

THRESHOLD CRITERIA



Effective from 30 June 2020

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About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society NI is the regulatory body for pharmacists and pharmacies 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 and the standards for Registered pharmacy premises;
- maintaining a publicly accessible Register of pharmacists and pharmacy premises;
- handling concerns about the Fitness to Practise of pharmacists, acting as a complaints portal, acting to protect the public and maintaining public confidence in the pharmacy profession; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

1. Introduction

What is this document about?

- 1.1 The Registrar of the Pharmaceutical Society NI investigates allegations made against a pharmacist that their fitness to practise is impaired. This document sets out the Threshold Criteria which the Registrar applies, at the end of an investigation, when deciding on the referral of fitness to practise allegations to the Scrutiny Committee. The Society's legislation states that the Registrar must refer a fitness to practise allegation¹ to the Scrutiny Committee, unless the Council has provided in regulations for it not to be so referred.² Regulations state that the Registrar must not refer a fitness to practise allegation which is "of a type stated in the

¹ Or information which calls into question a registered person's fitness to practise, even though no allegation has been made to the Society: paragraph 5(1)(b) of Sch 3 to the Pharmacy (NI) Order 1976 (the '1976 Order').

² Paragraph 5(1) of Sch 3 to the 1976 Order.

threshold criteria which should not be referred".³The Threshold Criteria can be considered the test the Registrar will apply when deciding whether to refer a fitness to practise allegation to the Scrutiny Committee or close an investigation⁴.

- 1.2 This document sets out the Threshold Criteria as stated and published by Council⁵ which the Registrar must apply when deciding on referral and the context in which such decisions are taken. It also describes how the Registrar investigates concerns about pharmacists on the register and what actions the Registrar may take during and at the conclusion of an investigation.
- 1.3 The Registrar takes into account the principles of good regulation when investigating complaints and applying the Threshold Criteria, endeavoring to act in a timely way which is:
 - Proportionate
 - Consistent
 - Targeted
 - Transparent
 - Accountable and
 - Agile.
- 1.4 Other guidance is in place in relation to the referral of allegations to the Statutory Committee from the Scrutiny Committee ([Referral Criteria](#)) and on the imposition of sanctions by the Statutory Committee on a finding of impairment ([Indicative Sanctions Guidance](#)).

Who is this document for?

- 1.5 This document provides criteria from the Council⁶ of the Pharmaceutical Society NI for the Registrar of the Pharmaceutical Society NI to use when deciding on the referral of fitness to practise allegations to the Scrutiny Committee. The document is designed to provide a decision-making framework to assist with the delivery of consistent, proportionate and reasonable decisions on referral and must be considered by the Registrar when coming to a decision on referral.
- 1.6 The document will also be useful for anyone else involved in a fitness to practise investigation including:
 - pharmacists and their representatives;

³ Regulation 5(2)(a) of Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012 (the 'Fitness to Practise Regulations').

⁴ More information on the processes of Fitness to Practise can be found on our website: <https://www.psn.org.uk/wp-content/uploads/2012/12/Investigation-processes-and-committee-structure.pdf>

⁵ Paragraph 5(2)(a) of Schedule 3 to the 1976 Order.

⁶ Paragraph 5(1) and 5(2) of Sch 3 to the 1976 Order.

- anyone who has raised a concern or is thinking of raising a concern about a pharmacist.
- 1.7 The Threshold Criteria will be regularly reviewed to take account of legislative changes and new case law, to ensure it is consistent with other related guidance and remains fit for purpose and accessible to stakeholders.

Equality and Diversity Statement

- 1.8 The Pharmaceutical Society NI is committed to promoting equality and valuing diversity and to operating procedures and processes which are fair, objective, transparent and free from unlawful discrimination.

2. Investigations

- 2.1 The Registrar handles all investigations. Once investigations are complete, the Threshold Criteria are used to determine if allegations should be referred to the Scrutiny Committee.
- 2.2 These criteria are applicable only to those complaints where the Registrar considers that the matter may call into question the fitness to practise of a registered pharmacist. A pharmacist is 'fit to practise' if they have the appropriate skills, knowledge, character and health to do their job safely and effectively and to maintain the reputation of the profession. A pharmacist's fitness to practise may be impaired for a number of reasons, including:
- Misconduct;
 - Deficient professional performance;
 - Ill-health;
 - Not having the necessary knowledge of English;
 - A conviction for a criminal offence.⁷
- 2.3 When a concern is raised with the Pharmaceutical Society NI, the Registrar considers if he can act on the issues raised and decides if an investigation should be opened. The Registrar will not investigate complaints relating solely to employment disputes, claims for compensation or customer service. Further details of the matters which will and will not be investigated by the Registrar are outlined in the [Complaints Leaflet](#).
- 2.4 The Registrar may refer a complaint to another regulator or agency if he considers that it would be better dealt with by them, but he may also carry on an investigation alongside another regulator or agency.

⁷ See paragraph 4 of Sch 3 to the 1976 Order for all the categories of impairment.

- 2.5 The Registrar will investigate a fitness to practise allegation concerning a registered pharmacist when he considers that it is necessary to ensure patient safety, in the registered persons own interests or otherwise in the public interest.
- 2.6 Investigations may include requesting further information or evidence from the registered person, complainant or other persons, asking the Pharmacy Inspectors of the Department of Health NI to undertake further inquiries, instructing solicitors or, in the case of a health allegation, asking the registered person to be medically examined.⁸
- 2.7 During the course of an investigation, the Registrar may decide to apply for an interim order ('IO') to suspend or restrict the registered person's practice.⁹ The Statutory Committee may make an IO if satisfied that it is necessary for the protection of the public, otherwise in the public interest or is in the interests of the registered person.¹⁰
- 2.8 In exceptional cases, the Registrar may allow a person subject to a fitness to practise investigation to voluntarily withdraw from the register where the Registrar considers that the public interest would be best served by doing so.¹¹

3. Concluding an investigation

- 3.1 At the conclusion of an investigation, the Registrar reviews all the evidence gathered and decides if the Threshold Criteria for referral has been met.
- 3.2 Allegations may, or in some circumstances must, be referred directly to the Statutory Committee in certain circumstances including if the Registrar considers that the public interest is best served by urgent consideration of the case.¹²
- 3.3 The Registrar cannot refer an allegation where:
 - The allegation does not meet the test set out in the Threshold Criteria for referral (see below);
 - 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;

⁸ Regulations 5(3) and (4) of the Fitness to Practise Regulations.

⁹ Paragraph 5(3)(b) of Sch 3 to the 1976 Order.

¹⁰ Paragraph 8 of Sch 3 to the 1976 Order.

¹¹ Regulation 7 of the Fitness to Practise Regulations.

¹² Regulations 5(5) to 5(9) of the Fitness to Practise Regulations.

- The allegation is made by an informant who is anonymous or does not cooperate with the investigation and the allegation is not capable of verification from an independent source.¹³
- 3.4 Allegations that are not referred by the Registrar to the Scrutiny Committee or the Statutory Committee are closed either:
- with no further action; or
 - with advice to the pharmacist on how to uphold professional standards.

4. Understanding the Threshold Criteria

- 4.1 The Threshold Criteria is stated and published by the Council¹⁴ and must be applied by the Registrar at the end of an investigation when deciding on the referral of fitness to practise allegations.¹⁵ The Threshold Criteria ensure that consistent referral decisions are taken.
- 4.2 The Threshold Criteria has been formulated to ensure that the purpose of regulation and three limbs of public protection¹⁶ are central to referral decisions. The three limbs of public protection are:
- Protecting the public from harm;
 - Maintaining public confidence in the profession;
 - Upholding professional standards.
- 4.3 The Threshold Criteria continues to be linked to the *Code: Professional Standards of conduct, ethics and performance for pharmacists in Northern Ireland* (the 'Code') which sets out what is expected of a pharmacist. The heading 'Conduct, ethics and performance' is used in the Threshold Criteria to reflect this. The Threshold Criteria also reflects the Statutory Committee fitness to practise criteria¹⁷ which includes consideration of conduct, honesty and health. The focus of the Threshold Criteria is on examining the impact of breaches of the Code and/or health concerns on public protection.
- 4.4 The emphasis of decision making when applying the Threshold Criteria is the existence of evidence of impairment. The Registrar must not encroach upon the Scrutiny Committee whose main role it is to

¹³ Regulation 5(2) of the Fitness to Practise Regulations.

¹⁴ Paragraph 5(2)(a) of Sch 3 to the 1976 Order.

¹⁵ Regulation 5(2)(a) of the 'Fitness to Practise Regulations.

¹⁶ The Pharmaceutical Society NI is the only healthcare regulator which is not subject to the statutory over-arching objective and three limbs of public protection set out in the Health and Social Care (Safety and Quality) Act 2015. Despite the absence of this statutory objective, the Society is committed to fulfilling this objective at all stages of the fitness to practise process/ in all aspects of its work.

¹⁷ Regulation 4(2) of the Fitness to Practise Regulations.

determine if there is a real prospect of a finding of impairment so that a referral to a Statutory Committee is justified. The legislation, which applies to the Threshold Criteria, dictates that it is written in a certain way - the Threshold Criteria is set out below.

5. The Threshold Criteria

Threshold Criteria

The Registrar must refer an allegation to the Scrutiny Committee unless the evidence as a whole suggests that:

Conduct, ethics and performance

The pharmacist's conduct, ethics or performance:

- a. does not present an actual or potential risk to patient or public safety.
- b. does not undermine, or is not likely to undermine, confidence in the pharmacy profession.
- c. does not reveal a serious or persistent failure to meet any of the standards for pharmacists laid down in the Code.
- d. does not call their honesty or integrity into question.

Health

- e. There is no adverse physical or mental health which presents a risk to the pharmacist's ability to practise safely and effectively.

5.1 When applying the Threshold Criteria, the Registrar may consider, among other matters:

- The behaviour and actions (including failures to act) of the pharmacist;
- Whether the pharmacist's actions were deliberate or reckless;
- Whether the concern reflects a one-off or a recurring issue;
- Whether the pharmacist has acted with openness and honesty;
- Any harm caused;
- The context within which the issue arose.

5.2 In practice, the Registrar would consider the issues outlined in the Threshold Criteria in the following way:

Having considered the evidence as a whole, the Registrar answers the following questions:	YES	NO
a. Does the pharmacist's conduct, ethics or performance present an actual or potential risk to patient or public safety?		
b. Does the pharmacist's conduct, ethics or performance undermine, or is it likely to undermine, confidence in the pharmacy profession?		
c. Does the pharmacist's conduct, ethics or performance reveal a serious or persistent failure to meet any of the standards for pharmacists laid down in the Code?		
d. Does the pharmacist's conduct, ethics or performance call their honesty or integrity into question?		
e. Does the pharmacist suffer from adverse physical or mental health which presents a risk to their ability to practise safely and effectively?		

- 5.3 If the answer to any of the questions above is **YES** (and the other requirements set out at para 3.3 above are met), the allegation must be referred to the Scrutiny Committee (or the Statutory Committee where regulations provide for direct referral). Papers will be prepared to refer the allegations to the Scrutiny Committee, setting out clearly the Registrar's view on the relevant Threshold Criteria which are engaged and his reasoning for that decision.
- 5.4 If the answer to all of the questions above is **NO**, the case will be closed. The Registrar must consider if it is necessary to give advice to the pharmacist on how to uphold professional standards. The pharmacist and informant will be informed of the decision to close the case, setting out, as far as possible, the reasoning for that decision.
- 5.5 A record of this decision, setting out relevant considerations and the Registrar's reasoning will be made.

6. Available Outcomes

- 6.1 The following table outlines the outcomes available upon application of the Threshold Criteria:

Outcome	The impact on registration	Circumstances when this may apply
No further action	<p>This is not recorded on the register.</p> <p>The completed investigation may be considered when investigating any future concerns.</p>	<p>The Threshold Criteria have not been met.</p> <p>There is a lack of evidence to support the concern that has been raised.</p> <p>In the circumstances of the case informal advice is not considered appropriate.</p>
Closure with informal advice	<p>This is not recorded on the online register. However, the completed investigation may be considered when investigating any future concerns.</p> <p>The advice given should:</p> <ul style="list-style-type: none"> • be tailored to the concerns • be appropriate to assist with the maintenance of the relevant professional standards going forward 	<p>The Threshold Criteria are not met.</p> <p>There is no future risk to the public.</p> <p>The Registrar believes that informal advice that addresses specific issues raised in the concern is appropriate to assist with the maintenance of the relevant professional standards going forward.</p>
Referral to the Scrutiny Committee	<p>There is no record of the referral recorded on the online register. However, an outcome from the Scrutiny Committee or the Statutory Committee may be recorded.</p>	<p>This applies to more serious cases, when the Threshold Criteria has been met.</p>