## STATUTORY INSTRUMENTS

## 1987 No. 2202

## **MEDICINES**

## NATIONAL HEALTH SERVICE, ENGLAND AND WALES

## NATIONAL HEALTH SERVICE, SCOTLAND PHARMACISTS

The Pharmaceutical Qualifications (EEC Recognition)
Order 1987

Made - - -

18th December 1987

Coming into force

28th December 1987

At the Court at Buckingham Palace, the 18th day of December 1987 Present,

The Queen's Most Excellent Majesty in Council

Whereas a draft of this Order has been laid before Parliament and has been approved by a resolution of each House of Parliament:

Now, therefore, Her Majesty, in exercise of the powers conferred on Her by section 2(2) of the European Communities Act 1972(a), is pleased, by and with the advice of Her Privy Council, to order, and it is hereby ordered, as follows:—

#### Citation and commencement

1. This Order may be cited as the Pharmaceutical Qualifications (EEC Recognition) Order 1987 and shall come into force on 28th December 1987.

#### Amendment of the Pharmacy Act 1954

- 2.—(1) The Pharmacy Act 1954(b) shall be amended as follows.
- (2) In section 2(2) (entitlement to registration of persons qualified for registration in accordance with section 3 or byelaws made under section 4), for the words "the next following section" there shall be substituted the words "section 3 or 4A of this Act".

<sup>(</sup>a) 1972 c.68.

**<sup>(</sup>b)** 1954 c.61.

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- (3) In section 4 (qualification by degree, diploma etc. for registration), after subsection (2) there shall be inserted the following subsection—
  - "(3) The references in subsection (1) above to a diploma granted in respect of pharmacy in any place outside the United Kingdom shall not include references to a diploma by which a person is qualified by virtue of section 4A(2)(a) of this Act to have his name registered."
  - (4) After the said section 4 there shall be inserted the following section-
    - 4A.—(1) Any national of a member State who holds an appropriate European diploma and satisfies such conditions (if any) as to character and as to physical and mental health as may be prescribed shall be qualified to have his name registered; and where a name is registered by virtue of this section an indication that the name has been registered in respect of an appropriate European diploma shall be entered in the register against that name.

"Qualification by appropriate European diploma for registration

- (2) Subject to subsections (3) to (5) of this section, the following diplomas are appropriate European diplomas for the purposes of this section, namely-
  - (a) any diploma specified in Schedule 1A to this Act; 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 this section unless—
  - (a) in the case of a diploma specified in Schedule 1A to this Act, 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 paragraph (a)(ii) of this subsection.
- (4) Where under subsection (2) of section 2 of this Act it falls to the registrar or the Council to determine whether or not any of the conditions specified in subsection (3) of this section is satisfied in relation to any diploma—
  - (a) the satisfaction of the condition specified in paragraph (a)(i) of the said subsection (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 1A to this Act, or otherwise; and
  - (b) the satisfaction of the condition specified in paragraph (a)(ii) or (b) of the said subsection (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 the name of any person is registered in respect of the qualification specified in paragraph 5 of Schedule 1A to this Act 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 subsection shall be entered in the register against that 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

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under the Medicines Act 1968(a), the Misuse of Drugs Act 1971(b) or the Poisons Act 1972(c), except as an employed person.

(6) In this section and Schedule 1A to this Act-

"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 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;

"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(g) is not to benefit from Community provisions relating to the free movement of persons and services;

"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(h) 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 section 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."
- (5) In section 5 (certificates of registration), after subsection (2) there shall be inserted the following subsection-
  - "(3) Any certificate of registration issued to any person under this section shall reproduce any indication entered in the register against that person's name in pursuance of section 4A(1) or (5)(a) of this Act."
- (6) In section 8 (control of registrations by Statutory Committee), after subsection (1) there shall be inserted the following subsections-
  - "(1A) Where the Statutory Committee is satisfied that any person is subject to a disqualifying decision the Committee shall be entitled to exercise its powers under subsection (1) of this section 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 have his name on the register as would (apart from this subsection) justify the exercise of those powers.
  - (1B) For the purposes of this section 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;

<sup>(</sup>a) 1968 c.67.

**<sup>(</sup>b)** 1971 c.38.

<sup>(</sup>c) 1972 c.66.

<sup>(</sup>d) OJ No. L253, 24.9.85, p. 37. (e) OJ No. L372, 31.12.85, p. 42. (f) OJ No. L257, 19.10.68, p. 2 (OJ/SE 1968 (II) p. 475).

<sup>(</sup>g) See Cmnd 5179-I, p. 247.

<sup>(</sup>h) OJ No. L253, 24.9.85, p. 34.

- (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."; and, accordingly, in subsection (2) of that section for the words "the last foregoing subsection" there shall be substituted the words "subsection (1) of this section".
- (7) After Schedule 1 there shall be inserted the following Schedule-

### "SCHEDULE 1A

### QUALIFYING EUROPEAN DIPLOMAS

#### Belgium

1. Le diplôme légal de pharmacien/het wettelijk diploma van apoteker (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 8 May 1945 by the competent authorities of the German Democratic Republic are recognized as equivalent to those referred to in sub-paragraph (1) above.

#### Greece

5. Πιατοποιητικό των αρμοδίων αρχών, ικανότητας άσκησης της φαρμακευτικης, 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 section 4A of this Act by the Council.

#### The Netherlands

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

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#### 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.—(1) In subsection (1) of section 70 of the Medicines Act 1968(a) (conditions imposed on the carrying on by an individual or partnership of a retail pharmacy business), after paragraph (b) there shall be inserted the following words—

"and that it is the personal control of persons none of whom is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (qualification by European diploma), or any corresponding provision applying to Northern Ireland, which fulfils the condition imposed by virtue of paragraph (a) above in relation to such of those premises in Great Britain as have been registered pharmacies for less than three years."

- (2) In subsection (1) of section 71 of that Act (conditions imposed on the carrying on of a retail pharmacy business by a body corporate)—
  - (a) the word "and", in the second place where it occurs, shall be omitted; and
  - (b) after paragraph (b) there shall be inserted the following words-

"and that it is the personal control of persons none of whom (whether the superintendent or a manager or assistant) is a pharmacist by virtue of section 4A of the Pharmacy Act 1954, or any corresponding provision applying to Northern Ireland, which fulfils the condition imposed by virtue of paragraph (a) above in relation to such of those premises in Great Britain as have been registered pharmacies for less than three years."

## Amendment of the National Health Service Act 1977

- 4. In section 42(3) of the National Health Service Act 1977(b) (matters that may be included in the regulations which provide for the inclusion of registered pharmacists in lists of persons providing pharmaceutical services), after paragraph (b) there shall be inserted the following paragraph—
  - "(ba) that an application to a Committee by a person who qualified to have his name registered under the Pharmacy Act 1954 by virtue of section 4A of that Act (qualification by European diploma) shall not be granted unless the applicant satisfies the Committee that he has the knowledge of English which, in the interests of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Committee's locality."

#### Amendment of the National Health Service (Scotland) Act 1978

5. In section 27(4) of the National Health Service (Scotland) Act 1978(c) (matters that may be included in the regulations which provide for the inclusion of registered pharmacists in lists of persons providing pharmaceutical services), after paragraph (b) there shall be inserted the following paragraph—

"(ba) that an application to a Health Board by a person who qualified to have his name registered under the Pharmacy Act 1954 by virtue of section 4A of that Act (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

<sup>(</sup>a) 1968 c.67.

<sup>(</sup>b) 1977 c.49; section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1) and (2).

<sup>(</sup>c) 1978 c.29; section 27 was amended by the National Health Service Amendment Act 1986 (c.66), section 3(3).

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making use of the services to which the application relates, is necessary for the provision of pharmaceutical services in the Board's area."

G. I. de Deney Clerk of the Privy Council

#### **EXPLANATORY NOTE**

(This note is not part of the Order)

This Order which is made under the European Communities Act 1972 and comes into force on 28th December 1987 affects nationals of member States. It implements the provisions of Council Directive 85/433/EEC (OJ No. L 253, 24.9.85, p.37) as amended by Council Directive 85/584/EEC (OJ No. L372, 31.12.85, p.42) concerning the mutual recognition of diplomas certificates and other evidence of formal qualifications in pharmacy.

Article 2 inserts new section 4A and Schedule 1A into the Pharmacy Act 1954. It also amends section 8 of that Act and makes consequential amendments. The new section 4A gives pharmacists with defined qualifications the right to be registered under that section and the new Schedule 1A lists the European diplomas giving right to registration. It is also provided in pursuance of Article 3 of Directive 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 section 8(1A) deals with the effect on registration of disqualification in a member State other than the United Kingdom.

Article 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 section 4A of the Pharmacy Act 1954 (qualification by European diploma), or any corresponding provision applying to Northern Ireland, in relation to premises in Great Britain which have been registered pharmacies for less than 3 years.

Articles 4 and 5 amend section 42 of the National Health Service Act 1977 and section 27 of the National Health Service (Scotland) Act 1978 respectively, which sections provide power to make regulations as to pharmaceutical services. The amendments enable regulations to be made requiring the statutory bodies who are responsible for making arrangements for the provision of pharmaceutical services under those Acts, to satisfy themselves that a pharmacist qualified to have his name registered by virtue of the new section 4A and wishing to provide such services has a sufficient knowledge of English for that purpose.