

Good decision making: Investigations and threshold criteria guidance

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Contents

About us	4
1. Introduction	5
What this guidance is about	5
Who this guidance is for	5
Equality and diversity	6
2 About investigations	7
The guidance used at each stage of the process	7
Investigations	8
Once a concern is raised	8
Actions we can take during an investigation	9
Direct referral	10
Assessing health issues.	10
English language assessment	10
Applications for voluntary removal	11
Referring information to a barring body	11
3 Deciding on an outcome	12
The decision-making process	12
Applying the threshold criteria	12
Public interest considerations	14
Available outcomes	14
Deciding which outcome is appropriate	16
4 After a decision has been made	17
Quality assurance of decisions	17

About us

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 and 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

We are committed to protecting, promoting and improving the health and safety of people who use pharmacy services in England, Scotland and Wales. An important part of that role is dealing with the small number of pharmacists and pharmacy technicians who fall short of the standards that the public expect from healthcare professionals.



1. Introduction

What this guidance is about

1.1 This document is intended to help with understanding:

- how we investigate concerns about pharmacy professionals once a decision has been made to open an investigation
- our decision-making process, and
- when, and how, the threshold criteria are applied

It gives information about:

- our approach to investigations
- what the threshold criteria are, and
- how the threshold criteria are applied to concerns that may call into question a pharmacy professional's fitness to practise

1.2 The main aim of this guidance is to make sure that the public are properly protected by appropriate, consistent and proportionate decisions

Who this guidance is for

1.3 This guidance is aimed at everyone who:

- is involved in an investigation
- has raised a concern about a pharmacy professional, or
- has had a concern about them referred to the GPhC

1.4 This guidance is also intended to help GPhC staff, and pharmacy professionals, their representatives and employers. We believe it will be useful to anyone who is interested in the fitness to practise process, including people who may be thinking about raising a concern with us.

1.5 We will regularly review this guidance to:

- take account of changes to legislation and case law
- make sure it is consistent with other associated guidance documents
- make sure it stays 'fit for purpose' and accessible to all stakeholders

Equality and diversity

- 1.6 The GPhC is committed to promoting equality, diversity and inclusion when it does its work. We value diversity and individuality in our staff, the professions and our council. Our aim is to make sure that our processes are fair, objective, transparent and free from discrimination, and that all stakeholders receive a high level of service. We keep to the principles set out in the Equality Act 2010 and have developed an **equality, diversity and inclusion scheme**.
- 1.7 All GPhC staff are expected to demonstrate our values and to work towards these aims at all times during the fitness to practise process. The GPhC will act in accordance with the rights set out in the European Convention on Human Rights (ECHR) as incorporated into domestic law by the Human Rights Act 1998.

2 About investigations

- 2.1 The GPhC is responsible for maintaining the register of pharmacists, pharmacy technicians and pharmacy premises. To remain on the register, pharmacy professionals must be fit to practise;
- 2.2 One of the ways we make sure that pharmacy professionals on the register are fit to practise is to investigate the concerns we receive about them.
- 2.3 An investigation is just one part of the fitness to practise process that starts when a concern has been raised with the GPhC¹. This process can end at several different stages:
- after the investigation
 - at an investigating committee (IC) meeting
 - at a fitness to practise committee (FtPC) hearing²

The guidance used at each stage of the process



- 2.4 Decision-making guidance is used at each stage to help us decide what action to take. The guidance is based on the law and established procedures and takes account of the principles of good regulation. We publish the following decision-making guidance:
- *Good decision making: Investigations and threshold criteria guidance* (this guidance) is used to decide whether to refer a concern to the IC.

¹ If the concern is one that the GPhC is able to investigate

² Some cases are referred directly by the registrar – Article 52 (2)(b) and Article 54(1)(a) of The Pharmacy Order 2010

- *Good decision making: Investigating committee meeting and outcomes guidance* covers IC meetings, the decision-making process and the outcomes of IC meetings.
- *Good decision making: Fitness to practise hearings and sanctions guidance*, which covers fitness to practise hearings, and the decisions made by an FtPC during a hearing.

Our website has **more information on how to raise a concern** and on the **investigation and fitness to practise process**.

Investigations

2.5 The GPhC is committed to investigating concerns efficiently and effectively and to do so proportionately. This means investigating concerns to make sure the right regulatory action is taken, so that pharmacy professionals on the register are fit to practise. When a concern has been raised, we may carry out an investigation. Effective investigation and, when appropriate, resolution of concerns at a local level by employers help to make sure that our investigations are better targeted.

2.6 We will only investigate information that might call into question whether a pharmacy professional's fitness to practise is impaired. 'Fitness to practise' is where a pharmacy professional shows that they have the skills, knowledge, character and health to do their job safely and effectively and maintain the reputation of the profession. A pharmacy professional's fitness to practise can be impaired for a number of reasons, and these are set out in the legislation. The reasons include, but are not limited to³:

- misconduct
- deficient professional performance
- not having the necessary knowledge of English
- ill-health
- a conviction for a criminal offence

2.7 Our role in investigating fitness to practise cases does not involve resolving disputes between pharmacy professionals, employers, individuals or other organisations. We cannot help anyone with getting an apology or compensation.

Once a concern is raised

2.8 When we first receive a concern, we will:

- look at all the information provided
- consider whether the GPhC can act upon the issues raised, and

³ Article 51 of The Pharmacy Order 2010 has the full list of impairment categories

- consider whether we should begin an investigation

2.9 If the concern is better dealt with by another regulator or agency, we will pass it on to them. However, sometimes we may carry out an investigation alongside another body or agency.

2.10 When we first consider a concern, we will check to see whether the concern relates to:

- a pharmacy professional
- someone who is not registered, but is practising as a pharmacy professional, or using the title 'pharmacist' or 'pharmacy technician'
- any of the categories set out in our legislation⁴

2.11 The GPhC will investigate a concern when this is:

- needed to ensure patient safety
- in the registrant's own interests, or
- in the public interest for some other reason

2.12 We will not investigate concerns if they focus purely on customer service or employment issues. You can find **more details of what we do not investigate on our website**.

2.13 If the concern is one that the GPhC will deal with, we will confirm whether we are investigating and assign a case officer or inspector.

Actions we can take during an investigation

2.14 There are a number of actions we can take to help with the investigation and also to make sure that patient and public safety is maintained. We are able to:

- close the case without taking any further action
- issue informal guidance to the registrant, or
- refer the case to the investigating committee

2.15 The registrar may also decide to refer the case direct to the fitness to practise committee and/or apply for an interim order (IO).

Interim orders

2.16 The GPhC has the power to apply for an interim order (IO)⁵. This is an urgent action which can either suspend a pharmacy professional from practising or can restrict their practice in

⁴ Article 51 of The Pharmacy Order 2010

⁵ Article 52(3)(b) of The Pharmacy Order 2010

some way through imposing conditions. The IO can only be imposed by a fitness to practise committee and can remain in place until the fitness to practise process has ended⁶.

- 2.17 An IO may be needed to protect the public or be in the public interest or in the interests of the pharmacy professional concerned.

Direct referral

- 2.18 The registrar may refer the case direct to a fitness to practise hearing in certain circumstances⁷. These include if the public interest is best served by the case being considered urgently.

Assessing health issues

- 2.19 A concern may show that a pharmacy professional could be suffering from a health issue which is affecting their ability to practise safely and effectively, for example because of the use of alcohol or drugs. If so, we may ask them to allow us to contact their GP, hospital or healthcare provider. We may also ask them to have a health assessment. We often do this in cases when the pharmacy professional has been cautioned or convicted of an offence that has involved alcohol or drugs. However, it can apply to any investigation when there is information that suggests we should assess the pharmacy professional's health.

English language assessment

- 2.20 If we are concerned that a pharmacy professional does not have the necessary knowledge of English, the registrar (or an investigating or fitness to practise committee) may direct that they⁸:
- have an examination or other assessment of their knowledge of English, and
 - send the registrar evidence of the result of that examination or assessment
- 2.21 We may do this if we believe that a pharmacy professional does not have the knowledge of English needed to practise safely and effectively as a pharmacy professional in Great Britain. If we are considering cases of this nature we will take account of the **published guidance**.

⁶ An IO can be imposed for up to 18 months. After this it can only be extended by an application to the High Court or Court of Session in Scotland

⁷ Article 52(2)(b) of The Pharmacy Order 2010

⁸ Rule 6(4)(e) – The General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010



Applications for voluntary removal

2.22 In exceptional circumstances the registrar may remove the register entry of a pharmacy professional who is under investigation if they have made an application for removal.

Referring information to a barring body

2.23 The registrar can also refer information about a pharmacy professional to the Disclosure and Barring Service or Disclosure Scotland if the concern we are investigating suggests that there is a safeguarding issue in relation to vulnerable adults or children.

3 Deciding on an outcome

3.1 After we have finished our investigation, we will review the evidence we have gathered and decide on the action to take. There are a number of outcomes available including referral to the investigating committee.

3.2 The threshold criteria are at the centre of our decision-making process about whether the case should be referred to the investigating committee or if another outcome is appropriate. We will refer a case if the evidence, as a whole, suggests that at least one of the conduct, performance or health aspects are met and it is in the public interest to refer.

The decision-making process

3.3 When we have finished the investigation, we use the following decision-making process.



3.4 Once we have reviewed the evidence we will assess it against the threshold criteria.

Applying the threshold criteria

3.5 A case is considered against the threshold criteria⁹ once an investigation has finished. The power to develop and use threshold criteria is set out in our legislation, and they help the registrar decide whether a concern should be referred to the IC. They help to make sure we make consistent decisions across all investigations and that only appropriate cases are referred to the IC. The criteria we use are explained in the following section.

⁹ Article 52(2)(a) of the Pharmacy Order 2010 and rule 6(2)(a) of the Fitness to Practise and Disqualification etc. Rules 2010



Threshold criteria

The registrar should not refer a case to the IC unless the evidence as a whole suggests that:

Conduct, performance

- it presents an actual or potential risk to patient or public safety
- it undermines, or is likely to undermine, confidence in the pharmacy professions
- there has been a serious or persistent failure to meet any of the standards for pharmacy professionals, or
- the honesty or integrity of the pharmacy professional can no longer be relied upon

Health

- there is adverse physical or mental health which presents a risk to the pharmacy professional's ability to practise safely or effectively

Public interest

- and it is in the public interest to refer

3.6 When considering a case against the conduct, performance and health aspects, the registrar will take into account:

- the behaviour and actions of the pharmacy professional
- whether the pharmacy professional's actions were reckless or intentional
- whether the concern reflects a recurring issue, and
- whether the pharmacy professional acted with openness and honesty
- whether regulatory action is necessary to ensure public protection and maintain public confidence in pharmacy, examples where this may occur include for example where there are concerns involving racism or other discriminatory behaviour or sexual misconduct

3.7 The registrar may also consider the following:

- whether the pharmacy professional has learnt from the incident
- whether the pharmacy professional has taken remedial action, for example by having training or making changes to their practice

- whether previous guidance or advice has been issued to the pharmacy professional about the same or similar matters

3.8 The case will not be referred to the IC if **none** of these criteria are met. It may be closed with no further action, or with informal guidance given.

3.9 If **at least one** of these criteria are met the registrar will then consider the public interest. Public interest considerations are explained in the following section

Public interest considerations

3.10 If the evidence as a whole suggests at least one of the conduct or health aspects of the criteria is met, we will consider whether it is in the public interest to refer the concern to the investigating committee.

3.11 The public interest consideration is an important part of the decision-making framework. It 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.

3.12 When deciding whether it is in the public interest to refer to the IC, the registrar may 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.

3.13 The information will be viewed in the context of the case, our statutory objective to protect the public¹⁰ and the seriousness of the concerns. If the registrar believes it is in the public interest to refer, a referral will be made. If not, the case will not be referred to the IC and may be closed with no further action or with informal guidance.

Available outcomes

3.14 The outcome we decide on will depend on whether any of the conduct, performance or health criteria are met and whether the registrar decides a referral is in the public interest.

3.15 If *any* of the conduct, performance or health criteria are met *and* it is in the public interest to refer the case to the IC, then the registrar will refer.

¹⁰ Article 6 of The Pharmacy Order 2010

3.16 If *none* of the conduct, performance or health criteria are met, then all other outcomes *except* a referral are available.

3.17 If one or more of the criteria are met, *but* it is not in the public interest to refer, then all other outcomes *except* referral are available. This situation would only apply in exceptional circumstances.

3.18 The circumstances when each may apply, and their impact on registration, are set out in the following table.

Outcome	The impact on registration	Circumstances when this may apply
No further action	This is not recorded on the online register. This may be taken into account when investigating any future concerns.	There is a lack of evidence to support the concern that has been raised. The threshold criteria are not met. Also, in the circumstances of the case, informal guidance is not considered appropriate.
Closure with informal guidance	This is not recorded on the online register. However, it may be used when investigating any future concerns. The guidance given should: • be tailored to the concerns • address the relevant professional standards, and • be designed to prevent a similar incident happening in the future	The threshold criteria are not met. The pharmacy professional's actions were not reckless or intended to cause harm, and they can take remedial action. There is no future risk to the public. The registrar believes that informal guidance that addresses specific issues raised in the concern is a proportionate outcome in the circumstances of the case.
Referral to the investigating committee	There is no record of the referral recorded on the online register. However, an outcome from the IC or FtPC may be recorded.	This applies in more serious cases, for example: a serious breach of standards, racial or other discriminatory behaviour or sexual misconduct. It is in the public interest that the case be considered by the investigating committee.

Deciding which outcome is appropriate

3.19 Once we have assessed the conduct, performance and health aspects and the public interest we will make a decision on the outcome. The table below sets out the possible outcomes available.

Conduct, performance, health	Public interest	Possible outcome
None met	Not relevant	No further action Closure with informal guidance
One or more met	Not in public interest to refer	No further action Closure with informal guidance
One or more met	In the public interest to refer	Refer to the IC



4 After a decision has been made

- 4.1 When a case is closed, whether or not informal guidance was given, this information may be used by the GPhC when assessing any future concerns about the pharmacy professional. We may also use this information when inspecting relevant registered pharmacies. We will share information in line with our **publication and disclosure policy**.
- 4.2 Once a decision has been made, we will notify the relevant parties. The case will either be closed (with or without guidance given), or it will continue to the investigating committee. You can see more information on the next stage of the process in **Good decision making: investigating committee meetings and outcomes guidance**.

Quality assurance of decisions

- 4.3 The quality and consistency of decisions we take are very important. We aim to make sure we make fair and proportionate decisions across all investigations, so all decisions are covered by our internal quality assurance processes. This guidance plays a significant part in ensuring that we achieve our goal.



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