

# Managing concerns about pharmacy professionals: Our strategy for change

October 2020



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# About the GPhC

## Who we are

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain.

We work to assure and improve standards of care for people using pharmacy services.

## What we do

Our role is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy services.

We set standards for pharmacy professionals and pharmacies to enter and remain on our register.

We ask pharmacy professionals and pharmacies for evidence that they are continuing to meet our standards, and this includes inspecting pharmacies.

We act to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.

Through our work we help to promote professionalism, support continuous improvement and assure the quality and safety of pharmacy.



# Foreword

It is an important time for healthcare regulation in general. More specifically, it is an important time for how healthcare regulators manage fitness to practise concerns, as we apply what we have learnt from recently published reports and look forward to changes in the law to help reform regulation. We have the opportunity to review areas of our current approach and change things for the better.

A pharmacy professional may not be fit to practise for a number of reasons. For example, their behaviour may be putting patients at risk, they may be practising in an unsafe way, or their health may be affecting their ability to make safe judgements about their patients. We have a responsibility to make sure that we manage these types of concerns in a way that gives patients and the public better protection while being fair to pharmacy professionals.

We need a robust approach that:

- upholds standards
- maintains public confidence, and
- protects patients by taking action quickly when serious issues arise

But the approach also needs to enable professionals to achieve the standards required, by giving them an opportunity to put things right and learn and improve when it's right to do so. Some of the changes needed can be achieved partly through changes in the law. But changes to regulations can be slow, so our strategy describes the steps we can take now that don't need changes to our legislation.

The recent pandemic has reminded us all of how important it is to consider the wider context when understanding the nature of a concern about a pharmacy professional and identifying the appropriate outcome or action. Often an individual professional's behaviour may point to there being a wider system failing. The pandemic has also highlighted how much patients and the public rely on the professionalism of people providing care in the face of new challenges and different ways of working. As pharmacy and healthcare continue to evolve, and demands on pharmacy increase, we need to enable professionals to continue to practise safely.

We need to challenge ourselves by asking fundamental questions about the purpose of fitness to practise, and what it means to the public we protect and the professionals on our register. We are therefore developing a strategy that will clearly set out what we will do in the coming years.

This is part of our programme for change as we work towards legislative reform and begin to deliver **our Vision 2030**. This is an ambitious 10-year vision for safe and effective pharmacy care at the heart of healthier communities. We have also published our **strategic plan 2020-25**. This describes the work we plan to do in the coming five years to help us achieve our 10-year vision, including:

- delivering effective, consistent and fair regulation, and

- shifting the balance of our approach towards more anticipatory, proportionate and tailored approaches to regulating pharmacy

We are also developing our equality, diversity and inclusion (EDI) strategy alongside this fitness to practise strategy. We are committed to demonstrating how our approach to fitness to practise will support our EDI work.

## Overview

We have a responsibility to make sure that our fitness to practise (FtP) work remains relevant and that we continue to deliver our main objective of protecting the public. We want to move away from a process which can be adversarial and slow, and have an unintended adverse impact on the people involved. Instead, we want to take quick action to protect patients when that is needed, while at the same time promoting and encouraging a learning culture that allows pharmacy professionals to deal with any concerns and go back to practising in appropriate circumstances. We are therefore consulting until 22 January 2021 on developing our strategy for managing concerns about pharmacy professionals.

The strategy has been influenced by what we heard through our conversations with stakeholders and the people within the GPhC who deal with FtP concerns, and by the expected changes to the regulations covering FtP procedures. The strategy will build on improvements we've already made to the way we manage concerns. We believe this will help us to protect the public in a more effective, fair and proportionate way. The strategy helps us deliver on our commitments in the recently published strategic plan and also contributes to the 2030 vision.

Over the last eighteen months we've carried out a range of research and engagement work to help prepare our strategy. It is clear from this work that our present approach to fitness to practise can't remain as it is, and needs to change. In developing the strategy we have taken account of the following:

- stakeholder engagement that took place in the summer of 2019. For example, we spoke to patient organisations, professional bodies, legal defence organisations, representative bodies, employers and other health regulators
- a review into how a number of regulators from within and outside of healthcare regulation have changed their approaches to managing concerns. This includes views on the future of regulation as set out by Social Work England (SWE)
- a number of reports, including **the Professional Standards Authority's (PSA) Lessons Learned report** into the Nursing and Midwifery Council's handling of the cases relating to the Morecambe Bay maternity deaths (May 2018); the findings of **the report into patient deaths at Gosport Memorial Hospital** (June 2018); the **Williams review into gross negligence manslaughter** (June 2018); and the PSA's report **How is public confidence maintained when fitness to practise decisions are made?**
- what we learnt from our own response to the impact of the COVID-19 pandemic, including the use of remote hearings

We have also taken account of the PSA's published guidance *Right-touch reform: A new framework for assurance of professions*. The report included a number of guiding principles for fitness to practise reform. For example, it proposed using fitness to practise measures only when necessary, aiming for early resolution

and giving professionals the opportunity to put things right when this was appropriate.

## This consultation

This consultation covers two main areas:

- our strategic aims and outcomes
- our proposals and how we will achieve them

We are asking for your views on our proposed strategy, including the following key aspects:

- its strategic aims and outcomes
- a new approach to assessing concerns once they are raised with us
- the introduction of several, more flexible, outcomes to conclude a concern
- dealing with any inequalities and bias within decision-making
- improving the service we give by being more person-centred
- sharing best practice and learning from others

We want to hear your views about the impact of our proposals on patients, the public, pharmacy professionals and employers. We welcome responses from anyone with an interest in fitness to practise. But we are particularly interested to hear the views of patients, the public and pharmacy professionals – especially people who have been involved in a fitness to practise concern – and individuals and organisations representing professionals and patients.

# The consultation process

The consultation will run for 12 weeks and will close on 22 January 2021. During this time, we welcome feedback from individuals and organisations. We will send this document to a range of stakeholders, including patients' representative bodies, pharmacy professionals, pharmacy owners and others with an interest in this area.

Our person-centred work has already started. We are also making improvements to act on what we learnt from the PSA's review of our performance in 2018/19. We are working with other regulators to prepare for the new regulations which will introduce further changes in 2021 and beyond.

## Our report on this consultation

Once the consultation period ends, we will analyse what we have heard through the consultation, focus groups, workshops and face-to-face meetings. We will publish a report summarising what we have heard. Our Council will consider the feedback at a meeting in Spring 2021 before making decisions on our proposals. We will clearly communicate the decisions that our Council makes. If our Council approves, we expect to start implementing the changes in Spring 2021. We will set up formal work streams to make sure we deliver on our commitments, and will deliver these in partnership with stakeholders when this is appropriate.

We will publish our analysis of the responses and an explanation of the decisions we take.

You will be able to see this on our website [www.pharmacyregulation.org](http://www.pharmacyregulation.org).

## Why we consult

We have to consult before we set any standards or requirements under the Pharmacy Order 2010. We will also consult when we need to do this to make sure we carry out our statutory functions effectively and proportionately in meeting our overall aim of protecting the public.

## Responding to the consultation

### How we use your information

We will use your response to help us develop our work. We ask you to give us some background information about you and, if you respond on behalf of an organisation, about your organisation. We use this to help us analyse the possible impact of our plans on different groups. We are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties. There is an equality monitoring form at the end of the survey. You do not have to fill it in, but if you do, it will give us useful information to check that this happens.

### How we share your information

If you respond as a private individual, we will not use your name or publish your individual response. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full

unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

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

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

### Your rights

Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you, and you may also ask us to delete your response. For more information about your rights and who to contact please read our privacy policy on our website.

### How to respond

You can respond to this consultation by going to [pharmacyregulation.org/managing-concerns-consultation](https://pharmacyregulation.org/managing-concerns-consultation) and filling in the online questionnaire there.

We encourage respondents to use the online questionnaire. However, if you want to send a response by email, please write your response to the consultation questions and send it to us at [consultations@pharmacyregulation.org](mailto:consultations@pharmacyregulation.org).

### Other formats

Please contact us at [communications@pharmacyregulation.org](mailto:communications@pharmacyregulation.org) if you would like a copy of the consultation survey in another format (for example, in larger type or in a different language).

### Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to: [feedback@pharmacyregulation.org](mailto:feedback@pharmacyregulation.org), or post them to us at:

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

Please do not send consultation responses to this address.

# Our proposals

## Our present approach to fitness to practise and the issues we want to address

You can see our present approach to fitness to practise in the following guidance documents:

- **Good decision making: Investigations and threshold criteria guidance**
- **Good decision making: Investigating committee meetings and outcomes guidance**
- **Good decision making: Fitness to practise hearings and sanctions guidance**

We have already started to make improvements to the way we manage concerns. To make sure we focus our resources on the right concerns, our assessment of new concerns now involves people at a more senior level in the GPhC. This has given us an extra assurance that we are progressing concerns, or closing them, using the most appropriate route. We also use new 'threshold criteria' to help us decide which concerns should be referred to our Investigating Committee.

We have begun work to help people better understand our fitness to practise processes and the possible outcomes from them. This includes improving our communications with people involved in the process and improving the reasons we give for our decisions.

Looking further upstream, even earlier in the process, we have also been talking to stakeholders about managing concerns about pharmacy students and trainee technicians.

Professionalism is an important cornerstone for future pharmacy professionals too. Understanding what it means to be a professional in the early stages of their pharmacy career will help students prepare for the future and manage any potential concerns better.

We want to build on these improvements to deal with the wider issues we have identified through our strategy development work.

The fitness to practise process is still seen as being overly legalistic and adversarial. It is largely rigid and reactive when it needs to be flexible and proactive. To the patients, families, witnesses and professionals involved, the present approach can be confusing, inconsistent and slow. For employers, it's not always clear what amounts to a concern that should be referred to the regulator.

Investigations into concerns about professionals take a long time and can be frustrating for everyone involved. How we contact people, and the method and tone of our communications, can lead to unintended consequences such as an adverse impact on the mental health of the people we are investigating. Vulnerable people can find it hard to get support.

We need to make more progress on cutting down the time it takes to conclude cases. We accept that in the interests of fairness, some cases need more in-depth investigation. This will inevitably take time. But we need to find a balance and make efficiencies where we can, taking no longer than necessary to achieve the right outcome.



We need to better understand why we get a higher number of concerns about black, Asian and minority ethnic (BAME) professionals than we ought to expect statistically. Also, when we progress a concern, we need to be sure that we are minimising and dealing with the risk of potential biases in our decision-making.

We need to understand more about the impact of a professional not having legal representation or not attending a hearing, as our analysis shows this can result in a more serious outcome. We need to explore what we can do to help professionals understand the support available during the process and make use of it.

The number of concerns raised with us is going up year on year and puts pressure on resources. (**Our latest annual report** gives an overview of concerns received: who they are from and how they are concluded.) We also need to work 'smarter' within our legal limits to make operational efficiencies so that we can conclude concerns more quickly. There will be some efficiencies following the changes to the regulations. But there is a lot we can do ahead of these changes.

# Section one: Strategic aims and outcomes

## Strategic aims

We used what we learnt from our engagement and reviews to develop four strategic aims which will be the heart of this strategy. These aims reflect our ambition to drive improvement by promoting a just, learning culture for the benefit of patient and public safety and everyone in the pharmacy sector.

Our strategic aims are to:

- keep patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns
- take a person-centred approach that is fair, inclusive and free from discrimination and bias
- shift the perception from blame and punishment to openness, learning and improvement
- take account of context and work with others to deal with problems in the wider pharmacy and healthcare systems

## Strategic outcomes

To help us evaluate and measure the success of any changes we make, we have identified the following strategic outcomes. This is what we aim to achieve by taking action as a result of this strategy:

- Patients and the public receive safe and effective care because pharmacy professionals are safe to practise and can

get any support they may need to help them meet our standards.

- Professionals understand the importance of being open and honest, and that if they acknowledge any mistakes quickly this will minimise the need for a fitness to practise investigation.
- It is easy to raise a concern, and understand the process and what it means to everyone involved.
- Our decisions are clear, timely, free of bias, proportionate and deal with the cause of the regulatory concern.
- Professionals, patients, the public and any witnesses feel confident and supported to take part in the process.
- Our stakeholders are confident we are taking appropriate action to deal with concerns, even if we do not start a formal fitness to practise investigation.
- More concerns are resolved safely at an earlier stage through support, reflection and learning, without the need for a hearing.
- Only the most serious concerns reach a hearing.



## Section two: Our proposals and how we will achieve them

We explain below what we mean by each strategic aim and say what we will do to achieve each one.

### **Strategic aim 1: Keeping patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns**

Fitness to practise is about patient safety and public protection and we will act quickly to uphold these when a serious issue arises. We realise that there will be situations when the only outcome can be restrictions on a pharmacy professional's practice or their removal from practice. But we don't think that these cases are the norm. We will make sure that only the most serious concerns reach a hearing.

Sometimes a concern will reveal a wider system failure and a future public-protection issue. Regulatory action against an individual professional may not be enough, or even needed, to make sure this is dealt with. We will consider all the relevant factors and risks around what went wrong, including assessing whether there are underlying system failures.

We will only use formal fitness to practise processes when it is absolutely necessary. When we can, we will aim for early solutions and remediation (giving the professional the chance to put things right). Most pharmacy

professionals who have difficulties in their practice are willing and able to improve and put the problem right. We want to break down the barriers that stop them from doing so as early as possible. We will work with employers, other regulators and those that set our standards to achieve this goal.

Local investigations which are focused on learning and reflection, rather than blame, can manage risks better and lead to improvements to patient safety. Employers may often be best placed to recognise and manage some concerns. We will work with employers to help them identify the types of concerns that can be managed locally for faster, more focused and fairer resolutions.

There may be some concerns which don't present an ongoing risk or where the risk to the public has already been removed. It may be that these concerns do not need to be investigated. It may be in the public interest to take a 'restorative' approach: allowing the pharmacy professional to continue working or return to work, whenever this approach can be managed safely.

Managing certain types of health and performance concerns differently will allow a pharmacy professional – who has remediated, learnt and reflected – to return to safe practice as soon as it is right for them to do this. To help with this, pharmacy professionals will be encouraged to be open about what has

happened and to talk to us as early as possible about what they have done to put things right.

### How we will achieve this

#### Making more enquiries when we first receive concerns

We will develop proposals for making more enquiries in the early stages of our process after receiving a concern. This will help us make sure we investigate the right concerns, and that those that can be resolved through other means are dealt with more quickly.

The enquiries we make will look at:

- the impact of the concern on patient and public safety
- the likelihood of the behaviour being repeated
- whether there is enough evidence to support an allegation of impaired fitness to practise
- whether the concern suggests a pharmacy professional has failed to meet any relevant published professional standards or guidance
- the outcome of any investigation by another body such as an employer or the police
- whether the pharmacy professional has any history of fitness to practise concerns
- whether the matter appears to be part of a wider pattern of concern
- whether there are any wider systems issues or considerations

Once we have finished our enquiries we will use the following test to decide if the concern

should be referred for an investigation or whether an alternative is appropriate in the circumstances:

*Does the information suggest potential grounds for investigating whether a pharmacy professional's fitness to practise may be impaired?*

#### Taking quick action to protect patients and the public

Using this approach will help us take action quickly on the most serious concerns. We will be able to quickly identify any risk to patient safety and either refer these for immediate investigation or consider an interim order of suspension.

#### Introducing a flexible range of outcomes to manage some concerns outside our formal processes

We will use revalidation as a way of promoting reflection and learning. We will introduce a **reflective piece** for some concerns if there are health and performance issues.

Once we finish our enquiries we may, depending on the circumstances of the concern, ask the professional to complete a reflective piece specifically related to the nature of the concern. For example, we may ask them to tell us how they intend to deal with some shortcomings in performance or what they have learnt from a particular matter. We would aim to involve the employer so that everyone in the working environment can learn from it. The professional can submit the piece either as part of their revalidation or separately depending on timing.

We want to raise awareness about **voluntary agreements**. We can use these to support



professionals to voluntarily deal with issues with their practice, so that any potential risk doesn't develop into a future patient-safety issue. We already have these agreements in place and they have helped a number of professionals to remain in practice.

We will introduce an **information pack** for professionals who have health issues that don't pose a risk to patient safety. The pack will include material to support professionals with health issues, and detailed advice on where to go for support: for example, Pharmacist Support. There will also be learning points from professionals who have managed similar concerns.

We will consider wider use of **voluntary removal** from the register in appropriate cases. This will allow professionals who want to, to be removed. This would only apply to cases where there was no public interest in pursuing the concern through normal fitness to practise processes: for example, if there was a serious mental health or personal issue.

Discussions with stakeholders suggested that **mediation** could be used as an alternative to formal fitness to practise procedures, and that it could bring benefits to patients and the public as well as professionals. We understand that it has been successfully introduced in other regulated fields. We are keen to explore mediation as an alternative outcome and want to understand more about how we might use it.

### **Supporting employers and people making referrals**

We will develop and publish guidance, referral tools, templates and case studies for employers. This will help them:

- understand which cases they should refer to us, and
- decide when they are better placed to manage and resolve concerns quickly at local level when there is no immediate risk to patient or public safety

We will develop a web-based tool to share with employers the things we learn from the concerns we see, and how these are successfully resolved.

## **Strategic aim 2: Taking a person-centred approach that is fair, inclusive and free from discrimination and bias**

Taking a person-centred approach will help us recognise that everyone is an individual with different needs. It means we will be able to better understand the concern about the pharmacy professional. And it will help us understand the impact of our approach on the people directly affected: patients, their families and carers, as well as the wider public and pharmacy professionals.

We have a responsibility to make sure that everyone understands our FtP process so they have a clear expectation of what it can, and should, do for them and what it cannot do. If we are open and clear about this – and treat everyone involved with dignity, respect, empathy and compassion – this will help maintain public confidence in pharmacy and how we regulate it.

We know that when a concern is raised about a pharmacy professional it can have an impact on their mental health. A more person-centred approach can also help reduce the impact on pharmacy professionals.

Being fair and inclusive at all times is important. This isn't just because this is a statutory and regulatory requirement, but because we as a regulator can – and do our best to – make sure all aspects of pharmacy training, employment and service provision are fair, appropriate and inclusive. We do not want there to be any barriers in dealing with us once a concern has been raised. Nor do we want there to be any

when someone has a concern they want to self-report, such as a health issue.

We acknowledge that pharmacy professionals from BAME backgrounds are overrepresented in fitness to practise proceedings, and that this is because there are more referrals to us – across a range of sources – affecting these groups. We need to make sure that we are minimising and dealing with the risk of potential biases in our decision-making. We also need to better understand why we receive a disproportionate number of referrals in the first place. We deal with this point below under strategic aim 4.

### **How we will achieve this**

#### **Our website and communications**

We will provide better information on the type of concerns we deal with and how we deal with them. We will also improve the section of our website that people use to submit concerns. We have already started work on revising our online content and the online facility for submitting concerns.

We will also revise all our 'template' communications in line with our tone of voice and style guide, and learn from people who have been involved with a concern. We will use what we have learnt from other organisations, for example the NHS accessible information standard.

#### **Our service promises**

To help us provide a high level of service to the people we come into contact with throughout the process, we have developed some service promises.



We are committed to taking a person-centred approach to fitness to practise. This means we will put you at the centre of what we do.

To do this we will:

**Table 1: Our fitness to practise promises**

<b>Promise</b>	<b>What it means</b>
<b>Communicate with you clearly and tailor our communications to your needs</b>	<p>We recognise that communication is a two-way process and we want to make it as easy as possible for you to understand all aspects of the fitness to practise process.</p> <p>We will listen to you and adapt our communication methods based on your needs, accessibility requirements and preferences.</p> <p>We will try to contact you at a time and place that suits you.</p> <p>If you have a concern raised about you, or you have raised concerns about someone else, you will have a dedicated member of staff assigned to you. They will be your main point of contact to answer any questions you may have.</p> <p>We will tell you the likely timescales at the start of the investigation to reduce uncertainty, and keep you up to date throughout the process.</p>
<b>Explain what you can expect from us</b>	<p>We want to help you resolve your concerns appropriately and effectively. However, sometimes there may be concerns that we can't deal with directly. When this happens, we will explain clearly why this is the case and will help point you in the direction of an organisation who can help.</p>
<b>Handle your information with care</b>	<p>We will keep all personal and sensitive information confidential in line with data protection legislation. We will take extra care when handling information about health and protected characteristics.</p> <p>We may share health-related information with other organisations who can offer further support, but we will discuss this with you before we do that.</p>

Promise	What it means
<b>Act with professionalism, kindness and respect at all times</b>	Our staff are trained to act with courtesy, empathy and professionalism to help make sure concerns are managed appropriately and effectively.
<b>Provide an accessible service to everyone involved</b>	We want everyone involved to have a high-quality, transparent and accessible service, and feel that our fitness to practise processes are efficient and effective. In line with our Equality, Diversity and Inclusion commitment, we will make sure that our services are accessible and appropriate for everyone involved.
<b>Listen and respond to feedback and use this to learn and improve our services</b>	We are committed to providing a high-quality service. But if something goes wrong or we fall short of expected standards we want you to tell us about it. This will help us learn from our mistakes and improve our standards. We see this not as a nuisance, but rather as valuable feedback on the quality of our services. Equally, if you have experienced great service from our organisation, or you feel someone deserves praise, we encourage you to let us know.

**An ‘assessment of needs’ once we receive a concern**

We will develop an *assessment of needs* to make sure that people are at the centre of the concern once it is received.

This is a short assessment that records the 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 also alert us early on to whether there are any potentially vulnerable witnesses who we need to treat more sensitively.

**Being fair and inclusive**

We will speak to professional and representative bodies and pharmacy professionals to improve our understanding of the potential barriers that may prevent groups and individuals being able to engage effectively with us because of one or more protected characteristics. This will help us identify effective ways to deal with these barriers.

We are looking at the idea of providing lay advocacy services for patients, carers or witnesses who may need them.

We will also see if there is more we can do for professionals who aren’t legally represented. For example, we could provide support through guidance on the importance of being



represented, information on sources of support or partnerships with organisations that provide representation services.

We have successfully held some hearings remotely by videolink during the pandemic. We had the consent of everyone involved, and the response has been positive while public protection has been maintained. We are keen to take the positives from this period and to hear stakeholders' views on the potential benefits of continuing with some remote hearings in future, including the types of circumstances when this might be appropriate.

### **Dealing with discrimination and eliminating bias**

We will continue to provide training to all key FtP decision-makers on unconscious bias in decision-making. We will also carry out a pilot project to look into unbiased Investigating Committee decisions. The pilot aims to test if there is a way to minimise unconscious bias in decision-making by removing references to personal characteristics such as race and ethnicity from documents seen by the Investigating Committee.

We are developing our equality, diversity and inclusion strategy alongside this fitness to practise strategy. We are committed to demonstrating how our approach to fitness to practise will support our EDI work.

### **Managing concerns about pharmacy professionals with mental health conditions**

The mental health of a professional may be the basis of a concern, or contribute to a problem. A mental health condition may also affect how an individual can engage with support and the FtP

process itself. Being involved in the process can make some mental health conditions worse. We need to help the professional to engage with us so we can find the appropriate outcome.

We will make sure staff are trained to understand the nature of mental health issues and manage conversations sensitively when a concern is raised, or a professional self-refers. We will consider whether an issue can be resolved appropriately outside the formal FtP processes while still managing any risk to patient safety. This could be through a voluntary agreement, asking for a reflective piece, giving the professional an information pack, or through local support measures organised by an employer.

However, if a pharmacy professional's conduct calls into question their fitness to practise and they also have a mental health condition, their behaviour may need to be addressed by fitness to practise processes as well as support.

### **Personal experience statements**

We will look at the physical and emotional harm that might have been suffered by a patient or family member involved in raising a concern. We may do this during our initial enquiries or through a full investigation. This will help us understand the seriousness of any concern and help us decide on the appropriate outcome.

There are benefits and challenges attached to the timing of when we take these personal experience statements into account as we move through the various stages of fitness to practise. We are keen to get a better understanding of the wider implications and appropriateness of their use.

### **Strategic aim 3: Shifting the perception from blame and punishment to openness, learning and improvement**

Our conversations with stakeholders clearly showed that there was:

- a perception of punishment and blame attached to the FtP process, and
- a reluctance among professionals to contact the regulator

This means pharmacy professionals are likely to be concerned about how the regulator will view their fitness to practise, no matter what the nature of any concern is. For example, they may be reluctant to report a dispensing error or self-report a health concern.

If professionals conceal, or don't report, incidents this can affect patient safety. It also does not promote a professional culture of openness, learning and improvement.

We want pharmacy professionals to understand that learning and reflective practice is a basic part of professionalism. We know that when professionals are open and honest, and demonstrate that they have learnt from mistakes, it helps to promote a professional, just culture that will contribute to improving patient safety.

#### **How we will achieve this**

##### **Knowledge hub for case studies, insights and sharing learning**

We will promote a culture of learning, reflection and improvement when something has gone wrong. For example, we will develop a

'knowledge hub' to share insights and learning from a number of aspects of fitness to practise. This will include case studies for employers about referrals and action taken to avoid the need for a referral. We will also publish anonymised cases where we haven't taken any regulatory action, because:

- effective local action or remediation measures were taken, or
- they are examples of good learning when something has gone wrong

##### **Continuous improvement**

We want to include people who have been involved in a concern in helping us to improve. We will ask for feedback at various points and from various participants, including witnesses. This will include asking for feedback after the end of a case. This will make sure we continuously evaluate and improve the approach we take and the information we share.

##### **Engagement with educators and employers**

We want to help prevent things going wrong in the first place. We will do this by promoting a better understanding of the purpose of fitness to practise, and of professionalism and the importance of learning and reflection. We will work with educators, students and trainees by introducing new guidance for managing concerns in education and training. Supporting professionalism in this way could eventually lead to more effective and safer healthcare practice, and fewer concerns being raised about pharmacy professionals.

At the moment we are carrying out engagement activities across Great Britain. This includes our



inspectors and Directors for Wales and Scotland engaging with schools of pharmacy, pharmacy technician educators and key stakeholders. We want to work more closely with communications colleagues to make sure we share learning from, and communicate consistently across, all our engagement.

We will look at how we can most effectively liaise and engage with employers and educators to:

- give advice on issues related to fair and restorative regulation
- deliver events to share learning and good practice and to embed professional values and behaviours
- provide regular learning and feedback on FtP issues, including case studies on current and emerging issues.

## **Strategic aim 4: Taking account of the context and working with others to address problems in the wider pharmacy and healthcare systems**

We need to look beyond the individual and see the wider context when we assess concerns. Regulatory action against an individual professional may not be enough, or even needed, to make sure that a wider problem and a future public-protection issue has been dealt with. The root cause of an incident may be a wider system failing rather than an individual professional's behaviour. It is important that we consider all the relevant factors and risks around what went wrong, including assessing whether there are underlying system failures.

The wider context also includes changes in the role of the pharmacy professional, the scope and location of pharmacy practices, and how pharmacy services are delivered. Technological innovations, such as a shift to online services, and professionals working together as multi-disciplinary teams more often, show that pharmacy is still evolving. We need to anticipate the impact of these changes and be prepared to manage any new issues that appear.

When it is appropriate, we need to work with others to tackle wider system issues. For example, we are working with a range of other regulators to make sure we each play our part in ensuring that online pharmacy services are regulated effectively. We have also been working with the Competition and Markets Authority during the pandemic. This was to make clear our respective roles and responsibilities over concerns about essential

products being sold at excessively high prices in a small number of pharmacies.

We are not the only regulator facing challenges in developing good practice in how we consider equality, diversity and inclusion. Other regulators are facing similar challenges. We need to learn from the concerns referred to us, and share this with others within pharmacy and the broader healthcare sector, to influence them and find solutions to shared problems.

### **How we will achieve this**

#### **Consider the wider pharmacy context**

When we assess a concern, we will consider the wider context within which the professional is working and decide on the most appropriate way of managing the concern. This will help us understand if there is any alternative action we could take, or any action we could take alongside our usual process.

We will use all available sources of information when assessing the risk to patient and public safety. This includes making sure that public protection risks are managed effectively by the right people, including our team of inspectors. We will do this by taking action focused on ending any risk caused by the way a pharmacy is operating.

We can also share information we gather about the wider context with employers. This will support our work in developing a culture of openness, learning and improvement.

#### **Work with other regulators**

We will share information and work with other regulators who may be investigating the same incident or individual, to make sure we move



our investigations forward as quickly and effectively as we can.

We will also learn from and share good practice with other regulators on building EDI into our approach to fitness to practise. And we will explore opportunities for joint working when they're in the interests of public protection.

We need to improve our understanding of why we get a disproportionately high number of concerns about BAME professionals, and the context in which these are made. During 2019/20 55% of the concerns we received were from members of the public, with 17% from other healthcare professionals and 7% from employers. We are considering collecting more data about the sources of concerns, to help us take the appropriate action to deal with any bias that we discover.

We will work with other organisations facing similar challenges. We want to learn and adopt the best practices for dealing with this disproportionate representation, both when concerns are raised and throughout the process.

We will continue to improve our understanding of the impact of our approach and learn more about the approaches taken by other regulated healthcare professions. This will help us improve and be consistent where we can. For example, we will work with other regulators to understand and learn about what they do in supporting professionalism and prevention. As we work through the proposals for regulatory reform, we will also continue to share regulatory good practice and bring our approach into line with other regulators, when we can.

We will use our data to find trends and factors that often appear in concerns. We will share these with others, including employers and other regulators, to help prevent issues occurring or happening again. We will also share with other regulators what we learn from concerns where there is multi-disciplinary team-working, or where pharmacy professionals work in what for them are relatively new settings, for example, general practice.

# Consultation questions

We welcome your views on the following consultation questions. Please go to [pharmacyregulation.org/managing-concerns-consultation](https://pharmacyregulation.org/managing-concerns-consultation) to fill in the online survey.

Our strategy includes a number of proposals on which we are asking for views, and a number of areas that we are exploring. The consultation gives you an opportunity to influence how we get involved in these new areas.

## Section one: Strategic aims and outcomes

On page 12, we identify four strategic aims that will guide our work and help us to evaluate the impact of the strategy. We want your views on whether we have identified the right strategic aims.

1. Considering all four strategic aims, to what extent do you agree or disagree that these are appropriate?
  - Strongly agree
  - Agree
  - Neither agree nor disagree
  - Disagree
  - Strongly disagree
  - Don't know
2. Is there anything missing from the strategic aims, or anything that should be changed?
  - Yes
  - No
  - Don't know
- 2a. If yes, which of the following strategic aims need additions and/or amendments?  
(Please tick all that apply)
  - keep patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns
  - take a person-centred approach that is fair, inclusive and free from discrimination and bias



- shift the perception from blame and punishment to openness, learning and improvement
  - take account of context and work with others to deal with problems in the wider pharmacy and healthcare systems
  - additional aims are needed
- 2b.** Please give a brief description of the amendments, additions, or additional aims you think are needed.
- 3.** Considering the full set of strategic outcomes on page 12, to what extent do you agree or disagree that these are appropriate?
- Strongly agree
  - Agree
  - Neither agree nor disagree
  - Disagree
  - Strongly disagree
  - Don't know
- 4.** Is there anything missing from the strategic outcomes, or anything that should be changed?
- Yes
  - No
  - Don't know
- 4a.** If yes, which of the following strategic outcomes need additions and/or amendments? (Please tick all that apply)
- Patients and the public receive safe and effective care because pharmacy professionals are safe to practise and can get any support they may need to help them meet our standards.
  - Professionals understand the importance of being open and honest, and that if they acknowledge any mistakes quickly this will minimise the need for a fitness to practise investigation.
  - It is easy to raise a concern, and understand the process and what it means to everyone involved.
  - Our decisions are clear, timely, free of bias, proportionate and deal with the cause of the regulatory concern.
  - Professionals, patients, the public and any witnesses feel confident and supported to take part in the process.
  - Our stakeholders are confident we are taking appropriate action to deal with concerns, even if we do not start a formal fitness to practise investigation.
  - More concerns are resolved safely at an earlier stage through support, reflection and learning, without the need for a hearing.
  - Only the most serious concerns reach a hearing.
  - Additional outcomes are needed.
- 4b.** Please give a brief description of the amendments, additions, or additional outcomes you think are needed.

## Section two: Our proposals and how we will achieve them

We are proposing to make more enquiries when we first receive a concern, to help us gather enough evidence to make an informed decision on the most suitable action to take. We set out the areas of enquiry on page 14.

5. Have we identified the appropriate areas of enquiry?
- Yes
  - No
  - Don't know

After our enquiries conclude, we also propose to apply the following test to decide if a concern should be referred for investigation or an alternative is appropriate in the circumstances:

*Does the information suggest potential grounds for investigating whether a pharmacy professional's fitness to practise may be impaired?*

6. To what extent do you agree or disagree that the proposed test is appropriate?
- Strongly agree
  - Agree
  - Neither agree nor disagree
  - Disagree
  - Strongly disagree
  - Don't know
7. Please explain your responses to the two questions above.

We are proposing to invite pharmacy professionals in certain cases to produce a reflective piece as a way of managing some

concerns outside the formal processes. This proposal is set out on page 14.

8. To what extent do you agree or disagree that this is an appropriate and effective outcome for some concerns?
- Strongly agree
  - Agree
  - Neither agree nor disagree
  - Disagree
  - Strongly disagree
  - Don't know

9. Please explain your response.

Our discussions with stakeholders, including our work looking at other regulators, showed that mediation could play a role in resolving concerns.

10. To what extent do you agree or disagree that mediation can play a role in resolving concerns about pharmacy professionals?
- Strongly agree
  - Agree
  - Neither agree nor disagree
  - Disagree
  - Strongly disagree
  - Don't know

11. Please explain your response including, if it is appropriate, what form you think the mediation should take.

To make sure we put people at the heart of what we do, we are proposing a number of service promises that set out what you should

expect from us. These are included in the table on pages 17 and 18.

**12.** Do you think our service promises give you clear expectations of the service you will receive from us?

- Yes
- No
- Don't know

**13.** Please explain your response.

We want to improve our understanding about the potential barriers that may prevent groups and individuals being able to engage effectively with us because of one or more protected characteristics. This will help us develop effective measures to remove these barriers.

In particular, we want to understand whether people who share one or more protected characteristics encounter specific barriers in our fitness to practise processes, because of those characteristics, once a concern has been raised. Under the Equality Act 2010, there are nine protected characteristics:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race/ethnicity
- religion or belief
- sex
- sexual orientation

**14.** Do you think people who share one or more protected characteristics encounter specific

barriers in our fitness to practise processes because of that characteristic?

- Yes
- No
- Don't know

**14a.** If yes, please explain including any measures to remove these barriers.

During the pandemic we have learnt that remote hearings can be effective, but we know they shouldn't replace our usual ones. We want to understand more about when they could be used and what impact they may have.

**15.** Do you think that to continue with remote hearings would:

**a.** disadvantage anyone?

- Yes
- No
- Don't know

**b.** present any risks to a fair hearing?

- Yes
- No
- Don't know

**c.** have benefits for those involved?

- Yes
- No
- Don't know

**16.** Please explain your response.

We want to get a better understanding of the wider implications and appropriateness of using personal experience statements (see page 19) – from the people affected by the concern – in the fitness to practise process. The statements

could be taken into account at any stage, including during an investigation, at an investigating committee, or at a fitness to practise hearing.

**17.** Do you think that we should take personal experience statements into account when deciding what regulatory action is suitable?

- Yes
- No
- Don't know

**18.** Please explain your response.

We are committed to improving, and learning from people's experiences of being involved in a concern. We know we can improve how we communicate with people throughout our process to get feedback from everyone involved.

**19.** What methods would be effective in getting feedback from, and understanding the experience of, people that have raised a concern or had a concern raised against them?

We will consider the wider context within which a professional is working when we assess concerns and decide on the most appropriate way of managing the concern. We think that if we can better understand the context, then we can better identify whether there is a fitness to practise concern at all, or whether the issue would be better dealt with in another way, for example through our inspections.

**20.** To what extent do you agree or disagree that the wider context within which a professional is working should be a significant factor when assessing a concern?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

**21.** Please explain your response.

We plan to improve our website, website materials (guidance about what we deal with and guidance for witnesses) and online form for raising a concern. This is to improve the support we give to patients and the public involved in the fitness to practise process.

**22.** Are there any other ways, not identified in our proposals, we could provide support to patients and the public involved in the fitness to practise process?

We want to understand whether our proposals may have a positive or negative impact on any individuals or groups sharing any of the protected characteristics in the Equality Act 2010.

The protected characteristics are:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race/ethnicity
- religion or belief
- sex
- sexual orientation



**23.** Do you think our proposals will have a positive or negative impact on individuals or groups who share any of the protected characteristics?

- Yes - positive impact
- Yes - negative impact
- Yes - both positive and negative impact
- No impact
- Don't know

We also want to know if our proposals will have any other impact on any other individuals or groups (not related to protected characteristics), for example: patients, pharmacy owners or pharmacy staff.

**24.** Do you think our proposals would have a positive or negative impact on any other individuals or groups?

- Yes - positive impact
- Yes - negative impact
- Yes - positive and negative impact
- No impact
- Don't know

**25.** Please give comments explaining your answers to the two impact questions above. Please describe the individuals or groups concerned and the impact you think our proposals would have.



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