

## 1987 No. 457

## PHARMACY

**The Pharmaceutical Qualifications (EEC Recognition) Regulations (Northern Ireland) 1987**

*Made* . . . . . 21st December 1987

*Coming into operation* . . . . . 29th January 1988

The Department of Health and Social Services, being a department designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) 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, in exercise of the powers conferred on it by the said section 2(2) and of every other power enabling it in that behalf, hereby makes the following regulations:—

*Citation, commencement and interpretation*

1.—(1) These regulations may be cited as the Pharmaceutical Qualifications (EEC Recognition) Regulations (Northern Ireland) 1987 and shall come into operation on 29th January 1988.

(2) The Interpretation Act (Northern Ireland) 1954(c) shall apply to these regulations as it applies to a Measure of the Northern Ireland Assembly.

*Amendment of the Pharmacy (Northern Ireland) Order 1976*

2.—(1) The Pharmacy (Northern Ireland) Order 1976(d) shall be amended as follows.

(2) In Article 2(2) (interpretation) after the definition of “member” there shall be inserted the following definition—

“ “national”, in relation to a member State, means the same as in the Community Treaties, but does not include a person who by virtue of Article 2 of Protocol No. 3 (Channel Islands and Isle of Man) to the Treaty of Accession(e) is not to benefit from Community provisions relating to the free movement of persons and services;”.

(3) In Article 8(2) (qualifications for registration as pharmaceutical chemist), after sub-paragraph (b) there shall be added the following sub-paragraph—

“(c) every person who, being a national of a member State, holds an appropriate European diploma.”.

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(a) S.I. 1987 No. 448

(b) 1972 c. 68

(c) 1954 c. 33 (N.I.)

(d) S.I. 1976/1213 (N.I. 22)

(e) See Cmnd. 5179-I p. 247

(4) In Article 8(4) (registration of members of pharmaceutical societies outside Northern Ireland), after the words “(other than a person such as is described in paragraph 2(a))” there shall be inserted “or (c)”.

(5) After Article 8 there shall be inserted the following Article—

*“Registration by virtue of appropriate European diploma*

**8A.**—(1) Where a person is registered by virtue of Article 8(2)(c) an indication that he has been registered in respect of an appropriate European diploma shall be entered in the register against his name.

(2) Subject to paragraphs (3) to (5), the following diplomas are appropriate European diplomas for the purposes of Article 8(2)(c), namely—

- (a) any diploma specified in Schedule 2A; and
- (b) any diploma in pharmacy which is not so specified but has been granted in a member State either before the implementation date or to a person who commenced the training of which the diploma is evidence before that date.

(3) A diploma granted in a member State before the implementation date or granted to a person who began the training of which the diploma is evidence before that date is not an appropriate European diploma for the purposes of Article 8(2)(c) unless—

- (a) in the case of a diploma specified in Schedule 2A, either—
  - (i) the diploma guarantees that the holder of the diploma has undergone training that would have satisfied the requirements laid down by the Pharmacists Training Directive; or
  - (ii) the competent authorities of any member State have certified that the holder of the diploma has lawfully practised pharmacy for at least three consecutive years during the five years preceding the date of the certificate; or
- (b) in the case of any diploma which is not so specified, the competent authorities of any member State have certified as mentioned in sub-paragraph (a)(ii).

(4) Where under Article 11 it falls to the registrar or the Council to determine whether or not any of the conditions specified in paragraph (3) is satisfied in relation to any diploma—

- (a) the satisfaction of the condition specified in sub-paragraph (a)(i) of the said paragraph (3) may be established by the production of a certificate of the competent authorities of the member State in relation to which the diploma is specified in Schedule 2A, or otherwise; and
- (b) the satisfaction of the condition specified in sub-paragraph (a)(ii) or (b) of the said paragraph (3) shall be established by the production of the relevant certificate, and not otherwise.

(5) Where at any time during the period of the Greek derogation any person is registered in respect of the qualification specified in paragraph 5 of Schedule 2A or in respect of any other diploma awarded in the Hellenic Republic—

- (a) an indication that the registration is subject to the provisions of this paragraph shall be entered in the register against that person's name; and
- (b) the registration shall not authorise the person whose name is registered to do anything for which registration is required by any provision made by or under the Medicines Act 1968(a), the Misuse of Drugs Act 1971(b) or the Poisons (Northern Ireland) Order 1976(c), except as an employed person.

(6) In this Article and Schedule 2A—

“competent authorities”, in relation to a member State, means any authority or body designated by that member State in accordance with Community Council Directive No. 85/433/EEC(d), as amended by Community Council Directive No. 85/584/EEC(e), concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy;

“employed person” means an employed person in accordance with Council Regulation (EEC) No. 1612/68(f) on freedom of movement for workers within the Community;

“the implementation date”, in relation to a member State, means the date on which that State implemented the Pharmacists Training Directive;

“the period of the Greek derogation” means the period during which the Hellenic Republic makes use of the derogation provided by paragraph 1 of Article 3 of Community Council Directive No. 85/433/EEC; and

“the Pharmacists Training Directive” means Community Council Directive No. 85/432/EEC(g) concerning the co-ordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy.

(7) For the purposes of this Article a member State is to be regarded as having implemented the Pharmacists Training Directive on the date notified to the Commission of the European Communities as that on which it did so.”

(6) In Article 14 (certificates of registration), after paragraph (2) there shall be inserted the following paragraph—

“(2A) Any certificate of registration issued to any person under this Article shall reproduce any indication entered in the register against that person's name in pursuance of Article 8A(1) or (5)(a).”

(7) In Article 20 (removal of registered persons from, and restoration to, register), after paragraph (6) there shall be inserted the following paragraphs—

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(a) 1968 c. 67

(b) 1971 c. 38

(c) S.I. 1976/1214 (N.I. 23)

(d) O.J. No. L253, 24.9.85, p. 37

(e) O.J. No. L372, 31.12.85, p. 42

(f) O.J. No. L257, 19.10.68, p. 2 (O.J./S.E. 1968 (II) p. 475)

(g) O.J. No. L253, 24.9.85, p. 34

“(6A) Where the Statutory Committee are satisfied that any person is subject to a disqualifying decision the Committee shall be entitled to exercise their powers under paragraph (1), (5) or (6) in relation to that person on the assumption that the grounds on which the decision was expressed to be made constitute such misconduct rendering that person unfit to be or (as the case may be) remain on the register as would (apart from this paragraph) justify the exercise of those powers.

(6B) For the purposes of this Article a person is subject to a disqualifying decision if—

- (a) a decision is made in respect of that person by responsible authorities in a member State other than the United Kingdom;
- (b) that decision has the effect in that State either that that person ceases to be registered or otherwise officially recognised to practise pharmacy in that State or that he is prohibited from practising pharmacy there; and
- (c) that decision is expressed to be made on the grounds that that person has committed a criminal offence or has been guilty of any misconduct.”

(8) After Schedule 2 there shall be inserted the following Schedule—

#### “SCHEDULE 2A

##### QUALIFYING EUROPEAN DIPLOMAS

###### *Belgium*

1. Le diplôme légal de pharmaciens/het wettelijk diploma van apotheker (the legal diploma in pharmacy) awarded by the faculties of medicine and pharmacy of the Universities, by the Central examining board or by the State examining boards for university education.

###### *Denmark*

2. Bevis for bestået farmaceutisk kandidateksamen (the university pharmacy certificate).

###### *France*

3. The State diploma in pharmacy awarded by the universities or the State diploma of Doctor in Pharmacy awarded by the universities.

###### *Germany*

4.—(1) Zeugnis über die staatliche Pharmazeutische Prüfung (the State examination certificate in pharmacy) awarded by the competent authorities.

(2) Certificates from the competent authorities of the Federal Republic of Germany stating that the diplomas awarded after 8th May 1945 by the competent authorities of the German Democratic Republic are recognised as equivalent to those referred to in sub-paragraph (1).

5. Πιστοποιητικό των αρμοδίων αρχών, ικανότητας άσκησης της φαρμακευτικής, χορηγούμενο μετά κρατική εξέταση (the certificate attesting competence to pursue the activity of a pharmacist) issued by the competent authorities following a State examination.

*Ireland*

6. The certificate of Registered Pharmaceutical Chemist.

*Italy*

7. The diploma or certificate giving the right to practise pharmacy, obtained by passing a State examination.

*Luxembourg*

8.—(1) The State pharmacy diploma awarded by the State Examining Board and signed by the National Minister of Education.

(2) A diploma conferring on a national of the Grand Duchy a degree in respect of pharmacy which—

- (a) has been granted otherwise than in a member State;
- (b) is accorded official recognition by the National Minister for Education in accordance with the law of the Grand Duchy of 1st June 1969 on higher education and the recognition of foreign degrees and diplomas; and
- (c) is approved for the purposes of Article 8(2)(c) by the Council.

*The Netherlands*

9. Het getuigschrift van met goed gevolg afgelegd apothekersexamen (the university pharmacy certificate).

*Portugal*

10. Carta de curso de licenciatura em Ciências Farmacêuticas (the certificate in pharmaceutical sciences awarded by the universities).

*Spain*

11. Título de licenciado en farmacia (university degree in pharmacy awarded by the Ministry of Education and Science or by the universities)."

*Amendment of the Medicines Act 1968*

3. In sections 70(1) and 71(1) of the Medicines Act 1968(a) (conditions imposed on the carrying on of a retail pharmacy business)—

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(a) 1968 c. 67; sections 70(1) and 71(1) were amended by S.I. 1987/2202, Article 3

- (a) for the words “or any corresponding provision applying to Northern Ireland” there shall be substituted the words “or Article 8(2)(c) of the Pharmacy (Northern Ireland) Order 1976”; and
- (b) the words “in Great Britain” shall cease to have effect.

*Amendment of the Health and Personal Social Services (Northern Ireland) Order 1972*

4. In Article 63(2B) of the Health and Personal Social Services (Northern Ireland) Order 1972(a) (matters which may be included in regulations relating to arrangements for pharmaceutical services), after paragraph (b) there shall be inserted the following sub-paragraph:—

“(ba) that an application to a Health and Social Services Board by a person who qualified to have his name registered under the Pharmacy (Northern Ireland) Order 1976 by virtue of Article 8(2)(c) of that Order (qualification by European diploma) shall not be granted unless the applicant satisfies the Board that he has the knowledge of English which, in the interests of himself and the persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Board’s area;”.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 21st December 1987.

(L.S.)

*G. Buchanan*

Under Secretary

## EXPLANATORY NOTE

*(This note is not part of the Regulations.)*

These regulations which are made under the European Communities Act 1972 and come into operation on 29th January 1988 affect nationals of member States. They implement the provisions of Council Directive No. 85/433/EEC (O.J. No. L253, 24.9.85, p. 37) as amended by Council Directive No. 85/584/EEC (O.J. No. L372, 31.12.85, p. 42) concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy.

Regulation 2 inserts new sub-paragraph (c) to Article 8(2) and a new Article 8A and Schedule 2A into the Pharmacy (Northern Ireland) Order 1976. It also amends Article 20 of that Order and makes consequential amendments. The new Article 8(2)(c) gives pharmacists who hold an appropriate European diploma the right to be registered under that Article and the new Article 8A defines that qualification. The new Schedule 2A lists the European diplomas giving right to registration. It is also provided, in pursuance of Article 3 of Directive No. 85/433/EEC, that during the period of the Greek derogation registration by virtue of the Greek qualification is effective for purposes of compliance with certain named enactments only when a person so registered is acting in an employed capacity. The new Article 20(6A) deals with the effect on registration in Northern Ireland of disqualification in another member State other than the United Kingdom.

Regulation 3 amends sections 70(1) and 71(1) of the Medicines Act 1968 which specify conditions in respect of individual pharmacists, partners and bodies corporate, carrying on a retail pharmacy business. The amendments impose the additional condition that such business is not under the personal control of a pharmacist who is qualified by virtue of Article 8(2)(c) of the Pharmacy (Northern Ireland) Order 1976 or section 4A of the Pharmacy Act 1954 (qualification by European diploma), in relation to premises in Northern Ireland which have been registered pharmacies for less than 3 years.

Regulation 4 amends Article 63(2B) of the Health and Personal Social Services (Northern Ireland) Order 1972 which provides power to make regulations as to pharmaceutical services. The amendment enables regulations to be made requiring the Health and Social Services Boards to satisfy themselves that a pharmacist qualified to have his name registered by virtue of the new Article 8(2)(c) and wishing to provide pharmaceutical services has a sufficient knowledge of English for that purpose.