

Consultation on revised threshold criteria

December 2016



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Contents

About the GPhC	5
Overview	6
The consultation process	7
Background: fitness to practise and investigations	8
Why we are reviewing the threshold criteria	9
Key changes	10
Draft revised threshold criteria	12
How we will use your responses	14
Consultation response form	15
Consultation questions.....	18
Equality monitoring.....	20
Appendix A: Collated consultation questions	22

The deadline to respond to this consultation is Tuesday 7 March 2017



About the GPhC

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

Our main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals have to meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards

Overview

As the regulator, our main role is to protect, promote and maintain the health and safety of people who use services from pharmacy professionals or from registered pharmacies. This includes maintaining the register of pharmacists and pharmacy technicians, and making sure that people who are on the register are fit to stay on it.

We have the power to investigate concerns about pharmacists and pharmacy technicians. Once we receive them, we carefully review and assess all concerns that are raised with us, and we then consider whether we need to begin an investigation. If the concern is something we can deal with using our powers, we will carry out an investigation. Once we have finished our enquiries, we will decide whether the case should be referred to the investigating committee or if another outcome is appropriate in the circumstances. As one part of this decision-making process we use 'threshold criteria'.

The Pharmacy Order 2010 allows us to have threshold criteria, which help us decide whether a case should be referred to the investigating committee. They are used by decision-makers within the GPhC who are involved in investigating concerns. These criteria give us a framework to make sure we make proportionate, fair and consistent decisions in all investigations.

The present criteria have been in place since 2010. We are now consulting on revised criteria to make sure they are fit for purpose and take account of recent changes in pharmacy regulation. These changes include the new

standards for pharmacy professionals which will be introduced in 2017. This is also part of our wider review of all our statutory decision-making guidance.

The revised threshold criteria, along with our other published guidance, will go some way towards making sure that the decision-making throughout our fitness to practise procedures is as transparent and understandable as possible.

We also want to make sure the revised threshold criteria are accessible and easily understood by a wide range of stakeholders, not just people who use them as part of their work. This includes anyone who has raised a concern, or has had a concern raised about them. The criteria may also be useful to other interested parties such as members of the public, users of pharmacy services, registrants and registrants' representatives.

This consultation document has two main sections:

- **Background: fitness to practise and investigations:** This explains what we mean by 'fitness to practise' and briefly describes our investigation procedure, to help put the revised threshold criteria into context.
- **Why we are reviewing the threshold criteria:** This explains what our revised threshold criteria cover, what they are for and why we are reviewing them.

The consultation process

The consultation will run for 12 weeks and will close on **Tuesday 7 March 2017**. During this time we welcome feedback from individuals and organisations. We will send this document to a range of stakeholder organisations, including professional representative bodies, employers, education and training providers, and patients' representative bodies.

You can get more copies of this document on our website **www.pharmacyregulation.org/thresholdconsultation** or you can contact us if you would like a copy of the document in another format (for example, in larger type or in a different language).

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive and will take the responses into account when considering the final guidance in spring 2017.

We will also publish a summary of the responses we receive and an explanation of the decisions taken. You will be able to see this on our website www.pharmacyregulation.org

How to respond

You can respond to this consultation in a number of different ways. You can fill in the questionnaire at the end of this document or go to **www.pharmacyregulation.org/thresholdconsultation** and fill in an online version there.

If you fill in the questionnaire in this document, please send it to:

consultations@pharmacyregulation.org with the subject 'Consultation on revised threshold criteria'

or post it to us at:

Consultation on revised threshold criteria response

**Policy & Standards Team
General Pharmaceutical Council
25 Canada Square
London E14 5LQ**

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to:

feedback@pharmacyregulation.org

or post them to us at:

**Governance Team
General Pharmaceutical Council
25 Canada Square
London E14 5LQ**

Please do not send consultation responses to this address.

Background: fitness to practise and investigations

1. A pharmacy professional is 'fit to practise' when they have the skills, knowledge, character, behaviour and health needed to do their job safely and effectively. This means maintaining appropriate standards of competence, demonstrating good character, and also following the principles of good practice set out in our standards, guidance and advice.
2. When there is a concern that a pharmacy professional may have fallen short of the expected standards, their fitness to practise may be called into question. This can be for a number of reasons, including misconduct, deficient performance, ill-health or a conviction or caution for a criminal offence. This can lead to a concern being raised with the GPhC. There is more information about raising concerns and how we deal with them here:
www.pharmacyregulation.org/raising-concerns
3. In short, we have the power to investigate concerns about pharmacists and pharmacy technicians. We carefully review and assess all concerns that are raised with us, and we consider whether we need to begin an investigation. If the concern is something we can deal with, we will carry out an investigation. Once we have finished our enquiries, and have the information we need, we will decide whether the case should be referred to the investigating committee or if another outcome is appropriate in the circumstances.
4. As one part of this decision-making process we use 'threshold criteria'. We use the threshold criteria to decide whether to refer a concern to the investigating committee.



Why we are reviewing the threshold criteria

5. We have been using the present threshold criteria since 2010 and it is right to review them from time to time to make sure they are still fit for purpose. This is also part of our wider review of all our statutory decision-making guidance. For example, we have recently reviewed the guidance for our investigating and fitness to practise committees.
6. Another reason to review the threshold criteria is that they are linked to the seven principles set out in the standards of conduct, ethics and performance¹ which all pharmacy professionals must keep to. **You can see the current criteria and guidance here.** We will introduce new standards for pharmacy professionals in 2017 and we need to make sure that the criteria take account of these new standards. We propose to introduce the new criteria at the same time as we introduce the new standards for pharmacy professionals in May 2017.
7. Finally, the revised threshold criteria will be supported by information to explain our investigation procedure.
8. This consultation focuses on the revised threshold criteria and how we will use them.

¹www.pharmacyregulation.org/sites/default/files/standards_of_conduct_ethics_and_performance_july_2014.pdf

Key changes

9. We are proposing six criteria across conduct, behaviour and health. This will replace the current 15 criteria listed under the seven principles of the current

standards for conduct, ethics and performance. The current criteria are included below for comparison purposes.

The current threshold criteria

Cases are not to be referred to the investigating committee unless one of the following statements is true:

Principle 1: Make patients your first concern

There is evidence that the registrant's conduct or performance caused moderate or severe harm or death, which could and should have been avoided.

There is evidence that the registrant deliberately attempted to cause harm to patients and the public or others.

There is evidence that the registrant was reckless with the safety and wellbeing of others.

Principle 2: Use your professional judgment in the interests of patients and the public

There is evidence that the registrant put their own interests, or those of a third party, before those of their patients.

There is evidence that the registrant culpably failed to act when necessary in order to protect the safety of patients.

Principle 3: Show respect for others

There is evidence that the registrant failed to respect the human rights of patients, or demonstrated in their behaviour attitudes which are incompatible with registration as a pharmacy professional.

There is evidence that the registrant failed to maintain appropriate professional boundaries in their relationship with patients and/or others.

Principle 4: Encourage patients and the public to participate in decisions about their care

There is evidence that the registrant damaged or put at significant risk the best interests of patients by failing to communicate appropriately with patients or others.



Principle 5: Develop your professional knowledge and competence

There is evidence that the registrant practised outside of their current competence.

There is evidence that the registrant failed to maintain their knowledge and skills in a field relevant to their practice.

There is evidence of a course of conduct, which is likely to undermine public confidence in the profession generally or put patient safety at risk, if not challenged by the regulatory body.

Principle 6: Be honest and trustworthy

There is evidence that the registrant behaved dishonestly.

There is evidence of behaviour on the part of the registrant which is likely to undermine public confidence in the profession generally, if not challenged by the regulatory body.

Principle 7: Take responsibility for your working practices

There is evidence that the registrant has practised in a way that was systemically unsafe, or, has allowed or encouraged others to do so, where he or she has responsibilities for ensuring a safe system of working.

There is evidence of adverse physical or mental health which impairs the registrant's ability to practise safely or effectively. If the Registrar is in doubt as to whether the above criteria have been met, he shall refer the case to the investigating committee.

10. The next section sets out the revised threshold criteria.

Draft revised threshold criteria

Introduction

- 1.1 The Pharmacy Order 2010 ('the Order') recognises that purposeful, proportionate regulation does not mean that we refer allegations to the investigating committee (IC) automatically or indiscriminately. The Order allows the council to define 'threshold criteria' which the registrar, and people delegated by the registrar, must use to decide whether to refer a case to the IC.
- 1.2 Article 52(2)(a) of the Pharmacy Order 2010 provides that allegations that a pharmacy professional's fitness to practise is impaired must not be referred to the IC if the allegation is of a type stated in the threshold criteria that should not be referred.
- 1.3 This document sets out what those threshold criteria are and how we will apply them.

The threshold criteria and how we will apply them

- 1.4 The threshold criteria are one part of the decision-making process, and are applied when an investigation ends. It is a simple mechanism that assists the registrar in deciding whether a concern should be referred to the IC. The criteria ensure we make proportionate, fair and consistent decisions during all investigations and that only appropriate cases are referred to the IC.
- 1.5 When we finish our enquiries, we will review the evidence we have and decide on the appropriate action to take. A case should only be referred to the IC when this is the appropriate and proportionate action, taking into account the threshold criteria.
- 1.6 **These are the threshold criteria.** The registrar will **not** refer a case to the IC if:

Conduct and behaviour

- it does not present an actual or potential risk to patient or public safety
- it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession
- there has not been a serious or persistent failure to meet any of the standards for pharmacy professionals, and
- it does not show that the honesty or integrity of the registrant can no longer be relied upon

Health

- there is no self-harm or risk of self-harm, and
- there is no harm or risk of harm to patients and the public

- 
- 1.7 When considering a case against the criteria the registrar will take into account the behaviour and actions of the registrant. This will include whether the registrant acted recklessly or with intent, whether it is a recurring issue and whether the registrant has shown insight or acted with openness and honesty.
- 1.8 The case will not usually be referred to the IC if **all** the threshold criteria are met and it may be closed with no further action or with written feedback being given to the registrant.
- 1.9 If any of the threshold criteria are not met, and the case is one which is capable of being considered for referral to the IC, the registrar will then take into account the public interest when deciding whether or not to use his discretion to refer to the IC. Public interest considerations are listed below.

Public interest considerations

- 1.10 When making assessments against the criteria, the registrar will consider the wider public interest². Public interest considerations include:
- protecting the public
 - maintaining public confidence in the profession
 - maintaining proper standards of behaviour
- 1.11 The public interest consideration is an important part of the decision-making framework. The registrar may also consider whether:
- the registrant showed remorse or insight, and has learnt from the incident
 - the registrant has taken 'remedial' action, for example training or changes to their practice
 - previous advice has been issued to the registrant about the same or similar matters
 - the decision is sufficient to protect the public, and
 - referring the matter to the IC is a proportionate response
- 1.12 The importance of any of the situations listed in 1.11 will be considered in the context of the case and the seriousness of the concerns as a whole. If the registrar believes it is in the public interest to refer a case, then it will be referred. If not, the case will not be referred to the IC, and it may be closed with no further action or with written feedback given to the registrant.

² The public interest test is set out in case law including *CHRE v Nursing and Midwifery Council* (Grant); *Marinovich v General Medical Council* [2002]; *Bolton v The Law Society* [1994]; *R (on the application of Abrahams) v GMC* [2004].

How we will use your responses

After the consultation, we will publish a report summarising what we heard. If you respond as a private individual, we will not use your name or publish individuals' responses.

If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

The GPhC may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.



Consultation response form

Response to the consultation on revised threshold criteria

For organisations

If you want any part of your response to stay confidential, please explain why you think the information you have given is confidential. We cannot give an assurance that confidentiality can be maintained in all circumstances.

- ☐ Please keep parts of my response confidential

Please tell us if you have any concerns about our publishing any part of your response and explain which parts you would want to keep confidential:

Background questions

First, we would like to ask you for some background information. This will help us to understand the views of specific groups, individuals and organisations and will allow us to better respond to those views.

Are you responding:

- ☐ as an individual – please go to section A
- ☐ on behalf of an organisation – please go to section B

Section A – Responding as an individual

Please tell us your:

name:

address:

email:

Where do you live?

- ☐ England
 - ☐ Scotland
 - ☐ Wales
 - ☐ Northern Ireland
 - ☐ other (please give details)
-

Are you responding as:

- ☐ a member of the public
 - ☐ a pharmacy professional or owner – please go to section A1
 - ☐ a pre-registration trainee
 - ☐ a student
 - ☐ other (please give details)
-

Section A1 – Pharmacy professionals

Are you:

- ☐ a pharmacist
- ☐ a pharmacy technician
- ☐ pharmacy owner

Please choose the option below which best describes the area you mainly work in:

- ☐ community pharmacy
 - ☐ hospital pharmacy
 - ☐ primary care organisation
 - ☐ pharmacy education and training
 - ☐ pharmaceutical industry
 - ☐ other (please give details)
-

Section B – Responding on behalf of an organisation

Please tell us your:

name:

job title:

organisation:

address:

email:

a contact name for enquiries:

Please choose the option below which best describes your organisation:

- ☐ organisation representing patients or the public
- ☐ organisation representing pharmacy professionals or the pharmacy sector
- ☐ independent pharmacy (1-5 pharmacies)
- ☐ multiple pharmacy (6 or more pharmacies)
- ☐ NHS organisation or group
- ☐ research, education or training organisation
- ☐ other (please give details)

Please provide a brief description of what your organisation does and its interest in this particular consultation:

Consultation questions

We are particularly interested in your views on the following points, although we welcome your comments on any issues that you want to raise about the proposed threshold criteria.

General

- 1. The Pharmacy Order 2010 allows us to have threshold criteria, which help us decide whether a case should be referred to the investigating committee. Do you think the proposed threshold criteria are clear and understandable?**

☐ Yes ☐ No

Please explain why.

- 2. The criteria are used by decision-makers within the GPhC who are involved in investigating concerns to decide whether the case should be referred to the investigating committee. Do you think how we apply the criteria in practice is clear?**

☐ Yes ☐ No

Please explain why.

- 3. The criteria give us a framework to make sure we make proportionate, fair and consistent decisions in all investigations. Do you think the proposed threshold criteria will make sure the right cases are referred to the investigating committee?**

☐ Yes ☐ No

Please explain why.



Other comments

4. Do you have any other comments on the proposed criteria?

Equality analysis

We believe the issues the criteria focus on should have positive implications for people. The criteria will support good decision making against a set of objective criteria and this is one way of mitigating the risk of bias. We have not identified any implications that would discriminate against or unintentionally disadvantage any individuals or groups.

5. Are there any aspects of the proposed criteria that could have a negative impact on patients, members of the public, pharmacists, pharmacy technicians, or any other groups?

☐ Yes ☐ No

6. Do you have any comments on the potential impact of the criteria?

Equality monitoring

At the GPhC, we are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties.

We want to make sure everyone has an opportunity to respond to our consultation on standards for pharmacy professionals. This equality monitoring form will provide us with useful information to check that this happens.

You do not have to fill it in, and your answers here will not be linked to your consultation responses.

What is your sex?

Please tick one box

- ☐ Male
- ☐ Female
- ☐ Other

What is your sexual orientation?

Please tick one box

- ☐ Heterosexual/straight
- ☐ Gay woman/lesbian
- ☐ Gay man
- ☐ Bisexual
- ☐ Other
- ☐ Prefer not to say

Do you consider yourself disabled?

Disability is defined in the Equality Act 2010 as “physical or mental impairment, which has a substantial and long term adverse effect on a person’s ability to carry out normal day to day activities”. Please tick one box.

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

What is your age group?

Please tick one box

- ☐ 16 – 24 years
- ☐ 25 – 34 years
- ☐ 35 – 44 years
- ☐ 45 – 54 years
- ☐ 55 – 64 years
- ☐ 65 + years

What is your ethnic group?

Choose the appropriate box to indicate your cultural background. Please tick one box.

White

- ☐ British
- ☐ Irish

- 
- ☐ Gypsy or Irish traveller
 - ☐ Other white background (please fill in the box at the end of this section)

Black or Black British

- ☐ Black Caribbean
- ☐ Black African
- ☐ Other black background (please fill in the box at the end of this section)

Mixed

- ☐ White and black Caribbean
- ☐ White and black African
- ☐ White and Asian
- ☐ other mixed background (please fill in the box at the end of this section)

Asian or Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ other Asian (please fill in the box at the end of this section)

Chinese or Chinese British

- ☐ Chinese or Chinese British
- ☐ Other ethnic group (please fill in the box at the end of this section)

Arab

- ☐ Arab

Other

- ☐ Prefer not to say
- ☐ Other ethnic group background (please give more information in the box below)

What is your religion?

Please tick one box

- ☐ Buddhist
- ☐ Christian
- ☐ Hindu
- ☐ Jewish
- ☐ Muslim
- ☐ Sikh
- ☐ None
- ☐ Other (please give more information in the box below)
- ☐ Prefer not to say

Appendix A: Collated consultation questions

1. The Pharmacy Order 2010 allows us to have threshold criteria, which help us decide whether a case should be referred to the investigating committee. Do you think the proposed threshold criteria are clear and understandable?
2. The criteria are used by decision-makers within the GPhC who are involved in investigating concerns to decide whether the case should be referred to the investigating committee. Do you think how we apply the criteria in practice is clear?
3. These criteria give us a framework to make sure we make proportionate, fair and consistent decisions in all investigations. Do you think the proposed threshold criteria will make sure the right cases are referred to the investigating committee?
4. Do you have any other comments on the proposed criteria?
5. Are there any aspects of the proposed criteria that could have a negative impact on patients, members of the public, pharmacists, pharmacy technicians, or any other groups?
6. Do you have any comments on the potential impact of the criteria?



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