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 (**a**), being a Department designated (**b**) for the purposes of section 2(2) of the European Communities Act 1972(**c**) 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(**d**) 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(**e**), 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(**f**).

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

(**a**) See S.I. 1999/283 (N.I. 1) Article 3(6)
(**b**) S.I. 1996/1912
(**c**) 1972 c.68
(**d**) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51)
(**e**) OJ No. 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]*
(**f**) 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
(**g**) 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(**a**);" "

(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;" "

Amendment of Article 5 of the Order

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

(**a**) S.I.2007/2781
(**b**) Article 5(1)(a) is amended by S.R. 2004 No. 78

"(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(**a**) (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 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

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(**a**) Article 8A was inserted by S.R. 1987 No.457

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—

"**Visiting pharmaceutical chemist from a relevant European State**

8B. Schedule 2B (visiting pharmaceutical chemist from a relevant European State) shall have effect.".

Amendment of Article 9 of the Order

9. In paragraph (2) of Article 9 of the Order (The registrar) for "(c)" substitute ",(c) and (d)".

Amendment of Article 11 of the Order

10. In Article 11 of the Order (Evidence of qualification to be registered) after paragraph (1) insert—

"(1A) The registrar shall enter the name of a person whom the Society has directed him to register in the appropriate register kept under this Order for the purposes of the General Systems Regulations.".

Amendment of Article 14 of the Order

11. In paragraph (2A) of Article 14 of the Order (Issue of certificates of registration and penalties for failure to surrender, or abuse of, certificates) omit the words "or (5)(a)".

Amendment of Schedule 2A

12. For Schedule 2A of the Order (Qualifying European Diplomas) substitute the Schedules set out in the Schedule to these regulations.

PART 2

OTHER LEGISLATION

Amendment of the Medicines Act 1968

13. In the Medicines Act 1968(**a**)—

(a) in section 69(1ZA)(**b**) (general provisions), at the end insert—

"or a person registered in the register of visiting pharmaceutical chemists from a relevant European State maintained under Article 9 of the Pharmacy (Northern Ireland) Order 1976(**c**).";

(b) in section 71(**d**) (bodies corporate), at the end of subsection (3)(**e**) insert—

"or a person registered in the register of visiting pharmaceutical chemists from a relevant European State maintained under Article 9 of the Pharmacy (Northern Ireland) Order 1976.";

(c) in section 132 (general interpretation provisions), in subsection (1), in the definition of "pharmacist"(**f**) , after "Northern Ireland", where it appears for the second time, insert—

"or the register of visiting pharmaceutical chemists from a relevant European State".

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

14. In the Medicines for Human Use (Clinical Trials) Regulations 2004(**g**), in regulation 2 (interpretation), in paragraph (1), in paragraph (b) of the definition of "pharmacist", after "Northern Ireland", where it appears for the second time, insert ", or the register of visiting pharmaceutical chemists from a relevant European State,".

Amendment of the Health Act 2006

15. In the Health Act 2006(**h**), in section 28(1), in the substituted section 71 of the Medicines Act 1968, in subsection (7)(**i**), at the end insert "or a person registered in the register of visiting pharmaceutical chemists from a relevant European State maintained under Article 9 of the Pharmacy (Northern Ireland) Order 1976.".

(**a**) 1968 c.67
(**b**) 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. Sub-section (1ZA) was inserted by SI 2007/3101
(**c**) S.I. 1976/1213 (N.I. 22)
(**d**) Section 71 was amended by S.I. 2007/289 (c.28) and is to be substituted by section 28 of the Health Act 2006 on a date to be appointed
(**e**) Subsection (3) was inserted by S.I. 2007/3101 (regulation 98)
(**f**) The definition of "pharmacist" was amended by S.I. 1976/1213 and 2007/289
(**g**) S.I. 2004/1031 [amdmts]
(**h**) 2006 c.28
(**i**) Subsection (7) was inserted by S.I. 2007/3101 (regulation 103)

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 29th April 2008.

D.C. Bingham
A senior officer of the
Department of Health, Social Services and Public Safety

SCHEDULE

Regulation 12

"SCHEDULE 2A

TABLE IN RESPECT OF TRAINING IN THE FORMER CZECHOSLOVAKIA, THE FORMER SOVIET UNION OR THE FORMER YUGOSLAVIA

Column (a)	*Column (b)*	*Column (c)*
1st January 1993	Former Czechoslovakia	Czech Republic
1st January 1993	Former Czechoslovakia	Slovakia
20th August 1991	Former Soviet Union	Estonia
21st August 1991	Former Soviet Union	Latvia
11th March 1990	Former Soviet Union	Lithuania
25th June 1991	Former Yugoslavia	Slovenia

SCHEDULE 2B

VISITING PHARMACEUTICAL CHEMIST FROM A RELEVANT EUROPEAN STATE

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 pharmaceutical chemist in Northern Ireland 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 the register mentioned in Article 6(1)(d) 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 the register mentioned in Article 6(1)(d) as a visiting pharmaceutical chemist from a relevant European State, but who is not registered in that register, shall be treated as so registered in that register.

(3) Sub-paragraph (4) applies where a person's entitlement under sub-paragraph (1) to be registered in the register mentioned in Article 6(1)(d) ceases because, by reason of the operation of paragraphs 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 the register mentioned in Article 6(1)(d), the registrar may remove the person's name from 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 mentioned in Article 6(1)(d) on the basis of entitlement under sub-paragraph (1), of any other provision of this Order under which a registered person's name may be removed from the register mentioned in Article 6(1)(d).

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 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 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 Northern Ireland 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 sub-paragraph.

(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; and

(b) who has been previously entitled under this Schedule to provide occasional pharmacy services.

The visiting practitioner is once again entitled to provide occasional pharmacy services but, in a case where the practitioner's name is not in the register mentioned in Article 6(1)(d) 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 sub-paragraph (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 and includes 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 and includes 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 Great Britain or a pharmaceutical chemist in Northern Ireland; 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 name is removed from the register mentioned in Article 6(1)(d); and

(b) immediately before the time when the removal takes effect, the practitioner is entitled under this Schedule to provide occasional pharmacy services;

that entitlement ceases at that time.

Conditions

9.—(1) Sub-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 the register mentioned in Article 6(1)(d); and

(c) for any of the purposes of this Order it falls to be decided whether the practitioner's misconduct renders him unfit to be on the register mentioned in Article 6(1)(d).

(2) The matters that may be considered 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 sub-paragraphs (1) and (2) "condition" includes limitation."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations, which are made under powers contained in the European Communities Act 1972, implement, in part, Directive 2005/36/EC ("the Directive") which concerns the recognition of professional qualifications. The essential aim of the Directive is to facilitate free movement of persons between member States of the European Community, by setting out principles and procedures which member States are to apply in determining the rights of migrants to pursue professions which require professional qualifications.

The Directive repeals and replaces a number of previous Directives dealing with the recognition of professional qualifications. The Directive restates the majority of the provisions contained in those repealed Directives, but adds significant new provisions and makes many other minor changes to the existing regimes.

The regulations implement the majority of the Directive in relation to the pharmacy profession in Northern Ireland, by amending the Pharmacy (Northern Ireland) Order 1976 ("the 1976 Order") to reflect the changes made by the Directive.

Those provisions of the Directive relating to the pharmacy profession in Northern Ireland which are not implemented by these regulations are implemented by the European Communities (Recognition of Professional Qualifications) Regulations 2007 ("the General Systems Regulations").

The regulations apply in relation to the member States of the European Community and also in relation to the other EEA States, Iceland, Liechtenstein and Norway. The Regulations also apply in relation to Switzerland. The regulations use the term "relevant European State" to describe the member States of the European Community plus Iceland, Liechtenstein, Norway and Switzerland.

The main changes to the Order made by the regulations may be summarised as follows:

(1) Article 10 cases

Article 10 of the Directive is a new provision which describes certain cases ("Article 10 cases") in which migrants wishing to establish themselves in the practice of a sectoral profession (which includes pharmacy) in a different relevant European State are subject to the recognition regime set out in the General Systems Regulations.

The details of that regime are implemented in Part 3 of the General Systems Regulations, and these regulations amend the 1976 Order to implement Article 10 of the Directive by referring to persons who are entitled to practise their profession by virtue of that Part of the General Systems Regulations. See regulation 6 (Article 8(2)(c) of the 1976 Order).

(2) Provision of services on a temporary basis

Title II of the Directive sets out a regime for the provision of professional services on a temporary basis in a host relevant European State by a migrant who is established in the practice of the relevant profession in a different relevant European state. Such a regime already exists for the professions of doctor, dentist, nurse and midwife. However it is new for the profession of pharmacist. These regulations amend the 1976 Order to establish a register of visiting pharmaceutical chemists from a visiting European State. They also make provision to implement the details of the regime set out in Title II of the Directive, whose key features are:

the provision by the migrant of a declaration before provision of services in a host relevant European State;

the provision by the migrant of accompanying documents proving nationality, qualifications and lawful establishment in another relevant European State;

in the case of the sectoral professions in Article 10 cases only, the possibility for the competent authority to require verification of the migrant's qualifications; and

automatic registration of the eligible service provider in the competent authority's register.

See regulation 5 (Article 6 of the 1976 Order) regulation 8 and the Schedule (inserting Schedule 2B in the 1976 Order).

(3) Automatic recognition of qualifications and acquired rights

The Directive makes some changes to the regime of automatic recognition of listed European qualifications for the sectoral professions, and to the acquired rights provisions in relation to those professions. In particular, a certificate is now required to accompany a listed qualification, where the Directive requires this.

The provisions of the Order which deal with listed European qualifications and acquired rights are replaced by references made to the qualifications listed for the pharmacy profession in Annex V of the Directive, and the regulations. This approach has been facilitated by the ambulatory reference to the Directive which are included in the regulations.

See regulation 7 (Article 8A of the 1976 Order).

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