
STATUTORY RULES OF NORTHERN IRELAND

2012 No. 311

PHARMACY

The Council of the Pharmaceutical Society
of Northern Ireland (Fitness to Practise and
Disqualification) Regulations (Northern Ireland) 2012

Made - - - - *8th August 2012*

Coming into operation *1st October 2012*

The Council of the Pharmaceutical Society of Northern Ireland makes the following Regulations in exercise of the powers conferred upon it by Article 5(1)(fff) of, and paragraphs 1(1)(b), 4(5), 5(1) and (2), 9(3), 14(1), 15(1) to (3) and (5), 17(4) and 18(8) of Schedule 3 to, the Pharmacy (Northern Ireland) Order 1976(1). The Department of Health, Social Services and Public Safety (2) has approved these Regulations in accordance with Article 25A (2) of that Order(3).

PART 1

Preliminary matters

Citation and commencement

1. These Regulations may be cited as the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012 and come into operation on 1st October 2012.

Interpretation

2.—(1) In these Regulations—

“the Act” means the Medicines Act;

“allegation” means a disqualification allegation, a fitness to practise allegation or a health allegation;

“applicant concerned” means an applicant (or, where appropriate their representatives) for—

(1) 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; S.R. 2008 No.192; and S.R. 2012 No.308
(2) S.I. 1999/283 (N.I. 1) – Article 3 (6)
(3) Article 25A is inserted by Article 9 of S.R. 2012 No.308

(a) registration or renewal of registration whose application has been referred to the Statutory Committee for advice;

(b) restoration of registration;

“the chair” means the chair of the Statutory Committee (except in regulation 8);

“the Continuing Professional Development Regulations” means the Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012(4);

“disqualification allegation” means a complaint to, or concern of, the Society which gives rise to, or may give rise to, an inquiry under Part 4 of the Act;

“fitness to practise allegation” means a complaint to, or concern of, the Society which is an allegation for the purposes of paragraph 5(1), 6(1) or 7(1) of Schedule 3 to the Order, as appropriate;

“health allegation” means a complaint to, or a concern of, the Society which gives rise to, or may give rise to, an inquiry that a person’s fitness to practise is impaired by reason of paragraph 4(1)(c) of Schedule 3 to the Order;

“HSC body” means any of the bodies listed in section 1(5) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(5);

“informant” means a person who makes a complaint, or who raises a concern, to the Council relating to any person;

“interim order” means an interim order under paragraph 8 of Schedule 3 to the Order;

“interim order hearing” means a hearing solely for the purposes of considering whether to make, confirm, vary, replace or revoke an interim order;

“legal adviser” means the person appointed to be a legal adviser under paragraph 17 of Schedule 3 to the Order;

“medical practitioner” means a fully registered person within the meaning of Medical Act 1983(6) who holds a licence to practise under that Act;

“the Order” means the Pharmacy (Northern Ireland) Order 1976;

“parties” means the Society and the person concerned (or, where appropriate, their representatives) and “party”, except in the phrase “section 80 party”, is to be construed accordingly;

“person concerned” means, as the case may be, an applicant concerned, a registered person concerned or a section 80 party;

“prescribed fee” means a fee prescribed in regulations under Article 5(1)(e) of the Order;

“the presenter” means the person instructed to represent the Society at a hearing (and includes employees of the Society);

“principal hearing” means—

(c) in fitness to practise proceedings, a hearing of the Statutory Committee held in connection with making a determination under paragraph 7(1) of Schedule 3 to the Order (as opposed to any further hearing to consider varying or revoking any direction given as a consequence of a finding of impairment); and

(d) in disqualification proceedings, a hearing of the Statutory Committee held in connection with giving a direction under section 80 of the Act;

(4) S.R. 2012 No.312

(5) 2009 c.1(N.I.)

(6) 1983 c.54

“registered person concerned” in the context of fitness to practise proceedings means the registered person who is the subject of the allegation or investigation to which those proceedings relate (or, where appropriate, their representatives);

“restoration hearing” means a hearing in fitness to practise proceedings to consider an application for restoration to the Register;

“review hearing” means a hearing for the purpose of—

- (e) reviewing directions given by the Statutory Committee under paragraph 7(2)(d) or (e) of Schedule 3 to the Order;
- (f) reviewing undertakings agreed by the Statutory Committee; or
- (g) revoking a direction by virtue of section 83(1) of the Act;

“secretary” means, except in relation to references to the secretary of the Scrutiny Committee, the secretary of the Statutory Committee;

“section 80 party” means a person who is subject to proceedings before the Statutory Committee in connection with the giving of a direction under section 80(1) or (4) of the Act (or, where appropriate, their representatives);

“the standards” means the standards of conduct, ethics and performance published by the Society under paragraph 1(2) of Schedule 3 to the Order;

“threshold criteria” means the criteria published by the Society under paragraph 5(2)(a) of Schedule 3 to the Order;

“witness” means a person who gives evidence, or whose evidence is received, at a hearing.

(2) For the purposes of these regulations—

- (a) a meeting or hearing of the Statutory Committee, other than when it is deliberating in private, is considered to be “in private” if it is held in the presence of—
 - (i) the parties and any person present who is representing a party,
 - (ii) the person acting as secretary,
 - (iii) any witness giving evidence,
 - (iv) any legal, clinical or specialist adviser,
 - (v) any person responsible for the recording of the proceedings, or
 - (vi) any other person whose presence is deemed necessary by the chair,but otherwise excluding everyone else; and
- (b) a meeting of the Scrutiny Committee and the private deliberations of that Committee are considered to be “in private” if they are held in the presence of—
 - (i) the person acting as secretary to that Committee,
 - (ii) any legal, clinical or specialist adviser, or
 - (iii) any person responsible for the recording of the proceedings,but otherwise excluding everyone else.

Duty to provide information to the registrar

3.—(1) A registered person must notify the registrar in writing of the events specified in paragraph (2) within the period of 7 days starting on and including the day on which the event occurs.

(2) Those events are if the registered person—

- (a) is convicted of any criminal offence;
- (b) accepts a police caution;

- (c) has agreed to pay a penalty under section 109A of the Social Security Administration (Northern Ireland) Order 1992⁽⁷⁾ (penalty as an alternative to prosecution);
- (d) is notified by a regulatory body in the United Kingdom responsible under any statutory provision for the regulation of a health or social care profession of a determination to the effect that their fitness to practise is impaired, or a determination by a regulatory body elsewhere to the same effect;
- (e) becomes subject to an investigation into their fitness to practise by another regulatory body (apart from the Society);
- (f) becomes the subject of any fraud investigation by an HSC body;
- (g) is removed, contingently removed or suspended from, refused admission to or conditionally included in any list held by an HSC body or providers of pharmaceutical services on fitness to practise grounds;
- (h) is included in a barred list (within the meaning of the Safeguarding Vulnerable Groups Act 2006⁽⁸⁾ or the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007⁽⁹⁾); or
- (i) has agreed to be bound over to keep the peace by the magistrates' court in Northern Ireland.

Fitness to practise criteria

4.—(1) The Statutory Committee must have regard to the criteria specified in paragraph (2) or, where appropriate, (3), or, where appropriate, paragraphs (2) and (3), 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) In relation to evidence about the conduct or behaviour of the registered person which might cast doubt on whether the requirements as to fitness to practise are met in relation to the registered person, the Statutory Committee must have regard to whether or not that conduct or behaviour—

- (a) presents an actual or potential risk to patients or to the public;
- (b) has brought, or might bring, the profession of pharmacy into disrepute;
- (c) has breached one of the fundamental principles of the profession of pharmacy as defined in the standards; or
- (d) shows that the integrity of the registered person can no longer be relied upon.

(3) In relation to evidence about the registered person's physical or mental health which might cast doubt on whether the requirements as to fitness to practise are met in relation to the registered person, the Statutory Committee must have regard to whether or not that evidence shows actual or potential—

- (a) self-harm; or
- (b) harm to patients or to the public.

(7) 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

(8) 2006 c.47

(9) [S.I. 2007/1351 \(N.I.11\)](#)

PART 2

Initial consideration by the registrar

Initial action in respect of allegations

- 5.—(1) The registrar may only refer an allegation where—
- (a) the person concerned is identifiable; and
 - (b) the allegation is capable of being referred.
- (2) The registrar must not refer the allegation where—
- (a) in the case of a fitness to practise allegation, the allegation is of a type stated in the threshold criteria which should not be referred;
 - (b) more than 5 years have elapsed since the most recent events referred to in the allegation unless the registrar considers that it is necessary for the protection of the public, or otherwise in the public interest, for the allegation to be referred; or
 - (c) the allegation is made by an informant who—
 - (i) is anonymous and the allegation is not capable of verification from an independent source; or
 - (ii) is identifiable but does not participate in the consideration of the allegation and the allegation is not capable of verification from an independent source.
- (3) The registrar’s consideration of an allegation under paragraphs (1) and (2) may include the carrying out of any investigations which, in the registrar’s opinion, are appropriate to the consideration of it.
- (4) Investigations referred to in paragraph (3) may include—
- (a) requesting the Pharmacy Inspector to undertake further inquiries;
 - (b) requesting the informant to provide a written statement or statutory declaration;
 - (c) instructing solicitors; or
 - (d) in relation to a health allegation, requiring the person concerned to agree to be medically examined by a medical practitioner nominated by the Society.
- (5) The allegation must be referred to the Statutory Committee instead of to the Scrutiny Committee if the registrar considers that—
- (a) the Statutory Committee should consider making an interim order, and if the registrar does so consider, the registrar must notify the Statutory Committee accordingly; or
 - (b) the public interest is best served by urgent consideration of the case.
- (6) The registrar must also refer an allegation to the Statutory Committee instead of to the Scrutiny Committee if it relates to a conviction for one or more criminal offences and the sentence imposed in respect of one offence or in respect of some or all of those offences, is a custodial or suspended custodial sentence.
- (7) The registrar may refer an allegation to the Statutory Committee instead of the Scrutiny Committee if—
- (a) it relates to a determination by a regulatory body in the United Kingdom responsible under any statutory provision for the regulation of a health or social care profession that the registered person’s fitness to practise is impaired; and
 - (b) the registrar considers that the allegation should be so referred.
- (8) The registrar may refer an allegation to the Statutory Committee instead of to the Scrutiny Committee where—

- (a) in so far as the allegation relates to an entry in the register, the registrar has reasonable grounds for believing that that entry may have been fraudulently procured or incorrectly made; and
 - (b) the registrar considers that the allegation should be so referred.
- (9) The registrar may refer an allegation to the Statutory Committee instead of to the Scrutiny Committee where the allegation relates to—
- (a) a failure to comply with the requirements or conditions of the framework adopted by the Council under Article 4A(6)(a) of the Order relating to the continuing professional development of registered persons; or
 - (b) the making of a false declaration about compliance with the requirements or conditions of that framework;

and the registrar considers that the circumstances of the failure or false declaration are such that the allegation should be so referred.

(10) Where the registrar refers an allegation to the Statutory Committee under any of paragraphs (5) to (9) the registrar must inform the person concerned and the informant, if any, that the allegation has been so referred.

Notices of referral and documents to be supplied to persons concerned

6.—(1) Once the registrar has taken a decision to refer a fitness to practise allegation or a disqualification allegation to the Scrutiny Committee, the registrar must—

- (a) send to the person concerned a notice of referral to the Scrutiny Committee;
 - (b) provide that person with—
 - (i) copies of all documentation, including summaries of relevant information, to be placed by the registrar before the Scrutiny Committee; and
 - (ii) a copy of the threshold criteria.
- (2) The notice of referral to the Scrutiny Committee must in terms—
- (a) particularise the allegation;
 - (b) set out any recommendations for disposal of the case made by the registrar;
 - (c) specify a date for the meeting of the Scrutiny Committee which will consider the allegation, which must be no less than 28 days after the date of service of the notice of referral;
 - (d) inform the person concerned of the Scrutiny Committee's powers—
 - (i) to dismiss the case,
 - (ii) in relation to a health allegation, to require the person concerned to undergo a medical examination,
 - (iii) to issue warnings,
 - (iv) to agree undertakings,
 - (v) to give advice to the person concerned or to other persons, and
 - (vi) to refer the matter to the Statutory Committee;
 - (e) invite the person concerned to indicate, no later than 21 days after the day of service of the notice, whether the particulars of the allegation set out in the notice are admitted or denied;
 - (f) invite the person concerned to provide written representations on the allegation, and on any recommendations for disposal of the case made by the registrar;

- (g) state that any written representations must be submitted to the Scrutiny Committee no later than 21 days after the day of service of the notice;
- (h) inform the person concerned that any representations, or extracts of any representations, received may be shown to the informant, if any, for comment;
- (i) inform the person concerned that the Scrutiny Committee may seek further information from any source for the purposes of carrying out its functions in investigating the allegation, including from the person concerned's employer, if any.

Voluntary removal of names from the register

7.—(1) Subject to the following paragraphs, applicants for the voluntary removal of their names from the register may apply to the registrar.

(2) An application under this regulation must be made to the registrar using the relevant application form which must be in such form as the Society may from time to time determine.

(3) The application form must, in particular—

- (a) require the applicant (“A”) to—
 - (i) specify A's full name, home address and contact details (including a telephone number and electronic mail address, where possible),
 - (ii) specify their registration number in the register to which the application relates;
- (b) if A is a superintendent pharmacist, require A to state that fact;
- (c) require A to—
 - (i) declare that A is not aware of any investigation by any enforcement or regulatory body, or proceedings brought by such a body, that relate to A's fitness to practise, or of any act or omission on A's part which might render A liable to an allegation being referred to the Society that A's fitness to practise is impaired,
 - (ii) provide any supporting documents, information or evidence as mentioned in the application form, and
 - (iii) sign and date the application.

(4) The applicant must also provide such additional documents, information or evidence as the registrar may reasonably require for the purposes of verifying the information in, or determining, the application.

(5) Upon receipt of an application under this regulation, the registrar must make such inquiries as the registrar considers necessary in order to be satisfied that there are no ongoing investigations or outstanding proceedings relating to the registered person's fitness to practise.

(6) The registrar must not grant an application under this rule unless—

- (a) the registrar is satisfied that there are no ongoing investigations or outstanding proceedings relating to the registered person's fitness to practise; or
- (b) in cases where there are such investigations or proceedings, the registrar considers that the public interest would be best served by granting the application.

(7) Where the registrar grants an application under this regulation, the registrar must remove their name from the register and must publish that fact on the Society's website.

Voluntary removal: supplementary provision

8.—(1) Where the registrar becomes aware that an application for the voluntary removal of a name from the register—

- (a) has been granted in reliance upon information provided by the applicant (“the former registered person”) relating to fitness to practise matters that was false or misleading; and
- (b) but for that information, the application would have been refused by virtue of regulation 7(6),

the registrar must revoke the decision to grant the application and must restore the name to the register.

(2) The restoration shall have effect as from the date on which the name was removed from the register.

Applications for restoration

9.—(1) Subject to the following provisions of this regulation, any person applying for restoration to the register under paragraph 9 of Schedule 3 to the Order must apply using the relevant application form, which is to be in such form as the Society may from time to time determine.

(2) The application form must (amongst other matters)—

- (a) require persons applying under paragraph (1) to—
 - (i) provide their full home address and contact details (including a telephone number and electronic mail address, where possible),
 - (ii) give reasons for saying that their fitness to practise is no longer impaired,
 - (iii) specify the register to which they are applying to be restored,
 - (iv) provide any necessary supporting documentation, as mentioned in paragraph (3), and
 - (v) sign and date the application; and
- (b) include a demand that any relevant prescribed fee be paid.

(3) Persons applying for restoration to the register under paragraph 9 of Schedule 3 to the Order must provide to the registrar, together with their completed application form—

- (a) at least two certificates attesting to their identity and good character, one of which must be given by a registered person in good standing with the Society;
- (b) sufficient evidence to demonstrate their fitness to return to practice, which may include—
 - (i) evidence of activities designed to address or learn from the original allegation,
 - (ii) evidence of learning activities designed to keep up to date with skills and knowledge, and with developments in practice, and
 - (iii) evidence demonstrating insight into the gravity of the allegation which resulted in their removal from the register; and
- (c) any necessary supporting documentation, information or evidence as mentioned in the completed application form, and such additional documents, information or evidence as the registrar may reasonably require for the purposes of verifying the information in, or determining, the application.

(4) The registrar must not accept a certificate of the type referred to in paragraph (3)(a) as a valid part of the application unless there is an indication on the face of the certificate that the person signing it—

- (a) knows why the person was removed from the register; and
- (b) has seen a copy of the reasons given for the person’s removal from the register.

(5) The registrar must refuse the application if the relevant prescribed fee is not paid.

PART 3

Consideration by the Scrutiny Committee

Procedures of the Scrutiny Committee

- 10.**—(1) The Scrutiny Committee is to meet in private.
- (2) The chair of the Scrutiny Committee may give practice directions of general application to any proceedings of the Scrutiny Committee.
- (3) The Scrutiny Committee may not hear oral evidence.
- (4) Before disposing of any allegation before it, the Scrutiny Committee—
- (a) must—
 - (i) consider all documents and recommendations placed before it by the registrar, and
 - (ii) have regard to its own published referral criteria;
 - (b) may—
 - (i) direct that further investigations should be undertaken;
 - (ii) obtain advice from a legal, clinical or other specialist adviser; and
 - (iii) adjourn its consideration of an allegation until such time as any further information has been obtained, any comments from the informant, if any, are received, or where the person concerned has undergone a medical examination, a report on the person concerned has been prepared.
- (5) In fitness to practise or disqualification proceedings the Scrutiny Committee—
- (a) must in all cases—
 - (i) consider any written representations received from the person concerned, and
 - (ii) have regard to any relevant practice directions given by the chair of the Scrutiny Committee, and
 - (b) may send any written representations received from the person concerned to the informant, if any, for comment.
- (6) In relation to a health allegation, the Scrutiny Committee may—
- (a) require the person concerned to agree to be medically examined by a medical practitioner nominated by the Society, and
 - (b) where it receives information that the person concerned has refused to co-operate fully with a medical examination, refer that matter to the Statutory Committee as a separate allegation.
- (7) Where the Scrutiny Committee decides to refer an allegation to the Statutory Committee and is of the view that—
- (a) case management directions should be given; or
 - (b) an interim order should be made,
- it must notify the Statutory Committee accordingly.
- (8) The Scrutiny Committee must not refer any—
- (a) fitness to practise allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will make a finding that the registered person's fitness to practise is impaired; or
 - (b) disqualification allegation to the Statutory Committee unless it is satisfied that there is a real prospect that the Statutory Committee will give a direction for disqualification.

Agreement of undertakings by the Scrutiny Committee

11.—(1) Where the registered person concerned admits that their fitness to practise is impaired, the Scrutiny Committee may, if it thinks fit, dispose of fitness to practise proceedings by agreeing undertakings with the registered person concerned (that is, that the registered person concerned will comply with such undertakings as the Scrutiny Committee considers appropriate), instead of referring the allegation to the Statutory Committee.

(2) Where the Scrutiny Committee has disposed of a case in accordance with paragraph (1) and it subsequently receives information that those undertakings have not been complied with, it may—

- (a) refer the original allegation to the Statutory Committee and treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the Statutory Committee; or
- (b) determine not to refer the original allegation to the Statutory Committee but treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the Statutory Committee.

(3) Where the Scrutiny Committee has disposed of a case in accordance with paragraph (1) and it subsequently receives information that those undertakings may no longer be appropriate, it may—

- (a) with the agreement of the registered person concerned, vary those undertakings; or
- (b) determine that those undertakings no longer apply.

Recording in the register of decisions by the Scrutiny Committee

12. Where the Scrutiny Committee—

- (a) gives a warning to a registered person; or
- (b) agrees undertakings with a registered person that relate to the registered person's fitness to practise,

the registrar must ensure that an appropriate alteration to that registered person's entry in the register is made to record the details of that warning or undertaking.

Notices

13.—(1) In the case of a fitness to practise allegation, the information to be provided by the registrar under paragraphs 6(2)(b) or (3)(c) of Schedule 3 to the Order or under regulation 5(10) must be in a notice which is to be sent to the registered person concerned and the informant, if any, no later than 10 days after and including the date on which the relevant decision was made or, as the case may be, the allegation was referred.

(2) In the case of a disqualification allegation, the secretary to the Scrutiny Committee must inform the section 80 party of the decision of the Scrutiny Committee to refer, or not to refer, the allegation, and must do so in a notice of decision which is to be sent to the party no later than 10 days after and including the date on which the relevant decision was made.

(3) The notice under paragraph (1) or (2) must include the reasons for the decision or the referral and be accompanied by any legal advice considered by the Scrutiny Committee or the registrar.

(4) Where the Scrutiny Committee has decided not to refer an allegation to the Statutory Committee, the notice under paragraph (1) or (2) must inform the person concerned that the Scrutiny Committee may nevertheless reconsider the allegation in the circumstances set out in regulation 14.

(5) Where the Scrutiny Committee has decided to dispose of the allegation by agreeing undertakings or issuing a warning, the notice under paragraph (1) or (2) must, subject to paragraph (6), be accompanied by a statement setting out the undertakings or the warning.

(6) The statement referred to in paragraph (5) must not be sent to the informant if it includes undertakings relating to the health of a person concerned.

(7) If the statement relates to undertakings, it must also state, in terms, that if the Scrutiny Committee subsequently receives information that those undertakings have not been complied with, it may—

- (a) refer the original allegation to the Statutory Committee and treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the Statutory Committee; or
- (b) determine not to refer the original allegation to the Statutory Committee but treat the failure to comply with the undertakings as a separate allegation of misconduct and refer that allegation to the Statutory Committee.

(8) Where the Scrutiny Committee or the registrar has referred the matter to the Statutory Committee, the notice under paragraph (1) or (2)—

- (a) must particularise the matters to be referred; and
- (b) where the Scrutiny Committee or the registrar is of the view that the Statutory Committee should consider making an interim order, state the reasons for its view.

Reconsideration of allegations

14.—(1) Where—

- (a) the Scrutiny Committee has considered a fitness to practise or a disqualification allegation and decided not to refer it to the Statutory Committee; and
- (b) within 5 years from the date of service of the notice given under regulation 13, the Society receives a new allegation about the person concerned,

the Scrutiny Committee may take the action specified in paragraph (2).

(2) The Scrutiny Committee may—

- (a) when considering whether or not to refer the new allegation to the Statutory Committee, have regard to the original allegation; and
- (b) may refer both the original allegation and the new allegation to the Statutory Committee.

(3) Where the Scrutiny Committee has disposed of a fitness to practise or disqualification allegation, and within 5 years of that decision receives new evidence or information which makes the reconsideration of that decision—

- (a) necessary for the protection of the public;
- (b) necessary for the prevention of injustice to the person concerned; or
- (c) otherwise necessary in the public interest,

it may reconsider the allegation.

(4) The Scrutiny Committee may reconsider an allegation where it receives information that the Society has erred in its administrative handling of the case and it is satisfied that it is necessary in the public interest to do so.

(5) Where the Scrutiny Committee has decided to reconsider a fitness to practise or disqualification allegation, the secretary to the Scrutiny Committee must—

- (a) inform the person concerned and the informant, if any, of the decision to reconsider the allegation;
- (b) inform the person concerned and, where appropriate, the informant, if any, of any new evidence or information;

- (c) provide the person concerned and, where appropriate, the informant, if any, with copies of any new evidence and summaries of any new information received;
- (d) seek written representations from the person concerned and the informant, if any, on—
 - (i) the decision to reconsider the allegation, and
 - (ii) any new evidence or information received (unless, in the case of the informant, if any, this has not been sent to the informant).
- (6) Following reconsideration of the original allegation, the original decision not to refer the allegation to the Statutory Committee may be rescinded in appropriate circumstances.
- (7) Following reconsideration of the allegation, a new notice must be sent as provided for in regulation 13.

PART 4

Consideration by the Statutory Committee: initial stages

Action upon referral of an allegation

- 15.**—(1) After referral of an allegation by the registrar or the Scrutiny Committee to the Statutory Committee—
- (a) in the case of a health allegation, the chair may require the person concerned to agree to be medically examined by a medical practitioner nominated by the Society;
 - (b) the registrar must take such steps as, in the registrar’s opinion, are desirable or necessary to assist the Society in the preparation of the case for hearing; and
 - (c) the secretary must serve on both of the parties a listing questionnaire, which must be in the format determined by the secretary.
- (2) In a case where the registrar has referred an allegation to the Statutory Committee instead of to the Scrutiny Committee, the Society may request a case management meeting.

Disclosure provisions

- 16.**—(1) As soon as is reasonably practicable after the date on which the person concerned is served with the notice given under regulation 13 (“the referral date”), the Society must serve on the person concerned—
- (a) finalised particulars of the allegation, sufficiently particularised to enable them to understand the allegation;
 - (b) any statements of evidence, expert reports or other documents relied upon by the Society in support of its case, not previously served upon the person concerned;
 - (c) any evidence or documents that the Society has in its possession (other than documents for which privilege is claimed) which, whilst not relied upon by the Society, may assist the person concerned in the preparation of their defence;
 - (d) a list of witnesses whose evidence is (or whose oral evidence will be) relied upon by the Society in support of its case;
 - (e) a copy of the listing questionnaire duly completed by the Society; and
 - (f) any time estimate for the duration of the Society’s case.
- (2) As soon as reasonably practicable after the date of service of the material set out in paragraph (1), the person concerned must serve on the secretary—

- (a) an agreed time estimate for the duration of the hearing; and
 - (b) a copy of the listing questionnaire, duly completed by the person concerned.
- (3) If the parties are unable to agree a time estimate for the duration of the hearing, they must request case management directions.
- (4) As soon as reasonably practicable after the date of service of the material set out in paragraph (1) and in any event, not less than 28 days before the date of the hearing, the person concerned must serve on the Society—
- (a) any statements of evidence (including witness statements), expert reports or other documents; and
 - (b) a list of witnesses whose evidence is (or whose oral evidence will be),
- relied upon by the person concerned in support of their case.
- (5) The parties must notify the secretary of any changes to the agreed time estimate for the hearing or to the information provided by the parties in the listing questionnaire as soon as possible after becoming aware that that estimate or information has changed.

Inspection of documents

- 17.—(1) At any time after the service of a document by a party under this Part, up until the commencement of the relevant hearing, the party being served with the document may serve notification on the other party in possession of the original version of the document that the party wishes to inspect and examine it.
- (2) The party in possession of the original version of the document must provide facilities for its inspection and examination—
- (a) within 10 days from and including the date on which the request was notified; or
 - (b) if the request is notified less than 10 days before the date on which the relevant hearing commences, as soon as is reasonably practicable to provide those facilities.

Notices of hearing other than interim order hearings

- 18.—(1) Where the Statutory Committee is to hold a hearing, other than an interim order hearing, the secretary must serve a Notice of Hearing on the parties no less than 35 days before the date fixed for the hearing.
- (2) The Notice of Hearing must—
- (a) state the date, time and venue of the hearing;
 - (b) in the case of a principal hearing, contain the finalised particulars of the allegation;
 - (c) where the registrar is seeking the advice of the Statutory Committee under regulation 7(2)(b) of the Continuing Professional Development Regulations for the purpose of making findings of fact, contain a statement from the registrar of the matters on which findings of fact are sought;
 - (d) where the Statutory Committee is to review directions previously given (including in relation to applications for restoration and applications under section 83 of the Act), contain a copy of the directions under review and the Statutory Committee's reasons for making the directions;
 - (e) inform the person concerned of their right to attend and to be represented or accompanied at the hearing in accordance with regulation 42;
 - (f) inform the person concerned that the Statutory Committee may proceed with the hearing in their absence in accordance with regulation 27;

- (g) inform the person concerned of—
 - (i) the relevant provisions of regulations 34 to 38 relating to the procedure at the hearing,
 - (ii) the provisions relating to evidence set out in regulation 26, and
 - (iii) the provisions relating to witness evidence set out in regulations 45 and 46;
- (h) require the person concerned to inform the secretary, within 14 days beginning with and including the day on which the Notice is served, whether they intend to—
 - (i) attend the hearing,
 - (ii) be represented at the hearing, and if so, by whom,
 - (iii) seek to call any witnesses at the hearing, and if so whom,
 - (iv) in the case of a principal hearing, make any admissions in respect of the allegation, or
 - (v) where a case has been referred to the Statutory Committee under regulation 7(2)(b) of the Continuing Professional Development Regulations for the purposes of making findings of fact, make any admissions;
- (i) if the person concerned is a registered person, inform them of the powers of the Statutory Committee to make an interim order;
- (j) in the case of a principal hearing, inform the person concerned of the sanctions that may be imposed;
- (k) in the case of a review hearing in fitness to practise proceedings, inform the registered person concerned of the Statutory Committee's powers to vary or revoke any sanctions that have been imposed; and
- (l) in the case of a restoration hearing, inform the applicant concerned of the Statutory Committee's powers to impose conditions if they are restored to the register.

Interim Order Notices and court referrals

19.—(1) Where the Statutory Committee is to hold an interim order hearing, the secretary must serve on the registered person concerned an Interim Order Notice.

(2) The Interim Order Notice must—

- (a) state the date, time and venue of the hearing;
- (b) inform the registered person of their right to attend and to be represented or accompanied at the hearing in accordance with regulation 42;
- (c) inform the registered person that the Statutory Committee may proceed with the hearing in their absence in accordance with regulation 27;
- (d) require the registered person to inform the secretary, by a specified date, whether the registered person intends to—
 - (i) attend the hearing,
 - (ii) oppose the making of an interim order, and
 - (iii) be represented at the hearing, and if so, by whom;
- (e) invite the registered person, if they do not wish to attend the hearing, to submit written representations to the Statutory Committee before the date of the hearing;
- (f) if there is no interim order in force in relation to the registered person, state the reasons why the Society is seeking an interim order; and
- (g) where the hearing is to review an interim order, include the terms of the order under review.

(3) The Interim Order Notice must be served on the registered person on a date which provides the registered person with reasonable notice of the hearing in the particular circumstances of the case.

(4) Where it appears to the secretary that an application should be made to the High Court under paragraph 8(5) of Schedule 3 to the Order to extend, or further extend, the period of an interim order, the secretary must advise the Statutory Committee accordingly, and the Statutory Committee may advise the Society to make the application.

Hearing bundles

20.—(1) This regulation does not apply in respect of interim order hearings.

(2) Before any hearing, no later than 16 days before the Monday of the week in which the hearing is to take place before the Statutory Committee, the parties must serve on each other copies of the bundles on which they intend to rely at the hearing.

(3) No later than 9 days before the Monday of the week in which the hearing is to take place, the parties must serve on the secretary, 10 paginated copies of—

- (a) where the bundle for the hearing has been agreed between the parties, the agreed bundle; or
- (b) where the bundle for the hearing has not been agreed between the parties—
 - (i) any part of the bundle that has been agreed; and
 - (ii) a statement from the party seeking to rely on any disputed material why the party seeks to include it in their bundle;
- (c) a statement of each party's case; and
- (d) where the case necessitates consideration of a point of law, each party's skeleton argument.

(4) No later than 9 days before the Monday of the week in which the hearing is to take place, the parties must serve on the secretary a list indicating—

- (a) any witness whose evidence has been agreed and who therefore does not need to be called; and
- (b) any witness who is to be called to give oral evidence before the Statutory Committee.

(5) Any document which has not been served on the secretary by the end of the period specified in paragraph (3) is, except in exceptional circumstances, not to be admitted into evidence at the hearing.

Request for a case management meeting

21.—(1) A party to proceedings before the Statutory Committee may at any time serve on the secretary and the other party a written request for a case management meeting (in addition to the occasions on which they must, by virtue of these regulations, make such a request).

(2) The request must—

- (a) state the reasons why the party is seeking a case management meeting;
- (b) state what directions are sought for the management of the case (and the party may enclose draft directions where appropriate);
- (c) state whether the person making the request seeks the participation of the parties at the meeting (and if so, the preferred format for that meeting) or whether the issues can be dealt with by way of directions without oral representations from the parties.

(3) The secretary shall send a copy of the request, together with any other material considered relevant, to the chair.

(4) The chair must agree to the request for a case management meeting unless the chair determines that the meeting is unnecessary or the request is an abuse of process.

Case management meetings

- 22.**—(1) Case management meetings of the Statutory Committee are to be conducted by the chair.
- (2) Where requested by the chair, the secretary must list the matter for a case management meeting
- (3) The secretary must give the parties such notice of the meeting as is reasonable in the particular circumstances of the case.
- (4) Case management meetings may be conducted by video link, teleconference or such other method as is agreed by the parties or, where the parties fail to agree, decided by the chair.
- (5) The chair is to act independently of the parties and may give directions to secure the just, expeditious and effective running of the proceedings before the Statutory Committee.
- (6) Case management meetings are to be held in private.

Case management directions

- 23.**—(1) Case management directions may be given—
- (a) at a case management meeting;
 - (b) upon the request of a party (in circumstances where there is no request or requirement to hold a case management meeting); or
 - (c) by the chair of their own volition.
- (2) Such case management directions may be given as are considered necessary for the just and expeditious management of the case, and may include, but are not limited to—
- (a) providing that either or both parties must comply with the provisions of regulation 16, 17 or 20 within such period as may be specified in the direction;
 - (b) requiring the parties to obtain, and to disclose within a specified period, evidence and expert reports;
 - (c) requiring each party to provide an estimate of the length of the hearing and any dates on which they or any witnesses would not be able to attend the hearing;
 - (d) where facts are not in dispute or the allegation is admitted, requiring the parties to produce a statement of agreed facts;
 - (e) requiring the parties to state whether or not the health of the person concerned will be raised as an issue in the proceedings, and if so, whether, in their view, medical reports should be obtained;
 - (f) requiring a party to call the author of any expert report at the hearing;
 - (g) where agreed between the parties, directing that the witness statement of a witness is to stand as the evidence-in-chief of that witness;
 - (h) directing that special measures be put in place at the hearing for a vulnerable witness, including measures aimed at protecting the witness's identity;
 - (i) requiring chronologies and additional skeleton arguments to be produced by the parties;
 - (j) directing that a further case management meeting should be held; and
 - (k) obtaining rulings from the Statutory Committee for the purpose of resolving questions of law or admissibility of evidence.
- (3) Any rulings as mentioned in paragraph (2)(k) are binding on the committee hearing the allegation.
- (4) The secretary must keep a record of any case management directions given and must send written confirmation of such directions to the parties promptly.

(5) The Statutory Committee may draw such inferences as it considers appropriate in respect of the failure by a party to comply with case management directions.

PART 5

Matters arising both before and during hearings

Practice directions

24. The chair may give practice directions of general application to any proceedings of the Statutory Committee.

Clinical and other specialist advice

25. The Statutory Committee may, at any time in the course of proceedings before it (including at a hearing), seek advice from—

- (a) a clinical adviser, appointed under paragraph 18(1) of Schedule 3 to the Order, on a health related issue; or
- (b) another specialist adviser, appointed under paragraph 18(2) of Schedule 3 to the Order, on issues falling within their speciality or related to it.

Evidence

26.—(1) All questions of admissibility of evidence and law before the Statutory Committee are to be decided by the Statutory Committee (after having obtained the advice of the legal adviser, where appropriate).

(2) Subject only to the requirements of relevance and fairness, the Statutory Committee may receive—

- (a) subject to paragraph (3), any documentary evidence; and
- (b) where a hearing is held, any oral evidence,

whether or not such evidence would be admissible in any subsequent civil proceedings if the decision of the Statutory Committee were appealed to the High Court.

(3) Where a party wishes to adduce a witness statement, the Statutory Committee may only receive such evidence if the statement—

- (a) contains an attestation, in a format acceptable to the Statutory Committee, that the statement is true; and
- (b) is signed by the person making it.

(4) Where a person concerned has been convicted of a criminal offence in the British Islands (and has not successfully appealed against the conviction), a copy of the certificate of conviction certified by a competent officer of the court or for a conviction in Scotland, an extract conviction, is admissible as conclusive proof of that conviction and the findings of fact on which it was based.

(5) The only evidence which may be adduced by the person concerned in rebuttal of a conviction certified or extracted in accordance with paragraph (4) is evidence for the purpose of proving that the person concerned is not the person referred to in the certificate or extract.

(6) Where it is alleged that an applicant or registered person has been included in a barred list (within the meaning of the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007 or the Safeguarding Vulnerable Groups Act 2006 by the Independent Safeguarding Authority (“the Authority”))—

- (a) information provided by the Secretary of State under the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007 or the Safeguarding Vulnerable Groups Act 2006 that attests to that inclusion is to be conclusive proof of that inclusion, unless the applicant or registered person concerned can prove that they are not the person referred to in the information provided; and
 - (b) a document from the Authority, authenticated in whatever way the Society may approve, that provides a statement of the findings of fact that led to that inclusion is conclusive proof of those facts.
- (7) Where it is alleged that an applicant or registered person is included in the children's or the adults' list (within the meaning of the Protection of Vulnerable Groups (Scotland) Act 2007⁽¹⁰⁾)—
- (a) information provided by the Scottish Ministers under the Protection of Vulnerable Groups (Scotland) Act 2007 that attests to that inclusion is conclusive proof of that inclusion, unless the applicant or registered person concerned can prove that they are not the person referred to in the information provided; and
 - (b) a document from the Scottish Ministers, authenticated in whatever way the Society may approve, that provides a statement of the findings of fact that led to that inclusion is conclusive proof of those facts.
- (8) A formal notification of a determination about a person's fitness to practise made by a body responsible under any statutory provision for the regulation of a health or social care profession (in the United Kingdom or elsewhere), and signed by an officer authorised by that body to sign such a notification, is to be sufficient evidence, unless the contrary is proved, of any facts found proved by that regulatory body.
- (9) The Statutory Committee may only allow a party to adduce written evidence at a hearing which has not been served in accordance with these regulations (or these regulations as modified by case management directions) in such exceptional circumstances as it may determine.
- (10) In determining whether a registered person's fitness to practise is impaired by reason of physical or mental health, or when giving advice to the registrar in relation to an applicant's physical or mental health, the Statutory Committee may take into account, amongst other matters—
- (a) a refusal by the person concerned to submit to medical examination;
 - (b) the current physical or mental condition of the person concerned;
 - (c) any continuing or episodic condition suffered by the person concerned; and
 - (d) any underlying condition suffered by the person concerned which, although in remission, is capable of causing impairment of fitness to practise if it recurs.
- (11) Where the Statutory Committee finds that a registered person concerned has failed to comply with the standards, that failure—
- (a) may be taken into account by the Statutory Committee in determining whether or not the registered person concerned's fitness to practise is impaired; and
 - (b) is not, of itself, to be taken to establish that the registered person's fitness to practise is impaired.

Absence of the person concerned

27. Where the person concerned is neither present nor represented at any hearing and the Statutory Committee is satisfied that—

- (a) service of the Notice of Hearing or the Interim Order Notice has been properly effected; or

⁽¹⁰⁾ 2007 asp 14.

- (b) all reasonable efforts have been made to serve the person concerned with the Notice of Hearing or the Interim Order Notice,

the Statutory Committee may nevertheless proceed to consider and determine the matter or allegation.

Agreement of undertakings and giving of advice and warnings

28.—(1) The Statutory Committee may, if it thinks fit, dispose of fitness to practise proceedings by agreeing undertakings with the registered person concerned (that is, that the registered person will comply with such undertakings as the Statutory Committee considers appropriate) where they admit that their fitness to practise is impaired.

(2) The Statutory Committee may, if it thinks fit, dispose of disqualification proceedings by—

- (a) agreeing undertakings with the section 80 party (that is, that the section 80 party will comply with such undertakings as the Statutory Committee considers appropriate); or
- (b) giving advice or a warning,

instead of giving a direction under section 80 of the Act.

Recording in the register of decisions by the Statutory Committee

29.—(1) Where the Statutory Committee—

- (a) gives a warning to a registered person;
- (b) agrees undertakings with a registered person that relates to the registered person's fitness to practise;

the Registrar must ensure that an appropriate alteration to that registered person's entry in the register is made to record that warning or undertaking.

(2) Where, in the case of a registered person, the Statutory Committee determines that the registered person's fitness to practise is impaired, the Registrar must ensure that an appropriate alteration is made to that registered person's entry in the register to record the determination.

Joinder of allegations for a joint hearing

30.—(1) Unless it is of the view that there is a risk of prejudice to the fairness of the proceedings, the Statutory Committee may consider and determine a fitness to practise or a disqualification allegation against two or more persons concerned at the same hearing where—

- (a) the allegation against each person concerned arises out of the same circumstances; or
- (b) in the view of the Statutory Committee, a joint hearing is necessary or desirable.

(2) Where a joint hearing is held—

- (a) these regulations are to have effect in relation to the hearing with the necessary modifications directed by the chair; and
- (b) each person concerned is to be able to exercise any of the rights granted to that person under these regulations whether or not any other person concerned wishes to exercise that right.

Consideration of allegations that relate to more than one category of impairment

31.—(1) As regards any fitness to practise allegation before the Statutory Committee, if—

- (a) the particulars of the allegation in the Notice of Hearing relate to more than one category of impairment of fitness to practise; and

- (b) those particulars include a conviction or caution,

the chair must ensure (by adapting the procedure for the hearing, where necessary) that at the principal hearing, the Statutory Committee makes its findings of facts in relation to the allegations that do not relate to the conviction or caution before it hears and makes its findings of fact in relation to the conviction or caution.

(2) In the circumstances set out in paragraph (1), the chair must also ensure (by adapting the procedure for the hearing, where necessary), that the Statutory Committee only makes its decision as regards impairment of fitness to practise once it has made its finding of fact in relation to all the allegations set out in the Notice of Hearing.

Consideration of additional allegations

32. Where, before a principal hearing, the Society becomes aware of an additional allegation against a person concerned—

- (a) the Society may request case management directions; and
- (b) the chair may, where they consider it just to do so, direct that the new allegation be considered at the same hearing as the allegation that has already been referred, and that these regulations are to apply as modified to take into account the particular circumstances of the case.

Additional evidence for review hearings

33. Where, before a review hearing, the Society becomes aware of new evidence which it wishes to bring to the attention of the Statutory Committee (for example, evidence of a failure to comply with conditions)—

- (a) the Society may request case management directions; and
- (b) the chair may direct that the new evidence be considered at the review hearing, and that these regulations are to apply as modified to take into account the particular circumstances of the case.

PART 6

Procedure at hearings

Procedure at principal hearings before the Statutory Committee in fitness to practise proceedings

34.—(1) Unless the Statutory Committee determines otherwise, the order of proceedings at a principal hearing in fitness to practise proceedings is to be in accordance with paragraphs (2) to (18).

(2) The Statutory Committee must hear and consider any preliminary legal arguments.

(3) The chair must—

- (a) where the registered person concerned is present, require the registered person to confirm their name, or
- (b) otherwise, require the presenter to confirm the registered person concerned's name.

(4) The person acting as secretary must read out the allegation and the alleged facts upon which it is based.

(5) The chair must inquire whether the registered person wishes to make any admissions.

(6) Where facts are admitted, the chair must announce that such facts have been found proved.

(7) Where facts remain in dispute, the presenter is to open the case for the Society and may adduce evidence and, subject to paragraph (19), call witnesses in support of it.

(8) The registered person may make submissions regarding whether sufficient evidence has been adduced to find the facts proved or to support a finding of impairment, and the Statutory Committee must consider and announce its decision as to whether any such submissions should be upheld.

(9) The registered person may open their case and may adduce evidence and, subject to paragraph (19), call witnesses in support of it.

(10) The Statutory Committee must consider and announce its findings of fact.

(11) The Statutory Committee must receive further evidence and hear any further submissions from the parties as to whether, on the basis of any facts found proved, the registered person's fitness to practise is impaired.

(12) The Statutory Committee must consider and announce its finding on the question of whether the fitness to practise of the registered person is impaired, and give its reasons for that decision.

(13) The Statutory Committee may receive further evidence and hear any further submissions from the parties or from any other person who has a direct interest in the proceedings where the registered person's fitness to practise is found to be impaired, as to the appropriate sanction, if any, to be imposed, including evidence as to any mitigating circumstances and any relevant matters in the previous history of the registered person concerned.

(14) The Statutory Committee must consider and announce its decision as to the appropriate course of action to be taken in respect of the registered person of those specified in paragraph 7(2) of Schedule 3 to the Order and give its reasons for that decision.

(15) Where the Statutory Committee considers that it might make an order under paragraph 12(2) or (4) of Schedule 3 to the Order in relation to the registered person's registration (interim measures pending a direction taking effect), it must invite representations from the parties before considering and announcing whether it is to impose such an order, together with its reasons for that decision.

(16) The Statutory Committee must deal with any interim order in place in respect of the registered person.

(17) At any stage in the proceedings, before making a determination as to whether the registered person's fitness to practise is impaired, the Statutory Committee may, having regard to the nature of the allegation under consideration, adjourn and direct that a clinical adviser or a specialist adviser be appointed to assist the Statutory Committee under paragraph 18 of Schedule 3 to the Order.

(18) At any stage before making its decision as to a sanction, the Statutory Committee may adjourn for further information or reports to be obtained in order to assist it in exercising its functions.

(19) The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter—

- (a) if not satisfied that the witness is in a position to provide relevant testimony; or
- (b) if satisfied that all or part of the evidence that the witness is to provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.

(20) Notwithstanding the procedure set out in paragraphs (2) to (18), the Statutory Committee may allow the parties to make additional submissions at any time.

Procedure at principal hearings before the Statutory Committee in disqualification proceedings

35.—(1) Unless the Statutory Committee determines otherwise, the order of proceedings at a principal hearing in disqualification proceedings is to be in accordance with paragraphs (2) to (17).

(2) The Statutory Committee must hear and consider any preliminary legal arguments.

- (3) The chair must—
- (a) where the section 80 party or a representative of the party is present, require the party or representative to confirm the party's name, or
 - (b) otherwise, require the presenter to confirm the section 80 party's name.
- (4) The person acting as secretary must read out the allegation, and the alleged facts upon which it is based.
- (5) The chair must inquire whether the section 80 party wishes to make any admissions.
- (6) Where facts have been admitted, the chair must announce that such facts have been found proved.
- (7) Where facts remain in dispute, the presenter is to open the case for the Society and may adduce evidence and, subject to paragraph (19), call witnesses in support of it.
- (8) The section 80 party may make submissions regarding whether sufficient evidence has been adduced to find the facts proved and the Statutory Committee must consider and announce its decision as to whether any such submissions should be upheld.
- (9) The section 80 party may open their case and may adduce evidence and, subject to paragraph (19), call witnesses in support of it.
- (10) The Statutory Committee must consider and announce its findings of fact.
- (11) In a case falling within section 80(1)(b) or (4) of the Act, the Statutory Committee must consider and announce its finding on the question of whether, in its opinion, the offence or misconduct renders the section 80 party unfit to be a pharmacist or would so render the party if the party were a pharmacist and give its reasons for that decision.
- (12) Paragraph (13) applies where the decision under paragraph (11) is that the offence or misconduct renders the party unfit to be a pharmacist or would so render the party if the party were a pharmacist.
- (13) Where this paragraph applies, the Statutory Committee must—
- (a) receive evidence about the facts specified in section 81(2) of the Act; and
 - (b) consider whether, having regard to those facts, the board of the body corporate or, as the case may be, the representative, is to be regarded as responsible for the offence, misconduct or failure in question.
- (14) The Statutory Committee may receive further evidence and hear any further submissions from the parties or from any other person who has a direct interest in the proceedings as to whether a direction under section 80(1) or (4) of the Act should be given, including evidence as to any mitigating circumstances and any relevant matters in the previous history of the section 80 party.
- (15) The Statutory Committee must consider and announce its decision as to whether or not a direction under section 80(1) or (4) of the Act should be given and must give its reasons for that decision.
- (16) Where the decision under paragraph (15) is that the direction should be given, the chair must agree to that decision.
- (17) At any stage before making its decision as to disqualification, the Statutory Committee may adjourn for further information or reports to be obtained in order to assist it in exercising its functions.
- (18) Where the Society becomes aware that a section 80 party has failed to comply with any undertakings agreed under regulation 2 8(2)(a), the Statutory Committee must—
- (a) resume its consideration of the matter (the procedure at the hearing being for the Statutory Committee to determine); and
 - (b) reconsider the sanction imposed, and may instead issue a direction under section 80(1) or, as the case may be, (4), of the Act.

(19) The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter—

- (a) if not satisfied that the witness is in a position to provide relevant testimony; or
- (b) if satisfied that all or part of the evidence that the witness is to provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.

(20) Notwithstanding the procedure set out in paragraphs (2) to (17), the Statutory Committee may allow the parties to make additional submissions at any time.

(21) In this regulation “pharmacist” means registered person.

Procedure at review hearings

36.—(1) Unless the Statutory Committee determines otherwise, the order of proceedings at a review hearing is to be in accordance with paragraphs (2) to (9).

(2) The Statutory Committee must hear and consider any preliminary legal arguments.

(3) The chair must—

- (a) where the person concerned is present or represented, require the person concerned to confirm their name; or
- (b) otherwise, require the presenter to confirm the person concerned’s name.

(4) The presenter —

- (a) must inform the Statutory Committee of the background to the case, and the sanction previously imposed or undertaking entered into;
- (b) must direct the attention of the Statutory Committee to any relevant evidence, including transcripts of previous hearings; and
- (c) may adduce evidence and, subject to paragraph (10), call witnesses in relation to the person concerned’s fitness to practise or, as the case may be, their failure to comply with an undertaking or with any requirement imposed as a condition of registration.

(5) The person concerned may present their case, adduce evidence and, subject to paragraph (10), call witnesses in support of it.

(6) The Statutory Committee must receive further evidence and hear any further submissions from the parties—

- (a) where the Statutory Committee has given a direction under paragraph 7(2)(d) or (e) of Schedule 3 to the Order, as to what direction to give, if any, under paragraph 7(3) of that Schedule;
- (b) where the person concerned has given an undertaking, as to whether the person concerned has breached the undertaking;
- (c) where the Statutory Committee has given a direction under section 80(1) or (4) of the Act, as to whether that direction should be revoked.

(7) The Statutory Committee must consider and announce its finding on the relevant question in paragraph (6) and give its reasons for that decision.

(8) The Statutory Committee must consider and announce its decision as to—

- (a) the direction, if any, to be given under paragraph 7(3) of Schedule 3 to the Order; or
- (b) the revocation of the direction under section 80(1) or (4) of the Act,

and give its reasons for that decision.

- (9) Where the Statutory Committee finds that an undertaking has not been complied with, it may—
- (a) in fitness to practise proceedings, determine that the registered person’s fitness to practise is impaired on the basis of that failure to comply and make a determination under paragraph 7(2) of Schedule 3 to the Order;
 - (b) in disqualification proceedings, treat the failure as misconduct and give a direction under section 80(1) or (4) of the Act.
- (10) The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter—
- (a) if not satisfied that the witness is in a position to provide relevant testimony; or
 - (b) if satisfied that all or part of the evidence that the witness is to provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.
- (11) Notwithstanding the procedure set out in paragraphs (2) to (9), the Statutory Committee may allow the parties to make additional submissions at any time.

Procedure at restoration hearings

- 37.**—(1) Unless the Statutory Committee determines otherwise, the order of proceedings at a restoration hearing is to be in accordance with paragraphs (2) to (9).
- (2) The Statutory Committee must hear and consider any preliminary legal arguments.
 - (3) The chair must—
 - (a) where the applicant concerned is present, require the applicant concerned to confirm their name; or
 - (b) otherwise, require the presenter to confirm the applicant concerned’s name.
 - (4) The presenter—
 - (a) must address the Statutory Committee as to the background to the case and the circumstances in which the applicant’s name was removed from the register;
 - (b) must direct the attention of the Statutory Committee to any relevant evidence, including transcripts of previous hearings; and
 - (c) may adduce evidence and, subject to paragraph (11), call witnesses in relation to the applicant’s fitness to practise.
 - (5) The applicant may address the Statutory Committee, adduce evidence and, subject to paragraph (11), call witnesses in relation to any relevant matter, including their suitability for restoration to the register.
 - (6) The Statutory Committee may receive further evidence and hear any further submissions from the parties as to its decision whether to grant or refuse the application.
 - (7) The Statutory Committee must then consider and announce whether to grant or refuse the application and give its reasons for that decision.
 - (8) Before reaching a decision under paragraph (7), the Statutory Committee may adjourn and give such directions as it sees fit.
 - (9) Where the Statutory Committee adjourns under paragraph (8), it must—
 - (a) consider any assessment reports produced further to a direction under paragraph (8), together with any other relevant evidence and reports; and
 - (b) invite further representations and evidence from the parties,
 before reaching a decision as to whether the applicant’s name should be restored to the register.

(10) Where the Statutory Committee decides that a person's name should be restored to the register, the secretary must notify the registrar accordingly.

(11) The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter—

- (a) if not satisfied that the witness is in a position to provide relevant testimony; or
- (b) if satisfied that all or part of the evidence that the witness is to provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.

(12) Notwithstanding the procedure set out in paragraphs (2) to (9), the Statutory Committee may allow the parties to make additional submissions at any time.

Procedure at interim order hearings

38.—(1) The order of proceedings at an interim order hearing is to be in accordance with paragraphs (2) to (8).

(2) The Statutory Committee must hear and consider any preliminary legal arguments.

(3) The chair must—

- (a) where the registered person concerned is present, require the registered person concerned to confirm their name; or
- (b) otherwise, require the presenter to confirm the registered person concerned's name.

(4) The presenter must address the Statutory Committee regarding whether it is necessary to make or review an interim order in respect of the registered person concerned and, subject to paragraphs (9) to (11), may adduce evidence in this regard.

(5) The registered person may present their case and, subject to paragraphs (9) to (11), may adduce evidence in support of it.

(6) The parties and members of the Statutory Committee may put questions to any witness.

(7) Subject to paragraph (10), where the registered person gives oral evidence, the presenter and members of the Statutory Committee may put questions to the registered person.

(8) The Statutory Committee must announce its decision, and must give its reasons for that decision.

(9) The Statutory Committee may, subject to paragraphs (10) and (11), receive any evidence which appears to it to be fair and relevant to its consideration under paragraph 8 of Schedule 3 to the Order.

(10) No person may give oral evidence at the hearing unless the Statutory Committee considers such evidence is desirable to enable it to discharge its functions.

(11) The Statutory Committee may, at any stage in the proceedings—

- (a) with the consent of the registered person; or
- (b) where it is satisfied that to do so would be desirable to enable it to discharge its functions, allow a party to produce at the hearing any written evidence, notwithstanding that a copy has not been provided to the other party before the hearing or that its author is not being called as a witness.

(12) The Statutory Committee may vary the order of proceedings under paragraphs (2) to (8) where it is in the interests of justice to do so.

(13) Where—

- (a) an interim order is being reviewed by the Statutory Committee; and
- (b) the hearing is, or is likely to be, the last such hearing before the expiry of the interim order,

the Statutory Committee may, after making its determination, advise the registrar that an application should be made to the High Court for the interim order to be extended, or if it has been extended, further extended, under paragraph 8(5) of Schedule 3 to the Order.

(14) Where the terms of the order to be made or continued, or the terms of the variation to the order, or its revocation, are agreed between the parties, the Statutory Committee may make an order in those terms without the need for a hearing.

PART 7

General

Postponements and adjournments

39.—(1) The chair may, of their own motion or upon the application of a party, postpone any meeting or hearing of which notice has been given under these Regulations before the hearing begins.

(2) The Statutory Committee may, of its own motion or upon the application of a party, adjourn the proceedings at any stage, provided that—

- (a) no injustice is caused to the parties; and
- (b) the decision to adjourn is made after hearing representations from the parties (where present).

(3) In considering whether or not to grant a request for postponement or adjournment, the chair or the Statutory Committee must, amongst other matters, have regard to—

- (a) the public interest in the expeditious disposal of the case;
- (b) the potential inconvenience caused to a party or any witnesses to be called by that party;
- (c) the conduct of the party seeking the postponement or adjournment; and
- (d) fairness to the parties.

(4) Where a person concerned applies for a postponement or adjournment on grounds of ill-health—

- (a) the person concerned must adduce appropriate medical certification in support of that application; and
- (b) the chair or the Statutory Committee may, if not satisfied by the medical certification produced, require the person concerned to submit to be examined by a medical practitioner approved by the Society.

(5) Where the proceedings have been postponed or adjourned, the secretary must, as soon as practicable, notify the parties of the date, time and venue of the postponed or resumed hearing.

Disposal of allegations without hearings

40.—(1) Where—

- (a) an allegation has been referred to the Statutory Committee by the Scrutiny Committee;
- (b) a principal hearing has not yet taken place in the proceedings; and
- (c) the presenter for either the principal hearing or an interim order hearing that relates to the allegation considers that, on the basis of the evidence available or other information in the possession of the Society, the hearing should not be held,

the presenter must inform the Scrutiny Committee of their opinion forthwith, and of the reasons for their opinion.

(2) Upon receipt of the presenter's opinion, the Scrutiny Committee must consider the matter and may give a direction that the referral to the Statutory Committee (either for a principal or an interim order hearing, or both) is rescinded.

(3) The Scrutiny Committee must not rescind a referral for a principal hearing without first giving the maker of the relevant allegation (if any) a reasonable opportunity to comment on the proposed rescission.

Attendance of the public at hearings

41.—(1) Except as provided for in this regulation, hearings of the Statutory Committee must be held in public.

(2) Any hearing before the Statutory Committee relating to a health allegation, or an interim order hearing before the Statutory Committee, must be held in private, unless the Statutory Committee is satisfied—

- (a) having given the parties (where present), and any third party from whom the Statutory Committee considers it appropriate to hear, an opportunity to make representations; and
- (b) in the case of the hearing relating to a health allegation, having obtained the advice of the legal and clinical advisers,

that the public interest in holding the hearing in public outweighs the interest of the registered person concerned or the third party in maintaining their privacy.

(3) A hearing before the Statutory Committee other than a hearing referred to in paragraph (2) may be held wholly or partly in private if the Statutory Committee—

- (a) has given the parties (where present), and any third party from whom the Statutory Committee considers it appropriate to hear, an opportunity to make representations; and
- (b) is satisfied that the interest of the person concerned or the third party in maintaining their privacy outweighs the public interest in holding the hearing, or the part of the hearing, in public.

(4) The Statutory Committee may exclude from the whole or part of any hearing any person whose conduct, in its opinion, has disrupted or is likely to disrupt the proceedings.

Representation

42.—(1) The presenter is to be a person who is—

- (a) a barrister or solicitor; or
- (b) an employee of the Society.

(2) The person concerned may be represented by a person who is—

- (a) a barrister or solicitor; or
- (b) a representative from that party's defence organisation or their trade union.

(3) Where the person concerned is not represented, they may be accompanied and advised by a supporter, but the supporter—

- (a) must not be—
 - (i) a member of the Council or of one of its committees,
 - (ii) an employee of the Society, or
 - (iii) a witness at the hearing; and
- (b) may only address the Statutory Committee with the permission of the chair.

Amendment of the particulars of the allegation at principal hearings

43.—(1) At a principal hearing, at any stage before making its findings of fact, the Statutory Committee may of its own motion or following an application of one of the parties, amend the particulars of the allegation set out in the Notice of Hearing, unless it is of the view that the required amendment would prejudice the fairness of the proceedings.

(2) Before making any amendment under paragraph (1), the Statutory Committee must consider

- (a) any representations from the parties (where present); and
- (b) in the case of a hearing in relation to a health allegation, the advice of the legal and clinical advisers.

Burden and standard of proof

44.—(1) Where facts at a principal hearing are in dispute, the burden of proving the facts rests on the Society.

(2) At a restoration hearing, the Statutory Committee may only grant the application if the applicant has proved their entitlement to be registered.

(3) Where facts are in dispute, the Statutory Committee must consider whether they have been established in accordance with the civil standard of proof.

Witness evidence

45.—(1) Witnesses are to be required to take an oath, or to affirm, before giving their oral evidence.

(2) The Society may not compel the person concerned to be a witness.

(3) A party may not call a person to be a witness unless that party has provided to the other party a written statement of evidence provided by the witness which meets the requirements of regulation 26, at least 7 days before the day of the hearing, unless the chair determines otherwise.

(4) The Statutory Committee may, upon the application of the party calling the witness, direct that any details which may identify that witness must not be revealed in public.

(5) Where a witness's first language is not English, the Statutory Committee may direct that their evidence be given through an interpreter.

(6) Witnesses other than the person concerned—

- (a) must first be examined by the party calling them;
- (b) may be cross examined;
- (c) may then be re-examined by the party calling them; and
- (d) may then be questioned, with the leave of the chair, by the Statutory Committee or by a clinical, legal or specialist adviser.

(7) The parties may then question the witnesses on matters arising out of the Statutory Committee's questions, with the party calling the witness being given the last opportunity to do so (as between the parties).

(8) Where the person concerned is a witness, they—

- (a) must first be examined by the person representing them or, if there is no such person, must be questioned by the Statutory Committee through the chair;
- (b) may then be cross examined;
- (c) may then be re-examined by the person representing them if any; and

(d) may then be questioned, with the leave of the chair, by the Statutory Committee whether or not they are represented.

(9) Any further questioning of witnesses is to be at the discretion of the chair.

(10) Except for expert witnesses and the person concerned, witnesses are not to be allowed to attend the proceedings until after they have completed giving their evidence and been formally released by the chair.

Vulnerable witnesses at hearings

46.—(1) In proceedings before the Statutory Committee, the following may, if the quality of their evidence is otherwise likely to be adversely affected, be treated as vulnerable witnesses—

- (a) any witness under the age of 18;
- (b) any witness with a mental disorder (within the meaning of the Mental Health (Northern Ireland) Order 1986⁽¹¹⁾);
- (c) any witness who is significantly impaired in relation to intelligence or social functioning;
- (d) any witness with a physical disability who requires assistance to give evidence;
- (e) any witness, where an allegation against a person concerned is of a sexual nature and the witness was the alleged victim; or
- (f) any witness who complains of intimidation.

(2) Upon—

- (a) hearing representations from the parties; and
- (b) in relation to a health allegation, after seeking the advice of a legal adviser,

the Statutory Committee may adopt such measures as it considers necessary to enable it to receive evidence from a vulnerable witness.

(3) Measures adopted by the Statutory Committee may include, but are not to be limited to—

- (a) use of video links;
- (b) subject to paragraph (4), use of pre-recorded evidence as the evidence-in-chief of a witness, provided always that the witness is present at the hearing or via video link for cross-examination and questioning; and
- (c) use of interpreters (including signers and translators).

(4) Where—

- (a) there is an allegation against a person concerned of a sexual nature;
- (b) a witness is the alleged victim; and
- (c) the person concerned is not represented,

the person concerned is not to be allowed to cross-examine the witness directly in person.

(5) In the circumstances set out in paragraph (4), any questioning of the witness is to be undertaken by such person as the Statutory Committee considers appropriate.

Review of undertakings

47.—(1) Where undertakings have been agreed by the Statutory Committee under regulation 28, the registrar may carry out any investigations which may include (but are not limited to) requesting

⁽¹¹⁾ 1986 No.595 (N.I.4) “Mental disorder” is defined in Article 3(1) as mental illness, mental handicap and any other disorder or disability of the mind.

the provision of reports or directing an assessment to be carried out where, in the registrar's opinion these are appropriate to the consideration of—

- (a) whether the registered person concerned or section 80 party has complied with any undertakings in place; or
- (b) in the case of a registered person, the registered person concerned's fitness to practise.

(2) Where, as a result of information received by the Society, it appears to the registrar that any undertakings agreed under regulation 28 should be varied or cease to apply, the registrar must—

- (a) invite the registered person concerned or section 80 party to agree such varied undertakings as appear to the registrar to be appropriate; or
- (b) direct that the undertakings are no longer to apply.

(3) Where the registrar receives information that—

- (a) the registered person concerned or section 80 party has failed to comply with an undertaking agreed under regulation 28 or which, having been agreed under regulation 28, has been varied following an invitation to comply with it under paragraph (2)(a); or
- (b) in the case of a registered person, the registered person concerned's health or performance has deteriorated or otherwise gives further concern regarding their fitness to practise,

the registrar may refer the matter to the Statutory Committee for a review hearing.

Costs of the hearing

48.—(1) Where a principal hearing, a review hearing or a restoration hearing is to be held, a party may serve on the other party, and on the secretary, a schedule of costs or expenses relating to or connected with that hearing no less than 24 hours before the date of the hearing.

(2) After announcing the Statutory Committee's decision, the chair may invite representations as to whether costs or expenses should be assessed against either party.

(3) After hearing any representations from the parties, the Statutory Committee may, if it thinks fit and having regard to the party's ability to pay, order that a party pay by a specified date all or part of the costs or expenses relating to the hearing incurred by the other party.

(4) Where the Statutory Committee orders a party to pay costs or expenses, the chair may—

- (a) summarily assess the costs or expenses to be paid;
- (b) require the parties to agree either the figure for the costs or expenses to be awarded; or
- (c) require those costs or expenses to be assessed by a person appointed by the secretary.

(5) Where a person is appointed by the secretary in accordance with paragraph (4)(c), that person must also determine how the costs of the assessment are to be apportioned.

Notes and transcripts of hearings

49.—(1) Subject to paragraph (3), the Statutory Committee must arrange for all hearings to be recorded in writing or electronic form.

(2) Any party to the proceedings must, on application to the Statutory Committee be furnished with a transcript of the record of any part of the hearing at which he was entitled to be present.

(3) The private deliberations of the Statutory Committee must not be recorded.

Sealed with the Common Seal of the Pharmaceutical Society of Northern Ireland on 8th August 2012



Roberta Tasker
Trevor Patterson
President/Chief Executive

The Department of Health, Social Services and Public Safety hereby approves the foregoing Regulations.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 8th August 2012



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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations of the Council of the Pharmaceutical Society of Northern Ireland (“the Society”) set out various matters relating to the procedures to be followed by the Society when considering allegations that the fitness to practise of its registered persons is impaired, allegations that a person should be disqualified from inclusion in the register of pharmacy retail business premises kept by the Society and allegations of criminal conduct that the Society is under a duty to investigate.

Part 1 of the Regulations contains preliminary matters including setting out the criteria by which the Society’s Statutory Committee is to determine whether or not the requirements as to fitness to practise are met in relation to any registered person.

Part 2 of the Regulations deals with the initial consideration of information which may give rise to allegations. The registrar screens the allegation and determines whether it is appropriate to refer the allegation to the Statutory Committee. The registrar is also given powers in respect of the initial screening of applications for restoration to the Society’s registers. If an allegation is to be referred to the Statutory Committee, the registered person concerned will be sent a notice of the referral. If that referral is to the Scrutiny Committee, the notice of referral is to be accompanied by the evidence that the Scrutiny Committee is to consider, and the person concerned will be invited to make written representations on the allegation, and on any recommendations for disposal of the case made by the registrar. Provision is also made for the voluntary removal of names from the register. Applications for the voluntary removal of a name from the register will generally be refused where there is an ongoing investigation or there are outstanding proceedings relating to a registered person’s fitness to practise.

Part 3 of the Regulations deals with consideration of allegations by the Scrutiny Committee. That Committee does not hear oral evidence, but considers on the papers allegations referred to it and decides whether or not to refer cases on to the Statutory Committee and whether or not the Society should bring criminal proceedings. Instead of making a referral to the Statutory Committee, the Scrutiny Committee may decide to dispose of the case by issuing a warning to the registered person concerned, or by accepting undertakings from the registered person as to their future conduct. If the Scrutiny Committee decides to refer the case on to the Statutory Committee, it issues a notice of decision, particularising the matters to be referred. There is also provision allowing the Scrutiny Committee to reconsider its decisions in appropriate circumstances.

Part 4 of the Regulations deals with the initial consideration of the case by the Statutory Committee. There are disclosure provisions relating to the exchange of each party’s case. The parties are also given powers to inspect the original versions of documents disclosed to them. Once the exchange of each party’s case has taken place, a Notice of Hearing is sent and there are provisions relating to bundles for hearings. There are also arrangements for case management directions that may modify the standard procedures and special arrangements relating to interim orders hearings in fitness to practise proceedings where suspension or conditional registration pending the full hearing is being considered.

Part 5 of the Regulations deals with additional matters that may arise both before and during hearings, including provision for issuing practice directions and provisions relating to the admissibility of evidence. It also sets out particular arrangements for dealing with specified cases where the standard arrangements will need to be adapted: cases where the Statutory Committee considers that the case should instead be dealt with by the other Committee; cases where joinder is appropriate; and cases where additional allegations or additional evidence comes to light at a late stage in proceedings.

Part 6 of the Regulations sets out the procedures for hearings of the Statutory Committee. These include the arrangements for the order of proceedings at different classes of hearings.

Part 7 of the Regulations makes provisions of general application. These include provisions relating to postponements and adjournments; cases where the presenter for the Society decides before a hearing that, on the evidence available, the Society should not proceed with its case; review of undertakings agreed with the registered person concerned; standard of proof to be applied; holding of hearings in public (except in certain cases); representation and the calling and questioning of witnesses. There are also provisions relating to the award and assessment of costs or expenses and in relation to recording hearings and producing transcripts of them.