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—