#### STATUTORY INSTRUMENTS

# 1976 No. 1213 (N.I. 22)

# Pharmacy (Northern Ireland) Order 1976

- - - - [30th July 1976]



#### Title and commencement N.I.

1. This Order may be cited as the Pharmacy (Northern Ireland) Order 1976 ... Commencement ...

#### Interpretation N.I.

- **2.**—(1) The Interpretation Act (Northern Ireland) 1954 shall apply to Article 1 and the following provisions of this Order as it applies to a Measure of the Northern Ireland Assembly.
  - (2) In this Order—
    - "the Act of 1925" means the Pharmacy and Poisons Act (Northern Ireland) 1925;
    - "the Act of 1945" means the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945; "approved bye-laws" means bye-laws—
    - (a) submitted by the Council to a meeting of the Society called, after at least fourteen days' notice of the meeting has been served on every person appearing to be a member of the Society, for the purpose of approving bye-laws so submitted (whether or not the meeting has been called for any other purposes in addition), being a meeting at which at least thirty members of the Society are present; and
    - (b) approved by a majority of the members present and voting at such a meeting;
    - "associate" has the meaning assigned to it by paragraph 3(1) of Part I of Schedule 1;
    - "certificate of registration" has the meaning assigned to it by Article 12(3);
    - [FI " competent authorities " means any authority or body of a relevant European State designated by that State for the purposes of the Directive as competent to—
    - (a) receive or issue evidence of qualification or other information or documents,
    - (b) receive applications and take decisions referred to in the Directive in connection with the practice of pharmacy;]
    - "the Council" means the Council of the Society;
    - "the Department" means the Department of Health and Social Services;

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F2 ...

[F3":Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12th July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;

[F4 " the Directive " means Directive 2005/36/ EC of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications and references in this Order to the Directive, or to any provision of the Directive, are references to the Directive, or to that provision of the Directive, as amended from time to time;

[F5" electronic communication" has the meaning given in section 15(1) of the Electronic Communications Act (Northern Ireland) 2001 (general interpretation);]

"enactment" has the meaning assigned to it by section 1(b) of the Interpretation Act (Northern Ireland) 1954;

[F3. European professional card" has the meaning given in the Directive;]

[F6 " exempt person " means

- (a) a national of a relevant European State other than the United Kingdom;
- (b) a national of the United Kingdom who is seeking access to, or is pursuing, the profession of pharmacy by virtue of an enforceable Community right; or
- (c) a person who is not a national of a relevant European State but who is, by virtue of an enforceable Community right, entitled to be treated, for the purposes of access to, and pursuit of, the profession of pharmacy, no less favourably than a national of a relevant European State;

[F7":General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);]]

[F3":IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;]

[F3":IMI file" means a secure personal account in the IMI that is created in relation to an applicant for a European professional card by means of an online tool provided by the European Commission;]

[F8" 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.l

"the Medicines Act" means the Medicines Act 1968;

"member" has the meaning assigned to it by paragraph 2 of Part I of Schedule 1;

[ $^{F9}$  "national", in relation to a [ $^{F10}$  relevant European 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 is not to benefit from Community provisions relating to the free movement of persons and services; ]

[FII: the necessary knowledge of English", in relation to a person registered, or desirous of being registered, in the register of pharmaceutical chemists, means a knowledge of English which is necessary for the safe and effective practice as a pharmaceutical chemist in Northern Ireland;]

"the Pharmacy Inspector" means the inspector appointed under Article 24(1);

"prescribed" means prescribed by regulations under Article 5;

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- [F3" professional traineeship" means a period of professional practice, carried out under supervision, that—
- (a) constitutes a condition for access to the profession of pharmacy in the country in which it is carried out; and
- (b) takes place during or after completion of a course of education leading to an educational qualification pursued for the purpose of entry to that profession;]
- "registered" means in relation to a pharmaceutical chemist, [F12visiting pharmaceutical chemist from a relevant European State] druggist or student, registered in the appropriate register under Article 6;
- "registered person" means a person registered as a pharmaceutical chemist [F13, visiting pharmaceutical chemist from a relevant European State] or druggist;
- "registered pharmacy" has the meaning assigned to it by section 74 of the Medicines Act;
- "the registrar" means the registrar appointed under Article 9(1);
- [F14 " reference date" in relation to a relevant European State, means the date specified in relation to that State in the column entitled "Reference date" in Annex V, point 5.6.2. of the Directive;
- [F15" 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;]
- "relevant European State" means an EEA State or Switzerland;"]
- "retail pharmacy business" has the meaning assigned to it by [F16 regulation 8(1) of the Human Medicines Regulations 2012];
- [F17"Scrutiny Committee" means the committee established under paragraph 2(4) of Schedule 2;]
- "the Society" means the Pharmaceutical Society of Northern Ireland;
- "the Statutory Committee" means the Committee continued under Article 19(1);
- "student" means a registered student.
- [F3. third country" means a country other than a relevant European State.]
- F1 Art. 2(2): definition of "competent authorities" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(a)
- F2 Words in art. 2(2) omitted (25.5.2018) by virtue of Data Protection Act 2018 (c. 12), s. 212(1), Sch. 19 para. 12 (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)
- **F3** Words in art. 2(2) inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **18(3)** (with reg. 155)
- F4 Art. 2(2): definition of "the Directive" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(b)
- Words in art. 2(2) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **2(a)** (with Sch. 3)
- F6 Art. 2(2): definitions of "exempt person" and "General Systems Regulations" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(c)
- F7 Words in art. 2(2) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **18(2)** (with reg. 155)
- **F8** Words in art. 2(2) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **2(b)** (with Sch. 3)
- **F9** SR 1987/457

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- F10 Words in art. 2(2) in definition of "national" substituted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(d)
- F11 Words in art. 2(2) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 5; S.I. 2015/1451, art. 6(a)
- F12 Words in art. 2(2) in definition of "registered" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(e)
- F13 Words in art. 2(2) in definition of "registered person" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(f)
- F14 Art. 2(2): definitions of "reference date" and "relevant European State" inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 3(g)
- F15 Words in art. 2(2) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 2(c) (with Sch. 3)
- **F16** Words in art. 2(2) substituted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 47** (with Sch. 32)
- **F17** Words in art. 2(2) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **2(d)** (with Sch. 3)

# PART II N.I.

#### THE PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

### The Society N.I.

- **3.**—(1) There shall continue to be a Pharmaceutical Society of Northern Ireland ("the Society").
- (2) The constitution of the Society shall be as provided in that behalf in Part I of Schedule 1; and the supplementary provisions contained in Part II of that Schedule shall have effect with respect to the Society.
  - (3) The objects of the Society shall be—
    - (a) to advance chemistry and pharmacy;
    - (b) to promote pharmaceutical education and the application of pharmaceutical knowledge;
    - (c) to maintain the honour and safeguard and promote the interests of the members of the Society in their exercise of the profession of pharmacy;
    - (d) to execute all such functions as may be entrusted to the Society under any enactment;
    - (e) to provide relief for distressed persons, being—
      - (i) members of the Society;
      - (ii) persons who at any time have been members of the Society or have been registered as either pharmaceutical chemists, or chemists and druggists, or druggists or apprentices to pharmaceutical chemists, or as students of the Society; or
      - (iii) [F18 surviving spouses, surviving civil partners,] orphans or dependants of deceased persons who were at any time members of the Society or registered as aforesaid.
  - (4) Without prejudice to any other provision of this Order, the Society may—
    - (a) acquire and hold land for the purposes for which the Society is constituted, and either dispose of or charge any such land;
    - (b) approve bye-laws made under Article 4;
    - (c) undertake and execute any lawful trust for the furtherance of any of the objects of the Society;

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- (d) accept gifts and donations and support, or aid in the support of, charitable or benevolent associations or institutions, or any cause which appears to the Society to be deserving of its support or aid;
- (e) invest any funds of the Society not required for immediate use or to meet the usual accruing liabilities of the Society in any investment authorised by law for the investment of trust property;
- (f) apply funds under the Society's control towards providing scholarships for the furtherance of education and research in pharmacy, in accordance with regulations under Article 5;
- (g) do all such other matters and things as are reasonably necessary for, or incidental to the furtherance of, the objects of the Society or any of them, or the exercise of the powers of the Society or any of them.
- (5) Any money received by the Society on the disposal of any land under paragraph (4)( a) shall be applied by the Society to some purpose of its functions to which capital moneys are properly applicable.

**F18** 2004 c.33

#### The Council N.I.

- **4.**—(1) There shall continue to be a Council of the Society ("the Council") with a President and a Vice-President.
  - [F19(2) The provisions of Schedule 2 shall have effect with respect to the Council.]
  - (3) The Council may on behalf, and for the benefit, of the Society—
    - (a) direct and manage the business and affairs of the Society, and exercise all such powers of the Society as are not by this Order required to be exercised by the Society in general meeting, in accordance with and subject to approved bye-laws made by the Council;
    - (b) control and manage the property and funds of the Society and invest and apply the same in such manner as the Council may determine, subject to such general or special directions (if any) as may be contained in approved bye-laws made by the Council with respect to the control and management of such property and funds;
    - (c) regulate the functions of the secretary, treasurer, clerks and other subordinate officers and their terms and conditions of service;
    - (d) employ and pay such auditors, accountants and other advisers as the Council may think fit.

**F19** Art. 4(2) substituted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **3** (with Sch. 3)

# [F20Continuing professional development N.I.

- **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);

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- (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—
    - (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

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- (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.

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- (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.

**F20** Arts. 4A-4D inserted (1.10.2012, 1.6.2013) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 4 (with Sch. 3)

#### The Council's duties in respect of publications N.I.

- **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.

**F20** Arts. 4A-4D inserted (1.10.2012, 1.6.2013) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 4 (with Sch. 3)

#### Accounts N.I.

- **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 (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).

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**F20** Arts. 4A-4D inserted (1.10.2012, 1.6.2013) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 4 (with Sch. 3)

#### Reports and statistical information N.I.

- **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—
  - (a) a statistical report in respect of, and which includes a description of, the procedures which the Society has in place to protect members of the public from registered persons whose fitness to practise is impaired, together with the Council's observations on the report; and
  - (b) a report, submitted to the Department, on the Society's exercise of its functions, and the Department shall lay before the Assembly a copy of the report submitted by the Council under this sub-paragraph.]

**F20** Arts. 4A-4D inserted (1.10.2012, 1.6.2013) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 4 (with Sch. 3)

#### [F21Regulations made by the Council: general] N.I.

- **5.**—(1) The Council may, subject to the provisions of this Order, make regulations with respect to all or any of the following matters—
  - (a) the meetings and other proceedings of the Council and the Society (including meetings for the reading of papers and discussions of scientific subjects);
  - (b) the examination (including the subjects of examination) or the qualifications of persons desirous of being registered as pharmaceutical chemists under this Order;
- [F22(bb) the conditions as to character, physical and mental health [F23, the necessary knowledge of English] and other matters to be satisfied by persons desirous of being registered as pharmaceutical chemists under this Order;]
  - (c) the qualifications of persons desirous of being registered as students under this Order;
  - (d) the conditions on which persons who are members of pharmaceutical societies outside Northern Ireland may be registered as pharmaceutical chemists under this Order, and the societies whose members may be so registered;
  - (e) the fees (being of a reasonable amount) for examination and registration, [F24] for retention of registration and for annotation of the register,] which are to be paid to the Society under this Order;
  - (f) the conditions on which persons may be required to undergo a course of practical training for the purpose of qualifying for registration as pharmaceutical chemists;
- [F25(fff)] the recording in the register of fitness to practise matters, including any warnings or advice given by, or undertakings agreed with, the Statutory Committee or the Scrutiny Committee;
  - (ffg) the recording in the register of continuing professional development matters.]
- [F24(ff)] annotation of the register of pharmaceutical chemists to indicate particular qualifications, specialist areas of practice and status;]
  - (g) the making of special provision with respect to the examinations to be passed by exservicemen;

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- (h) generally, any matters with respect to which the Council thinks that provision should be made for the purpose of carrying this Order into effect.
- [F26(1A)] Regulations made by the Council under this Article may not make provision for the payment of fees in connection with registration as a visiting pharmaceutical chemist from a relevant European State.]
- [F27(1B)] Regulations made by the Council under this Article must provide for a person desirous of being registered as a pharmaceutical chemist under this Order to satisfy the registrar that the person has the necessary knowledge of English.]

- (3) Before approving any regulations with respect to—
  - (a) the matters mentioned in paragraph (1)(b), (c) and (g); or
  - (b) the prescribing of any body for the purposes of Article 7(5) or (6); or
  - (c) the provision of scholarships under Article 3(4)(f);

the Department shall consult the Department of Education.

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- (5) For the purposes of paragraph (1)(g), the expression "ex-servicemen" includes—
  - (a) men who have served whole time in the armed forces of the Crown or in the Merchant Navy or the mercantile marine; F30. . .

Sub-para. (b) rep. with saving by 1981 c. 55

- **F21** Art. 5 heading substituted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **5(1)** (with Sch. 3)
- F22 1994 NI 2
- **F23** Words in art. 5(1)(bb) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 6(2); S.I. 2015/1451, art. 6(a)
- F24 SR 2004/78
- **F25** Art. 5(1)(fff)-(ffg) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **5(2)(a)** (with Sch. 3)
- **F26** Art. 5(1A) inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 4
- F27 Art. 5(1B) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 6(3); S.I. 2015/1451, art. 6(a)
- **F28** Art. 5(2) omitted (1.10.2012) by virtue of The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **5(2)(b)** (with Sch. 3)
- **F29** Art. 5(4) omitted (1.10.2012) by virtue of The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **5(2)(b)** (with Sch. 3)
- F30 1981 c. 55

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# PART III N.I.

# REGISTRATION OF PHARMACEUTICAL CHEMISTS, DRUGGISTS AND STUDENTS

#### The registers N.I.

- **6.**—[F<sup>31</sup>(1) In relation to the registers mentioned in sub-paragraphs (a), (b) and (c) there shall continue to be kept, and in relation to the register mentioned in sub-paragraph (d) there shall be kept, in accordance with the succeeding provisions of this Order,—
  - (a) a register of pharmaceutical chemists;
  - (b) a register of druggists;
  - (c) a register of students; and
  - (d) a register of visiting pharmaceutical chemists from a relevant European State.]
- (2) Registration under this Order shall not entitle any person so registered to practice medicine or surgery or any branch of medicine or surgery.
  - F31 Art. 6(1) substituted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 5

#### **Examinations N.I.**

- 7.—(1) For the purpose of ascertaining the proficiency in any subjects of persons desirous of being registered under this Order as pharmaceutical chemists, the Council may cause examinations to be held at such times and in such manner as may be prescribed, and shall appoint examiners to conduct any such examinations.
- (2) A person shall not conduct any such examination until his appointment has been approved by the Head of the Department, and such appointment shall not continue in force for more than five years except with the consent of the Head of the Department on application being made by the Council.
- (3) The Society shall allow the Pharmacy Inspector or any other officer appointed by the Department for that purpose to be present during the progress of any examination held for the purposes of this Order.
- (4) Examiners appointed to conduct any examination under this Article may, after such examination, grant or refuse to the persons taking part in the examination, as the examiners in their discretion may consider fit, recognition of the proficiency of such persons in the subjects of the examination, or any of them.
- (5) The Council may make arrangements for the holding of examinations for the purposes of this Order with—
  - (a) any university in Northern Ireland;
  - (b) any institution of further education or other body in Northern Ireland which may be prescribed for the holding of such examinations.
- (6) For the purpose of ascertaining the proficiency of candidates in any subject, the Council may recognise—
  - (a) the examinations of, or any examinations accepted by—
    - (i) any university in Northern Ireland; or
    - (ii) any institution or body such as is referred to in paragraph (5)( b) which is prescribed for the purposes of this paragraph;

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- (b) the examinations of—
  - (i) any other university in the United Kingdom;
  - (ii) any body in the United Kingdom which is recognised by the Council as a body of comparable academic status to a university and is prescribed for the purposes of this paragraph.

#### Qualifications for registration N.I.

- **8.**—(1) Every person who possesses the prescribed qualifications and gives to the registrar such reasonable proof of such qualifications as may be prescribed shall, upon payment to the Society of the proper fees (if any), be entitled to be registered as a student under this Order.
- (2) [F32Subject to paragraph (2A),] The following persons shall, upon payment to the Society of the proper fees (if any), be entitled to be registered under this Order as pharmaceutical chemists—
  - (a) every person who, immediately before the commencement of this Order, was entitled to be registered as a pharmaceutical chemist under the Act of 1925;
  - (b) every person who-
    - (i) is registered as a student;
    - (ii) has been duly examined in such subjects as may be prescribed and has obtained from the examiners recognition of his proficiency therein; or possesses such qualifications as may be prescribed and, having been duly examined in any additional subject which may be prescribed for a person of those qualifications, has obtained from the examiners recognition of his proficiency in that subject;
    - (iii) has undergone such a course of practical training as may be prescribed; and
    - (iv) has attained the age of twenty-one years;

and who gives to the registrar such reasonable proof of those facts as may be prescribed.

#### [F33(c) every exempt person—

- (i) who holds an appropriate European diploma; or
- (ii) (aa) whose case falls within regulation [F343(8)(a) or (e)] of the General Systems Regulations,
- (bb) to whom regulations [ $^{F35}27$  to 34] of those regulations apply by reason of the operation of regulation [ $^{F36}3(5)$ ] of those regulations, and
- (cc) who is permitted to pursue the profession of pharmacy in the United Kingdom by virtue of Part 3 of those regulations (having, in particular, successfully completed any adaptation period, or passed any aptitude test, that he may be required to undertake pursuant to that Part of those regulations).]
- [F32(2A) A person shall not be entitled to be registered under this Order as a pharmaceutical chemist by virtue of paragraph (2)(b) or (c) unless he satisfies such conditions (if any) as to character, physical or mental health [F37, the necessary knowledge of English] or other matters as may be prescribed.]
- (3) Every person who, immediately before the commencement of this Order, was entitled to be registered as a druggist under the Act of 1925 shall, upon payment of the proper fees (if any), be entitled to be registered as a druggist under this Order.
- (4) Notwithstanding anything in paragraph (2), the Council may, if it thinks fit, cause to be registered under this Order as a pharmaceutical chemist any person (other than a person such as is described in paragraph (2)( a)[F38 or (c)] who is a member of a prescribed pharmaceutical society outside Northern Ireland and who—

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- (a) satisfies the Council as to his competence to practise as a pharmaceutical chemist;
- (b) pays to the Society the proper fees (if any) for registration; and
- (c) complies with such other conditions as may be prescribed.
- [F39(5) Where a person—
  - (a) gives to the registrar such reasonable proof as may be prescribed that he satisfies the prescribed requirements for a particular annotation to be recorded against his name in the register of pharmaceutical chemists in accordance with regulations under Article 5(1)(ff); and
  - (b) pays the prescribed fee to the Society,

he shall be entitled to have that annotation recorded against his name in that register.

- **F32** 1994 NI 2
- F33 Art. 8(2)(c) substituted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 6
- **F34** Words in art. 8(2)(c)(ii)(aa) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **19(2)** (with reg. 155)
- F35 Words in art. 8(2)(c)(ii)(bb) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 19(3)(a) (with reg. 155)
- **F36** Word in art. 8(2)(c)(ii)(bb) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 19(3)(b) (with reg. 155)
- F37 Words in art. 8(2A) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 7; S.I. 2015/1451, art. 6(a)
- F38 SR 1987/457
- **F39** SR 2004/78

#### **Modifications etc. (not altering text)**

C1 Art. 8(2)(c) power to restrict conferred by S.I. 1972/1265 (N.I. 14), art. 63AA(3)(c) (as inserted (26.3.2008) by Health (Miscellaneous Provisions) Act (Northern Ireland) 2008 (c. 2), ss. 10(3), 18(1) (a))

#### [F40Registration by virtue of appropriate European diploma N.I.

**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.

- [<sup>F43</sup>(2) [<sup>F44</sup>Subject to paragraph (7)] the following diplomas are appropriate European diplomas for the purposes of article 8(2)(c)(i), namely—
  - (a) a diploma listed in Annex V, point 5.6.2 of the Directive which has been granted in a relevant European State after its reference date and which is evidence of training commenced after that date, provided that the diploma is accompanied, where appropriate, by the certificate listed in relation to that State in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma"; or
  - (b) any diploma which—
    - (i) subject to paragraph (3), has been granted in a relevant European State before its reference date or which is evidence of training commenced before that date but completed on or after that date,

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- (ii) subject to paragraph (4), was awarded by the competent authorities of, or which is evidence of training started in, the territory specified in column (b) of the table in Schedule 2A before the date specified in the corresponding entry in column (a) of that table.
- (iii) subject to paragraph (5), is evidence of training commenced before 3 <sup>rd</sup> October 1990 and undertaken in the territory of the former German Democratic Republic, or
- (iv) subject to paragraph (6), does not fall within heads (i) to (iii) and is not listed in Annex V, point 5.6.2 of the Directive but which is a diploma in pharmacy granted in a relevant European State on or after its reference date.
- (3) A diploma to which paragraph (2)(b)(i) applies is only an appropriate European diploma if—
  - (a) in the case of a diploma which is listed in Annex V, point 5.6.2 of the Directive—
    - (i) the registrar is satisfied (by means of a certificate from the relevant competent authorities or otherwise) that the diploma guarantees that the holder's training satisfies the requirements of Article 44 of the Directive (requirements for pharmacists' training), and
    - (ii) the diploma is accompanied, where appropriate, by the certificate listed in relation to the relevant European State in which the diploma was awarded in the column of Annex V, point 5.6.2 of the Directive entitled "Certificate accompanying the diploma";
  - (b) in the case of a diploma which is not listed in Annex V, point 5.6.2 of the Directive, the diploma is accompanied by a certificate from the competent authorities of the relevant European State in which the diploma was awarded which attests that the diploma—
    - (i) is evidence of training which satisfies the requirements of Article 44 of the Directive, and
    - (ii) is treated by the competent authorities of the relevant European State in which it was awarded as equivalent to a diploma listed in relation to that State in Annex V, point 5.6.2 of the Directive, and the certificate is made available to the registrar: or
  - (c) whether or not the diploma is listed in Annex V, point 5.6.2 of the Directive, the competent authorities of a relevant European State have certified that the holder has, in a relevant European State, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years during the five years preceding the date of the certificate, and the certificate is made available to the registrar.
- (4) A diploma to which paragraph (2)(b)(ii) applies is only an appropriate European diploma if—
  - (a) the competent authorities of the relevant European State specified in the appropriate row of column (c) of the table in Schedule 2A have certified that the diploma has, in its territory, the same legal validity as regards access to the practice of pharmacy as the diploma listed in Annex V, point 5.6.2 of the Directive in respect of their State;
  - (b) those competent authorities have also certified that the holder of the diploma has, in the relevant European State specified in the appropriate row of column (c) of the table in Schedule 2A, been effectively and lawfully engaged in the practice of an activity open to pharmacists in that State for at least three consecutive years during the five years preceding the date of that certificate; and
  - (c) the certificates are made available to the registrar.
- (5) A diploma to which paragraph (2)(b)(iii) applies is only an appropriate European diploma if —

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- (a) the diploma entitles its holder to practice pharmacy throughout the territory of Germany on the same conditions as those that apply to the holder of the diploma listed in Annex V, point 5.6.2 of the Directive in respect of Germany; and
- (b) the competent authorities in Germany have certified that the holder of the diploma has been effectively and lawfully engaged in Germany in the practice of an activity open to pharmacists in Germany for at least three consecutive years during the five years preceding the date of that certificate; and
- (c) the certificate is made available to the registrar.
- (6) A diploma to which (2)(b)(iv) applies is only an appropriate European diploma if—
  - (a) the competent authorities of the European State that awarded it have certified that the diploma—
    - (i) is evidence of training which satisfies the requirements of Article 44 of the Directive, and
    - (ii) is treated by them as equivalent to a diploma listed in Annex V, point 5.6.2 of the Directive in respect of their State; and
  - (b) the certificates are made available to the registrar.
- (7) A diploma is only an appropriate European diploma if—
  - (a) in a case where the registrar or the Council has justified doubts about the authenticity of the diploma made available to the registrar 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 registrar or the Council has justified doubts about whether the holder of the diploma has completed training which satisfies the requirements of Article 44 of the 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 registrar or the Council has justified doubts concerning training received in a relevant European State other than that in which the diploma was awarded, and has required confirmation of the relevant competent authorities in accordance with Article 50(3) of the Directive, the relevant competent authorities have provided confirmation in accordance with that Article.]]
- F40 SR 1987/457
- F41 SR 1996/393
- F42 Art. 8A(1A) revoked (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 7(1)
- F43 Art. 8A(2)-(7) substituted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 7(2)
- **F44** Words in art. 8A(2) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **20** (with reg. 155)

# [F45Supplementary provisions as to the necessary knowledge of English N.I.

- **8AA.**—(1) The Society must publish guidance about—
  - (a) the evidence, information or documents to be provided by an applicant for the purpose of satisfying the registrar under regulations made under Article 5(1) by virtue of Article 5(1B) that the applicant has the necessary knowledge of English; and

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- (b) the process by which the registrar is to determine whether the registrar is satisfied as mentioned in sub-paragraph (a).
- (2) The registrar must have regard to the guidance published under paragraph (1) in determining whether the registrar is satisfied as mentioned in paragraph (1)(a).
- (3) Paragraphs (4) and (6) apply if, having considered any evidence, information or documents provided by the applicant in support of the applicant's application, the registrar is not satisfied under Article 5(1B) that the applicant has the necessary knowledge of English.
- (4) The registrar may request the applicant to provide further evidence, information or documents within such period as the registrar may specify.
- (5) The registrar may not exercise any power under paragraph (4) unless the registrar has complied with any duty under Article 11ZA(2).
  - (6) The registrar may require the applicant—
    - (a) to undergo an examination or other assessment; and
- (b) to provide information in respect of that examination or assessment, within such period as the registrar may specify.
- (7) In the case of an applicant who is an exempt person, the registrar may not exercise the power under paragraph (6) without having first—
  - (a) exercised the power under paragraph (4); and
  - (b) considered any further evidence, information or documents provided by the applicant.
- (8) Guidance published under paragraph (1) may make different provision in relation to different cases or classes of case.
- (9) Before issuing such guidance or varying or withdrawing it, the Society must consult such persons, or representatives of such persons, as it considers appropriate including, as it sees fit—
  - (a) registered pharmaceutical chemists;
  - (b) employers of registered pharmaceutical chemists;
  - (c) users of services of registered pharmaceutical chemists; and
  - (d) the Regional Health and Social Care Board.
- (10) In this article, references to an applicant are to a person desirous of being registered as a pharmaceutical chemist under this Order.]
  - F45 Art. 8AA inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 8; S.I. 2015/1451, art. 6(a)

## [F46Visiting pharmaceutical chemist from a relevant European State N.I.

**8B.** Schedule 2B (visiting pharmaceutical chemist from a relevant European State) shall have effect.]

**F46** Art. 8B inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 8

#### [F47Professional traineeships carried out in other relevant European States, etc. N.I.

**8**C.—(1) If a person is required to carry out a professional traineeship of a particular standard in order to be appropriately qualified to be registered in the register of pharmaceutical chemists, a

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professional traineeship of an equivalent standard which has been carried out by a person whose home Member State is the United Kingdom and which satisfies the conditions in paragraph (2) is treated as meeting that requirement.

- (2) The conditions are that—
  - (a) at least three quarters of the time of which the professional traineeship consisted, or such lesser proportion as the Society may consider appropriate in any particular case, was spent in the United Kingdom; and
  - (b) the remaining time of which the professional traineeship consisted was spent in another relevant European State.
- (3) Paragraph (4) applies if—
  - (a) a person whose home Member State is the United Kingdom applies to the registrar to be registered as a pharmaceutical chemist; and
  - (b) the person has carried out a professional traineeship, all or part of which was carried out in a third country.
- (4) The registrar must take the professional traineeship into account when considering whether the person satisfies any requirement as to the qualifications needed in order to be registered in the register of pharmaceutical chemists which includes a requirement to carry out a professional traineeship in the United Kingdom.
- (5) The Society must publish guidelines on the organisation and recognition of professional traineeships carried out in relevant European States and third countries (including, in particular, guidelines on the role of the supervisor of the professional traineeship).
  - (6) In this Article, "home Member State" has the meaning given in article 1 of the Directive.
  - **F47** Arts. 8C, 8D inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **21** (with reg. 155)

#### European professional card N.I.

- **8D.**—(1) Schedule 2C (Directive 2005/36/EC: European professional card) has effect.
- (2) The Society may charge a reasonable fee to cover the costs of processing an application for or in relation to a European professional card under Schedule 2C.
- (3) The Council must determine, and the Department must approve, the amount which the Society may charge under paragraph (2).]
- [<sup>F48</sup>(4) In Schedule 2C, "the GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), read with Chapter 2 of Part 2 of the Data Protection Act 2018.]
  - F47 Arts. 8C, 8D inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 21 (with reg. 155)
  - **F48** Art. 8D(4) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 13** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

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# F49 Temporary registration in the register of pharmaceutical chemists in certain emergencies N.I.

- **8E.**—(1) The registrar may register a person, or the persons comprising a specified group of persons, in the register of pharmaceutical chemists if the conditions set out in paragraph (2) are satisfied.
  - (2) The conditions are that—
    - (a) the Department has advised the registrar that an emergency has occurred, is occurring or is about to occur and that the registrar should consider acting under this Article; and
    - (b) the registrar considers that the emergency registration requirement is met in relation to the person or group of persons.
  - (3) The emergency registration requirement is met—
    - (a) in relation to a person, if the person is a fit, proper and suitably experienced person to be registered as a pharmaceutical chemist with regard to the emergency;
    - (b) in relation to a group of persons, if the group is comprised of persons who are of a type who may reasonably be considered fit, proper and suitably experienced persons to be registered as pharmaceutical chemists with regard to the emergency.
- (4) The registrar may register all of the persons comprising a specified group of persons without first identifying each person in the group.
- (5) A person's registration under this Article has effect subject to any conditions imposed by the registrar; and the registrar may at any time vary or revoke such a condition or add new conditions.
- (6) Where a person is registered under this Article as a member of a specified group, the person's registration may (but need not) be subject to the same conditions as the registration of other members of the group.
- (7) The registration of a person under this Article ceases to have effect if revoked by the registrar; and the registrar—
  - (a) must revoke the registration if the Department advises the registrar that the circumstances that led the Department to give the advice referred to in paragraph (2)(a) no longer exist;
  - (b) may at any time revoke the registration for any other reason, including where the registrar has grounds for suspecting that the person's fitness to practise may be impaired.
  - (8) A person's registration as a member of a specified group may be revoked—
    - (a) without revoking the registration of the other members of the group; or
    - (b) as a result of a decision to revoke the registration of all the members of the group.
- (9) Regulations made under Article 5 with respect to the following matters do not apply to persons registered under this Article—
  - (a) paragraph (1)(b) (examinations and qualifications for registration);
  - (b) paragraph (1)(bb), in so far as it refers to the necessary knowledge of English;
  - (c) paragraph (1)(e) (fees);
  - (d) paragraph (1)(f), (ffg) and (g) (qualifications etc in relation to registration);
  - (e) such other matters as the Council may by regulations provide;

but this is subject to paragraph (11).

- (10) The following provisions of this Order do not apply to persons registered under this Article—
  - (a) Article 4A (continuing professional development);
  - (b) Articles 7, 8 and 8AA (provisions relating to registration);

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- (c) Article 11(1) (evidence of qualification required for registration);
- (d) Article 15 (retention fees);
- (e) Article 20 and Schedule 3 (fitness to practise) other than paragraphs 1 to 3; and
- (f) such other provisions as the Council may by regulations provide; but this is subject to paragraph (11).
- (11) The Council may make regulations that provide that the following apply to persons registered under this Article—
  - (a) regulations with respect to any of the matters referred to in paragraph (9)(a) to (e); and
  - (b) any of the provisions of this Order referred to in paragraph (10)(a) to (f).
- (12) If a person breaches any condition to which the person's registration under this Article is subject, anything done by that person in breach of the condition is to be treated as not being done by a registered pharmaceutical chemist.
- (13) The registrar may make available information to assist with the identification of persons registered under this Article in such manner as the registrar sees fit.
  - (14) In this Article—
    - "emergency" means an emergency of the kind described in section 19(1)(a) of the Civil Contingencies Act 2004 (meaning of "emergency"), read with subsection (2)(a) and (b) of that section;
    - "specified" means specified in a direction given by the registrar or by a person authorised by the registrar.]
  - **F49** Art. 8E inserted (temp.) (25.3.2020) by virtue of Coronavirus Act 2020 (c. 7), s. 87(1), **Sch. 4 para. 3** (with ss. 88-90)

#### The registrar N.I.

- **9.**—(1) The Department may appoint a fit and proper person as a registrar for the purposes of this Order.
- (2) The registrar shall make out and maintain the registers mentioned in Article 6(1)(a), (b) and  $[^{F50},(c)]$  and  $[^{F50},(c)]$  are complete and separate registers of all persons registered respectively in respect of the several qualifications for registration prescribed by this Order  $[^{F51}]$  or in the case of the register mentioned in Article 6(1)(a) registered by virtue of Article 8E].
- (3) Each register shall be divided into such separate parts as may be required for the purposes of this Order, and in each register or separate part thereof the names shall be in alphabetical order according to the surnames, with the respective residences entered opposite to such names.
- (4) The registrar shall also keep proper indexes of the registers and all such other lists as may be required and as may be necessary for giving effect to this Order and to the regulations made thereunder.
- (5) The registrar shall keep each such register correctly and strike off the names of all registered persons as and when they die or are removed from any such register, and shall make any necessary alterations in the addresses of the persons registered under this Order.
- [F52(6)] The registrar may record an annotation against the name of a registered person denoting that the person is registered under Article 8E.]

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- **F51** Words in art. 9(2) inserted (temp.) (25.3.2020) by virtue of Coronavirus Act 2020 (c. 7), s. 87(1), **Sch.** 4 para. 4 (with ss. 88-90)
- F52 Art. 9(6) inserted (temp.) (25.3.2020) by virtue of Coronavirus Act 2020 (c. 7), s. 87(1), Sch. 4 para. 5 (with ss. 88-90)

## [F53 Temporary extension of prescribing powers in certain emergencies N.I.

- **9A.**—(1) In the register mentioned in Article 6(1)(a), the registrar may record an annotation under paragraph (2) against—
  - (a) the name of a registered person; or
- (b) the names of the persons comprising a specified group of registered persons, if the conditions set out in paragraph (3) are satisfied.
- (2) An annotation under this paragraph indicates that the person is qualified to order drugs, medicines and appliances in a specified capacity, notwithstanding that the person would not (but for this Article) be so qualified.
  - (3) The conditions are that—
    - (a) the Department has advised the registrar that an emergency has occurred, is occurring or is about to occur and that the registrar should consider acting under this Article; and
    - (b) the registrar considers that the emergency annotation requirement is met in relation to the person or group of persons.
  - (4) The emergency annotation requirement is met—
    - (a) in relation to a registered person, if the person is a fit, proper and suitably experienced person to order drugs, medicines and appliances in a specified capacity with regard to the emergency; and
    - (b) in relation to a group of registered persons, if the group is comprised of persons who may reasonably be considered fit, proper and suitably experienced persons to order drugs, medicines and appliances in a specified capacity with regard to the emergency.
- (5) The registrar may record the annotation in such a way as to distinguish between annotations recorded by virtue of this Article and other annotations.
  - (6) Annotations recorded by virtue of this Article—
    - (a) must be removed by the registrar if the Department advises the registrar that the circumstances that led the Department to give the advice referred to in paragraph (3)(a) no longer exist;
    - (b) may at any time be removed by the registrar for any other reason including where the registrar has grounds for suspecting that the person's fitness to order drugs, medicines and appliances may be impaired.
- (7) An annotation recorded against the name of a person in the register as a member of a specified group may be removed—
  - (a) without the removal by the registrar of the annotations recorded against the names in the register of the other members of the group; or
  - (b) by virtue of a decision by the registrar to remove the annotations recorded against the names in the register of all the members of the group.
- (8) Regulations made under Article 5 with respect to the following matters do not apply to persons with an annotated entry—
  - (a) paragraph (1)(e) (fees);
  - (b) paragraph (1)(ff) (annotations of the register); and

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- (c) such other matters as the Council may by regulations provide; but this is subject to paragraph (10).
  - (9) The following provisions of this Order do not apply to persons with an annotated entry—
    - (a) Article 4A (continuing professional development);
    - (b) Article 8 (qualifications for registration); and
- (c) such other provisions as the Council may by regulations provide; but this is subject to paragraph (10).
- (10) The Council may make regulations that provide that the following apply to persons with an annotated entry—
  - (a) regulations with respect to any of the matters referred to in paragraph (8)(a) to (c); and
  - (b) any of the provisions of this Order referred to in paragraph (9)(a) to (c).
  - (11) In this Article—

"emergency" means an emergency of the kind described in section 19(1)(a) of the Civil Contingencies Act 2004 (meaning of "emergency"), read with subsection (2)(a) and (b) of that section;

"person with an annotated entry" means a person who has an annotation under paragraph (2) against their name in the register; and

"specified" means specified in a direction given by the registrar or by a person authorised by the registrar.]

F53 Art. 9A inserted (temp.) (25.3.2020) by virtue of Coronavirus Act 2020 (c. 7), s. 87(1), Sch. 4 para. 6 (with ss. 88-90)

#### Power of registrar to require information N.I.

- **10.**—(1) The registrar may—
  - (a) serve notice in writing on any registered person requiring him, within two months from the service of the notice, to state in writing whether he has ceased to carry on business or has changed his residence, and, where that person fails to comply with that notice, serve a second such notice;
  - (b) where, within four months from the service of the first notice under sub-paragraph (a), a registered person has failed to comply with either of the notices mentioned in that sub-paragraph, strike the name of that person off the register, but subject to the restoration of that name by the direction of the Council if it thinks fit to make an order to that effect.
- (2) The registrar may at any time serve notice in writing on the occupier of any premises where a retail pharmacy business is carried on requiring the occupier, within seventeen days from the service of the notice to furnish in writing to the registrar a statement of the name and address of the bona fide proprietor of the business, and, if such proprietor does not personally manage and conduct the business, the name of the duly qualified manager or assistant managing or conducting the business and the description of his qualification.
- (3) Where a person on whom a notice has been served under paragraph (2), fails to comply with the notice, he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [F54] level 2 on the standard scale].
- (4) Where a person is convicted under paragraph (3) in respect of a failure to comply with a notice and the failure continues after conviction he shall be guilty of a further offence under paragraph (3) and shall be liable on summary conviction, in addition to the fine specified in that paragraph, to a

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fine not exceeding[F54 level 1 on the standard scale] for every day subsequent to the day on which he is first convicted of an offence under that paragraph on which the failure continues.

(5) Where a person on whom a notice has been served under paragraph (2), fails to comply with the notice, a retail pharmacy business shall not be carried on the premises and any person carrying on such a business in contravention of this paragraph shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding[F54] level 2 on the standard scale], unless he proves to the satisfaction of the court that he did not know of the failure to comply with the notice.

**F54** 1984 NI 3

#### Evidence of qualification to be registered N.I.

- 11.—(1) A name shall not be entered in any register kept under this Order unless the registrar is satisfied by the proper evidence that the person applying for the registration is entitled by virtue of this Order to be registered; and the registrar shall notify the secretary of the Society before entering a name in any of those registers.
- [F55(1A) The registrar shall enter the name of a person whom the Society has directed him to register in the appropriate register kept under this Order for the purposes of the General Systems Regulations.]
- (2) The secretary of the Society or a person aggrieved by any decision of the registrar may appeal from that decision to the Council which may decide the appeal; and any entry which is proved to the satisfaction of the Council to have been fraudulently or incorrectly made may be struck off, or amended in, the register [F56] under this Article] under an order made by the Council in writing.
  - [F57(3) No appeal lies to the Council against a decision of the registrar—
    - (a) to register or refuse to register a person under Article 8E;
    - (b) to register or refuse to register under that Article the persons comprising a group of persons;
    - (c) to impose, vary or revoke a condition as respects the registration of a person, or the persons comprising a group of persons, under Article 8E(5);
    - (d) to revoke a person's registration under that Article (and, in the case of a member of a group, it does not matter whether the registrar also decides to revoke the registration of any or all of the other members of the group);
    - (e) to record or refuse to record an annotation under Article 9A(2) against the name of a registered person, or the names of the persons comprising a group of registered persons;
    - (f) to remove an annotation under that Article (and, in the case of a member of a group, it does not matter whether the registrar also decides to remove the annotation of any or all of the other members of the group).]
  - F55 Art. 11(1A) inserted (22.5.2008) by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 10
  - **F56** Words in art. 11(2) inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 6 (with Sch. 3)
  - F57 Art. 11(3) inserted (temp.) (25.3.2020) by virtue of Coronavirus Act 2020 (c. 7), s. 87(1), Sch. 4 para. 7 (with ss. 88-90)

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## [F58 Appeals: decisions in relation to alerts and European professional cards N.I.

11ZZA. The following are appealable to the Council—

- (a) a decision of the Society under regulation 67 of the General Systems Regulations to send an alert about a person;
- (b) a decision of the Society to revoke, or not to issue, extend or vary, a European professional card under Schedule 2C or Part 4 of the General Systems Regulations;
- (c) a failure by the Society to make a decision in relation to a European professional card within the time limit under paragraph 10(4) or 12(4) of Schedule 2C or regulation 51(1) or 56(1) of the General Systems Regulations.

F58 Arts. 11ZZA, 11ZZB inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 22 (with reg. 155)

#### Appeals to the Council under Article 11ZZA N.I.

- **11ZZB.**—(1) A person in respect of whom a decision falling within Article 11ZZA(a) or (b) has been made may appeal to the Council by giving notice of appeal to the registrar within 28 days beginning with and including the date on which the Society gave notice of its decision to the person.
- (2) A person in respect of whom the Society has failed to make a decision falling within Article 11ZZA(c) may appeal to the Council by giving notice of appeal to the registrar within 28 days beginning with and including the date by which the Society was required to have given notice of its decision to the person.
- (3) The registrar may, by authorisation in writing, extend the time for giving notice of appeal under paragraph (1) or (2) by up to 14 days.
  - (4) Having considered the appeal, the Council may—
    - (a) dismiss the appeal;
    - (b) allow the appeal and quash the decision appealed against or, in the case of an appeal against a decision falling within Article 11ZZA(a), direct that the alert be withdrawn or amended;
    - (c) substitute for the decision appealed against any decision or other decision that could have been taken by the decision maker or, in the case of an appeal under paragraph (2), enter any decision which could have been taken by the Society; or
    - (d) remit or refer the case to the Society or the registrar for disposal of the matter in accordance with the Council's directions.
- (5) The Council must, as soon as reasonably practicable, send to the appellant a statement in writing giving the appellant notice of the Council's decision and the reasons for it.
- (6) Subject to paragraph (7), the Council must, as soon as reasonably practicable, publish, in such manner as it sees fit, its decision and the reasons for it.
- (7) If the Council has allowed the appeal, or has taken a decision or issued a direction that has the effect of allowing the appeal, it is not required to publish its decision or direction, and the reasons for it, unless the appellant so requests.]

F58 Arts. 11ZZA, 11ZZB inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 22 (with reg. 155)

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#### [F59Recognition of qualification of exempt persons N.I.

- 11ZA.—(1) Paragraph (2) applies in relation to a person applying for registration as a pharmaceutical chemist under this Order ("A") if—
  - (a) A has paid the prescribed fee for registration; and
  - (b) the registrar is satisfied that A falls within Article 8(2)(c); but
  - (c) the registrar decides to make a request under Article 8AA(4).
- (2) The registrar must notify A that the registrar recognises that A, by virtue of falling within Article 8(2)(c), is entitled to be registered in the register of pharmaceutical chemists, subject to meeting any other requirements for registration.]
  - F59 Art. 11ZA inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), 9; S.I. 2015/1451, art. 6(a)

#### [F60 Indemnity arrangements N.I.

- 11A.—(1) A registered person who practises as a pharmaceutical chemist must have in operation an indemnity arrangement which provides appropriate cover in relation to that registered person in respect of liabilities which may be incurred in practising as a pharmaceutical chemist.
  - (2) For the purposes of this Article, an "indemnity arrangement" may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person; or
    - (c) a combination of the two.
- (3) For the purposes of this Article, "appropriate cover", in relation to practice as a pharmaceutical chemist, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The Council may make such provision in regulations in connection with the information to be provided to the registrar—
  - (a) by or in respect of any person seeking to be registered (including on an application for restoration) for the purposes of determining whether if that person is so registered, there will be in operation in relation to that person by the time that person begins to practise an indemnity arrangement which provides appropriate cover; and
  - (b) by or in respect of a registered person who practises as a pharmaceutical chemist for the purposes of determining whether, at any time, there is in operation an indemnity arrangement which provides appropriate cover in relation to that registered person.
  - (5) Regulations under paragraph (4)(b) may require information to be provided—
    - (a) at the request of the registrar; or
    - (b) on such dates or at such intervals as the registrar may determine, either generally or in relation to a registered person or registered persons of a particular description.
- (6) The Council may also make regulations requiring a registered person who practises as a pharmaceutical chemist to inform the registrar if there ceases to be in operation in relation to that registered person an indemnity arrangement which provides appropriate cover.
- (7) The Council may also make regulations requiring a registered person who practises as a pharmaceutical chemist to inform the registrar if there is in operation in relation to that registered person appropriate cover provided under an indemnity arrangement by an employer.

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- (8) Where there is a failure to comply with the regulations under paragraph (4) by or in respect of a registered person who practises as a pharmaceutical chemist or a person who is seeking to be registered, the registrar may refuse to enter or retain the person's name in, or to restore their name to, the register.
- (9) If a registered person who practises as a pharmaceutical chemist is in breach of paragraph (1), or fails to comply with regulations under paragraph (4)(b), (6) or (7), or there is a failure to comply with regulations under paragraph (4)(b) in respect of that registered person—
  - (a) the registrar may remove that person's name from the register; or
  - (b) the breach or failure 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 that Schedule, whether or not to refer the matter to the Scrutiny Committee or (where regulations under paragraph 5(1) of that Schedule so provide) to the Statutory Committee.
  - (10) Where the registrar—
    - (a) refuses to enter or retain a person's name in, or restore their name to, the register pursuant to paragraph (8); or
- (b) removes a person's name from the register, pursuant to paragraph (9)(a), the registrar must send to the person a statement in writing giving the person notice of the decision and the reasons for it and the right of appeal to the Statutory Committee under paragraph (11).
  - (11) A person in respect of whom a decision has been made by the registrar to—
    - (a) refuse to enter or retain a person's name in, or restore their name to, the register pursuant to paragraph (8); or
- (b) remove a person's name from the register, pursuant to paragraph (9)(a), may appeal from that decision to the Statutory Committee which may decide the appeal.
- (12) This Article does not apply to a person who is registered as a visiting pharmaceutical chemist from a relevant European State.]

**F60** Art. 11A inserted (7.11.2013) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 (S.R. 2013/258), arts. 1(1), **2** (with art. 3)

#### Annual publication of registers N.I.

- **12.**—(1) The registrar shall, each year, publish copies of the various registers authorised by this Order, in alphabetical order according to the surnames.
- (2) Copies of the registers published under paragraph (1), or any extract therefrom or from the original registers certified under the hand of the registrar and countersigned by the President or two members of the Council, shall be evidence in all courts and proceedings that the persons specified therein are registered according to the provisions of this Order, and the absence of the name of any person from any such copy of any register shall be evidence, until the contrary is made to appear, that such person is not registered in the appropriate register according to the provisions of this Order.
- (3) An extract from a register or from a copy of a register certified and countersigned as provided by paragraph (2) is in this Order referred to as a "certificate of registration".

#### Copies of registers to be sent to Pharmacy Inspector, etc. N.I.

13. Each year the registrar shall send copies of the registers kept under this Order to the Pharmacy Inspector, the Poisons Inspector appointed under Article 16(1) of the Poisons (Northern Ireland) Order 1976 and the Society, and also to the divisional commander of each police division, and each

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such commander shall report to the Pharmacy Inspector any offence against the provisions of this Order committed within his division.

# Issue of certificates of registration and penalties for failure to surrender, or abuse of, certificates N.I.

- **14.**—(1) Subject to paragraph (2), the Council shall, on the demand of a registered pharmaceutical chemist, druggist or student, cause a certificate of registration in the appropriate register under Article 6 to be issued to such a person without any fee.
- (2) Where a certificate of registration has already been issued to the person making the demand, there shall not be any obligation upon the Council to cause a further certificate to be issued to him unless he satisfies the secretary of the Society that the original certificate has been lost or destroyed and pays such fee (if any) in respect of the issue of the further certificate as may be prescribed.
- [ $^{F61}(2A)$ ] 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) $^{F62}$ ...]
- [<sup>F63</sup>(2B) Any certificate of registration issued to any person under this Article shall reproduce any annotation entered in the register against that person's name in pursuance of Article 8(5).]
- (3) If a person to whom a certificate of registration has been issued ceases to be registered as a pharmaceutical chemist, druggist or student, he shall, within fourteen days after so ceasing, transmit the certificate to the secretary of the Society for cancellation by the registrar, and, if such a person fails to do so, he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [F64] level 3 on the standard scale].
- (4) Where a person is convicted under paragraph (3) in respect of a failure to transmit a certificate and the failure continues after the conviction he shall be guilty of a further offence under paragraph (3) and shall be liable on summary conviction, in addition to the fine specified in that paragraph, to a fine not exceeding[<sup>F64</sup> level 1 on the standard scale] for every day subsequent to the day on which he is first convicted of the offence under that paragraph on which the failure continues.
  - (5) If, with intent to deceive, a person—
    - (a) F65... uses, or lends to or allows to be used by any other person, a certificate of registration issued under this Article; or
    - (b) makes or has in his possession a document so closely resembling any such certificate as to be calculated to deceive:

he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [F64] level 3 on the standard scale] and where this paragraph is again contravened within one year after the conviction to a further fine not exceeding £10 for every day subsequent to the day on which he is first convicted of an offence under this paragraph on which it is so contravened. Para. (6) rep. by 1981 c. 45

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F61 SR 1987/457
F62 Words in art. 14(2A) omitted (22.5.2008) by virtue of European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 11
F63 SR 2004/78
F64 1984 NI 3
F65 1981 c. 45
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#### Retention fees N.I.

- **15.**—(1) Subject to paragraph (2), every member, associate or student of the Society shall, in addition to the fees payable on his registration in the appropriate register, pay to the Society in respect of each year such fee (a "retention fee") as may be prescribed, in respect of the retention of his name in the appropriate register in that year.
- (2) A retention fee shall not be payable by any person in respect of the year in which he first becomes a member or, as the case may be, an associate or student of the Society.
- (3) If a person on whom a demand has been made in the prescribed manner for payment of a retention fee payable by him under this Article fails to pay the fee within two months after the date on which the demand therefor was made, the Council may direct the removal of his name from the appropriate register; but, if, either within the year in respect of which the fee is payable or within such longer period as the Council may allow, the person whose name has been removed from the register pays to the Society the retention fee, together with such additional sum (if any) by way of penalty for the default as may be prescribed, his name shall be restored to the appropriate register and, if the Council so directs, the restoration shall have effect as from the date on which his name was removed from that register.
- (4) In this Article, "year" means a period of twelve months beginning on such date as the Council may determine or, where the Council varies that date, such period (whether greater or less than twelve months) immediately following the variation as the Council may determine.
  - (5) Nothing in this Article shall apply to honorary members of the Society.

#### Penalty for falsification of registers N.I.

- **16.** If the registrar wilfully makes or causes to be made any falsification in any matter relating to any register under this Order, he shall be guilty of an offence and shall be liable—
  - (a) on summary conviction, to a fine not exceeding[F66 level 3 on the standard scale];
  - (b) on conviction on indictment, to imprisonment for any term not exceeding twelve months or to a fine, or to both.

F66	1984 NI 3			

## Duty of registrar of deaths to give notice of deaths of registered persons N.I.

17. Every registrar of deaths, on registering the death of any person registered under this Order as a pharmaceutical chemist or druggist, shall forthwith transmit by post to the registrar a copy, certified under his hand, of the entry of such death; and, on receipt of such certified copy, the registrar shall strike the name of such deceased person off the appropriate register, and shall pay to the registrar of deaths the fee chargeable by law for such certified copy, together with the cost of its transmission, and may charge those payments as an expense of his office.

Disqualification of persons suffering from disability N.L.									
F6718	<b>3.</b>								
F67	Art. 18 repealed (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), <b>13</b> (with Sch. 3)								

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# PART IV N.I.

#### DISCIPLINARY PROCEEDINGS

#### The Statutory Committee N.I.

- 19.—(1) For the purposes of this Order, the Statutory Committee constituted under section 12 of the Act of 1945 shall continue in being and the provisions of this Article shall have effect with respect to the Statutory Committee and other matters relating to that Committee and their members.
  - I<sup>F68</sup>(2) The Statutory Committee shall consist of—
    - (a) a lay member who is the chair;
    - (b) 2 lay members who are deputy chairs;
    - (c) 3 other lay members; and
    - (d) 6 members who are registered persons

all of whom shall be appointed by the Council.

- (3) A member of the Statutory Committee shall hold office for a period of 4 years from the date of appointment, but shall be eligible for re-appointment at the expiration of that period.
- (4) No member of the Statutory Committee may hold office for more than an aggregate of 8 years in any 20 year period.
- (5) There shall be paid to the members of the Statutory Committee such remuneration and such travelling, subsistence or other expenses as the Council may determine.
- (6) The expenses of the Statutory Committee (including any such fees payable to any of the members thereof as may be fixed by the Council) shall be defrayed by the Society.
  - (7) The quorum of the Statutory Committee shall be 3 which must include—
    - (a) the chair or a deputy chair;
    - (b) a lay member; and
    - (c) a member who is a registered person.
  - (8) The Council may by regulations make provision as to—
    - (a) the procedure of the Statutory Committee (including the validation of proceedings in the event of vacancies or defects in appointment);
    - (b) the grounds on which persons are to be disqualified from appointment as members of the Statutory Committee; and
    - (c) the circumstances in which members cease to hold office or may be removed or suspended from office.]

**F68** Art. 19(2)-(8) substituted (1.10.2012) for art. 19(2)-(11) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 7 (with Sch. 3)

#### Fitness to practice N.I.

[<sup>F69</sup>20. The provisions of Schedule 3 shall have effect with respect to fitness to practise functions and proceedings of the Statutory Committee and the Scrutiny Committee.]

F69 Art. 20 substituted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 8 (with Sch. 3)

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Conditions a	s to the giving	of directions by	<b>Statutory</b>	Committee in	case of conviction	on, etc.,
of employee	N.I.		•			

**F70** Art. 21 repealed (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), **14** (with Sch. 3)

#### Provisions as to directions given by Statutory Committee and as to appeals N.I.

F71 Art. 22 repealed (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 15 (with Sch. 3)

# PART V N.I. MISCELLANEOUS

#### [F72The Directive: functions of competent authority, etc. N.I.

- **22A.**—(1) The Society is designated as the competent authority in Northern Ireland for the purposes of the Directive so far as it relates to the profession of pharmacy.
- (2) The Society must in Northern Ireland carry out (in particular) the functions specified in Schedule 2D.
- (3) The Society is designated as the competent authority in Northern Ireland for the award of evidence of formal qualifications in pharmacy listed in relation to the United Kingdom in Annex V, point 5.6.2 of the Directive.
- (4) The Department may give directions to the Society as to matters of administration in connection with the functions of the Society specified in Schedule 2D.
  - (5) The Society must comply with a direction given under paragraph (4).
  - (6) In Schedule 2D—
  - [ "the GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), read with Chapter 2 of Part 2 of the Data Protection Act 2018;]
    - (a) "NI pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by the Society;
    - (b) "non-UK pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by a competent authority of a relevant European State other than the United Kingdom;
    - (c) references in that Schedule to a pharmacist include a pharmaceutical chemist.]
  - F72 Art. 22A inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 23 (with reg. 155)
  - F73 Art. 22A(6)(za) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), Sch. 19 para. 14 (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

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#### Dispensing, etc., in public institutions N.I.

**23.** A person shall not be appointed to, or hold, the office of chemist, compounder or dispenser in any institution maintained at the cost of, or in receipt of aid from, public funds in Northern Ireland unless he is a registered pharmaceutical chemist or a fully registered person within the meaning of 1<sup>F74</sup> section 55 of the Medical Act 1983.

**F74** 1983 c. 54

#### Pharmacy Inspectors N.I.

- **24.**—(1) The Department may appoint one (or, subject to the approval of the Department of Finance, more than one) fit and proper person (being a registered pharmaceutical chemist) as a Pharmacy Inspector for the purposes of this Order ("the Pharmacy Inspector").
- (2) The Pharmacy Inspector shall discharge such duties as may be assigned to him by the Department, and the duties so assigned may include the duty of taking all reasonable steps to enforce the provisions of this Order.
- (3) The Pharmacy Inspector, on producing his authority (if requested to do so), may, for the purposes of enforcing the provisions of this Order, at all reasonable times enter any registered pharmacy and make such examination and inquiry and do such other things as may be necessary for ascertaining whether the provisions of this Order are being complied with.
- (4) If any person wilfully delays or obstructs the Pharmacy Inspector in the exercise of any powers under this Article, or fails without reasonable excuse to give any information which he is duly required under this Article to give, such person shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [F75] level 3 on the standard scale].

**F75** 1984 NI 3

#### Fees N.I.

- 25.—(1) The fees paid to the registrar under section 75(1) of the Medicines Act on the entry of premises in the register required to be kept under that section, and the retention or other fees, or any other sums, paid to him under section 76 of that Act, shall be paid by him to the Department.
- (2) Of the fees so paid to the Department, such portion, not less than one half, as may be determined by the Department, with the consent of the Department of Finance, shall be paid to the Society.

# [F76Regulations: procedure N.I.

- **25A.**—(1) Regulations made under this Order shall be subject to negative resolution.
- (2) Regulations made by the Council under this Order shall not come into operation unless and until they are approved by the Department.]

F76 Art. 25A inserted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 9 (with Sch. 3)

#### Transitional provisions, amendments and repeals N.I.

**26.** Without prejudice to the operation of sections 28 and 29 of the Interpretation Act (Northern Ireland) 1954 (effect of repeal and substituting provisions)—

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(a) the transitional provisions contained in Schedule 4 shall have effect; Para.(b), with Schedule 5, effects amendments; para.(c), with Schedule 6, effects repeals

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#### SCHEDULES

SCHEDULE 1 N.I.

Article 3(2).

#### THE PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

# PART I N.I.

#### THE CONSTITUTION OF THE SOCIETY

- 1. The Society is a body corporate.
- **2.** Every person registered as a pharmaceutical chemist shall, so long as he continues to be so registered, be a member of the Society.
- **3.**—(1) Every person registered as a druggist shall, so long as he continues to be so registered, be an associate of the Society.
- (2) Every associate of the Society shall have the privilege of attending and voting at all meetings of the Society, and otherwise taking part in the Society's proceedings, in the same manner as a member of the Society.
- **4.** Every person registered as a student shall, so long as he continues to be so registered, be a student of the Society.
- **5.** The Council may elect suitable members or associates of the Society as fellows of the Society and may elect suitable persons as honorary members of the Society.

# PART II N.I.

#### SUPPLEMENTARY PROVISIONS AS TO THE SOCIETY

#### The seal

**6.** The fixing of the seal of the Society shall be authenticated in such manner as may be prescribed, and any document purporting to be sealed with that seal so authenticated shall be receivable in evidence of the particulars stated in that document.

#### Officers

- 7.—(1) The Council may employ a secretary of the Society (who shall be a registered pharmaceutical chemist), a treasurer and such other subordinate officers as may be found necessary for the performance of the Society's functions.
- (2) All fees and other sums which are payable to the Society under this Order shall be paid to the treasurer and shall be applied to the purposes of the Society in such manner as may be determined by the Council under Article 4(3).

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#### Superannuation, etc.

- **8.**—(1) The Society may in its discretion, with the consent of the Department, grant to any officer whose whole time has been devoted to the service of the Society and who has become incapable of discharging the duties of his office with efficiency by reason of permanent infirmity of mind or body or old age, upon his resigning or otherwise ceasing to hold his office, an annual allowance not exceeding in any case two-thirds of his salary and emoluments at that time.
- (2) An officer shall not be qualified to receive an allowance under this paragraph on the ground of age unless he has attained the age of sixty years and has served as an officer of the Society for twenty years at least.
- (3) An allowance under this paragraph shall be payable to, or in trust for the officer concerned and shall not be assignable or chargeable with debts or other liabilities.
- (4) Where an officer whose whole time has been devoted to the service of the Society dies, after he has served five years or upwards, while still employed in that service, the Society may in its discretion, with the consent of the Department, grant to his legal personal representatives a gratuity equal to the annual salary and emoluments of his office.
- (5) Where an officer, having become entitled to an annual allowance under this paragraph, dies after he has retired from the service of the Society, and the sums paid or payable to him at the time of his death on account of that allowance are less than the amount of the annual salary and emoluments of his office, the Society may in its discretion, with the consent of the Department, grant to his legal personal representatives a gratuity equal to the deficiency.

[F77 SCHEDULE 2 N.I.

Article 4(2)

Sch. 2 substituted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 10, Sch. 1 (with Sch. 3)

# THE COUNCIL OF THE SOCIETY N.I. CONSTITUTION OF THE COUNCIL

- 1.—(1) The Council shall consist of—
  - (a) 7 registered persons; and
  - (b) 7 lay members.
- (2) The members of the Council shall be appointed by the Department.
- (3) The term of office of members of the Council shall be 4 years or such other period as may be determined by the Department at the time the appointments are made.
- (4) No member of the Council is to hold office for more than an aggregate of 8 years in any 20 year period.
- (5) The Council shall pay to its members such remuneration and allowances as the Department may determine.
- 2.—(1) Without prejudice to sub-paragraph (4), the Council may appoint one or more committees and sub-committees and delegate to such committees and sub-committees such of its functions as it thinks fit.

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- (2) A committee or sub-committee appointed under sub-paragraph (1) may include persons who are not members of the Society.
- (3) Every member of a committee or sub-committee appointed under sub-paragraph (1), who, at the time of appointment, was a member of the Council shall, if that person ceases to be a member of the Council, also ceases to be a member of the committee or sub-committee.
- (4) The Council shall have a Scrutiny Committee and it shall have the functions assigned to it by or under this Order.
  - (5) The Council may by regulations make provision as to—
    - (a) the constitution, appointment and procedure of the Scrutiny Committee (including the validation of proceedings in the event of vacancies or defects in appointment);
    - (b) the grounds on which persons are to be disqualified from appointment as members of the Scrutiny Committee; and
    - (c) the tenure of office of members of the Scrutiny Committee (including the circumstances in which they cease to hold office or may be removed or suspended from office).
- (6) There shall be paid to the members of the Scrutiny Committee and any committee or sub-committee appointed under paragraph (1) such remuneration and such travelling, subsistence or other expenses as the Council may determine.
  - 3. The Department may by regulations make provision as to—
    - (a) the grounds on which persons are to be disqualified from appointment as members of the Council;
    - (b) the appointment of a President and a Vice-President of the Council and the President's and Vice-President's term of office, and the regulations may provide that the term is to be determined by whoever makes the appointment of the President and Vice-President, on appointment;
    - (c) deputising arrangements in respect of the President and Vice-President;
    - (d) the quorum of the Council;
    - (e) the circumstances in which members cease to hold office or may be removed or suspended from office; and
    - (f) the procedure of the Council (including the validation of proceedings in the event of vacancies or defects in appointment).]

# [F78SCHEDULE 2A N.I.

F78 Sch. 2A, 2B substituted (22.5.2008) for Sch. 2A by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 12, Sch.

# TABLE IN RESPECT OF TRAINING IN THE FORMER CZECHOSLOVAKIA, THE FORMER SOVIET UNION OR THE FORMER YUGOSLAVIA

Column (a)	Column (b)	Column (c)
1st January 1993	Former Czechoslovakia	Czech Republic
1st January 1993	Former Czechoslovakia	Slovakia
20th August 1991	Former Soviet Union	Estonia

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21st August 1991	Former Soviet Union	Latvia
11th March 1990	Former Soviet Union	Lithuania
25th June 1991	Former Yugoslavia	Slovenia
[F79 8th October 1991	Former Yugoslavia	Croatia ]]

**F79** Words in Sch. 2A inserted (31.12.2013) by The European Qualifications (Health Care Professions) (Croatia Accession Amendment) Regulations 2013 (S.I. 2013/3036), regs. 1(1), **8** 

### F80SCHEDULE 2B N.I.

**F80** Sch. 2A, 2B substituted (22.5.2008) for Sch. 2A by European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), reg. 12, **Sch.** 

# VISITING PHARMACEUTICAL CHEMIST FROM A RELEVANT EUROPEAN STATE

#### Application and interpretation N.I.

- [F81]1. This Schedule applies to a person who—
  - (a) is an exempt person who is lawfully established as a pharmacist in a relevant European State other than the United Kingdom; and
  - (b) is not a person to whom paragraph 15 of Schedule 2C (European professional card and entitlement to registration: provision of occasional pharmacy services) to this Order or paragraph 15 of Schedule 2A (European professional card and entitlement to registration: provision of occasional pharmacy services) to the Pharmacy Order 2010 (S.I. 2010/231) applies.]
- F81 Sch. 2B para. 1 substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(2) (with reg. 155)

#### 2. In this Schedule—

- (a) a "visiting practitioner" means an exempt person to whom this Schedule applies;
- (b) the "home State", in relation to a visiting practitioner, means the relevant European State in which the practitioner is lawfully established as a pharmacist; and
- (c) a reference to the provision of occasional pharmacy services is a reference to the provision of services as a pharmaceutical chemist in Northern Ireland on a temporary and occasional basis.

#### Registration in respect of provision of occasional pharmacy services N.I.

**3.**—(1) A visiting practitioner is entitled to be registered in the register mentioned in Article 6(1) (d) if the practitioner is entitled under paragraph 4 or 7 to provide occasional pharmacy services; and the registrar shall give effect to the entitlement.

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- (2) A visiting practitioner who is entitled under sub-paragraph (1) to be registered in the register mentioned in Article 6(1)(d) as a visiting pharmaceutical chemist from a relevant European State, but who is not registered in that register, shall be treated as so registered in that register.
- (3) Sub-paragraph (4) applies where a person's entitlement under sub-paragraph (1) to be registered in the register mentioned in Article 6(1)(d) ceases because, by reason of the operation of paragraphs 8(1),(2) or (5), the person ceases to be entitled under this Schedule to provide occasional pharmacy services.
- (4) If the person's name is registered in the register mentioned in Article 6(1)(d), the registrar may remove the person's name from that register.
- (5) Sub-paragraphs (1) to (4) are not to be taken to prejudice the application, in relation to persons registered in the register mentioned in Article 6(1)(d) on the basis of entitlement under sub-paragraph (1), of any other provision of this Order under which a registered person's name may be removed from the register mentioned in Article 6(1)(d).

#### Entitlement to provide occasional pharmacy services: first year N.I.

- **4.** A visiting practitioner is entitled to provide occasional pharmacy services if—
  - (a) the practitioner has complied with requirements of paragraph 5; and
  - (b) where the practitioner's case falls within regulation [F823(8)(a) or (e)] of the General Systems Regulations, the provision by the practitioner of occasional pharmacy services is in accordance with regulations [F8319 to 23] of those regulations (the practitioner having, in particular, successfully completed any adaptation period, or passed any aptitude test, that the practitioner may be required to undertake pursuant to Part 2 of those regulations).

but paragraph 8 contains provision about the duration of entitlement under this paragraph.

- F82 Words in Sch. 2B para. 4(b) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(3)(a) (with reg. 155)
- **F83** Words in Sch. 2B para. 4(b) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(3)(b) (with reg. 155)

# First provision of services: required documents N.I.

- **5.**—(1) A visiting practitioner who proposes to provide occasional pharmacy services for the first time must, before providing any such services, send or produce to the registrar the required documents.
  - (2) The required documents are—
    - (a) a written declaration that—
      - (i) states the practitioner's wish to provide occasional pharmacy services, <sup>F84</sup>...
      - (ii) contains details of the insurance cover, or other means of personal or collective protection, that the practitioner has with regard to professional liability;

[ confirms that the practitioner does not have a criminal conviction; and <sup>5</sup>(iii)

- (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a pharmacist;]
- [ a written declaration as to whether the practitioner has the necessary knowledge of  $^{F86}$ (aa) English;]
  - (b) if the practitioner is a national of a relevant European State, proof of nationality;

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- (c) if the practitioner is not a national of a relevant European State, proof of the Community right by virtue of which the practitioner is an exempt person;
- (d) evidence of qualifications in pharmacy (see paragraph 6); and
- (e) a certificate issued by a competent authority in the practitioner's home State confirming—
  - (i) that the practitioner is lawfully established as a pharmacist in that State, and
  - (ii) that the practitioner is not prohibited (whether on a permanent or temporary basis) from practising as a pharmacist there.
- (3) A declaration under sub-paragraph (2)(a) [F87 or (aa)] may be supplied by any means.
- **F84** Word in Sch. 2B para. 5(2)(a)(i) omitted (18.11.2016) by virtue of The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(4)(a)(i) (with reg. 155)
- F85 Sch. 2B para. 5(2)(a)(iii)(iv) inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(4)(a)(ii) (with reg. 155)
- F86 Sch. 2B para. 5(2)(aa) inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(4)(b) (with reg. 155)
- F87 Words in Sch. 2B para. 5(3) inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(4)(c) (with reg. 155)

### [F88First provision of services: visiting practitioners from Great Britain N.I.

- **5A.**—(1) The registrar must treat a visiting practitioner who—
  - (a) applies to be registered in the register mentioned in Article 6(1)(d) as a visiting practitioner; and
  - (b) is entered in Part 4 of the register maintained under article 19 of the Pharmacy Order 2010 relating to pharmacists who are visiting practitioners to Great Britain,

as complying with the requirements of paragraph 5.

- (2) The registrar may require the visiting practitioner to provide additional information concerning his or her professional qualifications as a result of differences in the way that the profession is regulated in different parts of the United Kingdom.
- (3) Sub-paragraph (1) does not apply if the registrar has required the visiting practitioner to provide information under sub-paragraph (2) and the visiting practitioner has not done so.]
  - F88 Sch. 2B para. 5A inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(5) (with reg. 155)
- **6.**—(1) Subject to sub-paragraph (3), the evidence referred to in paragraph 5(2)(d) is evidence of the European-recognised qualifications which entitle the visiting practitioner to provide, in the practitioner's home State, the pharmacy services that the practitioner proposes to provide in Northern Ireland on a temporary and occasional basis.
- (2) This sub-paragraph applies to a visiting practitioner whose case falls within regulation [<sup>F89</sup>3(8) (a) or (e)] of the General Systems Regulations (with the result that the practitioner is not entitled to provide occasional pharmacy services unless their provision by the practitioner is in accordance with regulations [<sup>F90</sup>19 to 23] of those regulations).
- (3) If sub-paragraph (2) applies to a visiting practitioner, the evidence referred to in paragraph 5(2)(d) of the practitioner's qualifications in pharmacy is evidence of the qualifications which entitle the practitioner to practise as a pharmacist in his home State.

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- (4) In this paragraph, "European-recognised qualifications" means qualifications which relevant European States are required by the Directive to recognise.
  - **F89** Words in Sch. 2B para. 6(2) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 24(6)(a) (with reg. 155)
  - **F90** Words in Sch. 2B para. 6(2) substituted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **24(6)(b)** (with reg. 155)

### Entitlement to provide occasional pharmacy services after first year: renewals N.I.

- 7.—(1) Sub-paragraph (2) applies where the registrar receives the required renewal documents from a visiting practitioner who is entitled under this Schedule to provide occasional pharmacy services.
- (2) The visiting practitioner is entitled to continue to provide occasional pharmacy services, but paragraph 8 contains provision about the duration of entitlement continued under this sub-paragraph.
- (3) Sub-paragraph (4) applies where the registrar receives the required renewal documents from a visiting practitioner—
  - (a) who is not entitled under this Schedule to provide occasional pharmacy services; and
  - (b) who has been previously entitled under this Schedule to provide occasional pharmacy services.

The visiting practitioner is once again entitled to provide occasional pharmacy services but, in a case where the practitioner's name is not in the register mentioned in Article 6(1)(d) as a result of removal otherwise than under paragraph 3(4), only if the registrar decides, after having regard (in particular) to the fact of that removal and the reasons for it, that the entitlement should be renewed.

Paragraph 8 contains provision about the duration of entitlement under this sub-paragraph.

- (5) In relation to a visiting practitioner "the required renewal documents" are—
  - (a) a renewal declaration; and
  - (b) each evidence of change document (if any).
- (6) In this paragraph "renewal declaration", in relation to a visiting practitioner, means a written declaration that—
  - (a) states the practitioner's wish to provide occasional pharmacy services in a further year; and
  - (b) contains details of the insurance cover, or other means of personal or collective protection, that the practitioner has with regard to professional liability.
  - (7) Where a document—
    - (a) is, in relation to a visiting practitioner, one of the required documents for the purposes of paragraph 5;
    - (b) is not a declaration under paragraph 5(2)(a); and
    - (c) substantiates a matter as respects which there has been a material change since the practitioner last (whether under paragraph 5 or this paragraph) supplied the then-current version of the document to the registrar;

the version of the document current when under this paragraph the practitioner supplies a renewal declaration to the registrar is an "evidence of change document" for the purposes of subparagraph (5)(b).

(8) A renewal declaration supplied under this paragraph may be supplied by any means.

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### Duration of entitlement to provide occasional pharmacy services N.I.

- **8.**—(1) Unless an entitlement under paragraph 4 or 7(4) is continued (or further continued) by paragraph 7(2), the entitlement ceases at the end of the year that begins with and includes the day on which the registrar received the documents whose receipt gave rise to the entitlement.
- (2) Where an entitlement under paragraph 4 or 7(4) is continued (or further continued) by paragraph 7(2), the entitlement is extended so as to cease at the end of the year that begins with and includes the relevant day.
  - (3) For the purposes of sub-paragraph (2)—
    - (a) if the day on which the registrar receives the documents whose receipt gives rise to the continuation (or further continuation) is an anniversary of the start day, "the relevant day" means the day on which the registrar receives those documents;
    - (b) otherwise, "the relevant day" means the anniversary of the start day that is the first such anniversary to occur after the registrar receives the documents whose receipt gives rise to the continuation (or further continuation).
- (4) In sub-paragraph (3) "the start day", in relation to an entitlement under paragraph 4 or 7(4), means the day on which the registrar receives the documents whose receipt gives rise to the entitlement.
  - (5) An entitlement under this Schedule to provide occasional pharmacy services ceases if—
    - (a) the visiting practitioner concerned becomes established as a pharmacist in Great Britain or a pharmaceutical chemist in Northern Ireland; or
    - (b) a disqualifying decision is made against the visiting practitioner concerned.
- (6) In sub-paragraph (5) "disqualifying decision", in relation to a visiting practitioner, means a decision made by a competent or judicial authority in the practitioner's home State [F91 or, if different, a relevant European State in which the practitioner practises or has practised as a pharmacist] that has the effect that the practitioner—
  - (a) ceases in that State to be registered or otherwise officially recognised as a pharmacist; or
  - (b) is prohibited (whether on a permanent or temporary basis) from practising as a pharmacist in that State.
  - (7) If in the case of a visiting practitioner—
    - (a) the practitioner's name is removed from the register mentioned in Article 6(1)(d); and
    - (b) immediately before the time when the removal takes effect, the practitioner is entitled under this Schedule to provide occasional pharmacy services;

that entitlement ceases at that time.

**F91** Words in Sch. 2B para. 8(6) inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, **24(7)** (with reg. 155)

### Conditions N.I.

- 9.—(1) Sub-paragraph (2) applies if—
  - (a) the establishment of a visiting practitioner in the practitioner's home State is subject to a condition relating to the practitioner's practice as a pharmacist;
  - (b) the practitioner's name is registered in the register mentioned in Article 6(1)(d); and
  - (c) for any of the purposes of this Order it falls to be decided whether the practitioner's misconduct renders him unfit to be on the register mentioned in Article 6(1)(d).

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- (2) The matters that may be considered as misconduct include (in particular) any act or omission by the visiting practitioner during the course of the provision by the practitioner of occasional pharmacy services that is, or would be if the condition applied in relation to practice as a pharmacist outside the practitioner's home State, a breach of the condition.
  - (3) In sub-paragraphs (1) and (2) "condition" includes limitation.]

## [F92SCHEDULE 2C N.I.

Article 8D

Directive 2005/36/EC: European professional card

F92 Sch. 2C inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 25 (with reg. 155)

# PART 1 N.I.

#### General

### Introductory N.I.

**1.** This Schedule supplements the rights and obligations set out in the Implementing Regulation 2015.

### Interpretation N.I.

- 2. In this Schedule—
  - "automatically recognised pharmacist" means a person who is entitled to have his or her qualifications as a pharmacist automatically recognised under articles 21, 23, 49a or 49b of the Directive;
  - "disqualifying decision" means a decision made by a competent authority or a judicial authority in a person's home State or host State that has the effect that—
  - (a) the person ceases to be registered or otherwise officially recognised as a pharmacist in that State; or
  - (b) the person is prohibited, permanently or temporarily, from practising as a pharmacist in that State;
  - "EPC applicant" means a person making, or who has made, an EPC application;
  - "EPC application" means an application for a European professional card made by a person who is seeking to practise as an automatically recognised pharmacist;
  - "EPC holder" means a person who holds a valid European professional card as a result of an EPC application;
  - "home State" means the relevant European State specified by an EPC applicant in his or her EPC application in accordance with article 4 of the Implementing Regulation 2015;
  - "host State" means the relevant European State in which an EPC applicant seeks to practise as a pharmacist;

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"Implementing Regulation 2015" means Commission Implementing Regulation (EU) No 983 of 2015 on the procedure for issuance of the European professional card and the application of the alert mechanism pursuant to the Directive;

"missing document" means a document which an EPC applicant was required to provide with the EPC application but which the EPC applicant has not provided;

"occasional pharmacy services" means the provision of services as a pharmacist on a temporary and occasional basis; and

references to a pharmacist include a pharmaceutical chemist.

# PART 2 N.I.

General functions of the Society in relation to European professional cards

### Society not to request resubmission of valid documents N.I.

**3.** If a person ("P") who has already made an application for or in relation to a European professional card makes a subsequent or further application for or in relation to a European professional card, the Society may not request resubmission of documents that are contained in P's IMI file and which are still valid for the purposes of processing P's subsequent or further application.

### Power to revoke a European professional card N.I.

- **4.**—(1) The Society may revoke a European professional card issued under this Schedule if it appears to the Society that the person ("P") to whom the card was issued is not entitled to hold the card.
- (2) P is not entitled to hold a European professional card if, in particular, P is subject to a disqualifying decision.

### Rectification of the European professional card or the IMI file N.I.

- **5.**—(1) If an automatically recognised pharmacist ("P") holds a European professional card issued by the Society, P may, at any time, make a written request to the Society to rectify inaccurate or incomplete data in P's IMI file or to delete or block P's IMI file if it contains inaccurate or incomplete data.
- (2) If the Society is satisfied that the data in P's IMI file is inaccurate or incomplete, the Society must comply with a request by P under sub-paragraph (1).
  - (3) The Society must notify P of P's right under sub-paragraph (1)—
    - (a) at the time P's European professional card is issued;
    - (b) within the period ending two years after the date on which the European professional card was issued; and
    - (c) subsequently at intervals not exceeding two years from the date of the previous notification.
- (4) A notification under sub-paragraph (3)(b) or (c) must be sent to P by means of an automatic reminder sent through the IMI.
- (5) The Society must not charge P a fee in relation to the making of a written request under sub-paragraph (1) or in relation to complying with, or responding to, such a request.
  - (6) If—
    - (a) P's European professional card was issued for the purposes of establishment;

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- (b) P asks the Society to delete P's IMI file; and
- (c) P's host State is the United Kingdom,

the Society must provide P with evidence confirming that the Society recognises P's professional qualifications.

### Duty to give reasons and to notify of right of appeal N.I.

**6.** If the Society refuses to issue, extend or vary, or decides to revoke, a European professional card under this Schedule, the Society must notify the EPC applicant or the EPC holder of the reasons for that decision and of his or her right of appeal under Article 11ZZB.

### Updating the IMI file: disciplinary action or criminal sanctions N.I.

- 7.—(1) This paragraph applies if a person ("P")—
  - (a) makes an EPC application to the Society; or
  - (b) is an EPC holder and P's European professional card was issued by the Society.
- (2) The Society must update P's IMI file in accordance with sub-paragraphs (3) and (4) in a timely manner.
- (3) The Society must add to P's IMI file information, regarding disciplinary action or criminal sanctions, which—
  - (a) relates to a prohibition or restriction on P's entitlement to practise as a pharmacist; or
  - (b) has consequences for the pursuit of any activities by P, in P's capacity as a pharmacist.
- (4) The Society must delete from P's IMI file information regarding disciplinary action or criminal sanctions that is no longer required.
- (5) The Society must immediately inform P and the competent authorities of other relevant European States that have access to P's IMI file of any update under this paragraph.
  - (6) The information that may be added or deleted under this paragraph is limited to details of—
    - (a) P's identity;
    - (b) information about the national authority or court which has made a decision on a restriction or prohibition applying to P;
    - (c) the scope of the restriction or prohibition; and
    - (d) the period for which the restriction or prohibition applies.

### Access to data N.I.

- **8.**—(1) The Society may access information on the IMI file of an EPC applicant or an EPC holder, in accordance with [F93the GDPR], only if the United Kingdom is the home State or the host State of the applicant or the holder.
- (2) The Society must provide an EPC applicant or an EPC holder with information on the content of his or her IMI file on request.
  - F93 Words in Sch. 2C para. 8(1) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), Sch. 19 para. 15(2) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

### Processing data N.I.

9.—(1) The Society may process personal data to which it has access under paragraph 8—

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- (a) for as long as it is needed for the purposes of recognition of the professional qualifications of the EPC applicant or the EPC holder; and
- (b) as evidence of the recognition or transmission of the declaration required as part of the documents submitted under paragraph 12(2).

F94(2)																																
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F94 Sch. 2C para. 9(2) omitted (25.5.2018) by virtue of Data Protection Act 2018 (c. 12), s. 212(1), Sch. 19 para. 15(3) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

# PART 3 N.I.

European professional cards for establishment in the United Kingdom or another relevant European State

# European professional cards for establishment in a host State other than the United Kingdom N.I.

- **10.**—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Society for the purposes of establishment as a pharmacist in a relevant European State other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the appropriate documents listed in paragraph 1 of Part A of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with and including the date on which the Society receives the EPC application, the Society must acknowledge receipt of the application and inform P of any missing document.
- (4) The Society must, within the period of one month beginning with and including the date of the relevant day—
  - (a) decide whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
  - (b) transmit its decision (under paragraph (a)) and the EPC application to the competent authority of P's host State (in order for that competent authority to decide whether to issue the European professional card: see article 4d(2) of the Directive) and, at the same time, inform P of the status of the application.
  - (5) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Society receives the EPC application, beginning with and including the day on which the Society receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Society.
  - (6) For the purpose of sub-paragraph (5), "relevant document" means—
    - (a) any previously missing document; or
    - (b) any document that is requested by the Society in connection with the EPC application before the day described in sub-paragraph (5)(a).

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### Issue of European professional card for establishment in Northern Ireland N.I.

11.—(1) This paragraph applies if—

- (a) a person ("P") makes an EPC application to a competent authority of a relevant European State other than the United Kingdom for the purposes of establishment as a pharmacist in Northern Ireland:
- (b) P's home State is not the United Kingdom;
- (c) the competent authority of P's home State has decided whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
- (d) the competent authority of P's home State transmits the decision described in paragraph (c) and the EPC application to the Society (in order for the Society to decide whether to issue the European professional card: see article 4d(2) of the Directive).
- (2) The Society may request additional information or a certified copy of a document from the competent authority of P's home State if it appears to the Society—
  - (a) that the applicant may not be entitled to hold a European professional card in accordance with this Schedule; or
  - (b) that a document or information supplied as part of the EPC application is not, or may not be, valid or correct.
- (3) Subject to sub-paragraphs (4) to (6), the Society must issue the European professional card within one month beginning with and including the date on which the Society received the EPC application from the competent authority of P's home State.
  - (4) The Society may extend the period in sub-paragraph (3)—
    - (a) by two weeks; and
    - (b) if it considers it necessary to do so, in particular for reasons relating to public health or the safety of recipients or prospective recipients of pharmacy services from the applicant, by a further two weeks following expiry of the two week extension under paragraph (a).
- (5) The Society must notify the applicant of any extension under sub-paragraph (4) and the reasons for it.
- (6) If the Society does not receive the documents or information necessary to determine whether to issue the European professional card, the Society may refuse to issue the card (also see paragraph 6: duty to give reasons and to notify of right of appeal).
  - (7) If the Society fails to make a decision within the time limits set out in this paragraph—
    - (a) the applicant is to be treated as entitled to the European professional card; and
    - (b) the Society must issue the card to the applicant through the IMI immediately.

# PART 4 N.I.

European professional cards for the provision of occasional pharmacy services in a relevant European State other than the United Kingdom

Issue of European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom N.I.

12.—(1) This paragraph applies if—

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- (a) a person ("P") makes an EPC application to the Society for the purposes of providing occasional pharmacy services (which do not fall within article 7(4) of the Directive) in one or more relevant European States other than the United Kingdom; and
- (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the documents listed in paragraphs (a) to (c) of Part B of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with and including the date on which the Society receives the EPC application, the Society must acknowledge receipt of the application and inform P of any missing document.
- (4) The Society must within three weeks beginning with and including the date of the relevant day—
  - (a) consider P's EPC application, the authenticity and validity of the supporting documents and whether P is qualified as an automatically recognised pharmacist;
  - (b) decide whether to approve or refuse the application and whether to issue the European professional card; and
  - (c) transmit its decision (under paragraph (b)) and, if issued, the European professional card, to the competent authority of each host State concerned and, at the same time, inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (5) Unless its period of validity is extended under paragraph 13, a European professional card issued under this paragraph expires after 18 months beginning with and including the date on which it is issued.
  - (6) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Society receives the EPC application, beginning with and including the day on which the Society receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Society.
  - (7) For the purpose of sub-paragraph (6), "relevant document" means—
    - (a) any previously missing document; or
    - (b) any document that is requested by the Society in connection with the EPC application before the day described in sub-paragraph (6)(a).

# Variation of a European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom N.I.

- **13.**—(1) This paragraph applies to an automatically recognised pharmacist ("P") who holds a European professional card issued under paragraph 12.
- (2) If P wishes to provide relevant pharmacy services after the end of the period of 18 months beginning with and including the date on which the card was issued, P may apply to the Society for the period of validity of the card to be extended by 18 months or such shorter period as may be specified in the application.
- (3) If P wishes to provide relevant pharmacy services in a host State not already specified on the card, P may apply to the Society for the list of host States specified on the card to be supplemented with the addition of such relevant European States as may be specified in the application.
- (4) An application under sub-paragraph (2) or (3) must be accompanied by details of any material changes to documentation or information that—

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- (a) was, pursuant to the Implementing Regulation 2015, provided to the Society with the EPC application under paragraph 12; and
- (b) is recorded in P's IMI file.
- (5) After considering an application under sub-paragraph (2) or (3), the Society must—
  - (a) accept the application (see sub-paragraph (6)); or
  - (b) if it appears to the Society that P is not, or may not be, entitled to hold a European professional card, reject the application and inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (6) If the Society accepts the application, the Society must—
  - (a) issue an amended European professional card;
  - (b) transmit the card to the competent authority of each host State specified on the card; and
  - (c) notify P.
- (7) In this paragraph, "relevant pharmacy services" means occasional pharmacy services that are provided or to be provided in a relevant European State other than the United Kingdom.

# PART 5 N.I.

European professional card: requirements and entitlements as to registration

### Requirement to register: establishment cases N.I.

- **14.**—(1) A person ("P") who holds a valid European professional card for establishment in Northern Ireland is not entitled to practise as a pharmacist in Northern Ireland on the basis of establishment unless P complies with any requirements of, or under, this Order as to registration in Northern Ireland on that basis.
  - (2) For the purposes of registration, P is not required—
    - (a) to resubmit any document or evidence which is contained in P's IMI file and which is still valid; or
    - (b) to submit further evidence, or a certificate from the competent authority in P's home State which certifies, that P holds a qualification listed in Annex V, point 5.6.2 of the Directive.

### Entitlement to registration: provision of occasional pharmacy services N.I.

- **15.**—(1) This paragraph applies to a person ("P") who holds a valid European professional card, in relation to the provision of occasional pharmacy services in the United Kingdom, which—
  - (a) has been transmitted to the Society through the IMI by the competent authority of P's home State (pursuant to article 4c of the Directive); or
  - (b) has been issued by the Society under regulation 52 of the General Systems Regulations.
  - (2) Subject to sub-paragraphs (3) to (6)—
    - (a) P is entitled to be registered in the register mentioned in Article 6(1)(d) and the Society must give effect to that entitlement; and
    - (b) if P is not registered in the register mentioned in Article 6(1)(d), P is treated as being so registered.
- (3) If P's European professional card has been issued by the Society under regulation 52 of the General Systems Regulations, P's entitlement to be registered in the register mentioned in Article

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- 6(1)(d) ceases at the end of the period of 12 months beginning with and including the date on which the Society issued P's card.
  - (4) This sub-paragraph applies if—
    - (a) P's European professional card is, or becomes, invalid;
    - (b) P is subject to a disqualifying decision; or
    - (c) P becomes established as a pharmacist in the United Kingdom.
  - (5) If sub-paragraph (4) applies—
    - (a) the Society may refuse to register P in, or may remove P from, the register mentioned in Article 6(1)(d); and
    - (b) sub-paragraph (2) ceases to apply.
- (6) This paragraph is without prejudice to any other provision of this Order under which a person's registration under Article 6 may be suspended or under which a person may be removed from a register kept under Article 6.

# PART 6 N.I.

### Conditions in relation to fitness to practise

### Conditions in relation to fitness to practise: providers of occasional pharmacy services N.I.

**16.**—(1) Sub-paragraph (2) applies in relation to a person ("P") who—

- (a) falls within paragraph 15(1); and
- (b) is registered in the register mentioned in Article 6(1)(d).
- (2) If it falls to be decided whether P's fitness to practise is or may be impaired on the ground of misconduct for any of the purposes of this Order, then "misconduct" includes any act or omission by P during the course of P's provision of occasional pharmacy services—
  - (a) which constitutes a breach of a condition or limitation to which P is subject in relation to P's practice as a pharmacist in P's home State; or
  - (b) which would constitute a breach of the condition or limitation mentioned in paragraph (a) if that condition or limitation applied in relation to P's practice as a pharmacist outside of P's home State.]

# [F95SCHEDULE 2D N.I.

Article 22A

The Directive: Functions of the Society under Article 22A

F95 Sch. 2D inserted (18.11.2016) by The European Qualifications (Health and Social Care Professions) Regulations 2016 (S.I. 2016/1030), regs. 1, 25 (with reg. 155)

Provision of Directive	Function of Society
Article 4a	Ensuring that the holder of a European professional card benefits from all of the rights conferred by articles 4b to 4e of the Directive.

Provision of Directive	Function of Society
	Charging reasonable fees to cover the costs of processing applications for or in relation to European professional cards under Schedule 2C and under Part 4 of the General Systems Regulations.
Article 4b	Enabling pharmacists to apply for a European professional card in accordance with Schedule 2C and in accordance with Part 4 of the General Systems Regulations.
Article 4c	Verifying the application and supporting documents in the IMI file and issuing the European professional card for pharmacists for the temporary and occasional provision of pharmacy services other than those covered by article 7(4) of the Directive.
Article 4d	Verifying the authenticity and validity of the application and supporting documents in the IMI file for the purpose of issuing the European professional card for pharmacists for establishment or for the temporary and occasional provision of pharmacy services under article 7(4) of the Directive.
Article 4e	Updating, in a timely manner, the IMI file of a holder of a European professional card with information about disciplinary actions or criminal sanctions regarding a prohibition or restriction and which have consequences for the pursuit of any professional activities by that person under the Directive.
Article 4f	Considering applications for partial access to the profession of pharmacist under regulations 10 and 11 of the General Systems Regulations.
Article 7(2)(b)	Issuing certificates containing attestations in relation to persons established as a pharmacist in Northern Ireland.
Article 7(2a)	Requesting information from, and providing information to, other competent authorities in accordance with the declaration provided by the applicant to provide pharmacy services on a temporary and occasional basis.
Article 8(1)	In the event of justified doubts, receiving information from, or providing information to, other competent authorities in relation to—
	(a) the legality of a person's establishment as a pharmacist in Northern Ireland;
	(b) the good conduct of such a person;
	(c) the absence of any disciplinary or criminal sanctions of a professional nature against such a person.
	Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.
Article 8(2)	Receiving information from, or providing information to, other competent authorities in connection with the investigation of complaints made against persons providing services as a pharmacist.
Article 23(1)	Issuing certificates of effective and lawful practice in Northern Ireland to pharmacists.
Article 23(6)	Issuing certificates stating that NI pharmacy qualifications, which do not correspond to the titles set out in respect of the United Kingdom at point

Provision of Directive	Function of Society								
	5.6.2 of Annex V to the Directive, certify successful completion of training in pharmacy—								
	(a) that is in accordance with article 44 of the Directive; or								
	(b) that under article 22(a) of the Directive (part-time training), is to be treated as in accordance with article 44 of the Directive.								
Article 50(1) and	Providing information to other competent authorities concerning the training in Northern Ireland of a pharmacist to whom Chapter 1 of Part 3 of the General								
paragraph 1(b) of	Systems Regulations applies.								
Annex VII									
Article 50(1) and	Issuing, in respect of practice as a pharmacist, the certificates of current professional status referred to in sub-paragraph (d) of paragraph 1 of Annex								
paragraph 1(d) of	VII to the Directive within the time limits set by that sub-paragraph.								
Annex VII									
Article 50(1) and	Issuing certificates stating that evidence of NI pharmacy qualifications is that covered by the Directive.								
paragraph 2 of	cortical of the Breedite.								
Annex VII									
Article 50(2)	In cases of justified doubts—								
	(a) requiring confirmation of the authenticity of non-UK pharmacy qualifications;								
	(b) requiring confirmation that holders of non-UK pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or are to be treated as satisfying those conditions under article 22(a) of the Directive;								
	(c) providing confirmation to competent authorities of other relevant European States of the authenticity of any person's NI pharmacy qualification;								
	(d) providing confirmation that holders of NI pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or are to be treated as satisfying those conditions under article 22(a) of the Directive.								
Article 50(3)	In cases of justified doubts—								
	(a) verifying information provided in connection with non-UK pharmacy qualifications awarded following training in a relevant European State other than the State in which the qualification was awarded;								
	(b) providing information in connection with a person's NI pharmacy qualification awarded following training in another relevant European State.								
Article 50(3a)	In the event of justified doubts, seeking confirmation from, or providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the profession of pharmacist as a								

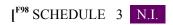
Provision of Directive	Function of Society
	result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's professional activities.
Article 50(3b)	Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI.
Article 53	Ensuring that any language controls imposed on a pharmacist are compliant with article 53 of the Directive.
Article 55a	When considering an application for registration as a pharmacist, ensuring that in respect of professional traineeships—
	(a) traineeships undertaken in a relevant European State are recognised in accordance with published guidelines; and
	(b) traineeships undertaken in a third country are taken into account.
Article 56(1)	Ensuring the confidentiality of information exchanged with other competent authorities.
Article 56(2)	Receiving information from, or providing information to, other competent authorities regarding disciplinary action, criminal sanctions or other serious circumstances likely to have consequences for practise as a pharmacist.
	Where such information is received by the Society—
	(a) examining the veracity of the circumstances;
	(b) deciding the nature and scope of any investigations that need to be carried out;
	(c) informing other competent authorities of the Society's conclusions.
	Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article $56(2)$ of the Directive is carried out in accordance with [F96the GDPR ] and Directive $2002/58/EC$ and through the IMI.
Article 56(2a)	Ensuring that the exchange of information carried out in accordance with article 56(2) of the Directive takes place through the IMI.
Article 56a (1) and (2)	Informing all other competent authorities, by way of an alert through the IMI, about a pharmacist whose professional activities have been restricted or prohibited, even temporarily, within three days beginning with and including the date of adoption of the decision; ensuring the information provided is limited to the information referred to in article 56a(2) of the Directive.
Article 56a(3)	Informing all other competent authorities, by way of an alert through the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications, within three days beginning with and including the date of the finding.
Article 56a(4)	Ensuring that the processing of personal data for the purposes of the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with [F97the GDPR] and Directive 2002/58/EC.
Article 56a(5)	Informing all other competent authorities through the IMI without delay when—

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Provision of Directive	Function of Society
	(a) a prohibition or a restriction referred to in article 56a(1) of the Directive has expired;
	(b) there is a change to the prohibition or restriction period notified under article 56a(2) of the Directive.
Article 56a(6)	Notifying the pharmacist, in respect of whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the pharmacist—
	(a) is the subject of an alert sent under article 56a(1) or (3) of the Directive;
	(b) has the right to appeal the decision or to apply for rectification of the decision;
	(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.
	Informing competent authorities, where applicable, that an alert is subject to appeal proceedings by the pharmacist.
Article 56a(7)	Ensuring that an alert made under article 56a(1) of the Directive is deleted from the IMI within three days of, beginning with and including—
	(a) the date of adoption of the revoking decision; or
	(b) the date of expiry of the prohibition or restriction referred to in that article.
Article 57a(1)	Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications as a pharmacist may be easily completed by the applicant remotely and by electronic means.]

**F96** Words in Sch. 2D (in the entry for Article 56(2)) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), Sch. 19 para. 16(2) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

**F97** Words in Sch. 2D (in the entry for Article 56a(4)) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 16(3)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)



Article 20

**F98** Sch. 3 substituted (1.10.2012) by The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308), arts. 1(1), 11, **Sch. 2** (with Sch. 3)

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# FITNESS TO PRACTISE N.I.

### Standards of conduct and performance N.I.

- 1.—(1) The Council shall—
  - (a) set standards relating to the conduct, ethics and performance expected of registered persons; and
  - (b) make provision in regulations regarding the criteria to which the Statutory Committee is to have regard when deciding, in the case of any registered person, whether or not the requirements as to fitness to practise are met in relation to that registered person.
- (2) The Council shall publish the standards set under this paragraph, as they exist from time to time, in such manner as it considers appropriate.
- (3) Where any registered person is alleged to have failed to comply with standards set under this paragraph, that failure—
  - (a) is not, of itself, to be taken to constitute misconduct on the registered person's part; but
  - (b) is to be taken into account in any proceedings against the registered person under this Order.

### Disclosure of information: general N.I.

- **2.**—(1) For the purpose of assisting the Council (including its staff and the Scrutiny Committee) and the Statutory Committee in carrying out functions in respect of the fitness to practise of a registered person a person authorised by the Council or the Statutory Committee may require—
  - (a) a registered person (except the registered person in respect of whom the information or document is sought), or
  - (b) any other person,

who, in the opinion of the authorised person, is able to supply information or produce any document which appears to be relevant to the discharge of any such function, to supply the information or produce the document.

- (2) Nothing in sub-paragraph (1) requires or permits—
  - (a) any disclosure of information which is prohibited by or under any statutory provision [F99 or the GDPR], but where that prohibition arises because the information is in a form which allows for the identification of an individual, the authorised person may require that information to be put in a form which does not allow for the identification of that individual; or
  - (b) the supplying of information or production of a document which a person could not be compelled to produce in civil proceedings in the High Court under paragraph 10.
- [<sup>F100</sup>(3) In determining for the purposes of sub-paragraph (2)(a) whether a disclosure is prohibited, it is to be assumed for the purposes of paragraph 5(2) of Schedule 2 to the Data Protection Act 2018 and paragraph 3(2) of Schedule 11 to that Act (exemptions from certain provisions of the data protection legislation: disclosures required by law) that the disclosure is required by this paragraph.]
- (4) If a person fails to supply any information or to produce any document within 14 days of being required to do so under sub-paragraph (1), or within such longer period as the Council or the Statutory Committee in the circumstances of a particular case may allow, the Council may seek an order of the county court requiring the information to be supplied or the document to be produced.

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[F101(5) In this paragraph, "the GDPR" and references to Schedule 2 to the Data Protection Act 2018 have the same meaning as in Parts 5 to 7 of that Act (see section 3(10), (11) and (14) of that Act).]

- **F99** Words in Sch. 3 para. 2(2)(a) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 17(2)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)
- **F100** Sch. 3 para. 2(3) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para.** 17(3) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)
- **F101** Sch. 3 para. 2(5) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 17(4)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

#### **Modifications etc. (not altering text)**

C2 Sch. 3 para. 2(1) modified (temp.) (25.3.2020) by Coronavirus Act 2020 (c. 7), s. 87(1), Sch. 4 para. 8 (with ss. 88-90)

### Disclosure of fitness to practise matters in the public interest N.I.

- **3.**—(1) The Council may, if it considers it to be in the public interest to do so, publish or disclose to any person, information—
  - (a) which relates to a particular registered person's fitness to practise, whether the matter to which the information relates arose before or after the entry in the register of that registered person's name, or arose in Northern Ireland or elsewhere; or
  - (b) of a particular description related to fitness to practise in relation to every registered person or to every registered person of a particular description.
- (2) For the purposes of sub-paragraph (1)(b), the Council need not consider whether it is in the public interest to publish or disclose the information in question in relation to each individual registered person to whom it relates.

### Impairment of fitness to practise N.I.

- **4.**—(1) A person's fitness to practise is to be regarded as "impaired" for the purposes of this Order only by reason of—
  - (a) misconduct;
  - (b) deficient professional performance (which includes competence);
  - (c) adverse physical or mental health which impairs their ability to practise safely and effectively or which otherwise impairs their ability to carry out the duties of a registered person in a safe and effective manner;
- [F102(ca) the person not having the necessary knowledge of English;]
  - (d) a conviction in the British Islands for a criminal offence;
  - (e) a conviction elsewhere than in the British Islands for an offence which, if committed in Northern Ireland, would constitute a criminal offence;
  - (f) having agreed to pay a penalty under section 109A of the Social Security Administration (Northern Ireland) Order 1992 (penalty as alternative to prosecution);
  - (g) a police caution in the British Islands;
  - (h) having agreed to be bound over to keep the peace by a magistrates' court in Northern Ireland;
  - (i) a determination made by a regulatory body in the United Kingdom responsible under any statutory provision for the regulation of a health or social care profession to the effect

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- that the person's fitness to practise as a member of a profession regulated by that body is impaired, or a determination by a regulatory body elsewhere to the same effect;
- (j) the Independent Safeguarding Authority including the person in a barred list (within the meaning of the Safeguarding Vulnerable Groups Act 2006 or the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007; or
- (k) the Scottish Ministers including the person in the children's list or the adults' list (within the meaning of the Protection of Vulnerable Groups (Scotland) Act 2007.
- (2) The demonstration towards a patient or customer, or a prospective patient or customer, by a registered person of attitudes or behaviour from which that person can reasonably expect to be protected may be treated as misconduct for the purposes of sub-paragraph (1)(a).
  - (3) References in this paragraph to a conviction include a conviction by court martial.
  - (4) A person's fitness to practise may be regarded as impaired because of matters arising—
    - (a) outside Northern Ireland; and
    - (b) at any time.
- (5) The Council may make such provision in regulations as it considers appropriate in connection with the information to be provided to the registrar by a registered person about fitness to practise matters that arise while their name is entered in any register kept under this Order.
- (6) If a registered person fails to comply with regulations under sub-paragraph (5) the failure may be treated as misconduct for the purposes of sub-paragraph (1)(a) and the registrar must consider in accordance with paragraph 5(1) whether or not to refer the matter to the Scrutiny Committee or (where regulations under paragraph 5(1) so provide) the Statutory Committee.

**F102** Sch. 3 para. 4(1)(ca) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), **10(2)**; S.I. 2015/1451, art. 6(a)

#### Initial action in respect of allegations N.I.

#### **5.**—(1) Where—

- (a) an allegation is made to the Society against a registered person that their fitness to practise is impaired; or
- (b) the Society has information that calls into question a registered person's fitness to practise, even though no allegation to that effect has been made to the Society,

the registrar must, except in such cases and subject to such considerations as the Council may provide in regulations, refer the matter (referred to in this paragraph as "the allegation") to the Scrutiny Committee.

- (2) Regulations under sub-paragraph (1) may provide for—
  - (a) an allegation not to be referred where it is of a type that the Council has stated in threshold criteria, which it has published and which it may amend from time to time, should not be referred: and
  - (b) an allegation to be referred, in certain cases specified in regulations, directly by the registrar to the Statutory Committee.
- (3) Where the registrar—
  - (a) refers an allegation directly to the Statutory Committee under regulations made by virtue of sub-paragraph (2)(b);and
  - (b) is of the opinion that the Statutory Committee should consider making an interim order under paragraph 8,

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the registrar must notify the Statutory Committee accordingly.

- (4) Where the registrar refers an allegation to the Statutory Committee under regulations made by virtue of sub-paragraph (2)(b), the registrar must inform the registered person who is the subject of the allegation and the person, if any, who made the allegation of that decision.
- (5) Once a decision has been taken to refer the allegation to the Scrutiny Committee or (where regulations so provide) the Statutory Committee, the registrar must, as soon as is reasonably practicable—
  - (a) require from the registered person who is the subject of the allegation details of any person—
    - (i) by whom the registered person is employed or engaged to provide services in, or in relation to, any area of pharmacy, or
    - (ii) with whom the registered person has arrangements to provide such services;
  - (b) notify the Department of the investigation of the registered person's fitness to practise;
  - (c) notify the Secretary of State, the Scottish Ministers and the Welsh Ministers of the investigation of the registered person's fitness to practise where the registered person is also entered in the register established and maintained under Article 19 of the Pharmacy Order 2010; and
  - (d) notify any person of whom the registrar is aware—
    - (i) by whom the registered person is employed or engaged to provide services in, or in relation to, any area of pharmacy, or
    - (ii) with whom the registered person has arrangements to provide such services,

of the investigation of the registered person's fitness to practise.

- (6) Where a registered person fails to comply with a requirement imposed under subparagraph (5)(a) within 14 days of the requirement being imposed, or within such longer period as the registrar may in the circumstances of the particular case allow—
  - (a) the failure may be treated as misconduct for the purposes of paragraph 4(1)(a) and the registrar may refer the matter to the committee that is considering the allegation in respect of the registered person; and
  - (b) the registrar may seek an order of the county court requiring the requested details to be supplied.

#### Consideration by the Scrutiny Committee N.I.

- **6.**—(1) Where an allegation or a matter (referred to in this paragraph as "the allegation") is referred to the Scrutiny Committee by the registrar under paragraph 5(1) or (6)(a) the Scrutiny Committee must decide whether the allegation ought to be considered by the Statutory Committee.
- (2) If the Scrutiny Committee decides that the allegation need not be considered by the Statutory Committee then unless the person who is the subject of the allegation (referred to in this paragraph as "the person concerned") has requested a referral under sub-paragraph (3)—
  - (a) the Scrutiny Committee may give—
    - (i) a warning to the person concerned in connection with any matter arising out of or related to the allegation and give a direction that details of the warning be recorded in the person's entry in the register;
    - (ii) advice to the person concerned in connection with any matter arising out of, or related to, the allegation, and
    - (iii) advice to any other person or other body involved in its investigation of the allegation on any issue arising out of, or related to, the allegation; and

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- (b) the registrar must inform the person concerned and the person who made the allegation, if any, of the Scrutiny Committee's decision and any action it is taking under head (a).
- (3) If the Scrutiny Committee determines that the allegation ought to be considered by the Statutory Committee or the person concerned has requested a referral under this sub-paragraph—
  - (a) the Scrutiny Committee must refer the allegation to the Statutory Committee;
  - (b) where the Scrutiny Committee considers that the Statutory Committee should consider making an interim order under paragraph 8, it must notify the Statutory Committee accordingly; and
  - (c) the registrar must inform the person concerned and the person who made the allegation, if any, of the Scrutiny Committee's decision to refer the allegation to the Statutory Committee.
- (4) If, having considered the allegation, the Scrutiny Committee considers that the Department should consider exercising any of its powers to bring criminal proceedings under any statutory provision, it must notify the Department accordingly.

### Consideration by the Statutory Committee N.I.

- 7.—(1) Where an allegation or matter (referred to in this paragraph as "the allegation") is referred to the Statutory Committee by the registrar—
  - (a) under regulations made by virtue of paragraph 5(2)(b);
  - (b) under paragraph 5(6)(a); or
  - (c) by the Scrutiny Committee under paragraph 6,

the Statutory Committee must determine whether or not the fitness to practise of the person in respect of whom the allegation is made (referred to in this paragraph as "the person concerned") is impaired.

- (2) Subject to sub-paragraph (6), if the Statutory Committee determines that the fitness to practise of the person concerned is impaired, it may give—
  - (a) a warning to the person concerned in connection with any matter arising out of, or related to, the allegation and give a direction that details of the warning be recorded in the person's entry in the register;
  - (b) advice to any other person or other body involved in the investigation of the allegation on any issue arising out of, or related to, the allegation;
  - (c) a direction to strike the name of the person concerned off the register;
  - (d) a direction that the entry in the register of the person concerned be suspended, for such period not exceeding 12 months as may be specified in the direction; or
  - (e) a direction that the entry in the register of the person concerned be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Statutory Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the person concerned.
- (3) Subject to sub-paragraph (6), where the Statutory Committee has given a direction under this paragraph, other than a direction to strike the name of the person concerned off the register, it may, if it thinks fit, following a review—
  - (a) where the entry in the register of the person concerned is suspended, give a direction that—
    - (i) the name of the person concerned be struck off the register.
    - (ii) the suspension of the entry be extended for such further period not exceeding 12 months as may be specified in the direction, starting from the time when the period of suspension would otherwise expire,

- (iii) the entry be suspended indefinitely, if the suspension has already been in force throughout a period of at least 2 years,
- (iv) in the case of an indefinite suspension, terminate the suspension, provided that the review takes place in the circumstances provided for in sub-paragraph (4), or
- (v) on expiry or termination of the period of suspension (including a period of suspension that was expressed to be indefinite), the entry be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Statutory Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the person concerned;
- (b) where the entry in the register of the person concerned is conditional upon that person complying with requirements specified in a direction given under this paragraph, give a direction that—
  - (i) the period specified in the direction for complying with the requirements be extended for such further period not exceeding 3 years as may be specified in the direction, starting from the time when the earlier period would otherwise expire,
  - (ii) the requirements be added to, removed or otherwise varied in such manner as may be specified in the direction,
  - (iii) the entry instead be suspended (for example, where that person has failed, whether wholly or partly, to comply with the requirements), for such period not exceeding 12 months as may be specified in the direction, or
  - (iv) the name of the person concerned be struck off the register, if that person has failed, either wholly or partly, to comply with the requirements.
- (4) If the Statutory Committee gives a direction under sub-paragraph (3)(a)(iii), the Statutory Committee must review the direction if—
  - (a) the person concerned asks it to do so; and
  - (b) at least 2 years have elapsed—
    - (i) since the direction took effect, or
    - (ii) if the direction has already been reviewed by the Statutory Committee, since the conclusion of the last review by the Statutory Committee.
- (5) If the Statutory Committee determines that the fitness to practise of the person concerned is not impaired—
  - (a) the Statutory Committee may give—
    - (i) a warning to the person concerned in connection with any matter that the Statutory Committee considers necessary or desirable taking into account the Statutory Committee's findings and give a direction that details of the warning be recorded in the person's entry in the register,
    - (ii) advice to the person concerned in connection with any such matter, and
    - (iii) advice to any other person or other body involved in the investigation of the allegation on any issue arising out of, or related to, the allegation;
  - (b) the registrar must inform the person concerned and the person who made the allegation, if any, of the Statutory Committee's decision and any action it is taking under head (a); and
  - (c) the Statutory Committee must, if the person concerned so requests, publish in such manner as it sees fit a statement summarising its determination, or may publish such a statement if that person consents.

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- (6) If the Statutory Committee determines under this paragraph that a person's fitness to practise is impaired solely by reason of adverse physical or mental health, it may not give a direction under sub-paragraph (2)(c), (3)(a)(i) or (b)(iv) that the name of the person concerned be struck off the register.
- (7) If the Statutory Committee gives a warning or a direction under this paragraph, the registrar must on its behalf send to the person concerned a statement in writing giving the person notice of the reasons for the warning or the direction and of any right of appeal under paragraph 10.
- (8) If, having considered the allegation, the Statutory Committee considers that the Department should consider exercising any of its powers to bring criminal proceedings under any statutory provision, it must notify the Department accordingly.
- (9) If the entry in the register of the person concerned is suspended, the person must be treated as not being entered in the register, even though the register still contains the person's name, except for the purposes of Articles 4A and 10 and this Schedule (and regulations under or that relate to those provisions).
- (10) Accordingly, a person whose entry in the register is suspended is not to be treated for the purposes of any statutory provision other than this Order as being entered in the register.
- (11) Nothing in this paragraph shall affect the provisions of Articles 9(5),10(1)(b), 11(2) and 17 with respect to the striking off the register of names and entries in the cases to which those provisions respectively relate.

### Interim Orders N.I.

- **8.**—(1) Where the Statutory Committee is satisfied that it is necessary for the protection of members of the public or is otherwise in the public interest or is in the interests of the registered person for an entry in the register relating to that registered person to be suspended or to be made subject to conditions, the Statutory Committee may make an order—
  - (a) that the entry in question be suspended for such period not exceeding 18 months as may be specified in the order (an "interim suspension order"); or
  - (b) that the entry in question be conditional upon the registered person complying, during such period not exceeding 18 months as may be specified in the order, with such requirements specified in the order as the Statutory Committee thinks fit to impose (an "order for interim conditional entry").
- (2) Subject to sub-paragraph (7), where the Statutory Committee has made an order under sub-paragraph (1), the Statutory Committee—
  - (a) must review it within the period of 6 months beginning with and including the date on which the order was made, and must after that, for so long as the order continues in operation, further review it—
    - (i) before the end of the period of 6 months beginning with and including the date of the decision of the immediately preceding review, or
    - (ii) if, after the end of the period of 3 months beginning with and including the date of the decision of the immediately preceding review, the person concerned requests an earlier review, as soon as practicable after that request; and
  - (b) may review it where new evidence relevant to the order has become available after it was made.
- (3) Where an interim suspension order or an order for interim conditional entry has been made in relation to any person under any provision of this paragraph (including this sub-paragraph) the Statutory Committee may—
  - (a) revoke the order;

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- (b) add to, remove or otherwise vary any condition imposed by the order; or
- (c) if satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest—
  - (i) replace an order for interim conditional entry with an interim suspension order having effect for the remainder of the term of the previous order, or
  - (ii) replace an interim suspension order with an order for interim conditional entry having effect for the remainder of the term of the previous order.
- (4) If an order is made, revoked or varied under any provision of this paragraph, the registrar must without delay send to the person in respect of whose entry in the register it relates a statement in writing giving the person notice of the order, the revocation or, as the case may be, the variation.
- (5) The Society may apply to the High Court for an order made by the Statutory Committee under sub-paragraph (1) or (3) to be extended or, if it has been extended, further extended, and on such application the High Court may extend, or further extend, for up to 12 months the period for which the order has effect.
- (6) Any reference in this paragraph to an interim suspension order, or to an order for interim conditional entry, includes a reference to such an order as extended under sub-paragraph (5).
- (7) For the purposes of sub-paragraph (2), the first review after the High Court's extension of an order made by the Statutory Committee, or after a replacement order made by the Statutory Committee under sub-paragraph (3)(c), must take place—
  - (a) if the order (or the order which has been replaced) has not been reviewed at all under sub-paragraph (2), within the period of 6 months beginning with the date on which the High Court ordered the extension or on which the replacement order under sub-paragraph (3) (c) was made; and
  - (b) if the order (or the order which has been replaced) has been reviewed under sub-paragraph (2), within the period of 3 months beginning with and including that date.
- (8) A registered person who is aggrieved by the decision of the Statutory Committee to make or vary an order under this paragraph may appeal against that decision to the High Court, and the court may—
  - (a) in the case of an interim suspension order, terminate the suspension;
  - (b) in the case of an order for interim conditional entry, revoke the order or remove or vary any condition imposed by the order; and
  - (c) in either case, substitute for the period specified in the order (or in the order extending it) some other period which could have been specified in the order when it was made (or in the order extending it),

but unless the court otherwise directs, the order remains in force pending the outcome of the appeal.

- (9) The decision of the High Court on any appeal under sub-paragraph (8) is final.
- (10) If an order is made in relation to any person under this paragraph and that order remains in effect immediately before the determination in respect of the allegation against that person under paragraph 7(1), the Statutory Committee must revoke the order once it has been determined whether or not the person's fitness to practise is impaired.

### Restoration of names to the Register: fitness to practise N.I.

- 9.—(1) Subject to sub-paragraph (2)—
  - (a) a person (hereinafter referred to as the applicant) whose name has been struck off the register, in accordance with a direction under paragraph 7(2)(c) or (3)(a)(i) or (b)(iv) may

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apply to the registrar under this paragraph for the restoration of their name to the register; and

- (b) the registrar must refer that application to the Statutory Committee.
- (2) An application may not be made under sub-paragraph (1)—
  - (a) before the expiration of 5 years from and including the date of removal; or
  - (b) within 12 months of the date of an earlier application under sub-paragraph (1) relating to the same entry.
- (3) The Council may make such provision in regulations in connection with applications for restoration by virtue of sub-paragraph (1) as it considers appropriate and may, in particular, make provision with regard to—
  - (a) the form and manner in which applications for restoration are to be made (and the regulations may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
  - (b) the information to be provided by the applicant, including—
    - (i) the name under which the applicant intends to practise, and
    - (ii) the applicant's home address;
  - (c) whether any, and if so what, additional education, training or continuing professional development is required before restoration (and the regulations may make provision for these issues to be determined in individual cases by the registrar);
  - (d) fitness to practise matters; and
  - (e) refusal of applications (including where the applicant has not paid the prescribed fee).
- (4) An application under this paragraph may not be granted unless the applicant provides such evidence of fitness to practise as the Statutory Committee directs.
- (5) Where the Statutory Committee refuses an application for restoration, the registrar must send to the applicant a statement in writing giving the applicant notice of the decision and of the reason for it
- (6) If the Statutory Committee grants an application, it may give a direction that the restoration of the applicant's name to the register be conditional upon the applicant complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Statutory Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the applicant.
- (7) Where the Statutory Committee gives a direction under sub-paragraph (6), that direction must, for the purposes of paragraph 7(3), be treated as a direction under paragraph 7.
  - (8) If—
    - (a) the Statutory Committee refuses an application under this paragraph ("the current application");
    - (b) it has refused a previous application under this paragraph made by the same person; and
    - (c) since the time when the previous application was refused, the applicant's name has not been entered in the register,

the Statutory Committee may direct that the applicant may make no further application under this paragraph.

(9) If the Statutory Committee gives a direction under sub-paragraph (6) or (8), the registrar must on its behalf send to the applicant a statement in writing giving the applicant notice of the decision and the reasons for it and, in the case of a direction under sub-paragraph (8), of the right of appeal under paragraph 10.

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### Appeals against appealable fitness to practise decisions N.I.

- **10.**—(1) The following decisions are appealable fitness to practise decisions for the purposes of this Order—
  - (a) a decision of the Statutory Committee under paragraph 7 to give a direction to strike the name of a registered person off the register;
  - (b) a decision of the Statutory Committee under paragraph 7 to give a direction for suspension or for conditional entry (including a direction extending a period of earlier suspension or of conditional entry or making a period of suspension indefinite);
  - (c) a decision of the Statutory Committee under paragraph 7 to give a direction to vary the conditions imposed by a direction for conditional entry;
  - (d) a decision of the Statutory Committee to give a direction under paragraph 9(8) that a person may make no further applications under that paragraph in respect of restoration of their name to the register.
- (2) A person in respect of whom an appealable fitness to practise decision has been made may appeal against that decision to the High Court.
- (3) Notice of any appeal under this paragraph must be filed at the High Court and served on the Society, in accordance with rules of court, within 28 days beginning with and including the date on which the written notice of the reasons for the decision was sent, or within such longer period as the High Court may, in accordance with rules of court, allow.
  - (4) Having considered the appeal, the High Court may—
    - (a) dismiss the appeal;
    - (b) allow the appeal, and quash the direction in respect of which the appeal is made;
    - (c) substitute for the direction in respect of which the appeal is made any other direction that the Statutory Committee could have given; or
    - (d) remit or refer the case to the registrar or the Statutory Committee for disposal of the matter in accordance with the High Court's directions,

and may make such order as to costs as the High Court thinks fit.

### The taking effect of directions in respect of appealable fitness to practise decisions N.I.

- 11.—(1) Where an appealable fitness to practise decision is taken in respect of a direction, that direction does not take effect—
  - (a) until the period for bringing an appeal in respect of the direction has expired; or
  - (b) where an appeal is brought within the period for bringing an appeal, until the date on which the appeal is fully disposed of, is abandoned or fails by reason of its non-prosecution.
- (2) Where, by virtue of sub-paragraph (3) of paragraph 10, the time for bringing an appeal in respect of the direction has been extended by the High Court in accordance with rules of court—
  - (a) sub-paragraph (1) applies to the direction as if the references to the period for bringing an appeal were references to that period as so extended; and
  - (b) if the High Court allows an appeal to be brought after the expiration of the period for bringing an appeal specified in sub-paragraph (3) of paragraph 10, the direction is deemed not to have taken effect on the expiration of that period.
- (3) Where, within the period for bringing an appeal (which includes that period as extended by virtue of paragraph 10(3)), an appeal is brought against an appealable fitness to practise decision in respect of a direction ("the later direction") that extends, varies or replaces an earlier direction, the

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earlier direction continues to have effect until the date on which the appeal is finally disposed of, is abandoned or fails by reason of its non-prosecution.

- (4) Where, as a result of an extension of an earlier direction pursuant to sub-paragraph (3), a later direction takes effect on a date after it was due to take effect, the period for which the later direction was originally expressed to have effect (howsoever expressed) is treated as commencing—
  - (a) on the date on which it was originally due to take effect; or
  - (b) if this would mean that the later direction would in practice expire before it commences, on the date on which the appeal is finally disposed of, is abandoned or fails by reason of its non-prosecution.
- (5) For the purposes of sub-paragraphs (3) and (4), an appeal is finally disposed of once all rights in relation to the appeal have been exhausted.

### Interim measures pending a direction taking effect N.I.

- 12.—(1) Sub-paragraph (2) applies where, under paragraph 7, the Statutory Committee gives—
  - (a) a direction to strike the name of a registered person off the register; or
  - (b) a direction for suspension.
- (2) If the Statutory Committee is satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest or in the interests of the registered person, it may order that the entry of the registered person who is the subject of the direction be suspended forthwith, pending the coming into force of the direction.
- (3) Sub-paragraph (4) applies where the Statutory Committee gives a direction for conditional entry under paragraph 7.
- (4) If the Statutory Committee is satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest or in the interests of the registered person, it may order that the entry of the registered person who is the subject of the direction be conditional upon that person complying, pending the coming into force of the direction, with such requirements specified in the order as the Statutory Committee thinks fit to impose.
- (5) Where the Statutory Committee makes an order under sub-paragraph (2) or (4), the registrar must send to the registered person who is the subject of the order a statement in writing giving that registered person notice of the contents of the order and the right of appeal under sub-paragraph (6).
- (6) A registered person who is aggrieved by a decision of the Statutory Committee to make an order under this paragraph may appeal against that decision to the High Court who may—
  - (a) dismiss the appeal;
  - (b) in the case of an order under sub-paragraph (2), terminate the suspension; and
  - (c) in the case of an order under sub-paragraph (4), revoke the order or remove or vary any condition imposed by the order,

and the decision of the High Court on any application under this paragraph is final.

# Registrar giving effect to directions or orders of the Statutory Committee or the High Court N.I.

13. Where a direction given or an order made by the Statutory Committee under this Schedule has taken effect, or an order has been made by the High Court under this Schedule on an appeal against any such direction or order the registrar shall make such alterations in the register, and in the register of premises required to be kept under section 75 of the Medicines Act, as are necessary to give effect to the direction or order.

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### Voluntary removal from the register N.I.

- **14.**—(1) The Council may make such provision in regulations as it considers appropriate in connection with applications by registered persons for voluntary removal of their names from the register and may, in particular, make provision with regard to—
  - (a) the form and manner in which applications are to be made (and the regulations may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
  - (b) the information to be provided by the applicant;
  - (c) fitness to practise matters;
  - (d) refusal of applications (in such circumstances as may be prescribed in the regulations including where there are outstanding fitness to practise proceedings in respect of the applicant);
- (2) Where the registrar refuses an application for voluntary removal from the register, the registrar must send to the applicant a statement in writing giving the applicant notice of the refusal and of the reasons for it.

### Regulations in respect of proceedings N.I.

- **15.**—(1) Subject to the following provisions the Council must make such provision as it considers appropriate in regulations in connection with the procedure to be followed and rules of evidence to be observed by—
  - (a) the Scrutiny Committee; and
  - (b) the Statutory Committee (whether exercising functions under this Order or the Medicines Act).
- (2) The regulations under sub-paragraph (1) in respect of the Statutory Committee must, and in respect of the Scrutiny Committee may, include provision—
  - (a) for securing that, where a hearing is to be held, notice of when and where the hearing is to be held is given, at such time and in such manner as may be specified in the regulations, to any person to whom the proceedings relate;
  - (b) for securing that the person concerned (which for the purposes of this paragraph, where appropriate, includes an individual who, or body corporate which, is subject to disqualification proceedings under Part 4 of the Medicines Act) and the Council are, if they so require, entitled to be heard by the Statutory Committee—
    - (i) at any hearing, or
    - (ii) in fitness to practise proceedings or on any other occasion when the Statutory Committee is considering making an interim suspension order or an order for interim conditional entry;
  - (c) for allowing the person concerned and the Council to be represented at any hearing, or in fitness to practise proceedings or on any other occasion when the Statutory Committee is considering making an interim suspension order or an order for interim conditional entry, by a barrister or solicitor;
  - (d) for proceedings before the Statutory Committee to be held in public, except and to the extent that regulations provide otherwise; and
  - (e) in respect of reviewing directions under paragraph 7—
    - (i) which are due to expire,
    - (ii) in circumstances where the Statutory Committee is considering varying the requirements specified in the direction, or

- (iii) in the case of a direction for suspension or for conditional entry—
  - (aa) at the request of the registrar or the person concerned, or
  - (bb) upon new evidence becoming available.
- (3) The regulations under sub-paragraph (1) may include provision—
  - (a) in respect of preliminary consideration of a case before the Scrutiny Committee or the Statutory Committee (including considering representations from the person concerned and the Society during its preliminary consideration);
  - (b) following preliminary consideration of a case—
    - (i) in the case of an appeal before the Statutory Committee, allowing the Statutory Committee, in specified circumstances, to allow the appeal or take a decision which has the effect of allowing the appeal,
    - (ii) in fitness to practise proceedings, allowing the Statutory Committee, in specified circumstances, to make a finding that the fitness to practise of the person concerned is not impaired, and
    - (iii) in a disqualification case, allowing the Statutory Committee, in specified circumstances, to dismiss the case;
  - (c) in respect of consensual disposal of a fitness to practise case following preliminary consideration of it, including provision—
    - (i) enabling the Scrutiny Committee or the Statutory Committee, in specified circumstances, to agree with the person concerned that the person concerned will comply with such undertakings as the Scrutiny Committee or the Statutory Committee considers appropriate, and
    - (ii) with respect to the procedure to be followed when any such undertakings are breached (the regulations may provide that the breach may be treated as misconduct for the purposes of paragraph 4(1)(a) and for the matter to be dealt with as a misconduct allegation that is before the Scrutiny Committee or the Statutory Committee);
  - (d) in respect of consensual disposal of a disqualification case following preliminary consideration of it, including provision—
    - (i) enabling the Statutory Committee, in specified circumstances, to agree with the individual or body corporate that the individual or body corporate will comply with such undertakings as the Statutory Committee considers appropriate, and
    - (ii) with respect to the procedure to be followed where any such undertakings are breached:
  - (e) in respect of case management meetings (and the regulations may provide that the preliminary consideration of a case is to take place at a case management meeting) and directions, including provision with respect to the procedure to be followed where case management directions are breached;
  - (f) in respect of cancelling, postponing or adjourning hearings and staying proceedings in appropriate circumstances;
  - (g) enabling the Statutory Committee to draw such inference as seems appropriate to it in the particular circumstances of the case if the person concerned fails—
    - (i) during fitness to practise proceedings, to submit to any examination or assessment required or directed to be carried out in accordance with the regulations made under this paragraph, or
    - (ii) to co-operate with the Statutory Committee;

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- (i) enabling the Scrutiny Committee or the Statutory Committee during the course of proceedings, to make such inquiries as it considers appropriate;
- [F103(ia)] enabling the Scrutiny Committee or the Statutory Committee during the course of proceedings, to direct the person concerned to undertake an examination or other assessment of the person's knowledge of English;]
  - (j) enabling the Statutory Committee, following consideration of a disqualification case, instead of issuing a direction under section 80 of the Medicines Act (disqualification, and removal from the register)—
    - (i) to agree with the individual or body corporate that the individual or body corporate will comply with such undertakings as the Statutory Committee considers appropriate (and the regulations may include provision with respect to the procedure to be followed where any such undertakings are breached), and
    - (ii) to dispose of the matter by giving advice or a warning; and
  - (k) for the award of, and in respect of the assessment of costs and may require the Statutory Committee or the Scrutiny Committee to have regard to a person's ability to pay when considering the making of an award against the person under the regulations.
- (4) An award of costs may, by leave of the High Court, be enforced in the same manner as an order of the High Court to the same effect.
  - (5) The regulations under paragraph (1) may make provision—
    - (a) as to the form which is to be used for any document (and may provide that documents specified in the regulations are to be in such form as the Council may determine from time to time); and
    - (b) for documents or certificates to be sent or received as an electronic communication.

**F103** Sch. 3 para. 15(3)(ia) inserted (1.6.2016) by The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806), arts. 1(3), **10(3)**; S.I. 2015/1451, art. 6(a)

### **Procedure for the Statutory Committee N.I.**

- **16.**—(1) For the purposes of proceedings under this Order
  - (a) the Statutory Committee may administer oaths; and
  - (b) the Statutory Committee or any party to proceedings before it may apply for the issue of a witness summons directing a person to attend the proceedings in order to give evidence or to produce a document.
- (2) No person may be compelled under any such summons to give any evidence or to produce any document which that person could not be compelled to give or produce on the trial of an action.
  - (3) Where—
    - (a) several sittings of the Statutory Committee are required to enable the committee to dispose of the case; or
    - (b) on an appeal to the High Court under paragraph 10, the case is remitted to the Statutory Committee to dispose of the case in accordance with directions given by the High Court,

the validity of the proceedings on the case before the Statutory Committee may not be called into question by reason only that members of the Statutory Committee who were present at a former meeting were not present at a later meeting of the Statutory Committee or that members present at a later meeting were not present at a former meeting of the Statutory Committee.

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### Legal advisers N.I.

- 17.—(1) The Council may appoint suitably qualified and experienced barristers or solicitors to be legal advisers.
- (2) Legal advisers appointed under this paragraph may not be a member of the Council, the Statutory Committee or the Scrutiny Committee.
- (3) Legal advisers appointed under this paragraph may be appointed either generally or for any proceedings or particular class of proceedings and are to hold and vacate office in accordance with the terms of the instrument under which they are appointed.
- (4) The Council may make regulations as to the functions of legal advisers appointed under this paragraph.

### Clinical and other specialist advisers N.I.

- **18.**—(1) The Council may appoint medical practitioners to be clinical advisers.
- (2) The Council may appoint persons to act as specialist advisers on issues on which, in the Council's opinion, specialist knowledge is required.
  - (3) Persons appointed to be—
    - (a) clinical advisers must have specialist expertise in a particular field or fields; and
    - (b) specialist advisers must have particular expertise in the speciality for which they are appointed.
- (4) If clinical advisers are appointed under sub-paragraph (1) their appointment is for the purpose of giving advice to—
  - (a) the Scrutiny Committee or the Statutory Committee on health related issues under consideration by either committee in the course of proceedings before it; and
  - (b) the Council on health related issues.
- (5) If specialist advisers are appointed under sub-paragraph (2), their appointment is for the purpose of giving advice to the Statutory Committee or the Scrutiny Committee on issues falling within their speciality which are under consideration by that Committee in the course of proceedings before it.
- (6) Advisers appointed under this paragraph may not be a member of the Council, a committee of the Council or the Statutory Committee.
  - (7) Advisers appointed under this paragraph may be appointed—
    - (a) generally; or
    - (b) for the purpose of any proceedings or particular class of proceedings,

and are to hold and vacate office in accordance with the terms of the instrument under which they are appointed.

- (8) The Council may make regulations as to the functions of advisers appointed under this paragraph.
- (9) In this paragraph "medical practitioner" means a fully registered person within the meaning of the Medical Act 1983 who holds a licence to practise under that Act.]

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## SCHEDULE 4 N.I.

Article 26(a).

#### TRANSITIONAL PROVISIONS

- 1. The Council may direct the registrar to register any name which was removed in pursuance of section 10(1)(b) of the Act of 1925 from the register of pharmaceutical chemists or the register of druggists.
- 2. If any person whose name has been removed in pursuance of section 8(4) of the Act of 1945 from the register of pharmaceutical chemists, the register of druggists or the register of students for non-payment of any fee, pays to the Society, before the expiration of such period (if any) as the Council allows, the fee and any additional sum prescribed in pursuance of Article 15(3), the registrar shall, subject to the provisions of any direction of the Statutory Committee which is in force in relation to the name, register the name of that person; and, if the Council so directs, the registration shall have effect from the date on which the name was removed from the said register.
- **3.** Where any person whose name has been removed as mentioned in paragraph 2, or a person employed by him in the carrying on of his business, has (whether before or after the removal of the name) been convicted of any such criminal offence, or been guilty of such misconduct, as, in the opinion of the Statutory Committee, renders the convicted or guilty person unfit to have his name on the register, the Committee may, after inquiring into the matter, direct that the name removed as aforesaid shall not be registered, or shall not be registered until the Committee otherwise direct; and, where the Committee direct that a name shall not be registered until the Committee otherwise direct, they may further direct that an application to the Committee in respect of the registration of the name shall not be entertained until the expiration of such period as is specified in the direction or the fulfilment of such conditions as are so specified.
- **4.** Where the name of any person was absent from the register of pharmaceutical chemists or the register of druggists immediately before the commencement of this Order in pursuance of a direction given under section 13(1) of the Act of 1945 for the removal of the name from that register, the Statutory Committee may, either of their own motion or on the application of that person, being an application made consistently with any direction of the Statutory Committee applicable to him, direct the registrar to register the name of that person, either without any fee or on payment to the Society of such fee as is prescribed in pursuance of Article 20(2); but, where a judge of the High Court has dismissed an appeal against the direction given under the said section 13(1), a direction under this paragraph shall not take effect unless approved by the Lord Chief Justice.
- **5.** The provisions of Articles 21 and 22 and of paragraph 1(2) of Schedule 3 shall apply in relation to a direction of the Statutory Committee under paragraph 3, and the provisions of Article 22 shall apply in relation to—
  - (a) a direction such as is mentioned in paragraph 4, as they apply in relation to a direction under this Order; and
  - (b) a refusal of an application such as is mentioned in paragraph 4, as they apply in relation to the refusal of an application under Article 20(2).
- **6.** Nothing in this Order shall affect any articles of apprenticeship entered into by any student of the Society before the 1st August 1967, and, in relation to any apprenticeship which is the subject of such articles, any provision of the Pharmacy and Poisons Acts (Northern Ireland) 1925 to 1955, and any regulation made under such a provision, which was applicable thereto immediately before the 1st August 1967 shall be deemed to continue in force and to have effect as if the Pharmacy Act (Northern Ireland) 1967 had not been passed and this Order had not been enacted.
- 7. Nothing in this Order shall affect the term of office of a member of the Council who holds office at the commencement of Article 4(2).

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N.I.

Schedule 5—Amendments

N.I.

Schedule 6—Repeals

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