts about the authenticity of the diploma made available to the registrar 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 registrar or the Council 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 registrar or the Council 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.".

8. After Article 8A of the Order (Registration by virtue of appropriate European diploma) insert—