Report on the Public Consultation on a Revised Threshold Criteria held between 15 January and 11 March 2020

This report was considered by the Council of the Pharmaceutical Society NI on 30 June 2020, with Council approving the recommendations outlined within.

Contents

1. About the Pharmaceutical Society of Northern Ireland

1.1 The Pharmaceutical Society NI is the regulatory body for pharmacists and registered 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 our 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 complaint's 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.

2. Purpose of the Public Consultation

The Threshold Criteria is a document published by Council[1] in which the Council states the type of fitness to practise allegations[2] which should not be referred to the Scrutiny Committee.[3] The Registrar must apply the Threshold Criteria when deciding, at the conclusion of a fitness to practise investigation, on referral to the Scrutiny Committee. If so referred, the Scrutiny Committee will then determine if the allegation ought to be considered by the Statutory Committee, on the basis that there is a real prospect of a finding of impairment.

Council has committed to reviewing the Threshold Criteria regularly 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.

Council published the Threshold Criteria for referral to the Scrutiny Committee in 2014 and this was revised in 2016 following the launch of the new Code: Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland (2016) (the 'Code'). Council considered in 2018, that the Threshold Criteria should be reviewed and consulted upon as five years had passed since its introduction and use.

[1] Paragraph 5(2)(a) of Schedule 3 to the 1976 Order.
[2] 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 Schedule 3 to the Pharmacy (NI)
[3] Paragraph 5(1) of Schedule 3 to the 1976 Order

The Council is committed to reviewing the Threshold Criteria regularly 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.

The Council's 2016 Threshold Criteria is closely aligned to the Code and is divided into five sections which correspond with the five Principles within the Code. The 2016 Threshold Criteria were not explicitly linked to the fitness to practise criteria which must be considered by the Statutory Committee and does not refer to the purpose of regulation and three limbs of public protection namely:

- Protecting the public from harm.
- Maintaining public confidence in the profession.
- Upholding professional standards.

Following an extensive desktop review of other healthcare regulators, the Council agreed that the revised Threshold Criteria should reflect the fitness to practise criteria considered by the Statutory Committee and should incorporate some key aspects of the public interest, namely the three limbs of public protection. In line with the purpose of regulation. It was decided that public protection should be placed at the heart of the referral decision and that the Threshold Criteria should continue to be linked to the Code which sets out what is expected of a pharmacist.

Council directed that an additional wider public interest test (which could include consideration of issues such as insight, remediation or proportionality) should not be included in the Threshold Criteria as it is more appropriate that such complex assessments are considered in the more formal setting of the Scrutiny Committee.

Council directed that the proposed changes should be the subject of a public consultation.

3. Methodology

3.1 The draft Threshold Criteria, explanatory documents together with a response form were posted on the Pharmaceutical Society NI website and were open for response online or by post between the 15 January 2020 and 11 March 2020.

The Consultation was highlighted to stakeholders involved in a fitness to practise investigation. including pharmacy representative bodies in Northern Ireland, organisations representing patients and service users, defence organisations and the Professional Standards Authority.

3.2 The consultation invited responses to the following questions and respondents asked to add further explanatory comments in support of their views.

1. Does the document clearly set out the purpose of the Threshold Criteria (page 2-3)?

   Yes, No, Unsure

2. Does the document clearly set out the context in which the Registrar takes decisions based on the Threshold Criteria (page 4-5)?

   Yes, No, Unsure

3. Is the inclusion of the three limbs of public protection in the Threshold Criteria appropriate (page 6)?

   Yes, No, Unsure

4. Is the section on the inclusion of the three limbs of public protection in the Threshold Criteria clear (page 7)?
   Yes, No, Unsure

5. Is the continued link to the *Code* in the Threshold Criteria appropriate (page 6-7)?

   Yes, No, Unsure

6. Is the continued link to the *Code* in the Threshold Criteria clear (page 7)?

   Yes, No, Unsure

7. Is the exclusion of an additional wider public interest test (which could include consideration of issues such as insight, remediation or proportionality) from the Threshold Criteria appropriate?

   Yes, No, Unsure

8. Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories?

   - Age
   - Gender
   - Disability
   - Pregnancy and maternity
   - Race /ethnicity
   - Religion or belief
   - Political Opinion
   - People with dependants
   - Sexual orientation
   - Marital Status

   Yes, No, Unsure

9. Do you have any other comments on the Draft Threshold criteria?

3.3 Consultees were informed that upon completion of the Consultation that the Council will consider all the responses and respond to feedback via a Consultation report published on the Pharmaceutical Society NI website. Following consideration of Consultation responses, the Council may approve or amend the proposed new Threshold Criteria

which will be published and regularly reviewed to take account of legislative changes and case law and to ensure it remains fit for purpose and accessible to stakeholders.

4. Responses

Six responses were received within the consultation period. Four from Pharmacy representative organisations (the Pharmacist's Defence Association (PDA), the Pharmacy Forum NI, the National Pharmacy Association (NPA) and the Community Pharmacy NI (CPNI)). A response was also received from the Health and Social Care Board (HSCB) and the Professional Standards Authority (PSA).

5. Overview of Main Findings

Question 1 Does the document clearly set out the purpose of the Threshold Criteria (page 2-3)?

Yes	No	Unsure	No direct response to the question
1	1	3	1

The National Pharmacy Association (NPA) responded to the question that they were unsure. While agreeing that the document sets out the purpose of the Threshold criteria, the NPA commented that it would be useful for registrants to understand why the Threshold Criteria have been changed to be presented in this way. The NPA notes that the proposals appear at odds with how the threshold/referral criteria of other registrars are presented (such as the General Pharmaceutical Council's criteria for pharmacy professionals in Great Britain, General Medical Council's criteria for doctors and the Nursing and Midwifery Council's criteria for nurses and midwives, which consider cases both in reference to specified threshold criteria and through application of a public interest test.

Community Pharmacy NI (CPNI) responded to the question that they were unsure, and commented that the wording of paragraph 1.1 of the Draft Threshold Criteria document was, '*unclear to those that may be responding from a position of no current understanding of the concept*.' They accepted that this is reproduced as the law states it, but a simplification of the position would have been more appropriate.

The CPNI also commented that additional document referred to by links were not included with the consultation at paragraphs 1.4 and 2.3. These documents (the guidance in relation to the referral of allegations to the Statutory Committee from the Scrutiny Committee, the Indicative Sanctions Guidance, and the Complaints Leaflet. The CPNI comment that would have been helpful for those unfamiliar with the roles of the Registrar (in respect of investigations), the Scrutiny Committee and Statutory Committee to have these more fully explained at this early stage.

The **Pharmacist's Defence Association** (PDA) comment that the document does not set out the purpose of the Threshold Criteria clearly.

The PDA helpfully, using some examples, highlighted that while the PSNI website clearly states that the organisation has the power to deal with:

- Complaints about the professional service provided by a pharmacist / pharmacy at all levels of healthcare, e.g. a dispensing error, wrong labelling, or out of date medicine supplied.

- Complaints about the conduct of a pharmacist, e.g. unprofessional behaviour.

- Complaints against owners of pharmacies including companies and pharmacy chains.

The PDA also notes that that the consultation document for the Threshold Criteria clearly states: 'that the Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists and pharmacies in Northern Ireland. 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 pharmacy premises.'

The PDA concludes that this organisation clearly understands that it is charged with protecting the public by having regulatory oversight for both pharmacists and pharmacies

The PDA comment that this proposed Threshold Criteria only refers to pharmacists and a member of the public would find it hard to know how a complaint about a pharmacy premises, or the superintendent pharmacist or the business owner would be investigated by the PSNI in a transparent and open manner.

The PDA comment that the PSNI was specifically given power by the Pharmacy Order 2016[4] to set Standards for Premises and was given the power of sanctions for premises that failed to meet these Standards.

The PDA, while accepting that the Standards for Premises is awaiting implementation following the 2016 legislation, argue that just as the PSNI has set standards (awaiting implementation) it must set properly aligned Threshold Criteria (awaiting implementation) in readiness for when the powers derived from the 2016 legislation comes into operation.

The PDA notes that there must be an unpublished Threshold Criteria for premises in existence as the Memorandum of Understanding between the PSNI and the DHSSPS in 2015[5] clearly refers to them otherwise, how could a DHSSPS Inspector be confident that a failing pharmacy that is a public health risk would be properly and fairly dealt with if it referred the pharmacy to the statutory PSNI regulator?

[4] https://www.legislation.gov.uk/ukdsi/2016/9780111142882/data.pdf
[5] http://www.hscboard.hscni.net/download/PUBLICATIONS/pharmacy_and_medicines_management/reports-and-publications/Memorandum-of-Understanding.pdf

The PDA argue that the Threshold Criteria for premises needs to be set out as part of an integrated suite of Criteria for both Pharmacists and Premises to ensure that the root cause of the complaint/concern was properly identified.

The PDA comment that there is a clear omission not to consult on premises Threshold Criteria during a process where it is seeking to alter the Threshold Criteria for pharmacists as without consulting on Threshold Criteria for premises as part of the Suite of Threshold Criteria there cannot be true and meaningful alignment as claimed by the PSNI Council. The PDA argue that this is irrespective of any implementation powers that are awaited for disciplinary provisions in respect of Premises Standards.

The **Pharmacy Forum NI** believed that the document clearly set out the purpose of the Threshold Criteria and made no further comments.

The **Professional Standards Authority** (PSA) commented that while recognising that the organisation may be restrained by the requirements within legislation, with regard to how the criteria themselves are framed, there may be scope to provide more context or explanation alongside. The PSA suggest that it may be useful to review clarity of language and layout to ensure that the document is accessible to a wide audience including members of the public as some parts of the document may not be easy to follow for anyone with limited understanding of professional regulation.

The PSA while noting that the threshold document (at paragraph 1.1) comments that that the PSNI legislation and Regulations require the criteria to be written in a certain way but that the organisation has sought to outline the process that would be following in practice nearer to the Threshold Criteria themselves in the document.

The PSA also note the tone used in the document varies for example at 4.5 and 4.6 the language used refers to 'may consider', 'would consider' whereas at 4.8 the language is 'must be referred' and 'the case will be closed'(emphasis added). The PSA suggest that it, '*may be useful to review for consistency of tone to ensure that it is sufficiently clear to anyone reading the document what is required of the Registrar at various points of the process'*.

The **Health and Social Care Board** (HSCB) responded to the question that they were unsure, and commented that the introduction section should clearly lay out the threshold criteria for consideration at 1.1 and that consideration should be given to using the table that is currently on page 7 (draft threshold), but with the wording turned into positive language rather than negative. They commented that it would be useful to give an overview / flowchart of the process from concern, to investigation to application of the threshold criteria. They further commented that in page 3, 1.3 (draft threshold) on the principles of good regulation the Registrar takes into account when investigating complaints and applying the Threshold Criteria it would be useful to include 'in a timely way' to the considered by the Registrar.

Question 1 Comment

Understanding the document
The majority of respondents, while accepting that the legislation requires the criteria to be written in a certain way, suggest that it may be helpful to include

this explanation nearer to the Threshold Criteria themselves in the document. Comments also suggested that the clarity of language and layout may be improved to ensure that the document is accessible to a wide audience, including members of the public, as some parts of the document may not be easy to follow for anyone with limited understanding of professional regulation. The Pharmacy Forum NI believed that the purpose of the document was clear and made no further comment.

As acknowledged by the PSA, the Threshold Criteria have been written to maintain the language of the Legislation. It is considered prudent to maintain the definitions used in the legislation. To enhance understanding the proposed Threshold Criteria document included a table outlining, how the Threshold Criteria will be applied in practice. This table is clear and easy to understand.

Two respondents the HSCB and the PDA commented that it would be useful to give an overview / flowchart of the process from concern, to investigation to application of the threshold criteria. (This comment is dealt with in response to Question 2.)

Based on the feedback received, it is recommended that a number of small changes be made to the document to help improve understanding as follows:

Recommendation 1: Paragraph 1.1. be amended to read as follows to enhance understanding of the document:

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 allegation to the Scrutiny Committee, unless the Council has provided in regulations for it not to be so referred. Regulations state that the Registrar must not refer a fitness to practise allegation which is "of a type stated in the threshold criteria which should not be referred". The 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 investigation.

Language and tone

The PSA raised the issue of language used in the Threshold Criteria and the variation in relation to the use of 'must' and 'may, for example'. A review of the proposed document was carried out in this regard and it was considered that the language used in the document is appropriate, proportionate and reflective of our legislative obligations.

Threshold Criteria for Premises

The PDA commented that the proposed Threshold Criteria only refers to pharmacists and a member of the public would find it hard to know how a complaint about a pharmacy premises, or the superintendent pharmacist or the business owner would be investigated by the Pharmaceutical Society NI in a transparent and open manner.

The PDA argue that the Threshold Criteria for premises needs to be set out as part of an integrated suite of Criteria for both Pharmacists and Premises to ensure that the root cause of the complaint/concern was properly identified.

The PDA comment that there is a clear omission not to consult on premises Threshold Criteria during a process where it is seeking to alter the Threshold Criteria for pharmacists as without consulting on Threshold Criteria for premises as part of the Suite of Threshold Criteria there cannot be true and meaningful alignment as claimed by the PSNI Council.

While accepting that the Standards for Premises is awaiting implementation following the 2016 legislation, they argue that just as the organisation has set standards (awaiting implementation) it must set properly aligned individual pharmacist and premises Threshold Criteria (premises awaiting implementation) in readiness for when the powers derived from the 2016 legislation comes into operation.

Paragraphs 5(1) (a) and 5(2) (a) of the Pharmacy (Northern Ireland) Order 1976 dictate that the Council must produce Threshold Criteria, which relate to an allegation made to the Society against **a registered person** that their fitness to practise is impaired. There is no provision within the 1976 Order to develop Threshold Criteria for pharmacy owners/premises. In this regard the comments of the PDA are out with the remit of this consultation.

The powers to disqualify and direct removal from register of a body corporate are currently set out in Section80 of the Medicines Act 1968. These relatively narrow powers currently direct considerations by the Regulator and any referral to the Statutory Committee of an investigation into a body corporate. It should be noted that the inspection function of premises sits within the Department of Health. It is acknowledged that the current legislative position in relation to body corporates/premises is limited. The implementation of the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 would significantly enhance our powers in relation to body corporates and premises, and we will continue to work with the Department of Health to secure their implementation at the earliest opportunity.

As part of Council's ongoing discussions with the Department of Health in relation to the inspection regime to be implemented against the new standards, considerations may be given to the referrals to a Statutory Committee for body corporates/premises, under the new premises standards. This should include appropriate Criteria for referral to the Statutory Committee. Any referrals document should include what role the DoH Inspectorate will play in providing

the findings of inspections to the Pharmaceutical Society NI and actions that may be recommended by the regulator, prior to a referral to the Statutory Committee.

In the interim period, a review should be carried out of the public information provided on how we progress allegations against body corporates.

Recommendation 2: Review the public information provided on how allegations against body corporates are progressed and update if necessary.

Timeliness

The HSCB commented that in page 3, 1.3 (draft threshold) on the principles of good regulation that the Registrar takes into account when investigating complaints and applying the Threshold Criteria it would be useful to include 'in a timely way' to the considered by the Registrar. The PDA comment that clear timelines are published as part of the Threshold Criteria.

It should be noted that timeliness in relation to Fitness to Practise is a significant concern for the organisation in relation to Fitness to Practise. The Key Performance Indicators, which outline our timeliness targets, are currently published on our website. However, this is considered a helpful suggestion and it is recommended that a reference to timeliness be made in the paragraph 1.3 to ensure the registrar endeavours to act in a timely way.

Recommendation 3: Amend Paragraph 1.3 to read:

1.1 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.*

Question 2 Does the document clearly set out the context in which the Registrar takes decisions based on the Threshold criteria (pages 4-5)?

Yes	No	Unsure	No direct response to question
0	3	2	1

The National Pharmacy Association (NPA) commented in response to the question that they were 'Unsure' and that further information is required on the guidance provided in relation to investigations and outcome of an investigation.

They comment that as the Registrar handles all investigations it would be useful to have further details of the decision-making process by which an investigation is opened and the Registrar's review process. They particularly would like clarity in relation to concerns that may show that a pharmacy professional could be suffering from a health issue, which is affecting their ability to practise safely and effectively, clarity on liaison with a GP or healthcare provider or the scope of a medical examination would also be helpful.

The NPA requests further guidance on the management of concerns in relation to a registrant's health. They comment, *'We recognise that an investigation may have a significant impact on the welfare of a registrant. It should be possible for the majority of health issues to be managed at an early stage by the Registrar without onward referral to the Scrutiny Committee including those cases where the pharmacist with a health issue has insight into the extent of their condition, and is following appropriate advice and treatment in relation to their work, and restricting their practice where necessary*'.

The NPA further comment that, '*Guidance should also indicate if the Registrar can refer information about a pharmacist professional to the Disclosure and Barring Service if the concern that is being investigated suggests that there is a safeguarding issue in relation to vulnerable adults or children'*

Community Pharmacy NI (CPNI) answered 'No' to the question, commenting that the section would benefit from a brief outline of roles of the Registrar, the Scrutiny Committee and Statutory Committee.

CPNI is concerned that the importance of a public interest test is cited in a number of sections here (2.5, 3.2 and 3.3), yet public interest is removed from the overlying threshold criteria.

CPNI comment that the provisions for referral by the Registrar to the next stage (Scrutiny Committee in the case of PSNI and Investigation Committee in the case of GPhC) are governed by the relevant Pharmacy Orders. They comment that the *'GPhC's wording of the associated threshold criteria reads: 'The Registrar should not refer a case to the IC unless...'.PSNI opted for the negative approach 'The Registrar must refer an allegation to the Scrutiny Committee unless the evidence shows that...'CPNI feels that the GPhC approach is more straight forward and appears less prejudicial in respect of the pharmacist'.*

The **Pharmacist's Defence Association** (PDA) commented that the document is not clear on the context in which the Registrar takes decisions based on the Threshold Criteria. They comment that the document, '*lays out the context in which the registrar takes decisions but fails to outline the risks for the approach that is proposed. There is no context given for how this risk could be mitigated and quality assured'*.

To illustrate the nature of this risk it references the PSA report Annual review of performance 2028/19 General Pharmaceutical Council[6] following the audit of GPhC Fitness to Practise (FtP) processes which the PDA recommends this organisation considers to avoid the same mistakes by not managing this risk (Sections 6.89, 6.99, 6.101 and 6.102 of the PSA report). The PDA comment that the GPhC did not follow its triage system which is failing at the very first point of any FtP system.

The PDA recommend that, 'the PSNI must publish details about its own "triage" process that it will employ and the "triage" guidance it will use (we have used the same terminology as the GPhC and PSA but the PSNI may use different terminology for what is essentially an initial filter)'.

The PDA makes comment on the next stage of the process which is when the Registrar is to investigate the matter further. The PDA expressed concerns about this potential in relation to Paragraph 2.8 and 3.4 in the Threshold Criteria which read.

> 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."
>
> 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 improve their practice."

The PDA comment that whilst agreeing that the Registrar should be able to dispose of cases where there is no impairment, comments that this has to be counterbalanced by the need for transparency and publication of decisions and it notes that decisions made behind closed doors do not inspire public confidence.

Referring to the Bawa-Garba case in 2018 and the PSA 2017 PSA report "Right Touch Reform"[7] noted in Chapter 3 expressed concerns about decisions behind closed doors:

> *3.5 We find that there are major inconsistencies in legislation, but also policy and implementation across the regulators. There is a concerning lack of clarity and transparency in this area, and the possibility of cases being closed where there is a risk to the public. We are recommending a review of the regulator's practices in this area, to identify areas of risk, and to encourage greater consistency and transparency. Consensual disposal (undertakings): increasingly, cases that meet the threshold for onward referral at the end of an investigation can be disposed of consensually through undertakings*
>
> *3.6 We note the piecemeal development of these processes, with differences between the regulators that have these powers currently, and further variations proposed for those that do not. Even more so than with hearing proceedings, there*

[6] https://www.professionalstandards.org.uk/docs/default-source/publications/performance-review---gphc-2018-19.pdf?sfvrsn=78c17720_0

[7] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-reform-2017.pdf?sfvrsn=2e517320_7

is a need for transparency and accountability because these decisions are made 'behind closed doors' by members of staff, rather than independent panels. Furthermore, there is little understanding currently of what works and where the risks are in these processes.

The PDA comment on the Bawa-Garba case and subsequent Williams Review[8] of 2018 which made a number of regulatory recommendations. The PSA response to the Williams review[9] highlighted:

7.47 An increase in the use of this form of disposal may suggest the need for a clearer published approach to how public confidence will be taken into account across the regulators and across different forms of decision making. Currently, whilst there is variable detail in Panel decisions, it is at least possible to attend a hearing or read a Panel decision to see whether public confidence was a factor in a particular outcome. With outcomes agreed consensually, including through use of undertakings, there is no public record of the rationale for a particular decision and therefore further detail on the factors considered by case examiners may be required to ensure public confidence in such a process.

The PDA argue that whilst they acknowledge that the proposed Threshold Criteria state the need to have a record it does not obligate the Registrar to publish this record. The proposed Threshold Criteria state:

4.8 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 improve their practice. 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.

4.9 A record of this decision, setting out relevant considerations and the Registrar's reasoning will be made.

To maintain public confidence this record, alluded to in section 4.9, must be in the public domain in a form that does not identify individuals but nevertheless records the case outline together with diversity characteristics of the registrants and the complainants.

Given that the initial allegation is the first, and maybe the final point of contact with the regulator and there may be no other record relating to this, it is vital that the PSNI has in place a full and transparent process of recording all the necessary details of the allegation.

The PDA are also concerned of the implications of the loose terminology on page 3 of the proposed Threshold Criteria:

1.3 "The Registrar takes into account the principles of good regulation when investigating complaints and applying the Threshold Criteria, endeavouring to ...."

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf

[9] https://www.professionalstandards.org.uk/docs/default-source/publications/how-is-public-confidence-maintained-when-fitness-to-practise-decisions-are-made.pdf?sfvrsn=c8c47420_0

1.5 "This document provides criteria ... 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."

Similarly, on page 7 of the proposed Threshold Criteria:

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

4.6 "In practice, the Registrar would consider the issues.

The PDA recommend using the word **must** in all 4 instances above

In addition, they propose publication of the summary for each type of complaint and its outcome. The quantum of complaints received by the PSNI is small and this would not be a disproportionate requirement.

The PDA comment that the, *'PSNI already publishes annual summaries for cases investigated by the Scrutiny Committee. We accept that this is a Statutory Duty imposed by the 2012 Regulations but the PSNI should use this as an example of best practice'.*

The PSA in its 2017 "Right Touch Reform" also suggests:

3.191 "Warnings and advice can be a helpful response from the regulator where the issues with the registrant's practice or behaviour are not so serious as to warrant action on registration, but where they could be remedied by the issuing of advice or a warning. If published, they can also raise awareness among other registrants, employers and patients of the boundaries of acceptable behaviour."

3.218 "We find it helpful here to distinguish between outcome and process. In our view, fitness to practise processes must be worthy of public trust through transparency, accountability, consistency, and fairness; but it is primarily the outcomes, (which for us would include the decision to publish information about the case) that protect the public, maintain public confidence and declare and uphold professional standards."

The PDA comment that the evidence clearly shows the benefit of publication, both from a public confidence aspect and the raising awareness within the profession of the boundaries of acceptable behaviour.

The PDA recommend, 'that the PSNI, to counterbalance decisions made behind closed doors and to enhance public confidence in the regulatory process, ***must*** publish:

- detailed guidance on how the criteria will be applied
- a summary outcome of every complaint it receives following both the triage and investigation stages.
- all data, which should be presented in a consistent set of tables each year in the Annual Report.

All information published should ensure that individuals are ***not*** identified unless the matter is progressed into open hearings.

The **Pharmacy Forum NI** commented that the document was unclear. They commented that clarification is needed in relation to section 2.4 on what 'another regulator or agency' refers to, specifically. Does that include the Public Prosecution Service for consideration of a criminal offence? Or agencies such as the Disclosure and Barring Service?

The **Professional Standards Authority** (PSA) commented that Paragraphs 2.3-2.5 of the draft threshold criteria were unclear about how the Registrar will decide whether to open an investigation when a case is received. Whilst the PSA recognise that this section doesn't directly relate to the threshold criteria, they comment that, *'the transparency and clarity of the document could be improved if this section were to elaborate on the factors the Registrar will take into account when deciding if the PSNI can act on the issues raised.'* The PSA suggest that for example, at 2.5 it might be better to link explicitly to the three limbs of public protection as the basis of decisions by the Registrar to open an investigation.

Referring to Section 4.8 of the Threshold document the PSA comment that, 'this section could be clearer how the Registrar will decide if advice is necessary'.

The PSA further comment in relation to Section 4.8 in reference to the questions that will be asked by the Registrar it states: 'If the answer to all of the questions above is NO, the case will be closed'. Whilst we recognise the value in clarity of process and note there is unlikely to be a circumstance that is not captured by the criteria, the PSA suggests it may be beneficial to leave some discretion for the Registrar to still refer to the Scrutiny Committee if it appears to be overwhelmingly in the public interest to do so.

The **Health and Social Care Board** (HSCB) responded to the question that they were unsure and commented that Pages 4 and 5 are confusing as the current title is "Investigations" and "Outcomes of an investigation". It would make more sense if the title of these sections was "context in which the Registrar takes decisions based on the Threshold Criteria" and then a statement at the start (2.1) included to say that before threshold criteria are applied, an investigation is carried out. 3.3. and 3.4 should be moved from section 3 (page 5) to after 4.9; potentially 3.4 and 4.8 could be merged.

Question 2 Comment

Transparency and Quality assurance of the FtP Process

It is acknowledged the transparency of the Fitness to Practise process is vitally important to maintaining public confidence in regulation. It should be noted that many of the comments in relation to transparency outlined above are out with the direct remit of this consultation, which is focused on Threshold Criteria alone. It should be further noted that the need for transparency in the investigation of stage of fitness to practise must be balanced against the rights of the complainant and the pharmacist involved. This is especially the case in relation to cases where no further action has been the conclusion of an investigation. Council should note, that aside from internal quality control mechanisms, the organisation is subject to an annual performance review from the PSA, which includes the submission of quarterly data, which covers all

aspects of Fitness to Practise. The organisation is also subject to periodic early stages audits by the PSA, which specifically focus on the early stages of Fitness to Practise which includes investigations, the application of the Threshold Criteria and Scrutiny Committee decisions. These reports are published. This is a welcome and proportionate approach adopted by Government to ensure proportionate transparency is maintained and that external quality assurance is provided in order to protect the public.

In light of the comments outlined and in acknowledgement of work already being undertaken, the following recommendations are made:

Recommendation 4: The document provides a link to the information already published on our website in relation to the investigations process: https://www.psni.org.uk/wp-content/uploads/2012/12/Investigation-processes-and-committee-structure.pdf

Recommendation 5: The information relating to our investigations process is reviewed, and consideration is given to including a flow chart for fitness to practise procedures.

Recommendation 6: The test applied on whether a complaint/allegation falls within our jurisdiction and can be investigated, will be published on our website

Clarity and structure of the document

The majority of respondents reported that the document did not clearly set out the context in which the Registrar takes decisions based on the Threshold Criteria or where 'Unsure' that it did so.

In light of the comments above a number of small changes are recommended to the document with a view to improving understanding.

Recommendation 7: Change the title of sections 3 and 4 and create a new section 5, entitled Threshold Criteria, in addition to minor wording changes, as outlined in the revised guidance document presented.

Health Cases

The NPA contended that health issues should be dealt with at an early stage without the matter necessarily being passed to Scrutiny Committee. The Registrar endeavours to resolve all cases at the earliest stage with only those necessary cases being referred. It should be noted that we take only the necessary regulatory action to meet our regulatory objectives of protecting the public, upholding the reputation of the profession and maintaining standards.

Broader Public Interest references

The CPNI comments that the importance of a public interest test is cited in a number of sections 2.5, 3.2 and 3.3), yet public interest is removed from the

overlying Threshold Criteria. Issues relating to the Public Interest Test are considered in response to Question 3.

Terminology

Several respondents comment on the implications of the terminology and tone used in the threshold criteria. These issues are dealt with in response to Question 1.

Question 3 Is the inclusion of the three limbs of public protection in the Threshold Criteria appropriate (page 6)

Yes	No	Unsure	No direct response to question
4	1		1

The National Pharmacy Association (NPA) agreed that it was appropriate and had no further comments.

Community Pharmacy NI (CPNI) answered no to the question commenting, '*CPNI would be of the view that it is appropriate to include these three limbs of public protection, but in keeping with the Guidance issued by the General Pharmaceutical Council (Good decision making: Investigations and threshold criteria guidance (updated January 2018))*[10]*, CPNI believes that there is no cogent argument for excluding a wider public interest test. By excluding the public interest test from the investigation stage, the Registrar appears to be effectively debarred from considering critical elements which may have a mitigating impact in exceptional cases. These could include: the circumstances and setting in which the issue happened; whether the pharmacist has learned from the incident; and whether the pharmacist has taken remedial action by undergoing training or making changes to their practice. These could be essential factors in determining whether referral to a Scrutiny Committee is the appropriate and proportionate response and they must be fully considered at the earliest stage, in line with processes in GB. Application of the threshold criteria as drafted would result in a two-tier system across the UK and one in which pharmacists in Northern Ireland could face a lesser chance than colleagues in GB of the matter being dealt with by closure with informal guidance, or closure with no further action*

This is clearly and simply demonstrated on page 16 of GPhC's document Good decision making: Investigations and threshold criteria guidance (updated January

[10] Reference added https://www.pharmacyregulation.org/sites/default/files/document/good_decision_making_investigations_and_threshold_criteria_guidance_january_2018.pdf

2018)where is it laid out that, despite one or more of the criteria for referral being met, pharmacists in GB may still not be referred to the next stage if the public interest test was not met. That pharmacists in Northern Ireland are excluded from this possible outcome is simply not acceptable'.

The **Pharmacist's Defence Association** (PDA) agrees that the three limbs of public protection should be included. They comment that this will bring the, 'PSNI in line with the other 8 regulators overseen by the PSA. As noted by the PSA in its post Williams report (of April 2019) to the Secretary of State:

> *"The PSNI is the only regulator which does not have the standardised wording of the single overarching objective and three limbs of public protection in its legislation, introduced for the other eight regulators in 2015-16. It stated however that public confidence is considered throughout the process and decision makers are supported with relevant guidance."*

However, the PSA also notes in "Right Touch Reform" that the three limbs of public protection should be fulfilled, wherever possible by meaningful remediation:

> ***3.39*** *Setting aside these tricky questions for the moment, we support the trend that we have seen in the case law, and across the regulators, for a greater emphasis on remediation, where it is the minimum regulatory force to achieve the desired result, namely protecting the public, maintaining confidence in the profession, and declaring and upholding professional standards. This approach to fitness to practise can be described as follows:*
>
> *Fitness to practise outcomes* ***should fulfil the three limbs of public protection through meaningful remediation where possible****, and degrees of restrictions on practice where not*.

The PDA continues that the PSA in recent blogs is clearly concerned about the current FtP processes and whether they deliver better outcomes. Whilst we commend the PSNI for having sought powers of consensual disposal, we would also welcome a greater use of these powers within the boundaries of the three limbs of public protection.

The PDA recommend that the PSNI should be clear that all 3 limbs apply equally to premises standards as much as they do to individual registrants.

The **Pharmacy Forum NI** agreed that they were appropriate and made no further comment.

The **Professional Standards Authority** (PSA) comment that they are supportive of the proposal to more explicitly link to the overarching objective and three limbs of public protection as these are criteria that will be considered by the Scrutiny Committee when making decisions on impairment.

The **Health and Social Care Board** (HSCB) agreed that they were appropriate and made no further comment.

Question 3 Comment

Most respondents agreed with the inclusion of the three limbs of public protection in the Threshold Criteria.

The Public Interest Test

The Community Pharmacy NI (CPNI) answered no to the question commenting, that while it agreed with the inclusion of the three limbs of public protection, but in keeping with the Guidance issued by the General Pharmaceutical Council (Good decision making: Investigations and threshold criteria guidance (updated January 2018)) , CPNI believes that there *'is no cogent argument for excluding a wider public interest test. By excluding the public interest test from the investigation stage, the Registrar appears to be effectively debarred from considering critical elements which may have a mitigating impact in exceptional cases.'*

The PSA in its answer to question 2 above commented that, whilst it is unlikely to be a circumstance that is not captured by the criteria, suggested that there should, 'be discretion for the Registrar to still refer to the Scrutiny Committee if it appears to be overwhelmingly in the public interest to do so'.

When considering the appropriateness of the decision not to include the wider public interest test in the Threshold Criteria, it should be noted that the role of the Registrar is to investigate allegations that a registrant's fitness to practise is impaired and to make a decision as to whether there is sufficient evidence to refer this case to the Scrutiny Committee. The primary function of the Scrutiny Committee is to make an assessment of this evidence and to consider if there is a 'real prospect' that a full fitness to practise committee (the Statutory Committee) would find the registrant's fitness to Practise to be impaired. In this regard the Threshold Criteria and the Scrutiny Committee are providing a filtering mechanism on the appropriateness of further considering and fully testing allegations of impairment at the Statutory Committee stage.

When considering the public interest test it should be noted that it is a concept not clearly defined in law, however, we would consider that the three limbs of public protection, which form part of the proposed Threshold Criteria, would already encompass a significant amount of any public interest test. What we have not included in the Threshold Criteria are any additional considerations that may also be considered part of a public interest test, such as insight or remediation. We consider it more appropriate that these complex and indefinite issues of public interest (over and above the three limbs of public protection), should be considered by a panel of the Scrutiny Committee, applying the more involved 'real prospect test' and not be at the discretion of the Registrar. This is even more apparent when, in a small organisation, these decisions may fall on a small number of individuals.

Council is further reminded of the PSA's response to the GPhC's consultation on its current Threshold Criteria, which includes the more indefinite aspects of the Public Interest within its Threshold Criteria, which stated:

"*We recognise the GPhC's ambition to give Case Workers more discretion to close cases when it may not be in the wider public interest for the case to go to the IC. However, we have some concerns about the potential impact of some of the changes proposed, in particular the reference to assessment of insight and remediation and the test of proportionality which may result in risks to public protection and may damage public perception of the GPhC as a regulator*"[11].

Whilst acknowledging the arguments put forward by respondents, it is still considered appropriate to not include a broader public interest test in the Threshold Criteria.

In relation to the PSA's comment that the Registrar should reserve the right to refer a case to the Scrutiny Committee, even if the Threshold Criteria is not engaged, if the public interest so dictates, it is considered hard to envisage a scenario whereby none of the Threshold Criteria (and consequently none of the 3 pillars of public protection, which reflect the broad purpose of regulation) are engaged and their remains a public interest to refer – to do so may be considered to be disproportionate and not treating the registrant in a 'fair' manner.

The PDA's further comments in relation to premises standards are dealt with in response to Question 2.

Question 4 Is the section on the inclusion of the three limbs of public protection in the Threshold Criteria clear (Page 7)

Yes	No	Unsure	No direct response to question
1	4		1

The National Pharmacy Association (NPA) reported that the Guidance was not clear. They commented that the proposed threshold criteria have been simplified so that they are much broader from the previous guidance that outlined 17 areas for referral across the five key themes of the Code. On the whole, this may be helpful to anyone raising a concern but could potentially result in a higher likelihood of cases being referred to the Scrutiny Committee and a subsequent increase in the associated costs.

They commented that the questions presented direct a binary response and it may be difficult to definitely answer "no" to the broad statements presented, in the absence of consideration of mitigating factors, leading to a referral to the Scrutiny Committee.

The NPA was concerned that the public interest consideration has been removed from the decision-making framework. It would be a more robust procedure to consider the

[11] https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2017/professional-standards-authority-response-gphc-threshold-criteria-consultation.pdf?sfvrsn=48a87020_6

outcome of a case considering whether any of the conduct, performance or health criteria are met and whether the Registrar decides a referral is in the public interest. In previous guidance public interest considerations were clear and succinctly written, and without the ability to screen investigations according to a "public interest" test there may be an unnecessary increase in the number of cases referred to the Scrutiny Committee. However, as written, the proposed criteria may not capture the full range of issues that registrants present to the Pharmaceutical Society. For example, where would an affray conviction fit? (As it is unlikely this aligns with principles of honesty and integrity).

The NPA recommended that the Society reviews cases that have been received since 2016 using the proposed criteria to ensure that there is consistency in the referral rate of cases to the Scrutiny Committee.

Community Pharmacy NI (CPNI) answered no to the question referencing their comments at Question 3 above.

The **Pharmacist's Defence Association** (PDA) commented that the document is not clear. The PDA commented that, '*the three limbs of public protection would be clearer in the Threshold Criteria with the following rewording which still keeps within the boundaries of the legislation (i.e. the not to refer, thus context is kept but it's easier to comprehend)* ***and*** *also by the inclusion of an explicit mention of the public interest test'.*

They also suggest removing pharmacists, *'because the PSNI is the statutory* ***regulator for pharmacies and pharmacists*** *and any Threshold Criteria needs to recognise this statutory duty (in the current absence of any published Threshold Criteria for premises)'.*

The PDA comment that there has been significant debate about the word "allegation" and how it could be restrictive for regulatory purposes. However, the PSA did acknowledge in its 2017 report "Right Touch Reform" that:

> ***3.103*** *The Law Commissions therefore proposed the following: 'A regulator should have the power to initiate fitness to practise proceedings where an allegation suggesting impaired fitness to practise is made to the regulator or the regulator otherwise has reason to believe that a registrant's fitness to practise is impaired.'*
>
> ***3.104*** *We support the Law Commissions' arguments on* ***the use of the term allegation****: it enables the regulators to establish whether a concern falls under their statutory remit,* ***and provides some clarity for the public and for registrants*** *about what regulators can consider. This fulfils the aims of transparency and agility.*

The PDA agree with the PSA and recommend that the use of the word allegation in the Threshold Criteria which would be applied after any complaint, because any such complaint is merely an allegation at this stage and the wording must reflect this as such.

The proposed Threshold Criteria also used the words "alleged/allegation" on 21 occasions but then fails to reflect this for the wording of the actual Threshold Criteria.

The PDA suggested the following wording

Added words: ***BLUE ITALICS***
Removed words ~~***RED strikethrough italics***~~

Threshold Criteria

The Registrar must ***not*** refer an allegation to the Scrutiny Committee unless the evidence, as a whole, suggests that:

Conduct, ethics and performance

The ~~*pharmacist's*~~ ***alleged*** conduct, ethics or performance:
• ~~does *not*~~ present***s*** an actual or potential risk to patient or public safety.
• ~~does *not*~~ undermine***s***, or is *not* likely to undermine, confidence in the pharmacy profession.
• ~~does *not*~~ reveal***s*** a serious or persistent failure to meet any of the standards for pharmacists laid down in the Code.
• ~~does *not*~~ call***s*** their honesty or integrity into question.

Health

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

Wider Public Interest

• and it is in the wider public interest to refer

The PDA made a submission on the wider public interest in their response to question 7.

The **Pharmacy Forum NI** did not believe the section was clear. They commented 'We note the removal of an additional wider public interest test and query why other regulators, in particular the GPHC, currently include this consideration. See for reference, GPHC's 'Good decision making: Investigations and threshold criteria guidance', January 2018, (section 3.10-3.13).[12] We would question why PSNI would be out of step with other regulatory bodies. In addition, in the best use of resources, would it not make more sense to dispose of such cases where it is not in the public interest to be disposed of at the appropriate level, i.e. before Scrutiny Committee consideration?'

The **Professional Standards Authority** (PSA) general comments on clarity at question 1 refer.

12 https://www.pharmacyregulation.org/sites/default/files/document/good_decision_making_investigations_and_threshold_criteria_guidance_january_2018.pdf

The **Health and Social Care Board** (HSCB) agreed that the section was clear and made no further comment.

Question 4 Comment

Public Interest

The majority of respondents reported that the section on the inclusion of the three limbs of public protection in the Threshold Criteria was not clear.

The NPA commented that the criteria were much broader than the previous guidance that outlined 17 areas for referral across the five key themes of the Code. They argued that this may be helpful to anyone raising a concern but that the questions presented direct a binary response and it may be difficult to definitely answer "no" to the broad statements presented which in the absence of consideration of mitigating factors and public interest may lead to an increase of referral to the Scrutiny Committee with potentially increase costs. The Pharmacy Forum NI also comment on the removal of the public interest test and argue that for the best use of resources, is it not best to dispose of cases where it is not in the public interest to proceed, before Scrutiny Committee consideration.

It is again considered helpful to reflect on the different tasks that the Registrar and the Scrutiny Committee are being tasked to undertake and our comments outlined in response to Question 3 in relation to why we have not included a broader public interest test in the Threshold Criteria.

Increased Costs

In relation to the NPA's recommendation that the Pharmaceutical Society NI reviews cases that have been received since 2016 using the proposed criteria to ensure that there is consistency in the referral rate of cases to the Scrutiny Committee. It is suggested that while costs are an important aspect of managing fitness to practise within a defined overall budget, it should not be the deciding factor which overrides our legal and regulatory obligations to protect the public. Fitness to Practise costs are regularly reviewed and managed within the organisation's budget and any impact of the revised Threshold Criteria will be reviewed going forward.

Question 5 Is the continued link to the *Code* in the Threshold Criteria clear (Page 6-7)

Yes	No	Unsure	No direct response to question
6			

The National Pharmacy Association (NPA) agreed with the continued link to the *Code* and had no further comments.

Community Pharmacy NI (CPNI) notes the continued reference and has no objection.

The **Pharmacist's Defence Association** (PDA) commented that professional standards for individual registrant pharmacists are explained in "The Code" and they agree that the Threshold Criteria should be linked this.

They continue that, 'The public would rightly expect that failure to abide by professional standards would constitute a fitness to practice issue. Similarly, failure by owners to abide by "Standards for Registered Pharmacy Premises 2018" would also constitute a fitness to practice issue and thus the Threshold Criteria for pharmacy premises, be consulted upon and published.

A clear transparent process must apply to all registrants within the jurisdiction of the PSNI.'

The **Pharmacy Forum NI** agreed that it was appropriate and made no further comment.

The **Professional Standards Authority** (PSA) are supportive of the intention to maintain a link to the to the *Code* in determining whether a case is relevant to consider.

The **Health and Social Care Board** (HSCB) agreed that it was appropriate and made no further comment.

Question 5 Comment

All the respondents agreed that the continued link to the Code in the Threshold Criteria (page 6-7) was clear.

The PDA's comment that failure by owners to abide by "Standards for Registered Pharmacy Premises 2018" would also constitute a fitness to practice issue and thus the Threshold Criteria for pharmacy premises, be consulted upon and published, has been considered in response to Question 2.

Question 6 Is the continued link to the *Code* in the Threshold Criteria appropriate (Page 7)

Yes	No	Unsure	No direct response to question
4		2	

The National Pharmacy Association (NPA) reported that they were unsure and commented that the Guidance provided in considering a case under conduct, ethics and performance is clear but the NPA believes that the other matters that the Registrar could consider should be expanded.

We recommend that the Registrar may also take into account what remedial action the registrant has taken for example by having training or making changes to their practice, or what they have learnt from the incident. Their judgement may also consider whether previous guidance or advice has been issued to the pharmacy professional about the same or similar matters.

Community Pharmacy NI (CPNI) answered that they were unsure commenting 'It is assumed that it is proposed that the criteria listed below is to be replaced by the current draft which is no longer to be referenced. https://www.psni.org.uk/wp-content/uploads/2012/12/threshold-criteria-amended-October-2016.pdf

The **Pharmacist's Defence Association** (PDA) answered yes and commented that the continued link to "The Code" is clear for pharmacists but is non-existent for pharmacies. The PDA also referred to their previous comment on Threshold Criteria for premises'.

The **Pharmacy Forum NI** agreed with the retention of the link to the *Code.*

They commented in relation to section 4.4. Threshold Criteria under Conduct, ethics and performance, reference to 'does not call their honesty or integrity into question', we question whether this goes far enough when the direction of travel for healthcare providers in Northern Ireland is moving towards considering criminal prosecution of a health professional who is not acting with a duty of Candour in a particular set of circumstances (rather than having a Statutory Duty of Candour).

The **Professional Standards Authority** (PSA) commented are supportive of the intention to maintain a link to the to the Code in determining whether a case is relevant to consider.

The **Health and Social Care Board** (HSCB) agreed that it was appropriate and made no further comment.

Question 6 Comment

The majority of the respondents agreed that the continued link to the Code in the Threshold Criteria (Page 7) was appropriate.

Two respondents reported that they were unsure.

The NPA commented that the Guidance provided in considering a case under conduct, ethics and performance is clear but, the NPA considered that the other matters that the Registrar could consider should be expanded to include remedial action the registrant has taken for example, by having training or making changes to their practice, or what they have learnt from the incident. Their judgement may also consider whether previous guidance or advice has been issued to the pharmacy professional about the same or similar matters. These comments reflect the same issues outlined in relation to the inclusion of the wider public interest test and have been considered in response to Question3.

The CPNI commented that they were unsure if the criteria noted was replacing the 2016 criteria which was referenced on Page 4. The final version of the revised 2020 will not reference the 2016 criteria and the reference will be removed.

The Duty of Candour

The Pharmacy Forum NI raised the issue of whether the criterion '*does not call their honesty or integrity into question*', goes far enough when the direction of travel for healthcare providers in Northern Ireland is moving towards considering criminal prosecution of a health professional who is not acting with a duty of Candour in a particular set of circumstances (rather than having a Statutory Duty of Candour). There is a meaningful debate in relation to the overlap between the failure to meet the duty of candour and a lack of honesty and integrity. It should be noted that under the Code (2016), there is a specific obligation to adhere to the professional duty of candour, and should there be evidence that this obligation has not been adhered to, this will be engaged under the "*does not reveal a serious or persistent failure to meet any of the standards for pharmacists laid down in the Code*" criterion of the Threshold Criteria. The Pharmaceutical Society NI has released a regulatory statement on the seriousness of failing to meet the duty of candour[13] and it is within this context that it is considered that, should there be sufficient evidence, the Threshold Criteria as presented will be adequately engaged with regards potential breaches of the duty of candour.

[13] https://www.psni.org.uk/wp-content/uploads/2013/02/Joint-statement-on-the-professional-duty-of-candour-FINAL.pdf

Question 7 Is the exclusion of an additional wider public interest test (which could include consideration of issues such as insight, remediation or proportionality) from the Threshold Criteria appropriate?

Yes	No	Unsure	No direct response to question
2	4	0	

The National Pharmacy Association (NPA) believes that the wider public interest test should be retained within the Threshold Criteria. It would appear proportionate that if an investigation suggests at least one of the conduct or health aspects of the criteria the Registrar will consider whether it is in the public interest to refer the concern to the Scrutiny Committee.

The public interest consideration is an important part of the decision-making framework and will usually be met if any of the criteria are met. However, there may be exceptional circumstances in which the public interest factors are not in favour of making a referral.

The Threshold Criteria should enable the Registrar to take into account the seriousness, or potential seriousness, of the concerns, whether referral is the proportionate response, the circumstances and setting in which the issue happened, whether there are any risks posed to the person that raised the concern or any witnesses and the particular circumstances of the registrant, for example a significant health issue. These factors are not exhaustive and not all factors will be applicable in every case. The NPA believes that the application of the public interest test provides for the most robust consideration of information and is key to upholding professional standards and protecting the public from harm.

Community Pharmacy NI (CPNI) answered no to the question commenting.

'The decision to recommend referral to a Scrutiny Committee is a serious step with significant implications for pharmacists. Such a decision must be undertaken with the utmost care, and the Pharmacy Regulator, through its Registrar, must always act in the interests of the public but also fairly, equitably and proportionately in respect of the pharmacist.'

'To that end, and in keeping with guidance issued by the General Pharmaceutical Council (Good decision making: Investigations and threshold criteria guidance (updated January 2018)), CPNI believes that there is no cogent argument for excluding a wider public interest test which should be a critical part of the decision-making framework. By excluding the public interest test from the investigation stage, the Registrar appears to be effectively debarred from considering critical elements which may have a mitigating impact in exceptional cases. These could include: the circumstances and setting in which the issue happened; whether the pharmacist has learned from the incident; and whether the pharmacist has taken remedial action by undergoing training or making changes to their practice. These could be essential factors in determining whether referral to a Scrutiny Committee is the appropriate and proportionate response and they must be fully considered at the earliest stage, in line with processes in GB. Application of the threshold criteria as drafted would result in a

two-tier system across the UK and one in which pharmacists in Northern Ireland could face a lesser chance than colleagues in GB of the matter being dealt with by closure with informal guidance or closure with no further action. This is simply not acceptable'.

(a) *Importantly, in the interests of natural justice, this public interest test should also be applied at the Scrutiny Committee stage (as is evident in the systems in place in GPhC).The consultation proposes that this test be retained at this stage of the process.*

(b) *CPNI is also of a view that the consultation would have benefited from a section detailing the impact on a registrant resulting from the outcome of the investigation stage and the application of the threshold criteria. This is clearly and very helpfully laid out in tabular form by GPhC (page 15, Good decision making: Investigations and threshold criteria guidance (updated January 2018)). This would have been most useful to inform respondees in respect of the process and the implications.'*

The **Pharmacist's Defence Association** (PDA) answered no and commented 'the PSNI consultation document on the proposed Threshold Criteria states:

> *"It was decided that an additional **wider public interest test** (which could include consideration of issues such as insight, remediation or proportionality) should **not** be included in the Threshold Criteria as it is more appropriate that such complex assessments are considered in the more formal setting of the Scrutiny Committee."*

The PSA report submitted to Government in 2019 in response to the Williams review following the Bawa-Garba case notes:

> ***3.8** "Williams Review, have demonstrated there may be different understandings and approaches to public confidence amongst professionals, the bodies that regulate them and the public. The question continues to arise about **to what extent consideration of public confidence requires a regulator to be seen to be taking action, even when the professional in question poses no current risk to the public and has fully remediated any clinical failings**."*
>
> ***4.30** "It is notable that the term public confidence is also frequently used interchangeably with references to the wider public interest. The **wider public interest** is generally seen to refer to the two limbs of public protection beyond protecting patients from harm (maintaining public confidence and upholding standards). Whilst public confidence is clearly a part of the wider public interest, the lack of clarity on exactly what public confidence is and how it is damaged may lead to the use of more general terminology"*
>
> ***4.31** "It was also apparent from the **discussions we had with Panel Chairs** that there are some **different interpretations** of what is meant by the **wider public interest**."*

The PDA continue, 'So where does the wider public interest lie? It's a challenging question and it would be helpful if the PSNI explained what it considers to be the wider public interest. It is a matter for the PSNI to define with examples what it would consider to be a wider public interest and what it would consider ***not*** be in the wider public interest before we can express an opinion as to whether it is appropriate.

The GMC was clearly wrong in how it applied the wider public interest case in its appeal to have Mrs Bawa-Garba struck off. The High Court clearly understood the question of

proportionality and the issue of ongoing risk were the practitioner to continue to remain on the register:

> *"The [medical practitioners tribunal service] was an expert body entitled to reach [its] conclusions, including the important factor weighing in favour of Dr Bawa-Garba that she is a competent and useful doctor**, who represents no material continuing danger to the public** and can provide considerable useful future service to society.*

A wider public interest test is desirable as long as it is proportionately applied as interpreted in the manner by the High Court. Without having any guidance as to how the PSNI would apply such a wider public interest test it would be presumptuous to say that its exclusion is appropriate or inappropriate.'

The **Pharmacy Forum NI** answered no and referred to their answer to Question 4.

'We note the removal of an additional wider public interest test and query why other regulators, in particular the GPHC, currently include this consideration. See for reference, GPHC's '*Good decision making: Investigations and threshold criteria guidance*', January 2018, (section 3.10-3.13).[14] We would question why PSNI would be out of step with other regulatory bodies. In addition, in the best use of resources, would it not make more sense to dispose of such cases where it is not in the public interest to be disposed of at the appropriate level, i.e. before Scrutiny Committee consideration?'

The **Professional Standards Authority** (PSA) agreed with the PSNI decision not to try to try to take into account a wider public interest test at this stage (including considering insight, remediation and proportionality) and to leave these more complex considerations to the more formal setting of the Scrutiny Committee.

The PSA further commented that they have previously highlighted the risk of an inconsistent approach by allowing considerations about remediation, insight and proportionality to be taken into account at this early stage. They continue, *'Although for the PSNI this decision will be made by the Registrar so there is less scope for inconsistency we still agree with the rationale outlined in the consultation document that such complex assessments are best considered in the more formal setting of the Scrutiny Committee'.*

The **Health and Social Care Board** (HSCB) agreed that it was appropriate and commented that while these points are already covered under the existing three points however it would be useful to include them as additional points to consider in the checklist in the table in 4.6, possibly include in the first line of the table.

14 https://www.pharmacyregulation.org/sites/default/files/document/good_decision_making_investigations_and_threshold_criteria_guidance_january_2018.pdf

Question 7 Comment

Two respondents agreed that the exclusion of an additional wider public interest test (which could include consideration of issues such as insight, remediation or proportionality) from the Threshold Criteria was appropriate while four respondents disagreed.

We have outlined our considerations on the public interest test in detail in response to Question 3.

We agreed with the CPNI suggestion that a section detailing the impact on a registrant resulting from the outcome of the investigation stage and the application of the threshold criteria would be informative and propose the following recommendation.

Recommendation 8: Include a new Section 6 to include a table outlining the outcomes registrants can expect upon the application of the Threshold Criteria, as outlined the proposed Threshold Criteria.

Question 8 **Do any aspects of our proposals have equality implications for groups or individuals based on one or more of the following categories? If yes, please explain what could be done to change this.**

- **Age**
- **Gender**
- **Disability**
- **Pregnancy and maternity**
- **Race /ethnicity**
- **Religion or belief**
- **Political Opinion**
- **People with dependants**
- **Sexual orientation**
- **Marital Status**

Yes	No	Unsure	No direct response to question
2	1	2	1

The National Pharmacy Association (NPA) reported that they were unsure. They commented that they were concerned that the review of the Threshold Criteria and removal of the public interest test may lead to a rise in the number of cases inappropriately referred to the Scrutiny Committee, with subsequent increase in associated costs for the Society and registrants. Review of the Threshold Criteria and inclusion of the public interest test may lead to a more proportionate approach to investigations.

Community Pharmacy NI (CPNI) answered yes and commented that they believed that introducing the proposed criteria may discriminate against pharmacists in Northern Ireland.

They comment, *'CPNI recognises that this guidance mirrors closely in many policy areas and in terms of presentation and content, guidance issued by the General Pharmaceutical Council (Good decision making: Investigations and threshold criteria guidance (updated January 2018)). However, the issue of exclusion of a public interest test is a critical difference. CPNI believes that the draft threshold criteria may discriminate against those pharmacists registered in Northern Ireland in comparison to those registered in GB for the reasons outlined in our response to question 7 above. CPNI believes that imposition of this draft document would result in a two-tier system across the UK, and one in which pharmacists in Northern Ireland could face a lesser chance than colleagues in GB of the matter being dealt with by closure with informal guidance or closure with no further action. This is not acceptable*.

The **Pharmacist's Defence Association** (PDA) answered yes to the question and made the following comments.

'The PSNI notes that it has carried out an Equality and Diversity screening. It would be helpful if it published this alongside the consultation so that we could establish the robustness of the screening process.

We further note the total absence of any equality or diversity analysis in the PSNI Annual Report 2018-2019.

It is imperative that every step of the Fitness to Practice process has a mechanism built in so as to provide usable data.

This starts from the initial point of contact with the Regulator irrespective of any contextual interpretation and irrespective of whether the matter falls within scope or not.

At present we have no data about the total number of complaints made, how many the PSNI decided were within the scope of its regulatory power and how many complaints were outside scope.

This initial data is critical to establish how many complaints were registered against individuals, registered premises or about some other matter. The PSNI has never published data in its annual report about how many complaints it receives about pharmacies but always reports data about pharmacists.

It is at this point of the compliant process that datasets need to be established and in the absence of proper meaningful data collection the PSNI will be failing to monitor its obligations of fairness in equality and diversity in its FtP processes.

There is a notable paucity (or lack of) of any published data by the PSNI regarding any protected characteristics in its existing FtP process. In order to maintain public confidence in the fairness of the FtP process the PSNI must introduce and publish such data.

The Williams report noted:

> ***9.30**. "In addition, the SIF should provide guidance on how to consider equality and diversity considerations in investigations, including whether the investigations should include Black, Asian and Minority Ethnic (BAME) representation. **At a minimum, healthcare providers should ensure that all people conducting investigations have been appropriately trained, including in equality and diversity issues"***
>
> ***13.4.** "These are welcome steps, and the panel recognises that progress has been made to ensure that regulatory processes are sensitive to potential unconscious bias about certain groups of professionals. The panel recognises that the factors which lead to the over-representation of BAME professionals in fitness to practise proceedings are complex and are not solely within the control of the regulators. **However, the regulators should continue to take steps to ensure that their processes are fair to all registrants.**"*

The PSA in response to the Williams Report noted:

> ***5.9** "Panellists do refer to guidance from the regulator to support their decision making, receive regular updates on the case law and undergo training in areas such as unconscious bias. However, the fact that considerations, particularly on factors affecting public confidence, are likely to be shaped to some extent by background, suggest the need for research with the public to help inform the approach of Panellists. **It also suggests the need for regulators to ensure that Panellists are drawn from a sufficiently wide range of backgrounds with relevant considerations about diversity and representation.**"*

The GMC was sufficiently concerned about why certain groups of doctors were more likely to be referred than others that it commissioned its own report.[15] The findings noted (and this could be equally applicable across all healthcare professions):

> ***Page 20** "A quarter of BAME GPs surveyed reported experiencing discrimination from patients at least monthly, with three quarters saying they faced racial discrimination from their patients at some point."*
>
> ***Page 65** "I don't think doctors get nearly enough (indeed hardly any if at all) training on how to deal specifically with racism from patients – or even other colleagues … The medical profession doesn't like to talk about this, but it is a reality. I think it is really important that all those involved in healthcare - **including those who inspect or regulate us** – understand that bias can easily creep in even if open racism is less frequent. BAME GP partner"*

[15] https://www.gmc-uk.org/-/media/documents/fair-to-refer-report-pdf-79011677_pdf-79021583.pdf

The 2018-2019 Annual Report of the PSNI noted that 12 of the 24 Fitness to Practice cases opened were following complaints by members of the public.

The GMC findings should be a seminal reminder that bias within the healthcare regulatory process is a complex issue and the best defence against bias is to openly quantify, discuss and deal with the underlying profession specific issues.

Without knowing the quality and completeness of the PSNI records in relation to FtP processes we cannot say whether the whole process is utterly biased or totally bias free.

A recent survey by Unison[16], found that healthcare workers reported a widespread prevalence of casual racism both from patients and colleagues. There is no reason to suspect that the findings in 2019 by Unison have no impact on the disproportionality of complaints made against minorities.

It is for the PSNI to ensure that it has diligently collects and records data to ensure that it is applying the powers it has equitably. There is certainly a wider public interest in the public having faith in the regulator to applying its Fitness to Practice processes equitably and justly and free from any bias'.

The PDA recommended the following action.

(a) The recording of every complain (against a pharmacist or pharmacy), at point of first contact, on a standardised database to establish quantum.
(b) If the complaint is outside scope of PSNI that should be recorded within one dataset together with a clear explanation as to why it is outside scope.
(c) If the complaint is within scope for PSNI then 2 streams emerge:

- The matter is within scope for PSNI, but the Registrar deems that this does not call into question the fitness to practise of a registered pharmacist / pharmacy.

- The Registrar deems the matter is within scope and does call into question the fitness to practise of a registered pharmacist / pharmacy.

All datasets to incorporate diversity characteristics and to be the public domain.

The **Pharmacy Forum NI** answered no and did have comment.

The **Professional Standards Authority** (PSA) had no comments.

The **Health and Social Care Board** (HSCB) commented that they were unsure commenting that there were no obvious issues.

[16] https://www.unison.org.uk/news/article/2019/10/data-race-for-equality/

Question 8 Comment

Two respondents believed that aspects of our proposals had equality implications for groups or individuals. Two respondents reported that they were unsure.

Community Pharmacy NI (CPNI) believed that the proposals had equality issues commenting the proposed criteria may discriminate against pharmacists in Northern Ireland through the exclusion of a public interest test. They argued that pharmacists in Northern Ireland could face a lesser chance than colleagues in GB of the matter being dealt with by closure with informal guidance or closure with no further action. As the Pharmaceutical Society NI's jurisdiction is within Northern Ireland, we did not consider this to be a legitimate equality issue as defined by the categories outlined, which reflect Section 75 and equality legislation.

The PDA comment that the Equality and Diversity screening should be published alongside the consideration is acknowledged and this will be considered for future consultations.

The PDA argues that equality or diversity analysis should be an integral part of the Fitness to Practice process and published. While we agreed that this would be a useful safeguard, the number of registrants going through the process is very small and there is a risk that colleagues could identify a person from this information.

The relation to the PDA's comments concerning greater transparency and auditing of complaints, we refer to our response to Question 3, where we reflect on the proportionality of our approach and the quality assurance role of the Professional Standards Authority, with specific reference to the performance review and early stages audits.

Committee panellists are appointed on merit through an open competition and applications. While all panellists and responsible staff are appropriately trained, we will consider the PDA comments in relation to further improvements that can be made in our upcoming 2020 training cycle in relation to equality issues and decision making.

The HSCB commented that they were unsure but concluded that there were no obvious issues.

The NPA reported that they were unsure. They commented that they were concerned that the review of the Threshold Criteria and removal of the public interest test may lead to a rise in Northern Ireland in the number of cases inappropriately referred to the Scrutiny Committee, with subsequent increase in associated costs. They suggest that a review of the Threshold Criteria and inclusion of the public interest test may lead to a more proportionate approach to investigations. It was considered that

these comments are not equality issues as defined by the question and equality legislation.

The appropriateness of the referral of cases from the Registrar is tested by the PSA audit. There is no evidence of any equality issues in respect of this. We would argue that complex assessments, such as the public interest test, are best considered in the more formal setting of the Scrutiny Committee'.

Question 9 Do you have any comments about the Draft Threshold Criteria?

Yes	No	Unsure	No direct response to question
5	1		

The National Pharmacy Association (NPA) had no further comments.

Community Pharmacy NI (CPNI) commented, *'The decision to recommend referral to a Scrutiny Committee is a serious step with significant implications for pharmacists. Such a decision must be undertaken with the utmost care and any threshold criteria and associated guidance documents must be carefully considered. We have articulated our concerns in our responses above and would ask that the Pharmaceutical Society act so as not to negatively discriminate against pharmacists on the Northern Ireland register in comparison to GB registered colleagues'.*

The **Pharmacist's Defence Association** (PDA) recommend clear timelines are published as part of the Threshold Criteria. Any professional that is being investigated by an FtP process will be put under tremendous stress.[17] They comment that the GPhC has commissioned an external review to look into the stress impact of its FtP processes. The PDA comment that the organisation must resolve all allegations in a timely manner and publish clear timelines for the decision-making process.

The PDA also recommend a clear flowchart of what happens and with clear timelines as to when it happens. The flow chart would be transparent, easy to understand (especially for those that are making a complaint) and would enhance public confidence in the regulatory process. They suggest a flowchart from the General Optical Council Fitness to Practice[18] as a good example.

The **Pharmacy Forum NI** commented in relation to Section 4.8 (page 8 of the draft Threshold Criteria)

[17] https://www.pharmacyregulation.org/sites/default/files/document/gphc-council-meeting-papers-01-02-2019.pdf

[18] https://www.optical.org/download.cfm?docid=BABBFAF6-EC3E-48AB-B57A40FA9C6CEAB5

'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 improve their practice.

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'

The Forum also commented that clarity is required on the following in relation to 4.8 of the threshold criteria
'If in legislation the Registrar is not required to be a pharmacist, in what capacity would they be an authority to give advice on how to improve a pharmacists practice? If the advice is on how to comply with regulatory outcomes, then this should be made clearer.

The informant and the pharmacist will be informed of the decision. However, it is not clear if the informant will be advised of any advice given to the pharmacist. If they are informed of the advice, then we believe this is not appropriate if there are no grounds for referral to the Scrutiny Committee'.

The **Professional Standards Authority** (PSA) welcomed the opportunity to comment on the Pharmaceutical Society of Northern Ireland's (PSNI's) revised threshold criteria to be used by the Registrar when making decisions on whether to refer a case to the Scrutiny Committee.

The **Health and Social Care Board** (HSCB) commented that the box at the top of page 7 is not useful. They suggested it is included at the start in the introduction (1.1) but needs reworded away from the negative to the positive wording (as per table in 4.6). Negative way of wording the information makes this table hard to understand.

Question 9 Comment

Five respondents made additional comments.

The CPNI commented, that the decision to recommend to a Scrutiny Committee is a serious step with significant implications for pharmacists. Such a decision must be undertaken with the utmost care and any threshold criteria and associated guidance documents must be carefully considered. We agree with the CPNI of the significance of the Threshold Criteria and have welcomed the comments and recommendations from this public consultation which will inform the final document.

We have previously acknowledged the PDA recommendation for a clear flowchart which will be especially useful for those who are unfamiliar with the process and Recommendation 6 addresses this directly. We acknowledge the strain of the process on participants and have endeavoured to minimise this by resolving all allegations in a timely manner.

We accept the Pharmacy Forum NI comments in relation to the Registrar providing advice on professional practice. We regard this to be the case whether the Registrar is a pharmacist or not, as a pharmacist will not

necessarily have specific expertise in all areas of practice. The following recommendation is therefore made:

Recommendation 9: Amend section 3.4 and 4.7 to read: 'uphold professional standards'.

Advice provided to complainant

The Pharmacy Forum NI queried whether informal advice will be provided to the complainant if a case does not meet the Threshold Criteria. The complainant would be informed that advice has been provided to the registrant, but the nature of that advice will not be disclosed.

The Professional Standards Authority (PSA) welcomed the opportunity to comment on the Pharmaceutical Society of Northern Ireland's revised threshold criteria.

List of organisations who responded to the consultation	
Name	**Organisation Type**
Pharmacists' Defence Association	Pharmacy Representative Body
Pharmacy Forum NI	Pharmacy Representative Body
Health and Social Care Board	HSC organisation
National Pharmacy Association	Pharmacy Representative Body
Professional Standards Authority	Regulatory Body
Pharmacy Forum NI	Pharmacy Representative Body