



STATUTORY INSTRUMENTS

S.I. No. 489 of 2008

EUROPEAN COMMUNITIES (RECOGNITION OF PROFESSIONAL
QUALIFICATIONS RELATING TO THE PROFESSION OF
PHARMACIST) (NO. 2) REGULATIONS 2008

(Prn. A8/1884)

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EUROPEAN COMMUNITIES (RECOGNITION OF PROFESSIONAL
QUALIFICATIONS RELATING TO THE PROFESSION OF
PHARMACIST) (NO. 2) REGULATIONS 2008

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2005/36/EC¹ as amended by Directive 2006/100/EC², (insofar as those Directives concern the profession of pharmacist), hereby make the following Regulations:

PART 1

GENERAL PROVISIONS

Citation

1. These Regulations may be cited as the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) (No. 2) Regulations 2008.

Commencement

2. These Regulations shall come into operation on 29th November 2008.

Interpretation

3. (1) In these Regulations—

‘Council’ means the Council established by section 10 of the Pharmacy Act 2007 (No. 20 of 2007);

‘Professional Qualifications Directive’ means Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications, as amended by Council Directive 2006/100/EC of 20 November 2006 adapting certain Directives in the field of freedom of movement of persons by reason of the accession of Bulgaria and Romania.

(2) In these Regulations, words and phrases shall have the same meaning as in the Professional Qualifications Directive.

(3) In these Regulations, unless the context otherwise requires, any reference to a Regulation shall be construed as a reference to a Regulation contained in these Regulations and any reference in a Regulation to a paragraph shall be construed as a reference to a paragraph in that Regulation.

¹ Official Journal of the European Communities L255, 30.09.2005, p.22.

² Official Journal of the European Communities L363, 20.12.2006, p.141.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 2nd December, 2008.*

PART 2

AMENDMENTS TO PHARMACY ACT 2007

4. Section 16(4) of the Pharmacy Act 2007 is substituted by the following—

“(4) The second of those requirements is that—

(a) the person provides evidence—

(i) that he or she holds a formal qualification as a pharmacist which does not satisfy all the training requirements referred to in Article 44 of the Professional Qualifications Directive, but attests successful completion of training which began before—

(I) the relevant reference date laid down in Annex V, point 5.6.2, in the case of a qualification issued by a Member State of the European Union, or

(II) 3 October 1990, in the case of a qualification obtained in the territory of the former German Democratic Republic,

and is accompanied by a certificate, issued by the competent authority of a relevant state, stating that the person, being the holder of formal qualifications as a pharmacist, has been effectively and lawfully engaged in the activities in question for at least three consecutive years during the five years preceding the award of the certificate; or

(ii) that he or she holds a formal qualification as a pharmacist issued by the former Czechoslovakia, or that his or her training commenced, for the Czech Republic and Slovakia, before 1 January 1993, where the authorities of either of the two aforementioned Member States attest that such evidence of formal qualifications has the same legal validity within their territory as the evidence of formal qualification which they issue as regards access to the professional activities of a pharmacist, as referred to in Article 45(2) of the Professional Qualifications Directive, and the pursuit of such activities; or

(iii) that he or she holds a formal qualification as a pharmacist issued by the former Soviet Union, or that his or her training commenced—

(I) for Estonia, before 20 August 1991,

(II) for Latvia, before 21 August 1991,

(III) for Lithuania, before 11 March 1990,

where the authorities of any of the three aforementioned Member States attest that such evidence of formal qualifications has the same legal validity within their territory as the evidence of formal qualification which they issue in respect of access to the professional activities of a pharmacist, as referred to in Article 45(2) of the Professional Qualifications Directive, and the pursuit of such activities; or

- (iv) that he or she holds a formal qualification as a pharmacist issued by the former Yugoslavia, or that his or her training commenced, for Slovenia, before 25 June 1991, where the authorities of that Member State attest that such evidence of formal qualifications has the same legal validity within their territory as the evidence of formal qualification which they issue in respect of access to the professional activities of a pharmacist, as referred to in Article 45(2) of the Professional Qualifications Directive, and the pursuit of such activities; or
- (v) that he or she holds a formal qualification as a pharmacist which does not correspond to the titles given for the relevant Member State in Annex V, point 5.6.2, of the Professional Qualifications Directive, but is accompanied by a certificate issued by the competent authority or body in that Member State stating that the evidence of formal qualifications certifies successful completion of training in accordance with Article 44 of the Professional Qualifications Directive and is treated by the Member State in the same way as the qualifications whose titles are listed in Annex V, point 5.6.2, of that Directive,

and

- (b) in the case of an application for registration pursuant to subparagraphs (ii), (iii) and (iv) of paragraph (a) of this subsection, the attestation from the authorities of the relevant Member State is accompanied by a certificate issued by those authorities stating that the person has been effectively and lawfully engaged in the activities of a pharmacist within their territory for at least three consecutive years during the five years prior to the date of issue of the certificate.”.

5. Section 16(5) of the Pharmacy Act 2007 is substituted by the following—

“(5) The third of those requirements is the person provides evidence that—

(a) he or she holds—

- (i) a formal qualification as a pharmacist which does not meet the requirements of effective and lawful professional practice referred to in subsection (4), but has completed an adaptation

period as may have been required by the Council having regard to Article 14, paragraphs (1), (4) and (5), of the Professional Qualifications Directive, or

- (ii) a formal qualification as a pharmacist granted by a competent authority of a third country, which has been recognised by a competent authority in another relevant state for the purpose of access to the professional activities of a pharmacist as referred to in Article 45(2) of the Professional Qualifications Directive including the pursuit of such activities in that state, and who has experience of at least three years practising as such in that state certified in accordance with Article 3(3) of the said Directive,

and

- (b) in the case of an application for registration pursuant to subparagraph (ii) of paragraph (a) of this subsection, the person—

- (i) possesses the attestation of competence or evidence of formal qualification as a pharmacist required by a competent authority in another relevant state in order to gain access to and pursue the professional activities of a pharmacist in that state, as referred to in Article 45(2) of the Professional Qualifications Directive;
- (ii) in the initial recognition by the competent authority of the other relevant state, has satisfied the minimum training requirements specified in Article 44 of the Professional Qualifications Directive; and
- (iii) has completed an adaptation period, as may be required by the Council having regard to Article 14, paragraphs (1), (4) and (5), of the Professional Qualifications Directive.

6. Section 16(8) of the Pharmacy Act 2007 is amended—

- (a) by inserting the following before the definition of “competent authority”:

“‘adaptation period’ means a period of pursuit of the profession of pharmacist in the State under the supervision of a registered pharmacist;”;

- (b) by inserting the following after the definition of “competent authority”:

“‘national of a relevant state’ includes a person who is not a national of a relevant state, but who is, by virtue of any enforceable Community right, entitled to be treated no less favourably than a national of such a state;”;

- (c) by removing the words “(other than the State)” from subparagraph (a) in the definition of “relevant state”;
- (d) by removing the words “or the State” from the definition of “third country”.

7. Section 16 of the Pharmacy Act 2007 is amended by inserting the following new subsection after subsection (9)—

“(10) Where an adaptation period is required by the Council pursuant to Article 14 of the Professional Qualifications Directive—

- (a) the adaptation period shall be set having regard to the professional knowledge of the applicant and shall not exceed a period of 3 years;
- (b) the Council shall determine the detailed rules of the adaptation period, having regard to the circumstances of each individual applicant and, in particular, to the fact that he or she is a qualified pharmacist in another relevant state;
- (c) the Council may, in circumstances where it considers it necessary to do so, require the applicant to undergo further training during the adaptation period; and
- (d) the applicant’s performance during the adaptation period shall be assessed by the Council with the aim of assessing the ability of the applicant to pursue the profession of pharmacist in the State.”.

8. The Pharmacy Act 2007 is amended by inserting the following new section after section 21—

“Appeal against failure to make a determination

21A (1) An applicant whose application for registration under this Act is required to be, but is not, the subject of a determination by the Council within a set time period under paragraph 3 of Schedule 2 to this Act may appeal to the High Court against the failure to make a determination within a period of 3 months beginning on the last day on which, under paragraph 3(1), or as the case may be paragraph 3(4), of Schedule 2, the relevant determination was required to have been made by the Council.

(2) On an appeal under this section, the High Court may make any order that it considers appropriate.”

9. The Pharmacy Act 2007 is amended by inserting the following new sections after section 24—

“Visiting European pharmacists

24A (1) Subject to the provisions of this section and section 24B, the Council shall not, for any reason related to professional qualifications,

restrict a person who moves to the State to provide the services of a registered pharmacist, if he or she is legally established in another relevant state for the purpose of pursuing the same profession in that state.

- (2) (a) The provisions of this section shall only apply where the person moves to the State to provide the professional services of a registered pharmacist on a temporary and occasional basis.
- (b) The Council shall assess the temporary and occasional nature of the provision of the professional services of a registered pharmacist by a visiting pharmacist from another relevant state on a case by case basis, in particular having regard to its duration, its frequency, its regularity and its continuity.
- (3) (a) Subject to subsection (4), the Council shall require that where a person first moves from another relevant state to the State in order to provide the professional services of a registered pharmacist, he or she shall inform it by way of a declaration.
- (b) The aforementioned declaration shall—
 - (i) be made in advance of the service being provided,
 - (ii) include the details of any insurance cover or other means of personal or collective protection with regard to professional liability, and
 - (iii) be renewed once a year if the person intends to provide temporary or occasional services in the State during that year.
- (c) The declaration or renewal declaration supplied to the Council shall be provided in writing and may be supplied by any means.
- (4) (a) The Council shall require that the declaration be accompanied by the documents set out in paragraph (b) of this subsection in the following circumstances:
 - (i) on the first provision of services, or
 - (ii) if there is a material change in the situation substantiated by the documents.
- (b) The documents referred to in paragraph (a) of this subsection are:
 - (i) proof of nationality of the person or, where he or she is not a national of a relevant state, details of the Community right upon which he or she relies and the circumstances of his or her entitlement under that right,
 - (ii) an attestation from the competent authority of the other relevant state certifying that the person is—

- (I) lawfully established in that state for the purpose of providing services as a pharmacist, and
 - (II) not prohibited from providing such services, even temporarily,
at the moment of delivering the attestation.
- (iii) evidence of professional qualification as a pharmacist in a relevant state.
- (5) (a) The provisions of this subsection and of subsections (6) and (7) of this section shall only apply in the case of persons other than those who are eligible for automatic recognition as a pharmacist under Article 21 or Article 23 of the Professional Qualifications Directive.
- (b) Subject to the provisions of this subsection and subsections (6) and (7) of this section, the Council shall verify the professional qualifications of the person prior to the first provision of service.
- (c) Such a prior check shall be possible only where the purpose of the verification is justified and proportionate in order to avoid serious damage to the health or safety of the recipient of the service, or to the health or safety of animals to whom the service is to be given, due to a lack of professional qualifications of the person, and where this check does not go beyond what is necessary to achieve that purpose.
- (6) (a) Subject to subsection (7) of this section, the Council shall, prior to the first provision of services, give the person the opportunity to show that he or she has acquired the knowledge or competence lacking where:
- (i) the result of a check demonstrates that there is a substantial difference between the professional qualifications of the person and the training required to access and pursue the professional activities of a registered pharmacist in the State, and
 - (ii) the substantial difference is such as to be harmful to public health or safety.
- (b) In the circumstances specified in paragraph (a) of this subsection, the person shall demonstrate that he or she has acquired the knowledge or competence lacking, in particular, by taking and passing an aptitude test.
- (7) (a) Where subsection (5) of this section, or where both subsections (5) and (6) of this section apply, the Council shall, within the first month following receipt of the declaration and accompanying documents, endeavour to inform the person of:

- (i) its decision not to check his or her qualifications, or
 - (ii) the outcome of such a check.
- (b) Where there is a difficulty which would result in a delay of that decision, the Council shall send a duly substantiated request for further information to the person within the one month period referred to in paragraph (a) of this subsection stating the reason for the delay and the timescale for its decision.
- (c) In the event of a delay being notified to the person in paragraph (b) of this subsection, the Council shall make a decision based on the completed documentation within the second month.
- (d) The Council shall give the person the opportunity to show that he or she has acquired the knowledge or competence lacking within one month of the decision referred to in paragraphs (a) or (c) of this subsection.
- (e) In the absence of a reaction from the Council within the periods stipulated in paragraphs (a), (c) and (d) of this subsection, the person may provide the services concerned in the State.

(8) The Council may, in respect of a person who has made a declaration pursuant to subsection (3) of this section, request the competent authority in the state in which that person is established, for each provision of services, to provide any information relevant to the legality of that person's establishment, his or her good conduct and the absence of any disciplinary or criminal sanctions of a professional nature.

(9) A person providing services under this section shall be subject to the statutory and administrative rules applicable to those pursuing the profession of a registered pharmacist in the State which are directly linked to the professional qualification, including the disciplinary provisions contained in Part 6 of this Act.

(10) Persons providing services in the State pursuant to this section must have knowledge of the Irish or English languages sufficient for that purpose.

(11) In this section—

‘aptitude test’ means the test referred to in Article 3(1)(h) of the Professional Qualifications Directive;

‘establishment’ means the actual pursuit of an economic activity, as referred to in Article 43 of the Treaty, by the provider for an indefinite period and through a stable infrastructure from where the business of providing services is actually carried out;

‘person’ means a natural person who is a national of a relevant state and who seeks access to provide in the State, the professional services of a registered pharmacist on a temporary and occasional basis;

‘renewal declaration’ means a written declaration that—

- (a) states the person’s wish to provide occasional professional services of a registered pharmacist in a further year,
- (b) contains details of the insurance cover, or other means of personal or collective protection with regard to professional liability, and
- (c) identifies any material change to the documents that had previously been supplied to the Council under this section and is accompanied by such materially changed documents.

‘service’ means any self employed economic activity, normally provided for remuneration, as referred to in Article 50 of the Treaty;

‘Treaty’ means the Treaty establishing the European Economic Community, signed at Rome on the 25th day of March, 1957 (as amended).

(12) In this section—

- (a) expressions also used in section 16 have the same meaning as in that section;
- (b) expressions also used in the Professional Qualifications Directive have the same meaning as in that Directive.

Division of Register for visiting European pharmacists

24B. (1) The Register referred to in section 13(1)(a)(i) of this Act shall have a second part, hereinafter referred to as Part B, which shall be entitled “Visiting Pharmacists from Relevant EEA States”.

(2) The Council shall enter, in Part B of the Register of Pharmacists the names of persons legally established as pharmacists in other relevant states who are visiting the State to provide the services of a registered pharmacist on a temporary and occasional basis and have satisfied the requirements of section 24A of this Act.

(3) A person shall no longer be entitled to provide services by virtue of sections 24A and 24B of this Act, nor shall he or she be entitled to retain registration under Part B of the Register of Pharmacists, if—

- (a) he or she becomes established in the State; or
- (b) he or she is subject to a decision of the competent authority of the relevant state in which he or she is established, which has the effect that he or she is no longer lawfully established in that state or that he or she is prohibited (even temporarily) from practicing there; or

- (c) he or she fails to provide the Council with a renewal declaration pursuant to subsection (3)(b)(iii) of section 24A of this Act, or
- (d) he or she is otherwise found by the Council to have infringed the disciplinary rules applicable to registered pharmacists in the State.

(4) Notwithstanding the provisions of Part 6 of this Act, the Council may cancel a registration under Part B of the Register of Pharmacists in any of the circumstances referred to in subsection (3) within two months of the date on which the information concerned becomes known to the Council.

(5) In this section—

- (a) expressions also used in section 16 have the same meaning as in that section;
- (b) expressions also used in section 24A have the same meaning as in that section;
- (c) expressions also used in the Professional Qualifications Directive have the same meaning as in that Directive.”.

10. Schedule 2 to the Pharmacy Act 2007 is amended by the substitution of the following paragraphs for paragraphs 1 to 5—

“1. (1) The Council is hereby designated as the competent authority in the State for the purposes of—

- (a) the Professional Qualifications Directive in so far as that Directive relates to the profession of pharmacist, and
- (b) the award of evidence of formal qualifications in pharmacy listed in relation to Ireland in Annex V, point 5.6.2 of the said Directive.

(2) The functions of the competent authority in the State under the Professional Qualifications Directive, insofar as that Directive relates to the profession of pharmacist, shall be performed by the Council.

(3) The aforementioned functions of the Council shall be performed in such a manner as to ensure that—

- (a) the relevant requirements of the EU Treaties are met,
- (b) the relevant requirements of the Professional Qualifications Directive are met, in particular, the requirements of Article 44 of the said Directive, and
- (c) the confidentiality of information received is maintained,

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

(4) In this paragraph, the expression ‘EU Treaties’ means the Treaties governing the European Communities as defined in the European Communities Acts 1972 to 2007.

2. (1) The Council shall acknowledge receipt of an application received under section 14 as read with section 16(2)(a) and, within 1 month of the date of its receipt, shall inform the applicant of any missing document(s).

(2) When considering an application to which subparagraph (1) of this paragraph applies, the Council may, in accordance with the provisions of Annex VII to the Professional Qualifications Directive—

- (a) demand the documents and certificates listed in that Annex, and
- (b) invite the applicant to provide information concerning his or her training to the extent necessary in order to determine the existence of potential substantial differences between it and the required national training, or if it is impossible for the applicant to provide such information, address the contact point, the competent authority, or any other relevant body in the relevant state.

(3) The documents referred to in point 1(d), (e) and (f) of Annex VII of the Professional Qualifications Directive shall not be more than 3 months old by the date on which they are submitted.

3. (1) Subject to the provisions of this paragraph, the Council shall determine an application for registration made under section 14 as read with section 16(2)(a), as soon as possible after receiving all documents prescribed for the purposes of determining the application or required by the Council under paragraph 2 of this Schedule and, in any event, within 3 months after such receipt.

(2) Where the Council has a reasonable and justified doubt in relation to an application under section 14 as read with section 16(2)(a), it may require of a competent authority of a relevant state—

- (a) confirmation of the authenticity of diplomas, certificates and other evidence of formal qualifications as a pharmacist issued in that state,
- (b) where applicable, confirmation that the applicant has fulfilled the minimum training requirements specified in Article 44 of the Professional Qualifications Directive.

(3) Where the Council has a reasonable and justified doubt in relation to an application pursuant to section 14 as read with section 16(2)(a) by a person whose evidence of formal qualifications was issued by a competent authority in relevant state and includes training received in whole or in part in an establishment legally established in the territory of another relevant state, the Council may verify with the competent authority in the state of origin of the award:

- (a) whether the training course at the establishment which gave the training has been formally certified by the educational establishment based in the state of origin of the award;
- (b) whether the evidence of formal qualifications issued is the same as that which would have been awarded if the course had been followed entirely in the state of origin of the award; and
- (c) whether the evidence of formal qualifications confers the same professional rights in the territory of the state of origin of the award.

(4) In the case of applications for registration by persons claiming to hold qualifications appropriate for practice by virtue of section 16(5), the Council shall determine such applications as soon as possible after receiving all documents prescribed for the purposes of determining the application or required by the Council under paragraph 2(2) of this Schedule and, in any event, within 4 months after such receipt.

4. Where an applicant is required to swear a solemn oath or make a sworn statement, the form of which is such that it cannot be taken or made by applicants of a relevant state, the Council shall ensure that an appropriate equivalent form of oath or declaration is available for those applicants.

5. A document submitted, as part of an application under section 14 as read with section 16(2)(a), as evidence that the applicant holds a formal qualification as a pharmacist in another relevant state, hereinafter referred to in this paragraph as a diploma, is only appropriate as evidence if—

- (a) in a case where the Council has justified doubts about the authenticity of the evidence of the diploma made available to the Council 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 Council has justified doubts about whether the holder of the diploma has completed training which satisfies the requirements of Article 44 of the Professional Qualifications 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 Council has justified doubts concerning training received in another relevant State other than that in which the diploma was awarded, and has required confirmation of the relevant competent authorities in accordance with paragraph 3(3) of this Schedule, the relevant competent authorities have provided confirmation in accordance with that paragraph 3(3).”.

PART 3

OTHER MISCELLANEOUS PROVISIONS

Transitional arrangements

11. (1) An application made under section 22A of the Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57), as inserted by Regulation 3(b) of the European Communities (Recognition of Qualifications in Pharmacy) Regulations 1987 (S.I. No. 239 of 1987), and which has not been determined prior to the commencement of these Regulations, shall be considered as if it were an application made under section 14 of the Pharmacy Act 2007 as read with section 16(2)(a) of that Act.

(2) An application made under section 22A of the Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57), as substituted by Regulation 6 of the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2008 (S.I. No. 167 of 2008), and which has not been determined prior to the commencement of these Regulations, shall be considered as if it were an application made under section 14 of the Pharmacy Act 2007 as read with section 16(2)(a) of that Act.

Revocations

12. The European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2008 (S.I. No. 167 of 2008) are hereby revoked.

National contact point and national co-ordinator designated in other Regulations

13. With the exception of Regulations 2(4) and 26 of the Recognition of Professional Qualifications (Directive 2005/36/EC) Regulations 2007 (S.I. No. 139 of 2008), the provisions of those Regulations, insofar as they relate to the profession of pharmacist, shall not apply.



GIVEN under my Official Seal,
28 November 2008

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Regulations replace the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2008 (S.I. No. 167 of 2008).

The main purpose of these Regulations is to implement, in the context of the Pharmacy Act 2007, Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications as amended by Council Directive 2006/100/EC of 20 November 2006, insofar as those Directives concern the profession of pharmacist.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
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