

Acceptance criteria

Introduction

Our role

- 1.1 The regulatory remit of the GPhC covers both the **fitness to practise** of individual professionals, as well as the effectiveness of pharmacies and their **systems**. Our role is to **protect the public and uphold public confidence in pharmacy**. We ensure that **pharmacy services provide safe and effective care, and in a way that people can trust**.
- 1.2 Our role includes considering if our registrants are 'fit to practise'. Being fit to practise means that someone has **the appropriate knowledge, skills and health to provide effective healthcare**, and that they behave in an ethical and trustworthy manner.
- 1.3 Where there is a question over an individual's fitness to practise, we have the power to investigate. If we consider that there is a risk to patients, or to public confidence because of the way they are working, we can take enforcement action. This includes being able to place restrictions on their practice or even to prevent them working as a pharmacist or pharmacy technician.
- 1.4 To make sure registered pharmacies are operating safely and effectively, we carry out unannounced **pharmacy inspections**. Additionally, we carry out intelligence-led inspections in response to information we receive which might indicate that a pharmacy is not operating safely. Where we find that there is risk to patients or the public, there are a range of **enforcement measures** which we can take to secure necessary improvements. These include powers to restrict the services being provided.

The purpose of this guidance

- 1.5 Acceptance criteria is intended to provide guidance for members of GPhC staff, pharmacy professionals, members of the public and those who have raised - or are considering raising - concerns about pharmacy related issues. It clarifies those matters for which we can open an investigation into an individual pharmacy professional's fitness to practise, or where we may wish to inspect how safely a pharmacy is operating.
- 1.6 It is important to highlight that **we are a statutory regulator** with specific powers and responsibilities. We are **not a general pharmacy complaints body, and our role is not to resolve disputes** - even when those disputes relate to pharmacy professionals or pharmacies. Similarly, and even where something has gone wrong, we do not have the power to require that an apology be given or to order that compensation be awarded.
- 1.7 Our role, which is governed by law, is limited to those **matters where there is an ongoing risk to patient safety, or where public confidence could be seriously undermined** in pharmacy.

- 1.8 More information about how our fitness to practise process works, including how we make decisions at the end of an investigation, can be found via the following link to our website: **How we deal with concerns**
- 1.9 More information about our pharmacy inspections and enforcement work can be found at the following link: **<https://inspections.pharmacyregulation.org/>**

What are the acceptance criteria for?

- 1.10 Our acceptance criteria are a guide to assist us in deciding whether a concern we have received should be referred for an investigation into an individual's fitness to practise, or considered for potential inspection or enforcement action.
- 1.11 In respect of **pharmacy professionals**, the law states that an individual's fitness to practise can be called into question ('impaired') because of certain specific criteria, and these are detailed in **Article 51 of the Pharmacy Order 2010**.

Grounds of impaired fitness to practise

- Serious professional or personal misconduct.
- Deficient professional performance or competence.
- Adverse physical or mental health which affects the individual's ability to work safely.
- Criminal convictions or cautions and certain other non-conviction disposals.
- A finding by another healthcare regulator that the individual's fitness to practise is 'impaired'.
- being placed on certain 'barred lists' to prevent the individual from working with children or vulnerable adults.

- 1.12 When assessing these criteria, it is also important to take into account whether and to what extent the issue in question departs from our **standards for pharmacy professionals**. Not all departures from standards will call into question a professional's fitness to practise, however, any matters referred to investigation should be able to be attributed to a serious or persistent departure from one or more of the standards.
- 1.13 In respect of **pharmacies**, we require them to meet our **standards for registered pharmacies**, which have five overarching principles. Pharmacy owners, Superintendents and Responsible Pharmacists are accountable for making sure that the standards for registered pharmacies are being met every day.

Standards for pharmacy premises

- Principle 1 - The **governance** arrangements safeguard the health, safety and wellbeing of patients and the public.
- Principle 2 - **Staff** are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.
- Principle 3 - The **environment and condition** of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.
- Principle 4 - The way in which **pharmacy services**, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.
- Principle 5 - The **equipment and facilities** used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

1.14 If a concern we receive meets our acceptance criteria, we will either open an investigation into the fitness to practise of a pharmacy professional, or refer premises or systems related issues to our Inspections team to consider. Where an issue appears to engage both professional and systems related issues, and is sufficiently serious, it will be opened for investigation in order to ensure that both the professional and systems issues can be looked at in a holistic manner.

1.15 Whenever we are assessing concerns, we will always bear in mind:

- our fundamental role in **protecting the public**
- our **standards** for Pharmacy Professionals and Pharmacy Premises
- the wider **public interest** (public confidence)
- Whether the matter poses an **ongoing risk of harm** to patients and the public
- The **intelligence** we hold about the pharmacy, including its inspection, concerns and enforcement history
- Recent **changes in ownership** or Superintendent Pharmacist
- The inspector's **local knowledge**.

1.16 We will regularly review the acceptance criteria to take account of changes to legislation and case law, and to make sure they are consistent with other related guidance documents. We will also make sure they continue to be fit for purpose and accessible to all who need to use them.

Potential actions at triage

1.17 When considering a concern which has been received, there are a number of potential actions which we can take.

Potential outcomes at triage

- Open a fitness to practise investigation.
- Open a fitness to practise investigation and refer the matter to the Interim Orders Committee.
- Refer the matter to the Inspections team for consideration of premises and systems related issues.
- Close and signpost or refer to another more appropriate organisation.
- Close and provide a reminder to a pharmacy professional about the importance of upholding appropriate standards in future.
- Close with no further action.

1.18 In some cases, it can be obvious straightaway that a concern does not need to be investigated or referred to the Inspections team because it does not involve the sort of issue which could call into question a pharmacy professional's fitness to practise, or indicate a serious failing in how a pharmacy is operating. We will normally close these matters with no further action, or possibly with signposting to another organisation.

1.19 If a concern relating to an identified pharmacy professional or pharmacy premises is closed, a record of it will be kept within our internal case management system in accordance with our retention policy. This does not mean that an individual has some sort of negative finding against them, and we will not normally disclose the fact or detail of such closed concerns with any third party. However, it may be something that is considered if any future concerns are raised in relation that pharmacy professional, or pharmacy, and we may need to take into account such previous concerns if it appears that they form a pattern of similar issues.

2. Concerns we will accept

2.1 In their provision of pharmacy services, pharmacy professionals must have regard to our **standards for Pharmacy Professionals** and pharmacy owners must have regard to our **standards for Registered Pharmacies**. As an outcome focussed regulator, we do not specify how each of the standards should be met, but it is for pharmacy professionals and pharmacy owners to use their professional judgement in deciding how to do so and provide safe and effective patient care.

2.2 When considering all concerns, we will first consider whether there may have been a breach of the relevant standards. If so, we will then go on to consider **how serious** any breach may be, and whether there are **risks to the public**, or risks to **maintaining public confidence** in the profession should a matter not be opened. When considering these matters, we will also bear in mind that part of our role as a regulator to **declare and uphold proper standards**, which may mean that action is necessary even if there are no longer continuing risks to patients.

Individual pharmacy professionals

Misconduct

2.3 Misconduct can relate to both personal behaviour as well as professional issues such as mistakes made at work. Not everything that someone may do wrong will amount to misconduct, as the law requires an issue to be especially serious. Therefore, the fact that

someone may have made an error of judgement, or demonstrated an isolated instance of negligence, does not necessarily mean that we will open a formal investigation. When we are considering whether an issue raised with us could be misconduct, we will ask ourselves:

- is the issue **serious**; for example, could it reasonably be viewed as disgraceful, outrageous or deplorable?
- is the issue something that seems to be **part of a pattern** of similar or related matters?
- if the issue is an isolated professional error, is it one which is particularly serious, such as being **reckless** or ignoring high risks?

Conduct more likely to require investigation

- Dishonesty.
- Sexual or racial bullying and harassment.
- Repeated professional errors.
- Recklessness in respect of the handling, management or supply of high-risk medications.
- Actual or attempted inappropriate relationships with patients.
- Failing to be open about professional mistakes, or trying to hide the fact that they occurred (breach of the duty of candour).
- Failing to declare the fact of having received a criminal conviction or caution to the GPhC.
- Supplying medicines without appropriately considering if they are in the best interests of the individual patient.
- Providing services for which a professional does not have sufficient knowledge, experience or skills (acting outside scope of competence).

Conduct less likely to require investigation

- Isolated or minor professional errors that do not indicate an ongoing risk to patients.
- Issues which we consider have already been appropriately addressed locally, and where regulatory action would not achieve anything further.
- Poor customer service or rudeness with no additional features such as physical aggression or verbal threats.

Deficient professional performance

2.4 Deficient professional performance relates to issues which raise a question about whether a professional is **appropriately competent**, or is working to an **acceptable standard**. It will generally relate to either a number of different matters, or a pattern of similar issues.

Performance issues likely to require investigation

- Multiple medicines related errors.
- Failing to learn from mistakes, particularly when provided with feedback and support.
- Continuing to demonstrate poor performance despite having been subject to local performance management interventions.
- Making repeated inappropriate clinical judgements, suggesting a lack of knowledge or understanding.

Performance issues not likely to need investigating

- A small number of, or isolated, issues (though these could still amount to misconduct if sufficiently serious)
- Performance issues which are the subject of ongoing management and supervision, or which have been successfully addressed, at a local level.

Criminal convictions, cautions and disposals

- 2.5 The fact that someone has been convicted, cautioned or otherwise dealt with for a criminal offence does not necessarily mean that further regulatory action is necessary. Our **role is not to punish** people for a second time, and we recognise that that the criminal justice process can be sufficient to suitably deal with low level matters.
- 2.6 We do, however, also have to bear in mind that more serious offences, or those relating to particular types of behaviour, can undermine public trust in the profession and therefore require further action.

Factors likely to suggest impaired fitness to practise

- A sentence of imprisonment or suspended sentence has been imposed.
- The matter relates to a sexual, violent or dishonesty offence.
- The offence is connected to the individual's professional practice.
- Other particular features which mean that public confidence would be undermined without further action.

Factors unlikely to require further action

- Minor driving offences.
- Criminal damage.
- Youth convictions or cautions, unless particularly serious.
- Conditional cautions.
- Protected cautions and convictions.

Adverse health

- 2.7 A pharmacy professional having a health condition, even if they are 'signed-off' from work, does not mean that they are unfit to practise. It is important to understand that being 'unfit to work' is about protecting the welfare of the individual concerned; while being 'unfit to practise' is about **protecting the public**. Consequently, a fitness to practise issue will only arise where someone's health condition is **affecting their ability to provide services safely**, and where there are **inadequate measures** in place to manage the impact of their condition on their work or on themselves.
- 2.8 In deciding whether a health issue should be opened as a fitness to practise case, we will consider:
- the nature of the condition, and whether its effects could impact on the individual's ability to work safely and exercise appropriate professional judgement;
 - whether the individual is managing their condition, such as adhering to treatment and adjusting their working activities appropriate.
- 2.9 Some examples of when we are and are not likely to open a fitness to practise investigation can be found below.

Health issues more likely to require investigation

- Serious performance or behavioural issues where health could be a contributing factor.
- Issues where the individual appears to lack insight into their condition, and its impact on their ability to work safely.
- Matters where an individual has attended work when clearly not fit to do so, for example, while intoxicated.

Factors unlikely to require further action

- Health conditions which do not inherently affect someone's ability to discharge their professional duties.
- Conditions which could have the potential to affect work, but are well managed and with necessary adjustments.
- Substance misuse issues, but where an individual is abstinent and compliant with treatment.
- Mental health issues where the individual has insight into their condition and trigger factors and is suitably supported.

2.10 In situations where an individual has behaved inappropriately but where their health has been a contributing factor, such as stealing medication from a pharmacy or working while intoxicated, we are likely to open a case in respect of both misconduct as well as health. This is because of the fact that **health does not excuse inappropriate behaviour**, even though it might provide some explanation and potential mitigation.

Pharmacy premises and systems

2.11 Similarly to how we assess concerns about individual pharmacy professionals, **not all shortcomings involving a pharmacy will merit inspection or enforcement activity**. We consider whether a particular pharmacy poses any ongoing risks to patients or the public, and **what action is required to address those risks in order to protect the public and uphold our premises standards**.

2.12 The Inspector may:

- Request that the **pharmacy in question is contacted** to establish what action has been or will be taken to address issues and then update their risk assessment.
- Recommend that the matter is referred to the relevant Inspector in order that a **targeted inspection** is be undertaken.
- Recommend that the case should be considered for opening as a fitness to practise **investigation**.
- Recommend that the case should be **closed**.

2.13 Below are outlined each of the standards for Registered Pharmacies, together with some examples of when further inspection activity may or may not be merited.

Principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients and the public

Examples of concerns which likely to be viewed as higher risk, and likely to require a targeted inspection include

- Operating in a manner suggesting a lack of standard operating procedures, or failing to adhere to such.
- Pharmacy staff appearing not to understand their role and responsibilities.
- Inadequate professional indemnity and insurance.
- Indications of inadequate or inaccurate pharmacy records.
- Breaches of confidentiality including failures to dispose of confidential waste securely and misuse of patient information.
- Failures to respond appropriately to safeguarding concerns.

2.14 Isolated dispensing errors not involving high risk medicines, and which have been appropriately dealt with, will not be likely to require inspection activity. Neither will issues which represent customer service type complaints.

Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public

Examples of concerns which are likely to be viewed as high risk, and may require a targeted inspection include

- A lack of suitably qualified staff available to ensure the safe running of the pharmacy.
- Staff working outside the scope of their competence or training.

2.15 Matters not likely to require further inspection activity include staff members using reasonable professional judgement, even though the patient may be unhappy with the outcome.

Principle 3: The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public

Examples of concerns which are likely to be viewed as serious, and may require a targeted inspection include

- Significant health and safety failures.
- Inadequate hygiene and infection control.
- A failure to secure the premises from unauthorised access or use.
- Medicines are sold without obtaining sufficient information to be able to assess whether they are safe and appropriate for the patient - this includes online sales.

2.16 Concerns about premises being untidy, or in a poor state of decoration, are not matters which are likely to require an inspection in the absence of information to suggest actual risk to health and wellbeing.

Principle 4: The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public

Examples of concerns which are likely to be viewed as serious, and require an intelligence - led inspection include

- Indications that pharmacy (P) medicine are sold, prescriptions handed out, in the absence of the responsible pharmacist.
- The potentially unlawful supply of medicines.
- Returned medicines being re-used or not managed or disposed of safely.
- Out of date medicines being supplied.
- Failing to secure controlled drugs.
- Failing to store or transfer medicines requiring refrigeration appropriately.
- Failing to action patient recalls.

2.17 Issues which will not be likely to justify further inspection activity include pharmacies being out of stock of a particular medication, as this can often be out of their control, and the GPhC does not regulate the range and nature of stock which pharmacies are expected to carry. Additionally, delays and difficulties associated with deliveries will not normally indicate significant failings unless it appears that they are repeated, and/or put vulnerable patients at significant risk of harm.

Principle 5: The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public

Examples of concerns which are likely to be viewed as serious, and may require a targeted inspection include

- Inadequate management of equipment or facilities which impacts on the safety of patients.
- Evidence of harm or detriment to a patient due to equipment or facilities.

Communicating outcomes

2.18 Once a decision has been made about whether or not a case meets the acceptance criteria, this decision will be communicated to the person who raised the concern. If the decision has been informed by some information or assurance which has been obtained, then a brief explanation will be provided to enable the person who raised the concern to understand why the matter is not considered sufficiently serious, or does not pose ongoing risks.

2.19 If it has been decided that some Inspection activity is appropriate, it will often not be possible to explain what further activity is likely. This is because of the fact that it is important for the GPhC to be able to undertake inspections on an unannounced basis, in order to get a true picture of how a pharmacy is operating.

Right of review

2.20 Anyone who is dissatisfied by the decision to open or not to open an investigation or make a referral to the inspections team may request a review of that decision.

2.21 Any information provided in support of a request for a review of the decision will form part of the GPhC's investigation (if an investigation is commenced) and could therefore form part of the evidence in the case. A review of the decision will consider the following matters:

- Whether the original decision is **reasonable** and appropriate based on the information provided at the time.
- Whether any **new information** has been provided which now makes it appropriate to come to a different decision to that which was originally reached.

2.22 Requests should be made, **in writing with reasons**, within 21 days of the date of the decision. The decision will be reviewed by a member of the senior management team and a formal review decision issued within 21 days of receipt of the request for a review.

2.23 If a matter has been referred for investigation, the investigation will continue during the period of the review, as will any applications for an interim order should it be considered necessary.