

Pharmaceutical Society NI Working Guidance – Clinical Advisers

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Working Guidance

1. About the Pharmaceutical Society NI

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

2. Fitness to Practise Committees

The Pharmaceutical Society of Northern Ireland has two Fitness to Practise Committees; the Scrutiny Committee and the Statutory Committee.

The Statutory Committee

The Statutory Committee makes judgements on whether a registrant's fitness to practise is impaired for reasons concerning their conduct, professional performance or health. Meetings are generally held in public (except for health related cases and Interim Orders). The Statutory Committee has the power to issue formal warnings, agree undertakings, place conditions on the practice of a pharmacist, impose suspension and remove registrants from the Register. When a case concerns a Registrant's physical or mental health or a relevant health issue a clinical adviser will be selected, based on their area of expertise and the details of the case. For further information on the procedures of the Statutory Committee please see **Appendices A and B**

The Scrutiny Committee

The Scrutiny Committee considers concerns about a registrants fitness to practise, it has the power to dismiss a case, give advice, issue warnings and agree undertakings if appropriate. It must refer more serious cases to the Statutory Committee. For further information on the procedures of the Scrutiny Committee please see **Appendix C**

3. Appointment of Clinical Advisers

Clinical Advisers will be appointed to a Clinical Advisers List and will be engaged by the Secretary of the Committee, in consultation with the Chair on a case by case basis.

4. Role of Clinical Adviser to Statutory Committee

- a. The Clinical Adviser engaged to consider a Statutory Committee case, will receive a copy of the relevant papers in the region of seven days prior to the hearing (this may vary and will be considerably shorter for an Interim Order case). The Clinical adviser is to read and assimilate the papers.
- b. The function of the Clinical Adviser who is present at a meeting or hearing of the Statutory Committee is to advise the Statutory Committee on any issues within the Clinical Adviser's areas of medical expertise that may be referred to the Clinical Adviser by a member of the Statutory Committee¹.
- c. The Clinical Adviser is to intervene to advise the Statutory Committee on an issue where it appears to the Clinical Adviser that without their intervention, there is a possibility of an error being made².
- d. The Clinical Adviser may, under the leave of the Chair, question any witness³.
- e. The Clinical Adviser should not make a diagnosis.
- f. The Clinical Adviser should not dispute the diagnosis of a medical practitioner who has examined the registrant.
- g. The Clinical Adviser should not give an opinion on the fitness to practise of the registrant⁴.
- h. A Clinical Adviser must provide all advice in the presence of the Committee and all parties to the proceedings⁵.
- i. A Clinical Adviser must not be present during the private deliberations of the Statutory Committee⁶.
- j. A Clinical Adviser must not participate in the decision making of the Statutory Committee (and is not entitled to vote)⁷.
- k. Any advice given by the Clinical Adviser should be recorded in the formal transcript of the hearing and the transcript must be sent to all parties to the proceedings⁸.

¹ Regulation 19 (2) (a) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

² Regulation 19 (2) (b) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

³ Regulation 24 of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

⁴ Sandra Watson vs GMC 2005

⁵ Sandra Watson vs GMC 2005

⁶ Regulation 19 (3) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

⁷ Regulation 19 (4) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

⁸ Regulation 22 (3) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

- l. Where any advice tendered by the Clinical Adviser to the Statutory Committee is not accepted by the Committee, the Chair must announce the reasons for not accepting the advice tendered⁹.
- m. Those reasons should be recorded in the official transcript of the hearing and a copy of the transcript should be sent to all parties to the proceedings¹⁰

5. The Role of the Clinical Adviser to the Scrutiny Committee

- a. The Clinical Adviser engaged to consider a Scrutiny Committee case, will receive a copy of the relevant papers in the region of four days prior to the private meeting. The Clinical adviser is to read and assimilate the papers.
- b. The function of the Clinical Adviser who is present at a private meeting of the Scrutiny Committee is to advise the Committee on any issues within the Clinical Adviser's areas of medical expertise that may be referred to the clinical adviser by a member of the Scrutiny Committee based on the papers presented to the Committee¹¹.
- c. The Clinical Adviser is to intervene to advise the Statutory Committee on an issue where it appears to the clinical adviser that without their intervention, there is a possibility of an error being made¹².
- d. The Clinical Adviser should not make a diagnosis.
- e. The Clinical Adviser should not dispute the diagnosis of a medical practitioner who has examined the registrant.
- f. The Clinical Adviser should not give an opinion on the fitness to practise of the registrant¹³.
- g. The Secretary to the Scrutiny Committee must keep a record of any advice tendered by the Clinical Adviser to the Scrutiny Committee¹⁴
- h. A record of any advice tendered by the Clinical Adviser must be sent to the parties to the proceedings or their representatives as soon as it is practicable after it has been tendered¹⁵.
- i. Where any advice tendered by the Clinical Adviser is not accepted by the Scrutiny Committee the Chair must announce the reasons for not accepting the advice and the Secretary of the Committee must keep a record of the advice tendered and the reasons why the Scrutiny Committee refused to accept that advice¹⁶.

⁹ Regulation 23 of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹⁰ Regulation 23 of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹¹ Regulation 19 (2) (a) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹² Regulation 19 (2) (b) Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹³ Sandra Watson vs GMC 2005

¹⁴ Regulation 22 (1) Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹⁵ Regulation 22 (3) Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹⁶ Regulation 23 Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

- j. The Secretary must send a copy of the record of the advice and the reasons why the Scrutiny Committee refused to accept that advice, to the parties to the proceedings or their representatives as appropriate¹⁷.
- n. A Clinical Adviser must not be present during the private deliberations of the Scrutiny Committee¹⁸.
- o. A Clinical Adviser must not participate in the decision making of the Scrutiny Committee (and is not entitled to vote)¹⁹.

6. Conflict of interest

If at any point after engagement by the Secretary of either committee the Clinical Adviser believes that they have an actual or potential conflict of interest in relation to the case, he/she must inform the Chair of the Committee who may replace the Clinical Adviser and/or adjourn the hearing/private meeting.

7. Data protection

On conclusion of the hearing or private meeting the clinical adviser must return all papers to the Secretary of the relevant Committee for secure disposal.

¹⁷ Regulation 23 Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹⁸ Regulation 19 (3) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

¹⁹ Regulation 19 (4) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012

Annex A – Procedure at principal hearings before the Statutory Committee

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

[The Fitness to Practise and Disqualification Regulations 2012](#) set out the procedure for hearings before the Statutory Committee in fitness to practise proceedings in Regulation 34.

The order of proceedings, unless the Statutory Committee determines otherwise, shall be as follows;

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

The chair must:

where the registered person is present, require the registered person to confirm their name, or

otherwise, require the presenter to confirm the registered person's name.

The person acting as secretary must read out the allegation and the alleged facts upon which it is based. The chair must enquire whether the registered person wishes to make any admissions. Where facts are admitted, the chair must announce that the facts have been found proved.

Where facts remain in dispute, the presenter is to open the case for the Pharmaceutical Society of Northern Ireland and may adduce evidence and, subject to issues of relevance or admissibility,* call witnesses in support of it.

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.

The registered person may open their case and may adduce evidence and, subject to issues of relevance or admissibility,* call witnesses in support of it.

*(The * chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter:*

if not satisfied that the witness is in a position to provide relevant testimony; or

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 other party not calling the witness at an earlier stage of the proceedings.)

The Statutory Committee must consider and announce its findings on fact.

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. The Statutory Committee must consider and

announce its findings on the question of whether the fitness to practise of the registered person is impaired, and give its reasons for that decision.

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 of any mitigating circumstances in any relevant matters in the previous history of the registered person.

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

Where the Statutory Committee considers 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 (i.e. interim measures pending a direction taking effect), it must invite representations from the parties before considering and announcing whether to impose such an Order, together with its reason for that decision.

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

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 the Schedule 3 to the Order](#).

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

Notwithstanding the procedure set out above and governed by [Regulation 34](#), 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

Unless the Statutory Committee determines otherwise, the order of disqualification proceedings is as follows²⁰:

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

The chair must:

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

otherwise, require the presenter to confirm the section 80 party's name.

The person acting as Secretary must read out the allegation, and the alleged facts upon which it is based.

²⁰ [Regulation 35 of Fitness to Practise and Disqualification Regulations 2012](#)

The chair must enquire whether the section 80 party wishes to make admissions. Where facts have been admitted, the chair must announce that such facts have been found proved.

Where facts remain in dispute, the presenter is to open the case for the Pharmaceutical Society of Northern Ireland and may adduce evidence and subject to issues about admissibility or relevance and call witnesses in support of it.

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 submission should be upheld.

The section 80 party may open their case and may adduce evidence and, subject to issues regarding relevance or admissibility, * call witnesses in support of it.

*(*The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter;*

if not satisfied that the witness is in a position to provide relevant testimony; or

if satisfied that all or part of the evidence 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.)

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

In a case falling within section 80 (1) (b) or (4) (b) of the Medicines Act, the Statutory Committee must consider and announce its findings 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.

Where the Statutory Committee's decision 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); or in a case falling within section 80 (1) (c) of the Medicines Act, the failure in question is by a member of the board or any officer of, or the person employed by, the body in question – then the Statutory Committee must:

receive evidence about the facts specified in section 81 (2) of the Medicines Act;
and

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.

The Statutory Committee may receive further evidence and hear any further submissions from parties or from any other person who has a direct interest in the proceedings as to whether a decision under section 80 (1) or (4) of the Medicines Act should be given, including evidence as to whether any mitigating circumstances and any relevant matters in the previous history of the section 80 party.

The Statutory Committee must consider and announce its decision as to whether or not a direction under section 80 (1) or (4) of the Medicines Act should be given and must give its reasons for that decision.

Where the decision is that the direction should be given, the chair must agree to that decision (see [Regulation 35 \(15\) and \(16\)](#) of the Fitness to Practise and Disqualification Regulations 2012).

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.

A direction under section 80 of the Act shall not take effect until the end of the period of three months from the date on which notice of the direction is given to the body corporate or other person to whom it relates, and, if an appeal against the direction is brought under this section, shall not take effect until that appeal has been determined or withdrawn.

Where the Pharmaceutical Society of Northern Ireland becomes aware that a section 80 party has failed to comply with any of the undertakings agreed under Regulation 28 (2) (a) of the Fitness to Practise and Disqualification Regulations 2012, the Statutory Committee must:

Resume its consideration of the matter (the procedure at the hearing being for the Statutory Committee to determine); and

reconsider the sanction imposed and may instead issue a direction under section 80 (1) or, as the case may be, (4) of the Medicines Act.

Please note that notwithstanding the procedure set out above, the Statutory Committee may allow the parties to make additional submissions at any time.

Procedure at Review Hearings

Where, before a Review Hearing, the Pharmaceutical Society of Northern Ireland 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) the Society must request case management directions and the chair may direct that the new evidence be considered at the Review Hearing. The Fitness to Practise and Disqualification Regulations 2012 are to apply as modified to take into account the particular circumstances of the case.

Unless the Statutory Committee determines otherwise, the order of proceedings at a Review Hearing is to be as follows²¹:

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

The chair must:

where the registered person is present or represented, require the registered person to confirm their name; or

otherwise, require the person to confirm the registered person's name.

The presenter;

- must inform the Statutory Committee of the background to the case, and the sanction previously imposed or undertaking entered into;

²¹ [Regulation 36 of the Fitness to Practise and Disqualification Regulations 2012](#)

- must direct the attention of the Committee to any relevant evidence, including the transcripts of the previous hearing; and
- may adduce evidence and, subject to any issue on the relevance or admissibility, call witnesses in relation to the registered person'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.

The registered person may present their case, adduce evidence and, subject to any issue regarding relevance or admissibility, call witnesses in support of it.

The Statutory Committee may receive further evidence and hear any further submissions from the parties;

where the Statutory Committee has given a direction under [paragraph 7 \(2\) \(d\) or \(e\) of Schedule 3 to the Order](#) (suspension or conditional direction respectively) as to what direction to give, if any under paragraph 7 (3) of that schedule;

where the registered person has given an undertaking, as to whether the registered person has breached the undertaking;

where the Statutory Committee has given a direction under section 80 (1) or (4) of the Medicines Act, as to whether that direction should be revoked.

The Statutory Committee must consider and announce its findings on the relevant question above and give its reasons for that decision.

The Statutory Committee must consider and announce its decision as to the direction, if any to be given under [paragraph 7 \(3\) of Schedule 3 to the Order](#); or the revocation of the direction under section 80 (1) or (4) of the Act, and give reasons for that decision.

Where the Statutory Committee finds that an undertaking has not been complied with, it may:

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](#);

In disqualification proceedings, treat the failure as misconduct and give a direction under section 80 (1) or (4) of the Medicines Act.

*[*The chair may refuse to allow a witness to give oral evidence, or to give oral evidence on a particular matter:*

If not satisfied that the witness is in a position to provide relevant testimony; or

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.]

Please note notwithstanding the procedure set out above, the Statutory Committee may allow the parties to make additional submissions at any time.

For review hearings that include the consideration of undertakings agreed with the registered person or section 80 party, please have regard to [Regulation 47 of the Fitness to Practise and Disqualification Regulations](#).

Annex B – Procedure for Statutory Committee at Interim Order Hearings

[Regulation 38 of the Fitness to Practise and Disqualification Regulations 2012](#) provides the order of proceedings at interim order hearings although the Statutory Committee may vary the order proceedings where it is in the interests of justice to do so.

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

The chair must:

where the registered person is present, require the registered person to confirm their name; or

otherwise, require the presenter to confirm the registered person's name.

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 and, subject to issues regarding relevance or admissibility, may adduce evidence in this regard.

The registered person may present their evidence and, subject to issues about relevance or admissibility, may adduce evidence in support of it.

The Statutory Committee may receive any evidence which appears to it to be fair and relevant to its consideration under [paragraph 8 of Schedule 3 to the Order](#) but 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.

The parties and members of the Statutory Committee may put questions to any witness (if witnesses are allowed by the Committee). Where the registered person gives oral evidence, the presenter and members of the Statutory Committee may put questions to the registered person.

At any stage in the proceedings, the Statutory Committee may, with the consent of the registered person; or where it is satisfied that to do so would be desirable 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.

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

Where an interim order is being reviewed by a Statutory Committee and the hearing is, or likely to be, the last 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 of the Order](#).

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

Annex C – Procedure at Scrutiny Committee

The role, procedure and responsibilities of the Scrutiny Committee are set out in [Schedule 2 and 3 to the Order and Regulations 10-14 of the Fitness to Practise and Disqualification Regulations 2012](#).

After the initial action taken by the Registrar, allegations that met the threshold criteria are referred to the Scrutiny Committee for further consideration. In some specific defined circumstances, the Registrar may refer an allegation directly to the Statutory Committee, bypassing the Scrutiny Committee

The Scrutiny Committee's powers on consideration of an allegation are as follows²²:

- dismiss the case,
- in relation to a health allegation, to require the registered person to undergo a medical examination,
- issue warnings to the registered person in connection with any matter arising out of or related to the allegation and give a direction that details of the warning be recorded in the person's entry on the register;
- agree undertakings,
- to give advice to the registered person in connection with any matter arising out of, or related to, the allegation, and advice to any other person or other body involved in its investigation of the allegation on any issue arising out of, or related to, the allegation; or
- refer the matter to the Statutory Committee.

Procedure

The Scrutiny Committee meets in private and it does not hear oral evidence.

In fitness to practise or disciplinary proceedings, the Scrutiny Committee **must** in all cases²³:

- consider all documents and recommendations placed before it by the Registrar;
- consider any written representations received from the registered person;
- have regard to any relevant practice direction given by the chair;
- must ensure a clinical adviser is present at any meeting at which a decision is to be taken as to whether or not to refer a case to the Statutory Committee

²² Paragraph 6 (2) (a) & (3) to Schedule 3 of the Order, regulation 10 (6) & 11 of the Fitness to Practise and Disqualification Regulation 2012

²³ Regulation 10 (4) (a) & (5) (a) of the Fitness to Practise and Disqualification Regulations 2012 and Regulation 19 (1) (a) of the Statutory Committee, Scrutiny Committee and Advisers Regulations 2012.

where the health of the person who is the subject of the case is to be, or is likely to be, considered;

- have regard to its own published referral criteria before disposing of any allegation referred for its consideration.

The Scrutiny Committee **may**²⁴:

- direct that further investigations should be undertaken;
- send the written representations to the informant, if any, for comment;
- obtain advice from a legal, clinical or other specialist adviser; and
- adjourn its consideration of an allegation until such time as further evidence has been obtained, any comment from the informant, if any, are received, or where the person has undergone a medical examination, a report on the registered person has been prepared.

For allegations relating to health, the Scrutiny Committee may require the registered person to agree to be medically examined by a medical practitioner nominated by the Pharmaceutical Society of Northern Ireland. Should it receive information that the registered person refused to co-operate fully with a medical examination, the Scrutiny Committee may refer that matter to the Statutory Committee as a separate allegation²⁵.

Where the Scrutiny Committee decides to refer an allegation to the Statutory Committee and it is of the view that case management directions should be given or an interim order should be made, it must notify the Statutory Committee accordingly.

If the registered person has requested a referral to the Statutory Committee, the Scrutiny Committee must refer the allegation to that committee²⁶.

If, having considered the allegation, the Scrutiny Committee considers that the Department of Health should consider exercising any of its powers to bring criminal proceedings under any statutory provision; it must notify the Department accordingly²⁷.

²⁴ [Regulation 10 \(4\) \(b\) and 5 \(b\) of the Fitness to Practise and Disqualification Regulations 2012](#)

²⁵ [Regulation 10 \(6\) of the Fitness to Practise and Disqualification Regulations 2012](#)

²⁶ [Paragraph 6 \(3\) to Schedule 3 of the Order](#)

²⁷ [Paragraph 6 \(4\) to Schedule 3 of the Order](#)