

# STATUTORY INSTRUMENTS

S.I. No. 167 of 2008

EUROPEAN COMMUNITIES (RECOGNITION OF PROFESSIONAL QUALIFICATIONS RELATING TO THE PROFESSION OF PHARMACIST) REGULATIONS 2008

(Prn. A8/0733)

# EUROPEAN COMMUNITIES (RECOGNITION OF PROFESSIONAL QUALIFICATIONS RELATING TO THE PROFESSION OF PHARMACIST) 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  $2005/36/EC^1$  as amended by Directive  $2006/100/EC^2$ , (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) Regulations 2008.

#### Commencement

2. These Regulations shall come into operation on the date they are signed by the Minister.

#### Interpretation

3. (1) In these Regulations—

'competent authority' means any authority or body empowered by a relevant state specifically to issue or receive training diplomas and other documents or information and to receive the applications, and take the decisions, referred to in the Professional Qualifications Directive in respect of the profession of pharmacist;

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

'EU Treaties' means the Treaties governing the European Communities as defined in the European Communities Acts 1972 to 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

<sup>1</sup>Official Journal of the European Communities L255, 30.09.2005, p.22. <sup>2</sup>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 10th June, 2008.

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.

*Responsibility and performance of functions relating to the profession of pharmacist under the Professional Qualifications Directive* 

4. (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, in so far 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 and including, 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.

### PART 2

### AMENDMENTS TO PHARMACY ACT (IRELAND) 1875

5. Section 3 of the Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57) is hereby amended by the addition of the following definitions:

"the term 'adaptation period' has the meaning assigned to it by subsection (7) of section 22A of this Act;

the term 'competent authority' means any authority or body empowered by a relevant state specifically to issue or receive training diplomas and other documents or information and to receive the applications, and take the decisions, referred to in the Professional Qualifications Directive in respect of the profession of pharmacist;

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

the term '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;

the term '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;

the term '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;

the term 'relevant state' means-

- (a) a Member State of the European Union,
- (b) a state that is a contracting state to the EEA Agreement within the meaning given by the European Communities (Amendment) Act 1993 (other than a Member State of the European Union),
- (c) the Swiss Confederation;

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

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

6. Section 22A of the Pharmacy Act (Ireland) 1875 (38 and 39 Vict. c.57) (as inserted by Regulation 3(b) of the European Communities (Recognition of Qualifications in Pharmacy) Regulations 1987 (No. 239 of 1987)) is hereby substituted by the following—

# "Automatic recognition

22A. (1) Every person, being a national of a relevant state, on making the prescribed application and on paying the prescribed fee and who at the time of such application provides evidence that he or she holds a formal qualification as a pharmacist, which is referred to in Annex V, point 5.6.2, of the Professional Qualifications Directive (and is accompanied, where appropriate, by the certificate listed therein) and satisfies the minimum training conditions referred to in Article 44 of that Directive, shall be entitled under this Act to be registered in the Register of Pharmaceutical Chemists for Ireland.

# Acquired rights

(2) Notwithstanding subsection (1), each of the following persons, on making the prescribed application and on paying the prescribed fee, shall be entitled under this Act to be registered in the Register of Pharmaceutical Chemists for Ireland:

- (a) a national of a relevant state who, at the time of the application, provides evidence of 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 holder 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;

- (b) subject to subsection (3), a national of a relevant state who, at the time of the application, provides evidence that he or she holds a formal qualification as a pharmacist issued by the former Czechoslovakia, or whose 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 qualifications 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;
- (c) subject to subsection (3), a national of a relevant state who, at the time of the application, provides evidence that he or she holds a formal qualification as a pharmacist issued by the former Soviet Union, or whose 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 qualifications 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;

- (d) subject to subsection (3), a national of a relevant state who, at the time of the application, provides evidence that he or she holds a formal qualification as a pharmacist issued by the former Yugoslavia, or whose 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 qualifications 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;
- (e) a national of a relevant state who, at the time of the application, provides evidence of formal qualifications 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.

(3) The attestation to be provided in paragraphs (b), (c) and (d) of subsection (2) of this section shall be accompanied by a certificate issued by the authorities who issued the attestation stating that those persons have 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.

# General system — persons who do not have the full acquired rights of 3 years experience

(4) Where a person makes an application pursuant to subsection (2) of this section and the person does not meet the requirements of effective and lawful professional practice referred to in that subsection, such person shall, on completion of an adaptation period as may be required by the Council having regard to Articles 14(1), 14(4) and 14(5) of the Professional Qualifications Directive,

be entitled to be registered under this Act in the Register of Pharmaceutical Chemists for Ireland.

# General system — third country qualifications recognised in another Member State with 3 years experience in that State

(5) Every person, being a national of a relevant state, on making the prescribed application and on paying the prescribed fee, and who at the time of such application provides evidence of 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, shall be entitled to be registered under this Act in the Register of Pharmaceutical Chemists for Ireland where the requirements of subsection (6) are met.

(6) For the purposes of applications made under subsection (5) of this section, the applicant must—

- (a) possess 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;
- (b) in the initial recognition by the competent authority of the other relevant state, have satisfied the minimum training requirements specified in Article 44 of the Professional Qualifications Directive; and
- (c) complete an adaptation period, as may be required by the Council having regard to Articles 14(1), 14(4) and 14(5) of the Professional Qualifications Directive.
- (7) (*a*) In this section 'adaptation period' means a period of pursuit of the profession of pharmacist in the State under the supervision of a registered pharmaceutical chemist,
  - (b) The adaptation period shall be set having regard to the professional knowledge of the applicant and shall not exceed a period of 3 years.
  - (c) 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.
  - (*d*) The Council may, in the circumstances where it considers it necessary to do so, require the applicant to undergo further training during the adaptation period.

(e) 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) In order to pursue the profession of a pharmaceutical chemist in the State, persons registered under this section must have a knowledge of the Irish or English languages sufficient for that purpose.

(9) In this section, the term "prescribed" means prescribed by the Council of the Pharmaceutical Society of Ireland in regulations made with the approval of the Minister for Health and Children under the Pharmacy Acts 1875 to 1977.".

7. The Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57) is hereby amended by the insertion of the following new section after section 22A—

### "Visiting European pharmacists

22B (1) Subject to the provisions of this section and section 22C of this Act, 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 pharmaceutical chemist, 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 pharmaceutical chemist 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 pharmaceutical chemist 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 pharmaceutical chemist, 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 pharmaceutical chemist 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 service, give the person the opportunity to show that he or she has acquired the knowledge or competence lacking where:

- 10 **[167]** 
  - (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 pharmaceutical chemist 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 its decision:
    - (i) 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 pharmaceutical chemist in the State which are directly linked to the professional qualification, including disciplinary provisions.

(10) Persons providing services in the State pursuant to this section must have a 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;

'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 pharmaceutical chemist 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 pharmaceutical chemist 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.".

8. The Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57) is hereby amended by the insertion of the following new section after section 22B—

#### "Division of Register for visiting European pharmacists

22C. (1) The Register referred to in section 24 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 Pharmaceutical Chemists for Ireland, the names of persons legally established as pharmacists in other relevant states who are visiting the State to provide the services of a pharmaceutical chemist on a temporary and occasional basis and have satisfied the requirements of section 22B of this Act.

(3) A person shall no longer be entitled to provide services by virtue of sections 22B and 22C of this Act, nor shall he or she be entitled to retain registration under Part B of the Register of Pharmaceutical Chemists for Ireland, 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 22B of this Act, or
- (*d*) he or she is otherwise found by the Council to have infringed the disciplinary rules applicable to pharmaceutical chemists in the State.

(4) Notwithstanding section 25 of this Act, the Council may cancel a registration 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.".

9. The Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c. 57) is hereby amended by the insertion of the following new section after section 22C—

#### "Documentation and formalities

22D. (1) The Council shall acknowledge receipt of an application received under section 22A of this Act within 1 month of the date of its receipt and shall inform the applicant of any missing document(s).

(2) When considering an application under section 22A of this Act, the Council may, in accordance with the provisions of Annex VII of 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.

(4) Subject to subsections (5), (6) and (8) of this section, the Council shall determine an application for registration made under section 22A of this Act as soon as possible after receiving all documents prescribed for the purposes of determining the application or required by the Council under subsection (2) of this section and, in any event, within 3 months after such receipt.

(5) Where the Council has a reasonable and justified doubt in relation to an application under section 22A of this Act 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) confirmation that the applicant has fulfilled the minimum training requirements specified in Article 44 of the Professional Qualifications Directive.

(6) Where the Council has a reasonable and justified doubt in relation to an application pursuant to section 22A by a person whose evidence of formal qualifications was issued by a competent authority in a 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.

(7) 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.

(8) In the case of applications made under subsections (4) and (5) of Section 22A of this Act, 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 subsection (2) of this section and, in any event, within 4 months after such receipt.

(9) A document submitted, as part of an application under section 22A of this Act as evidence that the applicant holds a formal qualification as a pharmacist in another relevant state, hereinafter referred to in this subsection 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 subsection (6) of this section, the relevant competent authorities have provided confirmation in accordance with that subsection.".

# PART 3

#### OTHER MISCELLANEOUS PROVISIONS

#### False declarations

10. (1) Any person who procures or attempts to procure registration in the Register of Pharmaceutical Chemists for Ireland under sections 22A or 22B of the Pharmacy Act (Ireland) 1875, by making or producing or causing to be made or produced any false or fraudulent representation or declaration, either orally or in writing, shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €3,000 or to imprisonment for a term not exceeding 6 months or to both.

(2) An offence under paragraph (1) may be prosecuted by the Council.

(3) Subject to this Regulation, the Council may cancel a registration where it is satisfied that—

- (*a*) the registration in question was obtained in reliance upon a representation or declaration in respect of which a person has been convicted of an offence under this Regulation, or
- (b) information in reliance upon which the registration concerned has been obtained is not correct or is not correct in a material particular and that the experience or qualifications to which the representation or declaration attests have not been attained.

(4) Where the Council proposes to cancel a registration, it shall, by notice in writing to the person concerned,—

- (a) inform him or her of its intention to cancel the registration and the reasons for this,
- (b) identify—
  - (i) the false representations or declarations in respect of which he or she has been convicted of an offence, or
  - (ii) the incorrect information,

and

(c) invite him or her to make representations to the Council within 30 days of the date of the notice.

(5) If, at the end of the period provided for in paragraph (4)(c), the Council, having considered any representations made to it by or on behalf of the person concerned, remains of the view that the registration should be cancelled, then the Council may, by notice in writing, cancel the registration and state the reasons for the cancellation.

### Appeals to High Court

11. (1) If the Council refuses an application for registration in the Register of Pharmaceutical Chemists for Ireland under section 22A or section 22B of the Pharmacy Act (Ireland) 1875 or cancels a registration under Regulation 10, it shall notify the applicant in writing of its decision, the reason for it and the date when it was made.

(2) Any person whose application for registration as aforesaid is refused, or is not the subject of a determination by the Council within the applicable time period provided for under subsections (4) or (8) of section 22(D) of the Pharmacy Act (Ireland) 1875, or whose registration is cancelled by the Council under Regulation 10, may appeal to the High Court against the refusal, failure to make a determination, or cancellation, within—

- (*a*) in the case of a refusal or cancellation, a period of 3 months beginning on the date of receipt of the notification under paragraph (1), or
- (b) in the case of an absence of a determination, a period of 3 months of the last day on which under subsection (4) of section 22(D), or as the case may be under subsection (8) of the said section, the relevant determination was required to have been made by the Council.
- (3) On an appeal under this Regulation, the High Court may make—
  - (a) an order affirming the refusal or cancellation,
  - (b) an order setting aside the refusal or cancellation and requiring the Council to proceed with or to restore the registration,
  - (c) an order (with or without directions) remitting the refusal or cancellation to the Council for reconsideration and the making of a new decision, or
  - (d) any other order that it considers appropriate.

#### Transitional arrangements

12. (1) An application made under section 22A of the Pharmacy Act (Ireland) 1875 (38 & 39 Vict. c57) (as inserted by Regulation 3(b) of the European Communities (Recognition of Qualifications in Pharmacy) Regulations 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 22A of the aforementioned Act as that section has been substituted by Regulation 6.

(2) Subject to paragraph 3, regulations made, wholly or partly, under the aforementioned section 22A of the Pharmacy Act (Ireland) 1875, and in force immediately before the commencement of these Regulations, shall continue in force after such commencement as if made under the said section 22A (as substituted by Regulation 6).

(3) Every reference in the Regulations referred to in paragraph (2) to Council Directives 85/432/EEC and 85/433/EEC shall be construed as references to the Professional Qualifications Directive insofar as that Directive relates to the profession of pharmacist, and every reference in those Regulations to the provisions of the Pharmacy Act (Ireland) 1875 shall be construed as a reference to the provisions of that Act as amended by these Regulations.

#### Revocations and amendments

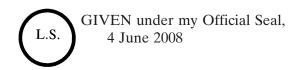
13. (1) The European Communities (Recognition of Qualifications in Pharmacy) Regulations 1987 to 2004 are hereby revoked.

(2) The definitions inserted into section 3 of the Pharmacy Act (Ireland) 1875, by Regulation 3(a) of the European Communities (Recognition of Qualifications in Pharmacy) Regulations 1987, are hereby deleted.

(3) Schedule 2 of the Pharmacy Act (Ireland) 1875, inserted by Regulation 3(c) of the European Communities (Recognition of Qualifications in Pharmacy) Regulations 1987, is hereby deleted.

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

14. 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.



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)

The purpose of these Regulations is to implement 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 Le ceannach díreach ón OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS, TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2, nó tríd an bpost ó FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA, AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS, CONTAE MHAIGH EO, (Teil: 01 - 6476834/37 nó 1890 213434; Fax: 01 - 6476843 nó 094 - 9378964) nó trí aon díoltóir leabhar.

> DUBLIN PUBLISHED BY THE STATIONERY OFFICE To be purchased directly from the GOVERNMENT PUBLICATIONS SALE OFFICE SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2, or by mail order from GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION, UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO, (Tel: 01 - 6476834/37 or 1890 213434; Fax: 01 - 6476843 or 094 - 9378964) or through any bookseller.



€4.06

Wt. (B25923). 285. 6/08. Cahill. Gr. 30-15.