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STATUTORY RULES OF NORTHERN IRELAND

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**2012 No. 308**

**PHARMACY**

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

*Laid before the Assembly in draft*

*Made - - - - 3rd August 2012*

*Coming into operation in accordance with Article 1*

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

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

- (i) persons appearing to the Department appropriate to represent the profession,
- (ii) persons appearing to the Department appropriate to represent those provided with services by the profession, and
- (iii) any other person appearing to the Department appropriate to consult about the draft.

**Citation, commencement and interpretation**

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

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

(3) In this Order—

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

“the principal Order” means the Pharmacy (Northern Ireland) Order 1976<sup>(3)</sup>.

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(1) S.I. 1999/283 (N.I. 1) Article 3(6)

(2) 2001 c.3 (N.I.)

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

### **Amendment to Article 2 of the principal Order**

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

(a) after the definition of “the Directive”(4) insert—

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

(b) after the definition of “General Systems Regulations” (6) insert—

““lay member” means a person who—

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

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

(c) after the definition of “the reference date”(7) insert—

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

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

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

### **Amendment to Article 4 of the principal Order**

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

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

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

#### **“Continuing professional development**

4A.—(1) The Council shall—

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

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

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

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

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

(5) The Council shall—

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(4) Definition inserted by regulation 3(b) S.R. 2008 No. 192

(5) 2001 c.9 (N.I.)

(6) Definition inserted by regulation 3(c) S.R. 2008 No.192

(7) Definition inserted by regulation 3(g) S.R. 2008 No.192

- (a) consult such persons as it considers appropriate about the development of criteria by reference to which compliance with the standards set under paragraph (1)(b) is to be monitored, and
  - (b) publish those criteria as they exist from time to time in such manner as it considers appropriate.
- (6) The Council shall—
- (a) adopt and maintain a framework relating to the requirements and conditions to be met by registered persons in respect of their continuing professional development; and
  - (b) require registered persons—
    - (i) to complete an annual declaration regarding their compliance with such requirements and conditions in respect of their continuing professional development as they are obliged to meet by that framework, and
    - (ii) to submit records about any continuing professional development undertaken by them to the registrar for review.
- (7) The framework adopted by the Council under paragraph (6)(a)—
- (a) must include provision relating to—
    - (i) the amount and type of continuing professional development that a registered person is required to undertake,
    - (ii) the information to be provided by a registered person about the continuing professional development that the registered person has undertaken and the form and manner in which that information is to be provided,
    - (iii) the times at which information about the continuing professional development that a registered person has undertaken is to be provided (including any continuing professional development that relates to an annotation in respect of a particular specialist area of practice that is to be recorded against the registered person's name in the register),
    - (iv) the keeping of records about the continuing professional development undertaken by registered persons; and
  - (b) must require that any continuing professional development that is undertaken by a registered person in accordance with it is relevant to—
    - (i) the safe and effective practice of pharmacy, and
    - (ii) a learning need for the individual registered person that is relevant to the current scope of the practice of pharmacy including any specialist area of practice of that individual registered person and the environment in which they practise;
  - (c) in so far as it relates to a person ("P") who is a registered person only as a result of being registered in the register mentioned in Article 6(1)(d)—
    - (i) may not impose requirements on P if P is required to undertake, in P's home State, continuing professional development in relation to the profession of pharmacy; and
    - (ii) where they impose requirements on P—
      - (aa) must take account of the fact that P is fully qualified to pursue the profession in P's home State, and

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

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

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

(10) Regulations under paragraph (9) must—

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

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

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

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

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

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

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

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

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

(iii) refusal of applications.

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

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

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

- (a) remove their name from the register;
- (b) impose such remedial measure as may be specified; or
- (c) refuse an application for restoration of their name to the register,

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

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

### **The Council's duties in respect of publications**

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

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

### **Accounts**

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

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

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

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

- (a) cause them to be published together with any report on them made by the auditors appointed under paragraph (2); and
- (b) send a copy of those annual accounts and of any such report to the Department,

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

### **Reports and statistical information**

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

- (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."

#### **Amendment to Article 5 of the principal Order**

5.—(1) For the heading to Article 5 of the principal Order (Regulations) substitute the following heading—

*“Regulations made by the Council: general”*

(2) In Article 5 of the principal Order (Regulations)—

(a) in paragraph (1) after sub-paragraph (ff) insert the following sub-paragraph—

“(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.”

(b) omit paragraphs (2) and (4).

#### **Amendment to Article 11 of the principal Order**

6. In Article 11(2) of the principal Order (Evidence of qualification to be registered) after “the registrar” insert “under this Article”.

#### **Amendment of Article 19 of the principal Order**

7. For paragraphs (2) to (11) of Article 19 of the principal Order (The Statutory Committee) substitute—

“(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.”.

#### **Substitution of Article 20 to the principal Order**

8. For Article 20 of the principal Order (Removal of registered persons from, and restoration to, register) substitute the following Article—

##### **“Fitness to practise**

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.”.

#### **Insertion of Article 25A to the principal Order**

9. After Article 25 of the principal Order (Fees) insert the following Article—

##### **“Regulations: procedure**

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.”.

#### **Substitution of Schedule 2 to the principal Order**

10. For Schedule 2 to the principal Order (The Council of the Society) substitute Schedule 2 as set out in Schedule 1 to this Order.

#### **Substitution of Schedule 3 of the principal Order**

11. For Schedule 3 to the principal Order (Proceedings of the Statutory Committee) substitute Schedule 3 as set out in Schedule 2 to this Order.

#### **Transitional Provisions**

12. The transitional provisions set out in Schedule 3 shall have effect.

#### **Repeal**

13. Article 18 of the principal Order (Disqualification of persons suffering from disability) shall cease to have effect.

14. Article 21 of the principal Order (Conditions as to the giving of directions by Statutory Committee in case of conviction, etc., of employee) shall cease to have effect.

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15. Article 22 of the principal Order (Provisions as to directions given by Statutory Committee and as to appeals) shall cease to have effect.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on  
3rd August 2012



*Diane Taylor*  
A senior officer of the  
Department of Health, Social Services and  
Public Safety



SCHEDULE 1

Article 10

Schedule 2 to the principal Order as substituted by this Order

“SCHEDULE 2

Article 4(2)

THE COUNCIL OF THE SOCIETY  
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.

(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 cease 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

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- 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).”

## SCHEDULE 2

Article 11

Schedule 3 to the principal Order as substituted by this Order

## “SCHEDULE 3

Article 20

# FITNESS TO PRACTISE

## **Standards of conduct and performance**

- 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**

- 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—

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- (a) any disclosure of information which is prohibited by or under any statutory provision, 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.

(3) In determining, for the purposes of sub-paragraph (2)(a) whether a disclosure of personal data is prohibited, it is to be assumed, for the purposes of section 35(1) of the Data Protection Act 1998<sup>(9)</sup> (disclosures required by law or made in connection with legal proceedings etc.), that the disclosure of personal data is required by sub-paragraph (1).

(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.

### **Disclosure of fitness to practise matters in the public interest**

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**

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;
- (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<sup>(10)</sup> (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;

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<sup>(9)</sup> 1998 c.29

<sup>(10)</sup> 1992 c.8; section 109A was inserted by the Social Security Administration (Fraud) Order (Northern Ireland) 1997 [SI 1997/1182 \(N.I.11\)](#), Article 14

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- (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 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<sup>(11)</sup> or the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007<sup>(12)</sup>); 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<sup>(13)</sup>).
- (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.

### **Initial action in respect of allegations**

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

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<sup>(11)</sup> 2006 c.47

<sup>(12)</sup> S.I. 2007 /1351 (N.I.11)

<sup>(13)</sup> 2007 asp 14

(b) is of the opinion that the Statutory Committee should consider making an interim order under paragraph 8,

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(14); 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 sub-paragraph (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**

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;

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- (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
- (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**

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—

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- (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;

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- (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.

(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**

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;
  - (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.

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### **Restoration of names to the Register: fitness to practise**

- 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 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.

### **Appeals against appealable fitness to practise decisions**

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**

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

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(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 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**

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**

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.

### **Voluntary removal from the register**

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**

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

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- 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;

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- (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;
  - (i) enabling the Scrutiny Committee or the Statutory Committee during the course of proceedings, to make such inquiries as it considers appropriate;
  - (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.

### **Procedure for the Statutory Committee**

- 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**

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**

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(15) who holds a licence to practise under that Act.”

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(15) 1983 c.54



## SCHEDULE 3

Article 11

### Transitional provisions

#### **Outstanding referrals to, and cases before, the Statutory Committee where no direction has been given**

1. In this Schedule—

“appointed day” means the day specified under Article 1(1);

“the former provisions” means Articles 20 to 22 of the principal Order as they had effect immediately before the appointed day;

“the new provisions” means Schedule 3 to the principal Order as substituted by Schedule 2 to this Order;

“the register” means the appropriate register kept under Article 6 of the principal Order;

“the Statutory Committee”, “the registrar” and “the Society” have the same meaning as in Article 2(2) of the principal Order.

2.—(1) Where—

(a) before the appointed day, an application for registration in or restoration to the register has been referred to the Statutory Committee;

(b) immediately before the appointed day there was no direction of the Statutory Committee in force in relation to the applicant; and

(c) an inquiry has not already opened in respect of the application,

the Statutory Committee shall dispose of it in accordance with the new provisions.

(2) Where—

(a) before the appointed day, an application for registration in or restoration to the register has been referred to the Statutory Committee;

(b) immediately before the appointed day there was no direction of the Statutory Committee in force in relation to the applicant; and

(c) an inquiry has already opened in respect of the application (including where a decision on the application has been postponed),

the Statutory Committee shall dispose of it in accordance with, and any appeal shall be disposed of in accordance with, the former provisions.

#### **Outstanding disciplinary proceedings**

3.—(1) Subject to the following provisions of this Schedule, where, as regards the registration of a person in the register, before the appointed day—

(a) a case of alleged misconduct has been referred by the registrar to the Statutory Committee whether or not a day has been appointed for holding an inquiry into the matter (including cases where an inquiry has been postponed or adjourned), the Statutory Committee shall dispose of the case in accordance with the former provisions but other allegations of misconduct that have been brought to the attention of the Society shall be dealt with in accordance with the new provisions.

(b) information about a conviction for a criminal offence has been submitted to the Statutory Committee by the registrar whether or not a day has been appointed for holding an inquiry into the matter (including cases where an inquiry has been postponed or adjourned), the Statutory Committee shall dispose of the matter in accordance with the former provisions

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but other information about a conviction for a criminal offence that has been brought to the attention of the Society shall be dealt with in accordance with the new provisions.

(2) Where the Department had been considering a case of a person suffering from a physical or mental disability under Article 18 of the principal Order as it had effect immediately before the appointed day the Department shall refer the case to the Statutory Committee which shall dispose of the case in accordance with the new provisions.

#### **Applicants for registration or restoration who are subject to directions given under the principal Order**

4.—(1) Where the Statutory Committee has given a direction in relation to a case falling within Article 20(5) of the principal Order, prior to the coming into operation of this Order, if the person in respect of whom the direction was given, (“the person concerned”) makes or before the appointed day has made, a further application for registration—

- (a) the application shall be determined by the registrar, even if it has already been referred to the Statutory Committee; and
- (b) the registrar shall determine the application in accordance with the provisions of Part III of the principal Order, except that the application may not be granted unless—
  - (i) if the Statutory Committee has given a direction that an application for registration from the person concerned shall not be entertained until the expiration of a specified period, that period has expired,
  - (ii) if the Statutory Committee has given a direction that an application for registration from the person concerned shall not be entertained until specified conditions have been fulfilled, those conditions have been fulfilled, and
  - (iii) the Statutory Committee has been consulted and it has advised the registrar that the person concerned’s fitness to practise is not or is no longer impaired.

(2) Where the Statutory Committee has given a direction in relation to a case falling within Article 20(4) or (6) of the principal Order, prior to the coming into operation of this Order, if the person in respect of whom the direction was given (“the person concerned”) makes or before the appointed day has made an application (or in relation to a case falling within Article 20(6) a further application) for restoration to the registrar—

- (a) the application shall be referred by the registrar to the Statutory Committee; and
- (b) the Statutory Committee shall dispose of the case in accordance with the new provisions except that—
  - (i) if it is the first application that the person concerned has made which is to be disposed of in accordance with the new provisions, paragraph 9(2) of Schedule 3 to the principal Order, as it has effect after the appointed day, shall not apply, but if the Statutory Committee has given a direction that an application for restoration from the person concerned shall not be entertained until the expiration of a specified period, that period must have expired, and
  - (ii) if the Statutory Committee has given a direction that an application for restoration from the person concerned shall not be entertained until specified conditions have been fulfilled, those conditions must have been fulfilled.

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## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order, which amends the Pharmacy (Northern Ireland) Order 1976 (“the 1976 Order”), makes provision for the following matters:-

- (a) the reconstitution of the Council of the Pharmaceutical Society of Northern Ireland (“the Council”) and the extension of its regulation making powers in relation to various matters;
- (b) the reconstitution of the Statutory Committee and the extension of its powers in relation to discipline and fitness to practise matters; and
- (c) the establishment of a Scrutiny Committee of the Council to deal with fitness to practise matters.

Articles 3, 10 and Schedule 1 amend the 1976 Order by substituting new provisions in respect of the composition, membership and functions of the Council. The Department has power to make regulations with regard to various matters which include the procedure of the Council and the appointment of a President and Vice President of the Council. A Scrutiny Committee is established and the Council has power to provide in regulations for its constitution, appointment and procedure etc.

The Council is also given various duties in respect of publications, including publication of annual accounts and an annual report. The Council is under a duty to establish and promote the standards of continuing professional development necessary for a registered person to achieve and maintain those standards of proficiency, to adopt a framework setting out the requirements and conditions in respect of a registered person’s continuing professional development and to make regulations in respect of persons who fail to comply with the requirements or conditions of the framework (Article 4).

Article 5 inserts new powers into the 1976 Order which enable the Council to make regulations with regard to the recording in the register of fitness to practise and continuing professional development matters.

Article 7 amends the 1976 Order to reconstitute the Statutory Committee. Articles 8, 11 and Schedule 2 amend the 1976 Order to insert a new Schedule 3 which provides for the procedure for the Scrutiny Committee and the Statutory Committee in relating to the fitness to practise of registered persons.

The Council is to establish the professional standards expected of registered persons and is given powers to obtain information from third parties about a particular registered person. The Council may also publish any information about the fitness to practise of a registered person where it is in the public interest to do so. (Paragraphs 1 to 3 of Schedule 3 to the 1976 Order).

Provision is included about what it means for fitness to practise to be impaired and a framework is set out within which allegations of impairment are to be considered. Usually, cases will firstly be considered by the registrar, who will then refer them to the Scrutiny Committee of the Council. The Scrutiny Committee has power to deal with the case by way of issuing warnings or advice. In addition, the Statutory Committee may suspend registered persons or attach conditions to their entry in the register and may also direct that the registered person be struck off the register. Provision also exists for the review of earlier decisions to suspend a registered person or to impose conditions on their entry in the register.

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Provision is also made for interim orders suspending a registered person's entry in the register or attaching temporary conditions to an entry in the register while an investigation is ongoing. (Paragraphs 4 to 8 of Schedule 3 to the 1976 Order)

If a person has been struck off the register for fitness to practise reasons, there are arrangements for restoration to the register in defined circumstances (Paragraph 9 of Schedule 3 to the 1976 Order)

Provision is also made for appeals to the High Court against appealable fitness to practise decisions and in respect of when fitness to practise decisions are to take effect – including provision for temporary measures pending the outcome of an appeal, if a decision is being appealed. (Paragraphs 10 to 12 of Schedule 3 to the 1976 Order)

Provision is also made for the registrar to make alterations to the register in accordance with any direction of the Statutory Committee and provision is made for the Council to make regulations as to voluntary removal from the register and to enable the registrar to refuse application for voluntary removal where there are outstanding fitness to practise proceedings. There are also provisions relating to proceedings before the Scrutiny Committee and the Statutory Committee. Essentially, these matters are to be provided for in regulations however, there are particular provisions relating to the use of legal, clinical and other specialist advisers. There are also provisions for dealing with witness summonses and orders for the production of documents, which may be enforced through the courts. (Paragraphs 13 to 18 of Schedule 3 to the 1976 Order)

Articles 12 to 14 of the Order contain repeals of provisions required as a result of the establishment of new provisions to deal with fitness to practise and discipline matters.

Schedule 3 to the Order deals with transitional provisions in relation to outstanding registration cases, disciplinary proceedings, and applicants for registration or restoration who are subject to directions given under the principal Order prior to the coming into operation of this Order.