

# Managing concerns: initial assessment guidance





# Contents

<b>About this guidance .....</b>	<b>2</b>
<b>Purpose .....</b>	<b>2</b>
<b>Who this guidance is for .....</b>	<b>2</b>
<b>Equality, diversity and inclusion.....</b>	<b>2</b>
<b>Quality assurance .....</b>	<b>3</b>
<b>Part one: about initial assessment .....</b>	<b>4</b>
<b>About fitness to practise .....</b>	<b>4</b>
<b>What is a concern? .....</b>	<b>4</b>
<b>Part two: remit assessment, assessing risk and immediate action.....</b>	<b>7</b>
<b>Receipt of concerns .....</b>	<b>7</b>
<b>Remit assessment.....</b>	<b>8</b>
<b>Risk assessment.....</b>	<b>13</b>
<b>Part three: making initial enquiries .....</b>	<b>17</b>
<b>Initial enquiries.....</b>	<b>17</b>
<b>Part four: deciding on an outcome .....</b>	<b>27</b>
<b>Concerns that may affect a pharmacy professional's fitness to practise.....</b>	<b>27</b>
<b>Part five: managing the individual concern.....</b>	<b>32</b>
<b>Case Planning .....</b>	<b>32</b>
<b>Managing initial enquiries .....</b>	<b>32</b>
<b>Communication and progress updates.....</b>	<b>32</b>
<b>Assessment of needs .....</b>	<b>35</b>
<b>Additional activities .....</b>	<b>35</b>
<b>Appendix A: Concern process map .....</b>	<b>37</b>
<b>Appendix B: Common concerns.....</b>	<b>38</b>
<b>Appendix C: Sources of advice and assistance .....</b>	<b>39</b>
<b>Appendix D: Signposting .....</b>	<b>40</b>

# About this guidance

## Purpose

1. This guidance is about how we manage concerns once they are raised with us. It provides information about initial assessment, how it is carried out and what outcomes can be decided. Appendix A sets out a map of the whole initial assessment process. This guidance is set out over five parts, as follows, with some additional information in the appendices:
  - **Part one** – about initial assessment
  - **Part two** – remit assessment, assessing risk and immediate action
  - **Part three** – making initial enquiries
  - **Part four** – deciding on an outcome
  - **Part five** – managing the individual concern
2. This guidance aims to:
  - provide a clear approach for consistent and proportionate decision making which encourages decision makers to exercise their judgment in assessing concerns
  - enable effective management and resolution of concerns which do not meet the threshold for further fitness to practise intervention
  - encourage a culture of discussion and exercise of judgement in the assessment of concerns
  - facilitate a focused, proportionate and risk-based approach to our fitness to practise process
  - make sure targeted enquiries are conducted where appropriate to gather information and evidence in a timely manner
  - provide informative and person-centred communication with people who have raised concerns with us
3. This guidance has been developed in line with the aims of our *2030 Vision* and *Strategic Plan 2020-2025* of having a more anticipatory, proportionate and tailored approach to regulating pharmacy.

## Who this guidance is for

4. This guidance is aimed at GPhC colleagues including:
  - Assessment Officers (AOs)
  - Assessment Managers (AMs)
  - Professionals Regulation Teams (PRTs)
  - other colleagues involved in making decisions about a pharmacy professional's fitness to practise

## Equality, diversity and inclusion

5. Equality is fundamental to our work as a health regulator and public body, in line with our legal duties under the Equality Act 2010. Our Equality, Diversity and Inclusion (EDI) Strategy sets out

how our refocused approach to EDI goes beyond legal compliance and intends to shape everything we do, including regulatory decisions, to make sure our processes are demonstrably fair and consider the needs and perspectives of different individuals and groups.

6. While the nine protected characteristics defined in the Equality Act are an essential foundation to our EDI work, we want to go beyond simply delivering interventions that support those who share particular legally protected characteristics. We will, therefore, holistically consider further key aspects such as intersectional perspectives, cultural diversity and influences, socio-economic factors, and language barriers or communication challenges.

## Quality assurance

7. This is a living document which will be updated and revised when necessary. It will be subject to periodic review, which will include an audit of the decisions made using this guidance.

# Part one: about initial assessment

8. This part of the guidance provides some useful background information on initial assessment, including explanations of some key concepts and an overview of our approach.

## About fitness to practise

9. Ensuring that the pharmacy professionals on our register are fit to practise is one of our statutory functions of regulating pharmacy and helps to keep patients and the public safe<sup>1</sup>. The Pharmacy Order 2010<sup>2</sup> makes provision for the GPhC to set fitness to practise procedures to manage concerns raised about a pharmacy professional's fitness to practise.
10. A pharmacy professional is considered fit to practise when they have the skills, knowledge, character and health necessary to do their job safely and effectively and act professionally. In practical terms, this means meeting the principles of good practice set out in our various standards, guidance and advice, and also maintaining appropriate standards of competence and demonstrating good character, both in a personal and professional capacity.
11. Our fitness to practise processes are in place to manage risk and maintain patient safety and are not aimed to be punitive on pharmacy professionals. By making sure pharmacy professionals are fit to practise, it helps us meet our overarching statutory objective to protect the public, which has three aspects to it:
- to protect, promote and maintain the health, safety and wellbeing of the public
  - to promote and maintain public confidence in the professions
  - to promote and maintain proper professional standards and conduct for the profession

## What is a concern?

12. A concern is information that we receive about a pharmacy professional's fitness to practise or an issue with operating practices within a pharmacy. It may include information such as:
- where and in what context the alleged incident took place
  - when the alleged incident took place
  - who was present at the time
  - if there was any harm involved
13. We receive concerns that vary in nature. They can involve one or multiple professionals in a range of roles. Similarly, they can occur in different settings such as a pharmacy premises, an online pharmacy, a hospital, doctors' surgery or in a professional's personal life.
14. Some of the concerns we receive are relatively simple in nature; for example, a professional has broken the law and receives a conviction. Others are more complex. These usually involve a number of professionals in different roles or are about the system in which a number of

---

<sup>1</sup> Article 4(3)(c) of the **Pharmacy Order** 2010 ("the 2010 Order")

<sup>2</sup> Part 6 of the 2010 Order supplemented by the **General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010** ('the 2010 Rules')

professionals, in various roles, have different responsibilities – for example, a responsible pharmacist, superintendent or pharmacy owner.

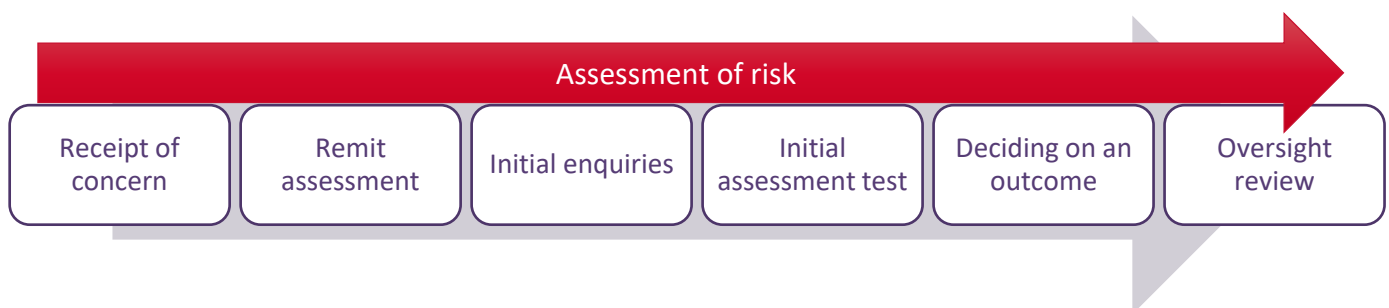
15. The amount of information that is included in a concern can vary, with some being more detailed than others. Every concern will be assessed on an individual basis.

### What is initial assessment and who does it?

16. When we first receive a concern, we assess the information to determine whether it falls within our remit. If it does, we then decide whether we should investigate or if alternative action is more appropriate. We call this process initial assessment and it is undertaken by the Assessment Team. The Assessment Team performs one of the most crucial roles within the GPhC, as it is the gatekeeper to our investigation process, as well being the route via which other regulatory concerns, such as illegal practice and disqualification cases, can be appropriately directed.
17. The Assessment Team reviews all the concerns we receive. As the majority of concerns received do not progress to a full investigation, most of the correspondence issued by the Assessment Team explains the reasons why a concern does not require regulatory action. Because of this, individuals who raise concerns with us have the most contact with the Assessment Team. Therefore, it is vital to make sure that the judgments and decision-making within the initial assessment process are properly evidenced and robust, and that the reasoning behind the decisions made is expressed with sufficient detail and explanation as to both stand up to scrutiny as well as conforming to a person-centred approach.

### The different stages of initial assessment

18. Our approach to initial assessment can, generally speaking, be categorised into the parts illustrated in the graphic below. The majority of the concerns we receive about pharmacy professionals will follow these stages; however, some concerns – for example, those that are not within our remit – will be concluded at that point and others, including those that require immediate action, will be expedited as they present a risk to patient and public safety or potentially impact on public confidence in the professions.



### The enquiries we make and the test we use to support our decision making

19. When information we receive is within our remit, proportionate and targeted enquiries will need to be made to determine whether a full investigation is required. Illegal practice and protection of title concerns will also be subject to some further information gathering prior to being forwarded to investigation colleagues.
20. Each concern about a pharmacy professional should be assessed on its own merits and the types of enquiries made will depend on the nature of the concern. Assessment Officers should exercise their judgment in deciding which lines of enquiries to undertake.

21. Examples of the enquiries that can be made include, but are not limited to:
- requesting relevant medical records
  - contacting organisations where there are ongoing external investigations
  - requests to the pharmacy for any investigations that have taken place, and any copies of reports
22. More information on the enquiries we make can be found in the [initial enquiries section](#).
23. If a concern relates to a pharmacy professional's fitness to practise, and once enquiries into the concern have been completed, Assessment Officers will need to consider the information in the context of a simple test to determine if further investigation is required or an alternative outcome is more appropriate. The test we use is:
- 'Does the information suggest a pharmacy professional's fitness to practise may be currently impaired?'*

### The action we can take

24. Once the information we have received has been considered and initial enquires undertaken, Assessment Officers will need to decide on an appropriate outcome. The possible outcomes are:
- refer those concerns, suitable for investigation, on for consideration at oversight review;
  - refer as intelligence to an inspector for a systems related risk assessment to be undertaken; or,
  - conclude, and refer to the closure review process, with a recommendation of:
    - no further action
    - signposting to another organisation that may be more suitable to help
    - information shared with an inspector
    - a reminder to a pharmacy professional, manager or owner
    - voluntary agreements made with the pharmacy professional
25. Assessment Officers should consider whether either of these are appropriate in cases where the information provided demonstrates sufficient risk to the public, or public confidence in the professions. More information on this can be found in the [risk assessment section](#).



## Part two: remit assessment, assessing risk and immediate action

26. This part of the guidance explains how to do the remit assessment and risk assessment as well as when to take any immediate action with a concern.

### Receipt of concerns

27. There are a number of ways that we receive concerns. Usually, concerns are raised with us via our online concerns form, which are forwarded automatically to the concerns inbox. Concerns can also be sent directly to this inbox. In a small number of cases, an individual will report a concern to us over the phone. In such instances, they will be directed to a member of the Assessment Team who will discuss the concern with them and make a record of it. Very occasionally, we receive hand-written concerns in the post, which should be scanned and uploaded to Case Tracker Docs.
28. We receive concerns from a variety of sources. Most commonly, concerns are raised with us by members of the public, pharmacy professionals (either self-referring a fitness to practise issue or referring a fellow professional), employers or other healthcare professionals. Other sources of concerns include, but are not limited to, the Police, a coroner, other healthcare regulators and our own Inspectorate.

### Anonymous concerns and concerns more than five years old

29. The person raising the concern (PRC) will normally identify themselves to us and provide some contact information so we can liaise with them about their concern. This will not always be the case, however, as PRCs have the option to remain anonymous when completing the online concerns form. All anonymous concerns should be assessed in the same way as other concerns to make sure any risks are identified and we are clear as to whether there is likely to be enough information to support the concern.
30. Where a concern is raised anonymously, and with no named witnesses to the events within the concern, or where the person raising the concern is not willing to engage with an investigation, the AO will consider the likely prospect of being able to obtain information to support the concern and the potential impact of such information. This does not automatically mean we cannot investigate the concerns and the reviewer should explore how this might be done. We are required to be proportionate and recognise that pharmacy professionals are at risk of being the subject of malicious or bad faith complaints. Therefore, we will take this into account where those that raise the concern are unwilling to cooperate, provide further details or information to support their concerns. In some circumstances, the person raising the concern may be vulnerable and, as such, engaging with an investigation may be difficult or not possible. For these scenarios, where we can make alternative enquiries, we will try to do so.
31. If a concern is over 5 years old, it is likely that a formal fitness to practise investigation will not be required, regardless of whether it is within our remit or not. This is because there has been an extended period of time between the alleged incident and the concern being raised with us and so there may be challenges gathering evidence to support the concern. However, in circumstances where the concern raises serious public protection issues or relates to public confidence in the pharmacy professions, we should undertake some initial enquiries to see if an investigation is

required. We may also reopen a concern that has been concluded should new information be provided. The decision to reopen a concern will be taken by the Deputy Head of Professional Regulation.

## Remit assessment

32. The first step of the initial assessment process is to establish whether the concern is within our remit; that is, something we can look into.
33. A concern is within our remit if one or more of the following apply:
  - a) it is, or could be, about a pharmacy professional and relates to one or more of our statutory grounds for impairment<sup>3</sup>,
  - b) it is about an illegal practice issue<sup>4</sup>,
  - c) it is about a protection of title issue<sup>5</sup>, or
  - d) it is about a pharmacy premises (and/or relates to one or more of our disqualification gateways)
34. The remit assessment involves checks to determine whether any of the above apply to the concern. Further information about each criterion and how to check whether it applies to a concern is available below.
35. If a concern falls within our remit, it will progress on to the **initial enquiries** part of the process. Concerns which are outside our remit will be closed, subject to approval from an Assessment Manager or the Deputy Head of Professional Regulation, and the PRC will be told about our decision and the reasons for making it. Where appropriate, they will also be directed to an organisation which may be able to help with their concern (information on signposting is available in appendix D).

### Criterion a: the concern is, or could be, about a pharmacy professional and relates to one or more of our statutory grounds for impairment

#### A pharmacy professional

36. When undertaking a remit assessment, Assessment Officers should firstly attempt to establish, as far as reasonably possible, whether the concern is about a pharmacy professional – a pharmacist or pharmacy technician that is registered with us – or if it could be about a pharmacy professional.
37. Where the PRC has named the individual their concern is about, this would involve, in the first instance, checking our register to see if the individual is a pharmacy professional. If the named individual is not on our register or the PRC has not provided a name in the first place, some limited enquiries should be carried out to try and determine if the concern relates, or could relate, to a pharmacy professional.

---

<sup>3</sup> Article 51 of the Order

<sup>4</sup> Article 3(2), 38(1) and 38(4) of the Order

<sup>5</sup> Article 38(2) of the Order and Section 78 Medicines Act 1968

38. The nature and scope of these enquiries will depend on the concern, but they must be targeted and proportionate. Assessment Officers should exercise their judgement when deciding what enquiries to undertake at this stage of the process. They could include, for example:
- liaising with the PRC to try and ascertain the role the referred individual fulfils at the pharmacy
  - contacting the employer to see if the named individual, or someone with a similar name, works at the pharmacy
  - asking inspections colleagues who may be aware of those who work at particular premises
39. It is important to remember that not all concerns will necessarily appear to relate to a particular individual from the outset. Additionally, it is possible that issues may relate to poor governance and oversight, as opposed to individual incidents, and in such situations a superintendent pharmacist could be considered to be at fault even if not directly involved in the matters raised with us.
40. It is also worth noting that we may, on occasion, receive concerns where the person identified is not a pharmacy professional but a pharmacy professional may be accountable for the issues raised to some extent. For example, a pharmacist or superintendent who failed to take action despite knowing that non-professional staff members were behaving inappropriately or making repeated errors, might require an investigation for allowing such a situation to arise and/or failing to address it.
41. If the Assessment Officer establishes that the concern is, or could be, about a pharmacy professional, they should then consider whether it relates to one or more of our **statutory grounds for impairment**.
42. Alternatively, if the Assessment Officer establishes that a concern is not, or could not be, about a pharmacy professional, it will be closed. Examples of when this may apply include, but are not limited to:
- when the concern is clearly about a different type of professional, such as a doctor or dentist
  - when the concern relates to a professional that practises outside Great Britain and is not registered with us

### Statutory grounds for impairment

43. Our governing legislation sets out the statutory grounds for impairment.<sup>6</sup> They establish whether a concern includes an allegation of impaired fitness to practise. This legislation makes it clear that we must only make enquiries about concerns which amount to an allegation of impaired fitness to practise.
44. The statutory grounds for impairment include, although are not limited to the following:
- misconduct
  - deficient professional performance

---

<sup>6</sup> Article 51 of the 2010 Order

- adverse physical or mental health
  - a conviction or caution in the United Kingdom for a criminal offence (including a criminal conviction elsewhere which would be a criminal offence if committed in England, Wales or Scotland)
  - a determination by another body that the pharmacy professional's fitness to practise is impaired
45. Assessment Officers should decide whether the concern relates to one or more of these categories. When doing so, it will be necessary to use their professional judgement and exercise a degree of caution. Some of the grounds for impairment – such as misconduct, deficient professional performance and adverse health – can cover a broad range of issues. Moreover, while the main issue raised by the PRC may not relate to one of our statutory grounds, there may be another issue involved that does and which the PRC has put less emphasis on but is as important to look into.
46. If a concern relates to one or more of our statutory grounds and there is, or could be, an identifiable pharmacy professional, the concern will move to the **next stage** of the process. Concerns which fall outside our statutory grounds are out of our remit and will therefore be concluded with no further action. In some circumstances we will provide information to make sure the person raising the concern is able to get support from the right organisation.
47. Not every concern raised with us will suggest a pharmacy professional's fitness to practise may be impaired. Some common types of concerns that typically fall outside our remit are outlined in **Appendix 2**.

## Common types of concerns that may indicate a pharmacy professional's fitness to practise is impaired

### Misconduct

48. Concerns relating to misconduct involve behaviour that would be considered to fall short of what would reasonably be expected of a pharmacy professional. It is important to note that not all breaches of our standards will be determined as misconduct.
49. We must use our regulatory powers responsibly which means some low-level matters which cannot be described as serious misconduct will not suggest a pharmacy professional's fitness to practise is currently impaired. Serious misconduct is behaviour which poses a risk to the public or could negatively impact public confidence in the pharmacy professions. Assessment Officers should carefully consider any wider implications of not looking into low level concerns and any impact on patient safety before making a decision. This also relates to concerns that appear to be more appropriate for employers to resolve, for example issues relating to unprofessional conduct.
50. Examples of serious misconduct include inappropriate behaviour, such as not maintaining proper professional boundaries, theft or dishonesty. Other common examples of serious misconduct include dispensing errors with 'aggravating features' that have resulted in or could increase the risk of patient safety concerns, and physical or verbal abuse of colleagues and/or members of the public.
51. Concerns that involve discriminatory behaviour against colleagues or patients will likely mean an investigation is necessary. This is because discriminatory behavior and attitudes are unacceptable in society, undermine public confidence in the pharmacy profession and can have an impact on

the reputation of pharmacy professionals. Examples of discriminatory behaviour include racism, homophobia, sexism and negative behaviour towards individuals with learning disabilities.

52. A pharmacy professional's behaviour outside work may also amount to misconduct if, for example, it has the potential to impact public confidence in the professions.

### **Deficient professional performance**

53. Deficient professional performance is a standard of professional performance that is unacceptably low. It relates to concerns that demonstrate that a pharmacy professional is not practising to the standards expected. Patterns of poor performance that have happened over time or dispensing errors that have occurred consistently over a length of time are common examples of deficient professional performance. In some circumstances, deficient professional performance may also be linked to a health condition and where this is present, it is important to look at the entirety of the concern raised and any impact one has on the other.

### **Adverse physical or mental health**

54. If a pharmacy professional has a health condition which might affect the way they work, we may need to investigate whether they are able to practise safely if there is a suggestion the professional is not able to manage the condition appropriately. In cases where the health condition is not being managed sufficiently, it is likely that fitness to practise action will be necessary.
55. Examples of concerns relating to physical or mental health include long-term or debilitating conditions, untreated or unacknowledged health conditions and substance misuse problems.
56. Not every health concern will require investigation. If the pharmacy professional's health condition does not have the potential to put patients at risk, then we do not need to investigate. This could include, for example, when the professional is managing their health condition and receiving appropriate treatment or when the professional concerned has removed themselves from work in light of their health issues.
57. Assessment Officers should also bear in mind that there is a difference between being deemed unfit to work, i.e. signed off, and not being fit to practise. Being signed off by a doctor as unfit to work is about someone's wellbeing and the management of their condition. Being unfit to practise, however, is about the welfare of the public, and whether someone's health means that they are not able to carry out their duties safely.

### **Criminal caution or conviction**

58. Where a pharmacy professional has received a criminal caution or conviction, we expect them to inform us as soon as possible. Delays in informing us about a criminal caution or conviction can also result in a pharmacy professional's fitness to practise needing to be investigated. Colleagues should bear in mind all the relevant information provided when considering a caution or conviction.
59. Not all cautions or convictions will require formal action, and it is not the role of a regulator to punish someone for a second time. Because of this, a judgement will have to be made about the nature of the offence and how serious it is.

### **A determination by another body that the professional's fitness to practise is impaired**

60. If we receive a determination about a pharmacy professional from another body, it may mean that we need to investigate. This is most likely to arise where the pharmacy professional holds registration with another regulator or equivalent overseas body.

### **Criterion b: the concern is about an illegal practice issue**

61. To practice in Great Britain, pharmacy professionals must be registered with us and satisfy us that they meet our various requirements for pharmacy professionals. Anyone who is not registered with us and practises as a pharmacy professional is breaking the law. We have the power to prosecute individuals that are practising illegally as pharmacy professionals.
62. There are a number of ways that an individual may be practising illegally as a pharmacy professional including, but not limited to, the following examples:
- a former registered pharmacy professional who has been removed from the register as an administrative measure, either because they did not keep up to date with their registration payments or failed to renew their registration, is continuing to practise
  - a former registered pharmacy professional who has been removed from the register by a fitness to practise committee is continuing to practise
  - a registered pharmacy professional who is currently suspended from the register is practising
  - a non-registered member of pharmacy staff is practising beyond their scope
63. If the Assessment Officer receives a concern about an illegal practice issue, they should progress on to the **next stage** of the initial assessment process.

### **Criterion c: the concern is about a protection of title issue**

64. The titles 'pharmacy' and 'chemist' are protected by the law. This means that organisations and businesses operating in Great Britain can only use these titles if they are registered with us. Equally, 'pharmacist' and 'pharmacy technician' are protected titles under UK law. We have the power to prosecute individuals, organisations or businesses operating in Great Britain using any of these titles if they are not registered with us.
65. Where it appears that a concern is about a protected title issue, the Assessment Officer should move on to the **initial enquiries** stage.

### **Criterion d: the concern is about a pharmacy premises and/or relates to one or more of our disqualification gateways**

66. Pharmacy premises must be registered with us in order to operate in Great Britain (England, Wales and Scotland). We have powers under the law to disqualify pharmacies from our register, permanently or for a set period of time. These powers also permit us to disqualify body corporates or individuals from being owners of a registered pharmacy in Great Britain in the future.
67. If a concern has been raised about a pharmacy premises, then the Assessment Officer should check whether it is on our register. If it is, then the concern should move on to the **initial enquiries** stage.

## Risk assessment

68. Risk assessment is an ongoing process which needs to take into account all information and evidence which might reveal an increased risk to patient safety or an impact on public confidence than had previously been identified. Where it has been identified that a concern presents a clear risk to patient and public safety, to colleagues or to the professional, further action is required so that these can be subject to formal assessment and, potentially, immediate action to suspend or restrict practice.
69. When we have completed the assessment, any risks – and the assessment of these risks - will be clearly and consistently recorded on our case management system.

## Immediate action

70. There are two principal avenues for risk-based onward referrals, although there may be occasions where they overlap:
  - i. **Interim order** – a referral may be required for concerns where there is a continuing, immediate and real risk to the public, the referred professional or public confidence in the professions.
  - ii. **Disclosure and Barring Service (DBS)** – a referral may be appropriate when there are safeguarding issues in respect of children and vulnerable adults.
71. PRMs and senior lawyers can provide advice to guide assessments relating to risk management and potential interim orders.

## Ongoing risk assessment

72. Throughout the initial assessment process, we should consider the level of risk presented to patients, members of the public, other colleagues, risk to the pharmacy professional raised in the concern and risk to the reputation of the pharmacy professions.
73. A holistic view of the concern and evidence you have available needs to be done in order to assess risk. This means that you should take into account:
  - the pharmacy professional's previous fitness to practise history – does it demonstrate a pattern of conduct, performance or health?
  - whether the pharmacy professional is currently practising or not and the nature of their practice – are they dispensing, a Responsible Pharmacist or Superintendent Pharmacist, do they have access to vulnerable people in the course of their work?
  - are there any factors known to you that might mitigate the risk (e.g. the pharmacy professional is closely supervised at work, currently not working, in prison)?
  - the nature of the concerns:
    - are they serious (e.g. include violence, crossing of professional boundaries, sexual misconduct or offences against children)?
    - does it involve a vulnerable person (e.g. a child, a disabled person, an elderly person, a person with learning disabilities or poor mental health)?



- is there a criminal investigation or conviction (e.g. has the pharmacy professional been arrested for/charged with/cautioned for/convicted of an offence that includes violence, sexual misconduct, fraud, theft)?
- is the pharmacy professional suffering with a serious health issue (a mental health condition or substance misuse that is not currently or effectively managed)?
- do the concerns identify deficient professional performance (e.g. a pattern of dispensing errors)?

74. When making enquiries, new information may come to light that highlights a risk. The need to take immediate action should always be at the forefront of the Assessment Officer's mind as they make enquiries and consider the information they receive.

75. The table below provides information on potential risks.

Potential risks	
<b>Risks to patients and the public</b>	<ul style="list-style-type: none"> <li>• The professional been convicted of a criminal offence and received a custodial or suspended custodial sentence</li> <li>• Another healthcare regulator determined that the professional's fitness to practise is impaired</li> <li>• The professional has refused to engage or fully co-operate with our health procedures</li> </ul> <p>There is evidence:</p> <ul style="list-style-type: none"> <li>• that the professional is a risk to patient safety</li> <li>• that the working practices of the professional are unsafe and expose the public to risk</li> <li>• of a deliberate intention to cause harm or recklessness as to whether harm may be caused</li> </ul>
<b>Risks to the pharmacy professional</b>	<p>There is evidence:</p> <ul style="list-style-type: none"> <li>• of substance abuse</li> <li>• that the professional lacks insight into their health condition</li> <li>• (medical evidence) which suggests that the professional is not currently fit to practise</li> </ul>
<b>Risks that may impact on public confidence</b>	<p>There is evidence:</p> <ul style="list-style-type: none"> <li>• that the matters alleged have the potential to seriously undermine public confidence in the professions of pharmacy</li> <li>• of an FtP history or likelihood of further offences</li> <li>• The allegation relates to an entry in the Register and we have reasonable grounds for believing that that entry may have been fraudulently procured or incorrectly made</li> </ul>
<b>Aggravating factors</b>	<ul style="list-style-type: none"> <li>• Any relevant additional aggravating factors that indicate risk</li> </ul>

## Concerns that may require immediate action

76. Once the risks have been assessed and recorded, you should determine whether an IO is required.



## Interim orders

77. If there is information to suggest that there is a sufficient risk of harm (and/or other factors in the table below) to potentially require urgent action to restrict the professional's practice, then the matter should be discussed with an Assessment Manager. If the Assessment Manager is in agreement, then a referral to the SPSRL should be made.
78. The table below provides information on some risks that may indicate the need for an IO.

Potential risks	
<b>Necessary for the protection of members of the public</b>	<ul style="list-style-type: none"> <li>There is evidence that the professional is a risk to patient safety and the presence of one of the following means that the risk is increased: <ul style="list-style-type: none"> <li>the professional is currently practising</li> <li>the professional has regular contact with patients and other members of the public in their professional capacity</li> <li>the professional is the sole pharmacist on the premises</li> <li>the working practices of the professional are unsafe and expose the public to risk</li> <li>there is evidence that the matters involve controlled drugs or drugs with potential for abuse</li> </ul> </li> </ul>
<b>In the interests of the professional</b>	<p>There is evidence:</p> <ul style="list-style-type: none"> <li>(medical evidence) which suggests that the professional is not currently fit to practise</li> <li>that the professional lacks insight into their health condition</li> <li>to suggest the professional has been inappropriately self-medicating</li> </ul> <p>The professional:</p> <ul style="list-style-type: none"> <li>has refused to engage or fully co-operate with the GPhC's health procedures</li> <li>has breached an undertaking given to the professional by the GPhC or an FTP Committee</li> <li>engaged with the GPhC's health procedures however new evidence suggests a subsequent deterioration in their health</li> </ul>
<b>Otherwise in the public interest</b>	<p>The professional:</p> <ul style="list-style-type: none"> <li>has received a custodial sentence</li> </ul> <p>There is evidence:</p> <ul style="list-style-type: none"> <li>that the matters alleged have excited widespread media coverage</li> <li>that the matters alleged have the potential to seriously undermine public confidence in the pharmacy professions</li> <li>of a likelihood of further offences</li> </ul>

## Disclosure and Barring Service/Disclosure Scotland

79. The Disclosure and Barring Service (DBS) and Disclosure Scotland (DS) are designed to identify individuals who may have conducted themselves in a manner which, if repeated, could pose a danger to children or vulnerable adults. Typically, such cases may involve inappropriate behaviour towards potentially vulnerable people or abuse of a position of trust. It should be noted that a user of pharmacy services is regarded as automatically falling within the category of being

vulnerable. We have a responsibility to identify and refer individuals to the relevant scheme when necessary.

80. If Assessment Officers come across any concerns that it appears may be necessary to be referred to the DBS, they should send an email to the internal DBS mailbox, **[DBS/DS.Referrals@pharmacyregulation.org](mailto:DBS/DS.Referrals@pharmacyregulation.org)**, providing the name and registration number of the professional and a summary of the concern as well as any relevant evidence. This step is only for a referral to the DBS/DS to be considered, so if Assessment Officers are unsure about whether a concern needs a referral, they should err on the side of caution and submit the concern to the inbox.
81. In cases where a DBS referral is appropriate, Assessment Officers should continue to review the concern following the process outlined in this guidance but be conscious of any delays or impact that the referral may have.

## Part three: making initial enquiries

82. This section sets out the enquiries we should make if a concern is within our remit and does not require any kind of immediate action.

### Initial enquiries

83. Concerns within our remit, and that do not require immediate action, will have some enquiries undertaken across a number of areas to gather further evidence or information. This will inform the most appropriate course of action to take.
84. The scope of these enquiries will depend on the nature of the concern. However, regardless of the issues raised, Assessment Officers should adhere to the following guiding principles when undertaking enquiries:
- each concern should be considered on a case-by-case basis and on its own individual merits – Assessment Officers should avoid drawing comparisons with similar concerns and making decisions based on these comparisons
  - all enquiries should be targeted and proportionate; this means that they focus on establishing if we need to investigate and should not extend beyond what is necessary to answer this question
  - not all of the enquiries outlined below will be appropriate for a particular concern – assessment officers should exercise their judgement when deciding which lines of enquiry are necessary and proportionate in the circumstances
  - all evidence and information gathered should be able to be stored on Case Tracker Docs
  - inspectors should be notified of enquiries about concerns when it is appropriate to do so

### Concerns that may impact a pharmacy professional's fitness to practise

85. For concerns about the fitness to practise of a pharmacy professional, the following enquiries should be made. It is worth remembering that these enquiries should be made in the context of the test that will be applied to determine if we need to investigate, which is:

*Does the information suggest that a pharmacy professional's fitness to practise may be currently impaired?*

#### The impact of the concern

86. As stated above, the overriding objective of our fitness to practise process is to protect the public. Harm or potential harm caused to members of the public by the matter described in the concern will therefore be an important consideration when deciding whether an investigation is necessary.
87. Harm can be physical, emotional, psychological or financial and it should be understood according to the everyday meaning of the word. Potential harm is where a patient or member of the public has been put at risk of harm, either through explicit actions or the inaction of a professional, even if harm may not have ultimately resulted.
88. Pharmacy professionals are more likely to cause harm to members of the public, or put someone at risk of harm, within a professional setting. However, harm or potential harm could also result

from behaviour in their personal life, such as domestic incidents involving vulnerable persons or involvement in discriminatory behaviour.

89. The following lines of enquiry may be useful when trying to establish the impact of the concern:
- liaising with the PRC to understand the nature of the harm and the context in which it came about
  - contacting the pharmacy in which the alleged incident took place for their version of events
  - engaging with our Pharmacy Advisor or a member of our Inspectorate in order to understand the risks associated with a particular medicine
90. Where there is evidence to suggest that a pharmacy professional's actions or failure to act has resulted in harm to a member of the public, or put the public at risk of harm, an investigation will usually be necessary. If the harm or potential harm was brought about by reckless or intentional actions on behalf of the pharmacy professional, it is even more likely that we will need to investigate.
91. In some instances, however, there may be mitigating factors which indicate that, despite the presence of harm or potential harm, an investigation is not appropriate. Mitigating factors could include, for example, evidence of insight, remorse and/or remediation or that the harm is minor. In such instances, the risk to the public may be properly dealt with via other means, such as a reminder to someone involved in the concern or intelligence to our Inspectorate.

#### **Whether there is evidence that the behaviour has been remediated**

92. Remediation is an important consideration when assessing the possibility of the behaviour being repeated. Evidence that the pharmacy professional has remediated may indicate that an investigation is not necessary. This helps us form an overall view of the risk that the pharmacy professional poses to the public. In this context, remediation is when the pharmacy professional takes steps to actively put right the concerns raised about them. When considering remediation, the following will be taken into account:
- Is the concern remediable?
    - Think about the conduct that led to the outcome, and consider whether the conduct itself, and the risks it could pose, can be remedied.
  - Has the concern been remedied?
    - Think about whether the professional recognised what went wrong.
    - Think about whether they have recognised and understood the potential public safety risks of their actions.
93. Assessment Officers should consider contacting the pharmacy professional to inquire into whether they have taken any remedial steps in respect of the concern. Relevant information about remediation may also be available from the professional's employer.
94. When considering remediation, Assessment Officers should pay close attention to the extent to which the activities undertaken by the pharmacy professional have addressed the issues raised in the concern. It should also be noted that some concerns, such as clinical mistakes, are more easily

remedied than others and that on occasions remediation is positive but it does not eliminate the need for an investigation.

#### **Whether the matter appears to be part of a wider pattern of concern**

95. In some cases, a single incident on its own may not be serious enough to suggest there is a risk to the public, and therefore that an investigation is needed. A pattern of concerns, however, may indicate that the pharmacy professional has some deficiencies in their practice which is putting members of the public at risk.
96. Where relevant, Assessment Officers should try and establish whether the incident raised in the concern was a one off or part of a broader pattern of misconduct or poor performance. The referred pharmacy professional's employer may be a good source of information when making such assessments, although a wider pattern of concerns may be evident from the original concern or FtP history. Asking for such requests when they may not be required can be burdensome on employers. Therefore, when deciding whether to ask an employer for this information, Assessment Officers should make sure the request for information is necessary, proportionate and will assist in making a fully informed decision.
97. Evidence that the concern is part of a pattern of behaviour will weigh in favour of an investigation.

#### **Whether the pharmacy professional has any history of fitness to practise concerns**

98. A pharmacy professional's fitness to practise history is a key indicator of the likelihood of repetition and of the risk they pose to the public. While on face value the impact of a concern may be only limited and the possibility of repetition may appear low, the risk to the public is heightened if the pharmacy professional has a history of similar issues being raised against them. Equally, if the professional has no relevant fitness to practise history, this could suggest that the misconduct or poor performance was a one-off incident. However, it should be remembered that we only learn about concerns when they are brought to our attention, which is usually because someone realises something has gone wrong. Patients may not always realise when mistakes have been made and, therefore, it may not always be the case that a single incident reported to us represents a 'one off' or isolated occurrence.
99. A pharmacy professional's fitness to practise history is available on CRM. When examining it, Assessment Officers should pay close attention to the relevance of the fitness to practise history, if there is one. Past concerns which are similar in nature to the one being assessed may point towards the test being met, even though they might not have actually resulted in action being taken on previous occasions.

#### **The likelihood of the behaviour being repeated**

100. Linked to the previous line of enquiry, Assessment Officers should consider, where appropriate, whether the issues raised in the concern are likely to be repeated. This is a key step in understanding the level of risk that the pharmacy professional poses to the public, and therefore whether we need to investigate or not.
101. When considering the likelihood of the behaviour being repeated, the following questions should be assessed:
  - is there any evidence of **remediation**?
  - does the pharmacy professional have any relevant **fitness to practise history**?

- is the matter part of a **wider pattern of concerns**?

102. Assessment Officers should balance any findings on the likelihood of the pharmacy professional's behaviour being repeated against the **impact of the concern**. This is because the higher the level of harm or potential harm, the greater the risk to the public, and public confidence, if the misconduct or poor performance is repeated.
103. If the Assessment Officer decides that there is a likelihood that the concerns will be repeated and the level of harm or risk of harm was significant, the test is likely to be met. However, if the probability of repetition is low and the harm caused is only minimal, an investigation may not be necessary.

**Whether there are any wider systems issues or contextual factors that may have had a bearing on the concern**

104. The context in which the concern took place is an important enquiry, which will be relevant for most fitness to practise concerns. This is because the issues raised may have been unduly influenced by the circumstances in which the professional was practising in at the time. If, for example, a pharmacy professional makes a dispensing error during an extremely busy period at their pharmacy, it may be that the wider context in which they are working played a role in the incident. It is important that the wider context in which a pharmacy professional is working in should be considered when determining if the incident is likely to be repeated.
105. Consideration of the context may also reveal wider systems issues which are putting patients at risk of harm. Such issues could merit formal action against the individuals responsible for ensuring their systems are safe and effective. If an Assessment Officer identifies potential, wider systems issues, they should seek advice on how to proceed. Inspections colleagues and PRMs, for example, are good sources of advice on such matters.
106. When making enquiries, Assessment Officers should consider, as far as reasonably possible, the full context surrounding the concern. Where there is evidence to suggest that contextual factors have influenced the concern, these should be given appropriate weight when deciding on an outcome. One key source could be a published inspection report.

**The need to maintain public confidence or uphold professional standards**

107. As frontline healthcare providers, pharmacy professionals are representatives of the professions and are expected to maintain standards of conduct which are deserving of the trust that patients and the public place in them. We have a responsibility to ensure that public confidence in the pharmacy professions is maintained and that proper professional standards are upheld. This is core aspect of our overarching objective to protect the public.
108. When considering public confidence, the Assessment Officer should think about whether an ordinary, well-informed member of the public who is aware of the concern would lose trust and confidence in the professions on learning about the concerns. They should also bear in mind that maintaining the reputation of the professions as a whole is more important than the interests of an individual pharmacy professional.
109. Actions which potentially undermine public confidence in the professions, irrespective of whether harm has or could have been caused by the pharmacy professional, will usually merit an investigation.

110. Evidence of remediation will not normally have much weight on such consideration, given that remedial steps are unlikely to address an issue where public confidence is at stake. Assessment Officers should therefore avoid placing too much emphasis on remediation when assessing concerns in which action may need to be taken to maintain public confidence or uphold proper professional standards.

**Whether the concern suggests a pharmacy professional has failed to meet any relevant published professional standards or guidance**

111. We set standards for pharmacy professionals to follow during their careers. These standards help ensure that pharmacy professionals are practising safely and effectively. Information which suggests that a pharmacy professional has failed to meet our standards or any of its associated guidance may indicate that the public is at risk of harm. Moreover, in such instances, it may also be necessary to mark the gravity of the behaviour in order to uphold professional standards.
112. Assessment Officers should, where appropriate, consider if the pharmacy professional has failed to meet any relevant published professional standards or guidance. Evidence of serious or persistent failures to meet professionals standards, will indicate that an investigation is necessary. It is worth noting that not all breaches of our standards or guidance will suggest that a pharmacy professional's fitness to practise is potentially impaired.

**Whether there is enough evidence to support an allegation of impaired fitness to practise**

113. Our governing legislation makes it clear that we should only investigate concerns which are capable of being supported evidentially. Assessment Officers will therefore need to carefully consider if the concern has, or will have, enough evidence to support it during an investigation. This could be evidence that is provided by a witness or documentary evidence depending on the nature of the concern.
114. Where a concern has been raised anonymously, there are no named witnesses to the events and/or the person raising the concern is unwilling to cooperate with our investigation, it may be less likely that there is, or will be, enough evidence to support the concern. Similarly, concerns with a significant gap between the time the incident took place and the concern being raised with us may be more challenging to support. Presence of one or more of these factors, however, will not automatically exclude an investigation.

**The outcome of any investigation by another body such as an employer or the police**

115. When available, the outcome of an investigation by another body – such as the pharmacy professional's employer, a healthcare regulator or the Police – should be considered by the Assessment Officer.
116. The evidence gathered and findings of such investigations will often be extremely useful information for assessing whether we need to investigate. Assessment Officers should be cautious, however, not to take the findings of another body's investigation at face value. We should form our own view on the evidence obtained and whether or not the information suggests that the fitness to practise of the pharmacy professional may be currently impaired. The one exception to this is for Police investigations, as we cannot go behind findings of fact from a criminal case.
117. The Assessment Officer will also need to consider whether any action taken as a result of such investigations have sufficiently addressed or mitigated the issues in question, and thereby rendered further regulatory action unnecessary.

### **Whether the concern needs to be shared with another investigatory body**

118. We have a responsibility to share information about concerns with other bodies where it is in the public interest or we are legally required to do so. Before making a decision on the appropriate outcome for the concern, Assessment Officers should consider whether the issues raised in the concern may be relevant to another regulatory body and if it is appropriate to share it with them. Our **publication and disclosure policy** sets out the principles we apply when deciding whether to disclose information to other organisations. Assessment Officers should use our publication and disclosure policy as a guide and seek advice if they are in any doubt.
119. Bodies that we regularly share information with include but are not limited to:
- MHRA (Medicines and Healthcare products Regulatory Agency)
  - CQC (Care Quality Commission)
  - HIW (Healthcare Inspectorate Wales) and HIS (Healthcare Inspectorate Scotland)
  - DBS/DS (Disclosure and Barring Service and Disclosure Scotland)
  - Controlled Drugs Accountable Officers
120. In some circumstances, it may be appropriate for us to share concerns with other health and social care regulators where information may indicate risks to the public or other professionals.<sup>7</sup> This could include:
- situations that may not be seen as an emergency, but which may indicate future risks
  - cultural issues within health and social care settings that may be noticed, but would not necessarily be raised through alternative formal systems
121. If an Assessment Officer thinks it is appropriate to share a concern in these circumstances, they should discuss with a Senior Assessment Officer. If they are in agreement, the decision should be sent to the Deputy Head of Professionals Regulation for final approval.

### **A requirement for employers to notify us whether the professional they are referring, or one that has been referred by a colleague working on the same premises, have themselves recently raised a concern with their employer**

122. When making enquiries, Assessment Officers should be mindful of any potential discrimination or vexatious use of fitness to practise. To help with this they should:
- ask employers to notify us whether the professional they are referring, or one that has been referred by a colleague working on the same premises, have themselves recently raised a concern with their employer
  - check whether the PRC has raised a concern about this professional on a previous occasion
123. Information from either of these enquiries should be included in the oversight review form so it can be considered in the context of the concern.

---

<sup>7</sup> This is in line with the Emerging Concerns Protocol which the GPhC signed alongside other health and social care regulators help share concerns with each other more effectively. For more information see [here](#)



## Further enquiries

124. Assessment Officers should be open and responsive to other lines of enquiry which could inform decision making on whether we need to investigate. They should not limit themselves to the enquiries outlined above if there is another source of easily obtainable information which may help us form a view on the most appropriate outcome. It will be necessary to remember relevance and proportionality. The fact that certain information may be interesting does not necessarily mean it is necessary or relevant for deciding if an investigation is required.
125. Taking witness statements and possession of medicines as evidence will not routinely be required. In the rare instances where such evidence may be felt necessary, advice should be sought as to how best to proceed and who might be the most appropriate person to undertake such steps. Any physical evidence obtained should be recorded and stored in accordance with the **procedure for the management of physical evidence**.

## Health concerns

126. Health concerns need to be handled with care, as it is important to respect the privacy of the professional concerned and recognise that simply because someone suffers from certain health challenges does not mean that their fitness to practise may be impaired. In light of this, health concerns require a slightly different approach to enquiries than other fitness to practise concerns.
127. The task at assessment is to consider whether the health condition has the potential to put patients at risk. If the answer to this is yes, the Assessment Officer will initially request that a Health Information Form (HIF) from the professional's GP/treating Doctor and employer are completed. Once the HIFs are received, an assessment will then be made, based on the information provided, to determine whether the professional's fitness to practise may be currently impaired, with particular regard to the circumstances of the professional and their working arrangements.

## Concerns from employers

128. If an employer is undertaking an investigation into the same concern, or if the concern comes from the employer, we may decide to not refer the matter for an investigation and close it until they have completed their investigation. For example, if there is no immediate risk to patient safety and local evidence is required to substantiate the concern. Each concern will be assessed on a case-by-case basis and we will always continue the investigation when we already have sufficient information to indicate that an IO may be necessary in order to manage the risks posed. In those circumstances, we would ask the employer to contact us once they have concluded their investigation and provide us with a copy of their report. This is because of the fact that, if the employer has not completed their investigation and there is no immediate public safety or public interest risk, we are unlikely to be able to do anything until matters are complete.
129. The AO should consider, however, if it may be appropriate to delay making any enquiries, particularly where an agreement can be put in place with an employer to ensure the effective and timely sharing of relevant information. Each concern will be considered on a case-by-case basis, taking account of the resources of the organisation conducting the investigation.
130. Information from employers can vary. Sometimes, where there is no immediate risk and further information is required, we will wait until any local action, such as an investigation, that is ongoing has been completed. However, on most occasions we will require information to allow us to

decide on the appropriate next steps. Information will be gathered through initial enquiries but as a general guide we should request the following information where it exists:

- any investigation reports
- any root cause analysis
- witness statements from people who saw the events taking place or can explain directly what happened
- where possible, any evidence from the pharmacy professional themselves
- relevant policies or standards in place at the time in circumstances where it is proportionate and will help to make a decision

### Concerns about registered pharmacy premises

131. Where it appears that a concern relates more to a pharmacy premises, systems or processes, as opposed to individuals, such concerns should be referred in the first instance to our Inspectorate so they can consider the information and manage via their inspection and enforcement processes.
132. If those inspection and enforcement processes indicate that systems deficiencies may be attributable to individuals' actions or omissions (such as professionals, SIs, owners or directors), then fitness to practise or disqualification action may also be appropriate.
133. Some concerns that we receive can involve both systemic and professional failings and, in those cases a joint regulatory and co-ordinated approach across both teams will be necessary to protect the public and confidence in the pharmacy professions.

### Illegal practice concerns

134. The Pharmacy Order sets out a number of offences relating to the Register and they are included in the appendix. Where it appears that a concern relates to illegal practice, the Assessment Officer should firstly examine our online register to check if the referred individual is registered or not and the date of registration. If they were registered at the time indicated in the concern, then the matter can be concluded. If the individual was not registered and the information suggests someone has been deliberately or recklessly practising without registration, i.e. practising illegally, then the concern should be referred for investigation. Prior to sending the concern for investigation, the Assessment Officer should attempt to collate the following information:
  - that the person has never been registered or is a non-pharmacy professional
  - that the individual is practising as a pharmacist / pharmacy technician, employed or otherwise
  - the number of occasions the individual worked as a pharmacist/pharmacy technician, employed or otherwise
  - that the individual has used the word 'pharmacist' or 'pharmacy technician' as their title or within their title
  - any harm caused to a patient/member of the public as a result of advice given or medication dispensed by the individual
  - age of the person

- registration history of the person, and the date of first registration
- fitness to practise history of the person – concerns raised/investigated as well as IC/FTPC outcomes
- legal history of the person – cautions/convictions

135. If, however, the information suggests that this may have occurred inadvertently, and for a short period of time, then an Investigation may not be required. In these latter instances, advice should be sought from an SPSRL or Deputy Head of Professionals Regulation.

### Concerns about protection of title

136. Similar to illegal practice concerns, those about protection of title may need to be expedited to investigation colleagues if it appears that the conduct may be deliberate. Prior to referring, as much information about the concern should be gathered to support an efficient investigation. Details about the person, whether they were a professional at any time, what title was used and where will help investigation colleagues. These enquiries should be brief.
137. If the circumstances suggest that there was no prospect of the public being misled as to the nature of a premise or person using a protected title, then an investigation may not be necessary. For example, a cocktail bar calling itself 'The Pharmacy' could not be confused with a provider of healthcare services, and is unlikely to merit formal action. In these situations advice should be sought from an SPSRL or Deputy Head of Professionals Regulation.

### Sources of advice and assistance

138. In undertaking the initial assessment process, particularly enquiries relating to the identification of risk, Assessment Officers may often need to seek advice and assistance from other areas of the organisation, in addition to those available within the Assessment Team. Potential avenues for support, and the issues which they may be able to assist with, are included in appendix C.

### The role of Inspectors

139. Inspectors are key partners in enquiries relating to fitness to practise concerns. Inspectors have significant knowledge, skills and experience to bring to assessments and enquiries. These can be particularly relevant to offering advice on medicines, pharmacy practice and possible lines of enquiry.
140. Given the established relationships between pharmacies and Inspectors, and the greater recognition within the profession of the Inspectors' role, it can often be the case that Inspectors can provide the most effective method of communication and liaison with pharmacy professionals. This includes information gathering or exploring options for concerns to be resolved without the need for a formal investigation. Finally, Inspectors can also offer advice in terms of the planning and conducting of enquiries.
141. For concerns which require initial enquiries and require technical pharmacy knowledge and/or input, Assessment Officers should let the relevant Inspector know at an early stage in the process. This will enable them to review the information, consider any intelligence they may have about the pharmacy or pharmacy professionals concerned and assess and manage any potential risks. It may well be that, in the vast majority of cases, no particular risks arise and no inspection activity is required.

142. Where an Assessment Officer identifies the potential need for more substantive investigative assistance from an Inspector, this will be discussed and agreed with an Assessment Manager. It will also be necessary to discuss matters in advance with the Inspector and/or Regional Manager so they can consider current workloads.
143. Some circumstances where Inspection assistance might be appropriate include the following:
- where a pharmacy visit is justified to obtain evidence or observe operations. (This might, however, be extremely rare for cases which have not been deemed appropriate for referral for investigation, though observational visits can provide helpful assurance)
  - communicating with a pharmacy or pharmacy professional in respect of matters which require some familiarity with medicines or pharmacy systems and processes
  - seeking information from a pharmacy about a clinical or systems error, including ascertaining what measures may have been taken to avoid reoccurrence
  - exploring with a pharmacy whether problems being reported to us by a patient can be readily resolved

## Part four: deciding on an outcome

144. Once all the relevant enquiries have been completed, the Assessment Officer should decide on the appropriate outcome. This section explains how to go about this and focuses solely on concerns about pharmacy professionals.

### Concerns that may affect a pharmacy professional's fitness to practise

145. For fitness to practise cases, Assessment Officers should apply the following test when making a decision on the right outcome:

*Does the information suggest a pharmacy professional's fitness to practise may be currently impaired?*

146. When applying this test, the Assessment Officer should carefully balance all the findings of their enquiries so they can form a holistic view of whether the information as a whole suggests the pharmacy professional's fitness to practise may be currently impaired.
147. *Information suggests* means it's more than a hunch but a less high bar than the *threshold criteria* (which we apply once an investigation concludes). This is a test that determines the appropriate channel, for example, entering into a formal investigation. In most cases, there will be enough evidence to either decide that the concern can proceed to full investigation or that another outcome is appropriate in the circumstances, for example, providing the professional with a reminder about our professional standards.
148. Whether the information suggests the professional's fitness to practise may be impaired will depend upon the assessment of the information available. For example, if care records have been destroyed which are essential to any investigation. The reviewer should avoid speculating or making assumptions about the evidence which may be able to be gathered, or its potential reliability. A robust regulatory process requires appropriate cases to be sufficiently scrutinised and investigated before a proper assessment can be made.
149. When considering the general question, the AO will need to bear in mind that our governing legislation starts from a point of expecting us to only investigate concerns that amount to an allegation of impaired fitness to practise and where that allegation is capable evidentially of being investigated. The Pharmacy Order makes it clear what the categories of impairment are and these are further defined through case law.
150. A pharmacy professional is fit to practise when they have the skills, knowledge, character and health necessary to practise safely and effectively. We will consider a pharmacy professional's fitness to practise to be impaired if:
- they pose a risk to the public,
  - their conduct or performance has undermined, or could undermine, public confidence in the pharmacy professions, or
  - they fail to meet our standards for pharmacy professionals, and it is therefore necessary to send a message to the professions about the standards expected of professionals
151. Assessment Officers should also be mindful of that fact that it is ultimately for a fitness to practise committee to decide whether a pharmacy professional's fitness to practise is impaired and, if so, if

any restriction on their registration or other action is necessary. It is not for Assessment Officers to make a decision on whether the professional is currently impaired, rather they should assess whether the information as a whole suggests that their fitness to practise may be currently impaired.

152. Where there is doubt about the appropriate outcome, Assessment Officers should err on the side of opening an investigation so that the context of the concern can receive further scrutiny.

## Available outcomes

153. There are a number of outcomes available to us for fitness to practise concerns. They include:
- refer those concerns, suitable for investigation, on for consideration at oversight review;
  - refer as intelligence to an inspector for a systems related risk assessment to be undertaken; or,
  - conclude, and refer to the closure review process, with a recommendation of:
    - no further action
    - signposting to another organisation that may be more suitable to help
    - information shared with an inspector
    - a reminder to a pharmacy professional, manager or owner
    - voluntary agreements made with the pharmacy professional
154. When an Assessment Officer is considering an appropriate outcome, it is important they make sure it is proportionate. This means that the outcome should be no more serious than it needs to be to achieve its aims of upholding patient safety and public confidence in the pharmacy professions.
155. Further information on each outcome is included below.

## Oversight review

156. Concerns that meet the test will be referred for oversight review.
157. Assessment Managers will check all concerns being referred for a concerns oversight review (COR) to ensure they are ready for the reviewer. If the Assessment Manager thinks a case clearly requires investigation, and that reviewer consideration would have no benefit, they will tell the Deputy Head of PR that the case is suitable for referral for investigation. If the Deputy Head of PR agrees with the Assessment Manager, then the case will progress to investigation without the need for a reviewer completing a concerns oversight review. The Deputy Head can discuss or check with a reviewer if they think it will help their decision making.
158. Assessment Managers, in all other concerns, will ensure there is enough information for the review to take place effectively and that the concern is accurately captured in the oversight review form. If there are any concerns about the information, the AM should discuss with an SPSRL in advance.
159. The reviewer will look at all concerns being referred for potential investigation by the Assessment Team. This should make sure only those concerns that require a full investigation are referred for

investigation and that we use the full range of regulatory tools available to bring a concern to the appropriate conclusion.

160. In the event of onward referral to investigation by the oversight review, the Assessment Officer should ensure that the OR form includes a summary of the case, all relevant information and an overview of the enquiries conducted to date and the findings of these enquiries. If the case is extremely complex or has been in triage for some time, an additional handover note may be necessary. The purpose of this is to enable the Case Officer who will be dealing with the case to be brought up to speed so they can commence their investigation efficiently.
161. The reviewer may decide that further enquiries are necessary or that an alternative outcome is more appropriate, for example, no further action or sharing information with our Inspectorate.

### **Sharing Information and Intelligence with an Inspector**

162. There will often be concerns which, while falling within our remit, are neither appropriate nor practicable to investigate as fitness to practise issues. These may include the following:
  - where the person raising the concern has refused to engage with the investigation, and where this makes progressing the concern particularly difficult
  - concerns which appear to relate more to a failure in systems or processes, as opposed to particular actions or omissions by individuals
163. In such instances, the Assessment Officer should refer the matter to the relevant Inspector for information or intelligence purposes. The Inspector will then be able to undertake an appropriate risk assessment if required. The information will also inform their knowledge of the pharmacy in question, as well as their decision making about the nature and timing of prospective inspections or whether any other action is required in the short term.
164. The person who raised the concern will be told about this course of action (if one is identified and we have contact details for them), as well as the reasons why the matter is being concluded. This provides people with assurance that, while formal fitness to practise action is not being taken, the information they have provided will inform our wider regulatory role.

### **Reminders to pharmacy professionals and others**

165. There are circumstances where, even though we are not referring a matter for investigation or taking regulatory action, it is appropriate to provide a reminder to a pharmacy professional or other person associated with the delivery of pharmacy services (e.g. a pharmacy manager or owner). The purpose of such reminders is to highlight issues to reflect upon, or to bear in mind for the future. These can include, but are not limited to, aspects of our professional standards and public facing guidance. Reminders are an informal way of encouraging people to deliver person centred care, and to ensure that they behave in a trustworthy manner. In turn, this can help to avoid future regulatory concerns arising.
166. The benefit of a reminder may be identified by an Assessment Officer themselves, by an Inspector or as a consequence of either the oversight review or closure review processes. Common examples of where a reminder may be appropriate include, amongst others:
  - Low level convictions, cautions and conduct related matters
  - Inappropriate use of social media

- Rudeness or poor customer service
- One-off clinical or medicines issues where a refamiliarization of relevant procedures may be beneficial.

167. An Assessment Manager will be responsible for approving the wording of any proposed reminder, and if there is any doubt about the appropriateness of either the reminder or its wording, it will be referred to the Deputy Head of Professionals Regulation. Care may need to be taken in the wording used in a reminder in order to avoid appearing to be preferring a particular version of events where there might be scope for different interpretations or recollections. This is less problematic, however, where there has been a factual finding, such as a conviction, caution or disciplinary outcome, or where the evidence is clear, e.g. CCTV footage, audio recording or screenshots.
168. Where a reminder is given, it may also be useful to refer to this fact in the closure letter to the person who raised the concern, as this can provide reassurance that steps have been taken to maintain proper standards, even if formal action is not required.

### Signpost to another organisation

169. There are occasions when we are not the right organisation to look into the concern that has been raised. In some circumstances, another organisation may be better placed to address the issues set out in the concern. In these circumstances, every effort should be made to identify the right organisation or person to help whoever raised the concern. Where appropriate, we should advise the person concerned that we could review any findings which arise as a result of signposting to another organisation, and reconsider at that point if any fitness to practise issues arise if they inform us of the outcome.
170. Information on where to signpost the person to is included in appendix D.

### No further action and voluntary agreements

171. If the Assessment Officer concludes, with the agreement of an Assessment Manager (or CRF), that there is no evidence to suggest impaired fitness to practise, the case will be concluded with no further action. There are two closure options available:
- The concern can simply be concluded with no further action. This may include, in health cases, providing the professional with information about support and advice or request that they update us if there is a change of circumstances regarding their condition or employment situation.
  - If it is considered that there is a need for some 'light touch' ongoing assurance, the Assessment Officer can come to a Voluntary Agreement with the professional. A guidance note relating to **Voluntary Agreements** sets out the process to be adopted in such cases.

### The closure review process

All cases which an Assessment Officer is proposing for closure, and which do not involve a referral to an Inspector as 'intelligence', must be approved by either an Assessment Manager or the Deputy Head of Professionals Regulation.

172. The closure review process is important for two main reasons:



- it provides assurance that closure decisions are not made by a sole person, and avoids the risk of cases being closed inappropriately, or without some suitable further regulatory action;
- it helps to ensure that avenues for appropriate signposting or resolution are identified, even where closure as a fitness to practise concern is the right outcome.

173. Concerns are appropriate for closure where adequate information has been obtained, and where:

- the concern relates to matters outside our geographical remit
- the concern relates to matters which are outside our regulatory remit – unrelated to a registered pharmacist, pharmacy technician or a registered pharmacy premises
- the concern falls within our remit, but does not meet our initial assessment test – the information does not suggest that an individual pharmacy professional's fitness to practise may be impaired;
- the concern does not meet our initial assessment test, but relates to premises or systems related matters that fall within the responsibility of our Inspectorate
- the concern relates to matters which have already been, or are being, considered or investigated, and which do not relate to any additional registrants or premises.

### **Concerns that may require immediate action during the making of enquiries**

174. There may be occasions when information arises whilst undertaking enquiries that indicate the presence of a significant risk and an interim order may be required or information needs to be shared with a barring authority. The same process will be followed where such risks are identified in the course of the remit assessment or assessment of risk.

### **Concerns about issues that do not relate to a pharmacy professional's practice**

175. There may also be occasions when information arises during the making of enquiries that indicates the presence of a breach of the legislation. For example, an illegal practice or protection of title issue. If this happens the same process will be followed where such risks are identified in the course of the remit assessment or assessment of risk.

## Part five: managing the individual concern

176. Planning, communicating and making sure all the right information is collected are important aspects of initial assessment. This part includes information on a number of areas to support good planning and communication to make sure we are person-centred from when the concern is received until it is concluded or referred for an investigation.

### Case Planning

177. Assessment Officers should be able to clearly demonstrate that the enquiries they have considered are necessary to establish the relevant facts and facilitate an appropriate risk assessment. This is important for future audit and review purposes and effective case management. Assessment Officers should be proportionate in their approach to case planning and only record information that is relevant to the progression or closure of a concern.

### Managing initial enquiries

178. Once matters have been concluded, the Assessment Officer must ensure that they have:
- attached all information / evidence and relevant correspondence to the case folder in CRM
  - completed an Enquiries Case Report form (ECR) and saved it to the case folder, unless the enquiries undertaken or information obtained have been minimal, in which case CRM will be an appropriate recording mechanism. It is important that all documents, evidence, CCTV footage must be saved in a separate file
  - received approval for the closure review process or oversight review process, depending on the outcome recommended
  - ensured that decision related correspondence has been issued, including to the person who has raised the concern as well as, in appropriate cases, the professional
179. If, during the course of enquiries, the Assessment Officer identifies that there is likely to be some delay in matters being concluded, they will discuss this with a Senior Assessment Officer. This should also be noted in CRM. If it is felt that there may be merit in further consideration and discussion of a concern, including potential enquiries, the Assessment Officer and Senior Assessment Officer can agree that the case should be referred to the oversight review process.

### Communication and progress updates

180. It is important that we keep those involved in a concern informed and updated as it progresses. This can help manage expectations, reduce anxiety and effectively manage the concern.

### Person who raised the concern

181. Once an Assessment Officer has begun initial enquiries into a concern, the person who raised the concern with us will be notified by the Assessment Officer. They will explain that further enquiries are required so that the matter can be properly assessed.
182. In their correspondence, Assessment Officers should also provide a provisional timescale for key points in the process in addition to assurance that updates will be provided if it appears that matters will take longer than anticipated.

183. It is important that the person who has raised the concern is kept updated appropriately by the Assessment Officer. If the enquiries appear likely to take longer than 1 month to complete then, as a minimum, the person raising the concern should be updated at least every additional month.

### Pharmacy professional

184. In concerns where the pharmacy professional is identified, Assessment Officers should consider whether to inform and notify the pharmacy professional of the concern. This could include making them aware of the facts, nature and issues that have been raised.

185. Informing the pharmacy professional of a concern that relates to them is important because:

- it demonstrates transparency in our fitness to practise processes
- the professional can provide any information which might help to inform the initial enquiries and decide on an appropriate outcome
- it provides an opportunity for clarification of matters raised
- pharmacy professionals can demonstrate any steps taken to remedy the issues which led to the concern being raised

186. Whether to inform a professional about a concern will depend on the individual circumstances and Assessment Officers should exercise their judgment in deciding whether to inform a professional about the concern. Some examples have been provided below:

- If a pharmacy professional has self-referred a concern, then it is likely that communicating with them is appropriate as they will be aware of the nature and information involved in the concern.
- If the concern is about a caution or conviction, it is likely to be appropriate to contact the pharmacy professional as they will be aware of that caution or conviction.
- If the concern has been referred by an employer, the Assessment Officer should consider any sensitivities around raising the concern and any impact on the professional's place of work and relations with others.
- If the concern relates to a pharmacy professional's health, then the Assessment Officer should consider the individual circumstances of the case. For example, if the pharmacy professional self-referred, then it may be appropriate to contact the pharmacy professional if further initial enquires are necessary.
- Concerns involving fraud or dishonesty may not be appropriate to share with the pharmacy professional if it potentially could impact gathering information and progressing the concern.

187. Assessment Officers should remember that pharmacy professionals are under no obligation to respond to our enquiries at this stage, as there is no regulatory investigation as such. If pharmacy professionals chose not to respond to us, this should not be viewed negatively or against the professional.

### Communicating with the pharmacy professional

188. Assessment Officers should exercise their judgment in deciding which is the most suitable means of contact. This may be an initial phone call followed by an email or letter depending on the

individual circumstances. There may be other appropriate channels for communication, such as through an Inspector or via the relevant superintendent or other role within the wider corporate structures of the pharmacy where the professional works.

189. Assessment Officers should also bear in mind that unexpected contact from the regulator, especially when perceived as relating to fitness to practise, can cause stress and anxiety for pharmacy professionals. Assessment Officers should strive to strike a balance in assessing whether it is appropriate to make contact. Inspectors may provide useful insights and/or advice in circumstances where the pharmacy professional may have anxiety or stress and they can provide an informed perspective on our FtP processes.
190. If the pharmacy professional has been notified, it is important that they are kept updated appropriately by the Assessment Officer. If the enquiries appear likely to take longer than 1 month to complete then, as a minimum, the pharmacy professional should be updated at least every additional month.

## **GPhC colleagues**

191. There may be circumstances where colleagues within the GPhC have an interest in a concern that has been raised with us. Examples of this include:
  - where the new concern relates to a pharmacy professional already subject to a full investigation, or pending a Fitness to Practise Committee
192. where any concern is received involving a controlled drug, the relevant Controlled Drugs Accountable Officer must be made aware of the concern in scenarios such as these, Assessment Officers should advise the relevant colleagues of the concern and nature of the issues involved. This will help identify any similarities, patterns of behaviour or other issues that may be relevant to ongoing cases.

## **Being person-centred**

193. Being person-centred is about focusing on the needs of an individual. Ensuring that we listen, understand people's needs and are responsive to them. It is about humanising what we do, understanding there is a person or people involved in every concern. To support this we have produced some service promises and developed an assessment of needs.
194. People who raise concerns with us, or the professional at the heart of the concern, can find it a stressful experience. We need to make sure we do not add to that stress by the way we communicate and interact with the people involved so we should communicate in a manner which demonstrates empathy. This might include expressing understanding of why a person may feel the way they do about a particular situation, even if we might not feel that way ourselves if we found ourselves in their place.

## **Our service promises**

195. To help us provide a high level of service to the people we come into contact with throughout the process, we will meet the following service promises:
  - communicate with you clearly and tailor our communications to your needs
  - explain what you can expect from us
  - handle your information with care

- act with professionalism, kindness and respect at all times
- provide an accessible service to everyone involved
- listen and respond to feedback and use this to learn and improve our services

196. Further information on the service promises is available [here](#).

## Assessment of needs

197. We will carry out an assessment of needs once a concern is raised with us and we have assessed it as something we can deal with. This will be a short assessment recorded on CRM..
198. It will include the communication needs of any person involved in the concern. For example, whether the person that raised the concern is a family member of someone that has been harmed or whether the professional has a mental health issue or specific communication needs. It will include information to help us tailor our approach or be prepared; for example if someone has a speech impairment and the member of staff needs to listen carefully to what is being said.

## Templates

199. To make sure that our communications are effective and consistent, we have a collection of communication templates, covering a broad range of contact points from the beginning of our concerns process to when it concludes. It is important that Assessment Officers throughout the initial assessment process use the correct templates. Assessment Officers are encouraged, however, to tailor these templates as appropriate to the person being communicated with. They are not intended to appear like a 'standard letter' with the names of the person and Assessment Officer simply added at the beginning and the end.

## Additional activities

200. Some important additional activities are required to complete the recording of the concern and to support policy development as well as meet statutory requirements. Details on these are included below.

## Potential protected disclosures

201. We occasionally receive concerns from employees raising public interest concerns about their employer. We call these types of concerns protected disclosures and they relate to potential wrongdoings at an employee's place of work. They need to be handled with care given the potentially serious nature of the issues being raised and the fact that the PRC, and their colleagues, may be impacted by speaking up.
202. All concerns at initial assessment that are raised by an employee about their employer should be shared with the disclosure inbox. If you are in any doubt as to whether a disclosure is a protected disclosure, it should be referred to the inbox.

## Adding a concern category

203. Achieving consistency and accuracy in how we classify concerns across a variety of fitness to practise issues is important for good analysis, policy development and reporting outputs. We collect a range of data relating to the nature of the concern. These include the more general alleged impairment type that relates to article 51 of the Pharmacy Order and a risk assessment in

the case description. We also need to know about the nature of the concern, i.e. what the concern is about.

### Selecting a category

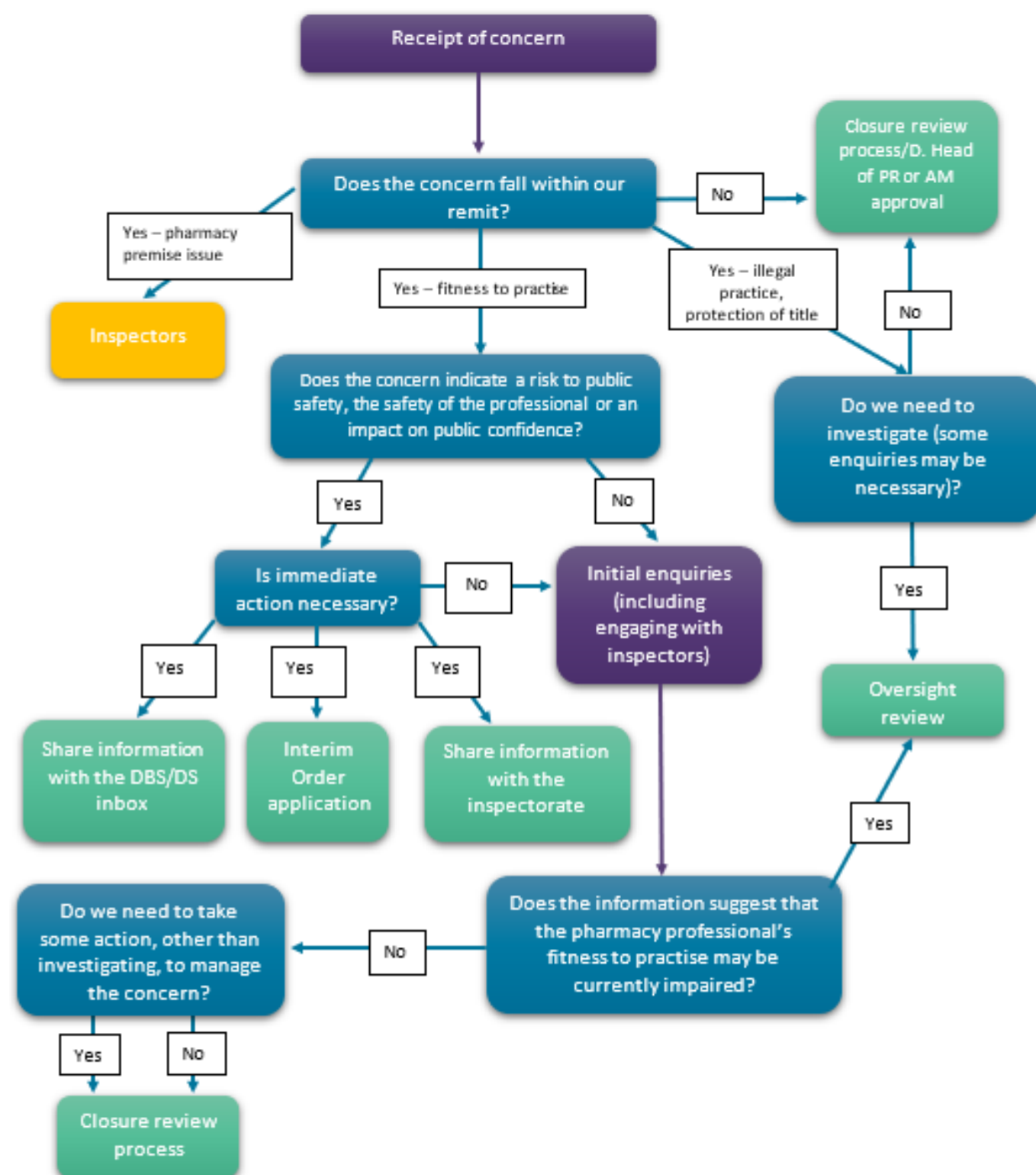
204. A concern category must be selected for each concern that is concluded without the need for an investigation. Concerns should not be classified in a habitual way. Time should be taken to assess the detail of the case in full prior to considering what the appropriate concern category should be. Some will be more straightforward than others. The category that most accurately describes the nature of the concern should be selected.

205. This only applies to concerns that are not referred for investigation.

### List of available categories

Initial category	Investigation categories
<b>Initial assessment</b>	Minor driving/motor vehicle related
	Customer service concerns
	Employment issues
	Advertising issues
	Student/Pre-reg related
	Restricted title issues notified by police (which does not involve a professional)
	Commercial concerns
	Disputes over pharmacy contracts
	Electronic Prescription Service
	Non-pharmacy premises
	COVID-related (no action)
	No evidence of impairment
	Other healthcare professional
	Non-professional pharmacy worker
	International issues
	Personal dispute
	COVID-related (inspector referral)

## Appendix A: Concern process map



## Appendix B: Common concerns

### Common issues which typically fall outside our statutory grounds

It is important to remember that not every concern we receive about a pharmacy professional will relate to one or more of our statutory grounds for impairment. Common examples of concerns which typically fall outside our statutory grounds for impairment are captured in the table below.

Concern Type	Reason for not being an FtP issue
Customer Service	We are not a complaints resolution service, and concerns which relate to day-to-day customer service matters are not fitness to practise issues. However, there may be circumstances where the conduct is such as to amount to a serious failure to treat someone with dignity and respect. Such matters may well require further investigation.
Employment Disputes	Concerns about how someone has been treated as a pharmacy employee, and allegations that their employment rights have been transgressed, are contractual matters rather than fitness to practise issues. There may be circumstances, however, where the conduct amounts to bullying and harassment, or discriminatory behaviour. These sorts of issues are likely to warrant investigation.
Business disputes	Commercial disagreements, which often relate to pharmacy purchases or supply contracts (including locums), are legal disputes which are outside our remit. If there appears to be evidence of fraud or dishonesty, however, then further investigation may be needed.
Electronic Prescription Service (EPS)	The operation of EPS is regulated by the NHS, and will therefore generally fall outside the remit of the GPhC. If, however, it appears that the system may be deliberately being abused for personal gain, including misusing patient data for such a purpose, then investigation may be appropriate, albeit that the NHS may be the suitable body to take the lead in such.
NHS Contractual matters	Issues regarding service standards, such as opening hours, will generally fall within the remit of the NHS, and will therefore be for the NHS to judge and, where appropriate, take action. There may be occasions, however, where it's felt that the issues in question might suggest some underlying issues with the management or operation of the pharmacy. In these instances, it may be appropriate to refer the matter to the relevant Inspector.



## Appendix C: Sources of advice and assistance

Potential avenues for support, and the issues which they may be able to assist with, are outlined below.

Team	Knowledge and Experience
Inspection	<ul style="list-style-type: none"> <li>• Drug uses and effects (including delayed or missed administration).</li> <li>• Pharmacy practice/procedures.</li> <li>• Soft intelligence.</li> <li>• Assistance in making enquiries with pharmacies and pharmacy professionals, where it appears that utilising Inspectors' contacts and local or professional knowledge may be a more effective method of acquiring information, or identifying avenues for resolution.</li> </ul>
Clinical Advisor/Senior Clinical Advisor and Clinical Fellow/Pharmacy Advisor (FtP)	<ul style="list-style-type: none"> <li>• Drug uses and effects (including delayed or missed administration).</li> <li>• Pharmacy practice/procedures.</li> </ul>
Senior Professionals and Systems Regulation Lawyers/Professionals Regulation Managers/Casework Managers	<ul style="list-style-type: none"> <li>• Whether an issue may appear to present a legitimate fitness to practise concern.</li> <li>• Public interest or confidence issues.</li> <li>• Joining new allegations with existing cases.</li> <li>• Whether or not the <b>Threshold Criteria</b> might potentially be met.</li> <li>• Whether or how the fitness to practise history of a professional may indicate an underlying issue.</li> </ul>
The Standards Team	<ul style="list-style-type: none"> <li>• Interpretation of our <b><u>Standards for Pharmacy Professionals.</u></b></li> <li>• Whether or not the professional has acted appropriately.</li> </ul> <p><i>NB The Standards Team will not recommend whether or not a particular concern should be investigated or the manner in which such an investigation should be conducted.</i></p>

## Appendix D: Signposting

Below are a number of organisations which may be able to assist those who have raised concerns with us, but where the case does not appear to be an appropriate fitness to practise issue.

United Kingdom	
<b>Medicines and Healthcare Products Regulatory Agency (MHRA)</b> <a href="mailto:CaseReferrals@mhra.gsi.gov.uk">CaseReferrals@mhra.gsi.gov.uk</a> 020 3080 6000	<ul style="list-style-type: none"> <li>➤ Regulates medicines (including homeopathic and herbal) and medical devices in the UK.</li> <li>➤ Issues import, export, manufacturer and wholesaler of medicines licences.</li> <li>➤ Also investigates websites from other countries, advertising of medicines and unlawful sales of prescription only medicines via the internet or non-pharmacy premises.</li> <li>➤ A whistleblowing charity.</li> </ul>
<b>Public Concern at Work</b> 0207 404 6609 <a href="http://www.pcaw.org.uk">www.pcaw.org.uk</a> <b>Advertising Standards Authority</b> 020 7492 2222 <a href="http://www.asa.org.uk">www.asa.org.uk</a>	<ul style="list-style-type: none"> <li>➤ Regulates advertising and take action on misleading harmful or offensive advertisements.</li> </ul>
<b>Information Commissioners Office</b> 0303 123 1113 <a href="http://www.ico.org.uk/concerns">www.ico.org.uk/concerns</a> <b>Department of Health (DoH)</b> 020 7210 4850	<ul style="list-style-type: none"> <li>➤ Upholds information rights in the public interest and promotes data privacy.</li> <li>➤ Regulates vitamins and nutritional supplements</li> <li>➤ Prison health issues (secure environments)</li> <li>➤ The Medicines, Pharmacy and Industry Division of the DoH are responsible for both the supply chain surrounding medicines and the reimbursement paid to community pharmacies for dispensing medicines.</li> </ul>
<b>Citizens Advice Bureau</b> <a href="http://www.citizensadvice.org.uk">www.citizensadvice.org.uk</a> <b>Health and Safety Executive (HSE)</b> <a href="http://www.hse.gov.uk">www.hse.gov.uk</a>	<ul style="list-style-type: none"> <li>➤ Provides advice on buying goods or services including poor service.</li> <li>➤ Regulates and enforces health and safety - working hours and legal requirements around safety in any workplace.</li> </ul>
<b>Pharmacist Support</b> 0808 168 2233 <a href="http://www.pharmacistsupport.org">www.pharmacistsupport.org</a>	<ul style="list-style-type: none"> <li>➤ An independent charity working for pharmacists and their families, former pharmacists and pharmacy students to provide help and support in times of need.</li> </ul>

<p><b>Association of Pharmacy Technicians UK (APTUK)</b>  <b>National Pharmacy Association (NPA)</b>  <a href="http://www.npa.co.uk">www.npa.co.uk</a>  <b>Pharmacists' Defence Association (PDA)</b>  0121 694 7000  <a href="http://www.the-pda.org">www.the-pda.org</a>  <b>Veterinary Medicines Directorate (VMD)</b>  <a href="http://www.gov.uk/government/organisations/veterinary-medicines-directorate">www.gov.uk/government/organisations/veterinary-medicines-directorate</a></p>	<p>They do not support pharmacy technicians.</p> <ul style="list-style-type: none"> <li>➤ Financial support – including contributions towards the cost of medical assessments and testing.</li> <li>➤ A listening friends service.</li> <li>➤ Advisory service – in partnership with Citizens Advice.</li> <li>➤ Addiction Support – in partnership with Action on Addiction.</li> <li>➤ They don't provide legal representation for FtP proceedings and they don't contribute to the cost of it either.</li> <li>➤ Offers support to pharmacy technicians.</li> <li>➤ Information services for staff if the pharmacy is a member of NPA.</li> <li>➤ A non-profit company that supports pharmacists in legal needs and provides insurance cover.</li> <li>➤ Protects animal health, public health and the environment.</li> <li>➤ Refer to the VMD if there is not a registered pharmacist and the issue is with the medicine.</li> </ul>
<p><b><u>Home Office</u></b></p> <p><b>Controlled Drug Liaison Officers (specialised local police officers)</b></p>	<ul style="list-style-type: none"> <li>➤ Controlled drug matters and enforcement of the Misuse of Drugs Regulations.</li> <li>➤ Issues controlled drug licence.</li> <li>➤ Signpost here if the CDs are not related to a pharmacy or professional.</li> </ul>

England	
<p><b>Local Clinical Commissioning Group (CCG) - overseen by NHS England</b></p>	<ul style="list-style-type: none"> <li>➤ Check that the services are delivering the best possible care and treatment.</li> <li>➤ The relevant CCG can be located by searching <a href="http://www.nhs.uk">www.nhs.uk</a>.</li> <li>➤ They may commission minor ailments services, palliative care schemes, MURs, sharps disposal etc. Award the contract between pharmacies &amp; the NHS.</li> <li>➤ Regulates health and social care services such as hospitals, adult social care, primary care services such as dental and general practices</li> <li>➤ Dispensaries in hospitals and GP surgeries do not have to be registered with the GPhC. If they are not registered</li> </ul>
<p><b>Care Quality Commission (CQC)</b> 03000 616161 <a href="http://www.cqc.org.uk">www.cqc.org.uk</a></p>	

**NHS England**

0300 311 2233

[england.contactus@nhs.net](mailto:england.contactus@nhs.net)**Prescription Pricing Division of NHS Business Services Authority (PPD-NHS-BSA)**[www.nhsbsa.nhs.uk/PrescriptionServices.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices.aspx)**NHS Protect**

020 7895 4500

[generalenquiries@nhsprotect.gsi.gov.uk](mailto:generalenquiries@nhsprotect.gsi.gov.uk)**Environment Agency (EA)**[www.gov.uk/government/organisations/environment-agency](http://www.gov.uk/government/organisations/environment-agency)**NHS England Area Teams**

with the GPhC, refer the complainant to the CQC. The pharmacists must be registered no matter where they work.

- Regulates online prescribing sites where pharmacists are not involved.
- Have many roles including regulating pricing.
- Deal with prescription submissions by pharmacies.
- Aim to identify and tackle crime across the health service.
- Hazardous waste issues and legislation.
- Commission primary care services such as pharmacy contracts, GP and dental services.
- Signpost contractual issue, opening hours etc.

**Scotland****NHS Boards**[www.gov.scot/Topics/Health/NHS-Workforce/NHS-Boards](http://www.gov.scot/Topics/Health/NHS-Workforce/NHS-Boards)**Healthcare Improvement Scotland**[www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)**NHS Borders**

01896 826 719

[www.nhsborders.scot.nhs.uk](http://www.nhsborders.scot.nhs.uk)**NHS Lothian Complaints Team**

0131 536 3370

**Scottish Environment Protection Agency (SEPA)**[www.sepa.org.uk](http://www.sepa.org.uk)

- Equivalent of English NHS Area Teams
- Equivalent of English CQC
- Take complaints about the place the incident occurred e.g. hospital, pharmacy, doctor's surgery. How the service is organised in the area.
- May be able to act as an intermediary between the complainant and the pharmacy/GP surgery
- Hazardous waste issues and legislation

**Wales****Local Health Boards**[www.wales.nhs.uk/ourservices/directory/localhealthboards](http://www.wales.nhs.uk/ourservices/directory/localhealthboards)**Healthcare Inspectorate Wales**[www.hiw.org.uk/home](http://www.hiw.org.uk/home)

- Equivalent of English CCGs
- Plans, secures and deliver healthcare services
- Equivalent of English CQC

**NHS Wales**  
029 2022 7744  
[www.wales.nhs.uk](http://www.wales.nhs.uk)

- Deals with prescription submissions by pharmacies and pricing

### Guernsey

**Mr E Freestone, Chief Pharmacist**  
Princess Elizabeth Hospital, St Martins, Guernsey GY4 6UU  
01481 725241 (these details were accurate in 2014)

- Refer allegations relating to a registered pharmacy in Guernsey to Mr Freestone

### Jersey

**Mr Paul McCabe**  
Jersey General Hospital, St Helier, Gloucester Street, Jersey JE1 3QS. 01534 622314

- Refer allegations relating to a registered pharmacy in Jersey to Mr McCabe

### Isle of Man

**Maria Bell**  
Dept of Health & Social Care, Crookall House, Demesne Road, Douglas, Isle of Man, IM1 3QA.  
01624 642608

- Refer allegations relating to a registered pharmacy in Isle of Man to Mr Morrison

### Medical Assistance

England – NHS 111  
Scotland – NHS 24 (08454 24 24 24)  
Wales – NHS Direct Wales (0845 46 47)

### Other Regulators

**General Medical Council (GMC)**

[www.gmc-uk.org](http://www.gmc-uk.org)  
[gmcftp@gmc-uk.org](mailto:gmcftp@gmc-uk.org)

**General Dental Council (GDC)**

[www.gdc-uk.org](http://www.gdc-uk.org)

**Pharmaceutical Society of Northern Ireland (PSNI)**

[www.psni.org.uk](http://www.psni.org.uk)

**Nursing & Midwifery Council (NMC)**

[www.nmc-uk.org](http://www.nmc-uk.org)

**Health & Care Professions Council (HCPC)**

[www.hpc-uk.org](http://www.hpc-uk.org)

### Representatives of Pharmacy Contractors

**Pharmaceutical Service Negotiation Committee (PSNC) in England**

[www.psnc.org.uk](http://www.psnc.org.uk)

**Community Pharmacy Scotland (CPS) in Scotland**

[www.communitypharmacyscotland.org.uk](http://www.communitypharmacyscotland.org.uk)

**Community Pharmacy Wales (CPW) in Wales**

[www.cpwwales.org.uk](http://www.cpwwales.org.uk)

- These organisations represent pharmacy contractors with NHS contracts, on NHS matters
- Signpost pharmacies/pharmacy professionals
- The PSNC gives advice to pharmacy contractors on NHS services and negotiates on behalf of the contractors

### **Local Pharmaceutical Committees (LPCs)**

with the Department of Health to agree the terms of the NHS contract.

- LPCs are local sub-groups of the PSNC.



