STATUTORY RULES OF NORTHERN IRELAND

2012 No. 308

PHARMACY

The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012

Laid before the Assembly in draft

Made - - - - 3rd August 2012

Coming into operation in accordance with Article 1

The Department of Health, Social Services and Public Safety(**1**) makes the following Order in exercise of the powers conferred on it by section 56 of, and Schedule 4 to, the Health and Personal Social Services Act (Northern Ireland) 2001(**2**).

In accordance with paragraph 9(2) of Schedule 4 to that Act the Department of Health, Social Services and Public Safety has published a draft of this Order and invited representations to be made to it about the draft by—

(i) persons appearing to the Department appropriate to represent the profession,

(ii) persons appearing to the Department appropriate to represent those provided with services by the profession, and

(iii) any other person appearing to the Department appropriate to consult about the draft.

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 and, subject to paragraph 2, shall come into operation on 1st October 2012.

(2) Article 4, in so far as it relates to Article 4A of the principal Order, shall come into operation on 1st June 2013.

(3) In this Order—

"the Department" means the Department of Health, Social Services and Public Safety;

"the principal Order" means the Pharmacy (Northern Ireland) Order 1976(**3**).

(**1**) S.I. 1999/283 (N.I. 1) Article 3(6)
(**2**) 2001 c.3 (N.I.)
(**3**) S.I. 1976/1213 (N.I.22) as amended by 1981 c.45 & c.55; 1983 c. 54; S.I.1984/703 (N.I.3); S.R. 1987 No.457; S.I. 1994/429 (N.I. 2); S.R.1996 No.393; 2004 c.33; S.R. 2004 No.78 and S.R. 2008 No.192

Amendment to Article 2 of the principal Order

2. In Article 2(2) of the principal Order (Interpretation)—

(a) after the definition of "the Directive"(**4**) insert—

""electronic communication" has the meaning given in section 15(1) of the Electronic Communications Act (Northern Ireland) 2001(**5**) (general interpretation);"

(b) after the definition of "General Systems Regulations" (**6**) insert—

""lay member" means a person who–

(a) is not and has never been a registered person: and

(b) does not hold qualifications which would entitle him to apply for registration under this Order."

(c) after the definition of "the reference date"(**7**) insert—

""regulatory body" means a regulatory body which has the function of authorising persons to practise as a member of a health or social care profession;"

(d) after the definition of "retail pharmacy business" insert—

""Scrutiny Committee" means the committee established under paragraph 2(4) of Schedule 2;".

Amendment to Article 4 of the principal Order

3. In Article 4 of the principal Order (The Council) for paragraph (2) substitute the following paragraph—

"(2) The provisions of Schedule 2 shall have effect with respect to the Council."

4. After Article 4 of the principal Order (The Council) insert the following Articles—

"**Continuing professional development**

4A.—(1) The Council shall—

(a) set the standards of proficiency for the safe and effective practise of pharmacy which it is necessary for a registered person to maintain in order for their name to be retained in the register; and

(b) set the standards of continuing professional development which it is necessary for a registered person to maintain in order to continue to meet the standards of proficiency referred to in sub-paragraph (a);

(2) The Council shall keep the standards set under this Article under review and may vary or withdraw those standards whenever it considers it appropriate to do so.

(3) The Council must publish the standards set under this Article, as they exist from time to time, in such manner as it considers appropriate.

(4) Before varying or withdrawing the standards referred to in paragraph (1), the Council shall consult such persons as it considers appropriate.

(5) The Council shall—

(**4**) Definition inserted by regulation 3(b) S.R. 2008 No. 192
(**5**) 2001 c.9 (N.I.)
(**6**) Definition inserted by regulation 3(c) S.R. 2008 No.192
(**7**) Definition inserted by regulation 3(g) S.R. 2008 No.192

(a) consult such persons as it considers appropriate about the development of criteria by reference to which compliance with the standards set under paragraph (1)(b) is to be monitored, and

(b) publish those criteria as they exist from time to time in such manner as it considers appropriate.

(6) The Council shall—

(a) adopt and maintain a framework relating to the requirements and conditions to be met by registered persons in respect of their continuing professional development; and

(b) require registered persons—

(i) to complete an annual declaration regarding their compliance with such requirements and conditions in respect of their continuing professional development as they are obliged to meet by that framework, and

(ii) to submit records about any continuing professional development undertaken by them to the registrar for review.

(7) The framework adopted by the Council under paragraph (6)(a)—

(a) must include provision relating to—

(i) the amount and type of continuing professional development that a registered person is required to undertake,

(ii) the information to be provided by a registered person about the continuing professional development that the registered person has undertaken and the form and manner in which that information is to be provided,

(iii) the times at which information about the continuing professional development that a registered person has undertaken is to be provided (including any continuing professional development that relates to an annotation in respect of a particular specialist area of practice that is to be recorded against the registered person's name in the register),

(iv) the keeping of records about the continuing professional development undertaken by registered persons; and

(b) must require that any continuing professional development that is undertaken by a registered person in accordance with it is relevant to—

(i) the safe and effective practice of pharmacy, and

(ii) a learning need for the individual registered person that is relevant to the current scope of the practice of pharmacy including any specialist area of practice of that individual registered person and the environment in which they practise;

(c) in so far as it relates to a person ("P") who is a registered person only as a result of being registered in the register mentioned in Article 6(1)(d)—

(i) may not impose requirements on P if P is required to undertake, in P's home State, continuing professional development in relation to the profession of pharmacy; and

(ii) where they impose requirements on P—

(aa) must take account of the fact that P is fully qualified to pursue the profession in P's home State, and

(bb) must specify that continuing professional development which P is required to undertake by the requirements may be undertaken outside Northern Ireland.

(8) The Council must publish the framework adopted by it under paragraph (6)(a), as it exists from time to time, in such manner as it considers appropriate.

(9) The Council must make such provision in regulations as it considers appropriate with respect to registered persons who fail to comply with any requirements of the framework adopted by the Council under paragraph (6)(a).

(10) Regulations under paragraph (9) must—

(a) make provision about the circumstances in which the registrar may remove the name of the registered person from the register, or impose such other remedial measures as may be specified in the regulations, where the registered person—

(i) has failed to comply with the requirements or conditions of the framework adopted by the Council under paragraph (6)(a) relating to the continual professional development of registered persons; or

(ii) has made a false declaration about compliance with those requirements or conditions;

(b) where the framework adopted by the Council under paragraph (6)(a) makes provision in respect of a person ("P") who is a registered person only as a result of being registered in the register mentioned in Article 6(1)(d), secure that any sanction imposed in relation to P by reference to that provision is appropriate and proportionate in view of P's continued lawful establishment in P's home State as a pharmacist;

(c) make provision for the registrar to send a statement in writing to the registered person concerned giving the registered person notice of the removal and the reasons for it and of right of appeal to the Statutory Committee under paragraph (13);

(d) make provision for the suspension of a registered person's entry in the register pending the outcome of any appeal against a decision to remove the name of the registered person from the register;

(e) make provision about the circumstances in which the registrar, upon an application being made by a person whose name has been removed from the register, may restore the name to the register and whether, and if so what, continuing professional development is required after restoration, and the regulations may make provision—

(i) for these issues to be determined in individual cases by the registrar,

(ii) enabling the registrar to determine that the application for restoration is to be granted subject to the applicant agreeing to comply with such undertakings with regard to continuing professional development as the registrar considers appropriate, and

(iii) refusal of applications.

(11) Where a person who has agreed to comply with an undertaking pursuant to regulations made under paragraph (10)(e) breaches that undertaking, that breach may be treated as misconduct for the purposes of paragraph (4)(1)(a) of Schedule 3 and the registrar must consider, in accordance with paragraph (5)(1) of Schedule 3, whether or not to refer the matter to the Scrutiny Committee or (where regulations under paragraph (5)(1) of Schedule 3 so provide) to the Statutory Committee.

(12) Where the registrar refuses an application for restoration of a person's name to the register, the registrar must send to the applicant a statement in writing giving the applicant notice of decision and the reasons for it and the right of appeal to the Statutory Committee under paragraph (13).

(13) In accordance with regulations made under paragraph (10), a person in respect of whom a decision has been made by the registrar to—

(a) remove their name from the register;

(b) impose such remedial measure as may be specified; or

(c) refuse an application for restoration of their name to the register,

may appeal from that decision to the Statutory Committee which may decide the appeal.

(14) In this Article "home State" in relation to a pharmaceutical chemist registered in the register mentioned in Article 6(1)(d), means the relevant European State in which the registered person is lawfully established as a pharmacist.

The Council's duties in respect of publications

4B.—(1) The Council shall from time to time publish or provide in such manner as it sees fit information about the regulation of pharmaceutical chemists and registered pharmacies.

(2) The Council may from time to time publish or provide in such manner as it sees fit guidance to registered persons, employers and such other persons it considers appropriate in respect of the standards for the education, training, supervision and performance of persons who are not registered persons but who provide services in connection with those provided by registered persons.

Accounts

4C.—(1) The Council shall be responsible for ensuring that the Society—

(a) keeps accounts, which shall be in such form as the Department may determine; and

(b) prepares annual accounts in respect of each year, which shall be in such form and shall be prepared by such date as the Department may determine.

(2) Those annual accounts shall be audited by auditors appointed by the Council, but no person may be appointed as an auditor under this paragraph unless that person is eligible for appointment as a statutory auditor under Part 42 of the Companies Act 2006(**8**) (statutory auditors).

(3) As soon as is reasonably practicable after those accounts have been prepared, the Council shall—

(a) cause them to be published together with any report on them made by the auditors appointed under paragraph (2); and

(b) send a copy of those annual accounts and of any such report to the Department,

and the Department shall lay before the Assembly a copy of those annual accounts and any report on the accounts made by the auditors appointed under paragraph (2).

Reports and statistical information

4D. The Council shall publish in such manner as it sees fit, at least once in each year, by such date as the Department shall determine—

(**8**) 2006 c.46