

The General Pharmaceutical Council's (GPhC) Fitness to Practise strategy 'Managing concerns about pharmacy professionals: Our strategy for change'

Section one: Strategic aims and outcomes

1. Considering all four strategic aims (page 12), to what extent do you agree or disagree that these are appropriate?

Aims are:

- 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

Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
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2. Is there anything missing from the strategy aims, or anything that should be changed?

Yes	No	Don't know
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2a. If yes, which of the strategic aims need additions and/or amendments?

Shift the perception from blame and punishment to openness, learning and improvement.

2b. Please give a brief description of the amendments, additions, or additional aims you think are needed.

Your four strategic aims are appropriate and relevant. Our [corporate strategy](#) for 2021-25, which covers all of our regulatory functions, shares similar messages and we also aim to have a fitness to practise process that is fast, focused, fair and forward looking. We agree that it is important to move away from a blame culture and you might want to consider a greater emphasis on how you will, and work with others to, support a more just culture in healthcare services. As part of that, it is important that pharmacy professionals are supported to raise public interest concerns, and it could be helpful to explicitly state that in your strategic aims. In recent years, we have added in greater safeguards to ensure that our processes are not used as retaliation against doctors who have raised public interest concerns.

3. Considering the full set of strategic outcomes (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
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4. Is there anything missing from the strategy aims, or anything that should be changed?

Yes	No	Don't know
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4a. If yes, which of the strategic outcomes need additions and/or amendments?

Professionals, patients, the public and any witnesses feel confident and supported to take part in the process.

4b. Please give a brief description of the amendments, additions, or additional outcomes you think are needed.

The strategic outcomes outlined seem appropriate and a good basis upon which to evaluate the success of any changes made. Again, we note they reflect similar commitments set out in our [corporate strategy](#).

There may be an opportunity to widen the above outcome to ensure that registrants who are referred to you after they have raised a concern about their workplace or environment feel supported, rather than in fear of reprisal. We address this by opening a provisional enquiry rather than a full investigation in order to ascertain if there is independent evidence to corroborate allegations about a doctor who has previously raised concerns in the wider public interest. More details about our approach can be found in our provisional enquiries [guidance](#).

We think that that hearings should focus on aspects of a case that are in dispute as opposed to 'only the most serious cases reaching a hearing'; however, we are aware that legislative reform is needed to achieve this. Whilst we agree with the approach you have outlined based on the current legal framework, we think that it might be helpful to consider in light of the direction for legislative reform.

Finally, we are not clear about how you intend to measure if the outcomes have been met. It might be helpful to provide further information about how you intend to do so.

Section two: our proposals and how we will achieve them

5. **The GPhC propose making more enquiries when they first receive a concern, to help gather enough evidence to make an informed decision on the most suitable action to take. Have they identified the appropriate areas of enquiry?** *Areas of enquiry: the impact of the concern on patient and public safety, the likelihood of the behaviour being repeated, evidence available to support the allegation, outcome of other investigations, FtP history, any wider patterns of concern, whether the individual has failed to meet professional standards and any wider systems issues or considerations.*

Yes	No	Don't know
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6. **To what extent do you agree that the proposed test 'Does the information suggest potential grounds for investigating whether a pharmacy professionals' fitness to practise may be impaired?' is appropriate to apply to decide if a concern should be investigated?**

Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
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7. Please explain your responses to the two questions above.

Appropriate areas of enquiry

We agree the eight areas of enquiry detailed on page 14 of the consultation document are appropriate. We currently undertake similar limited enquiries following initial receipt of a concern. The aim of these limited enquiries is to gather targeted information to help us decide whether a question is raised about a doctor's current fitness to practise. This is known as our provisional enquiry process. More details about our approach can be found in our published [guidance](#) on our ['how we make our decisions' page](#).

We've found in many cases provisional enquiries help to assess risk as early in the process as possible and to identify and promote cases needing full investigation. In turn, this enables us to respond quicker and more proportionately by closing cases without the need for a full investigation, which has the benefit of reducing stress to doctors and complainants. The types of information we gather through this process include medical records, objective evidence from local investigations, and any wider patient or public safety issues. We consider evidence of insight and remediation where the concern relates to specific categories of clinical care only during provisional enquiries.

Threshold test

We note you've used the word 'potential' when considering whether the information suggests there are grounds for investigating. This may set quite a low threshold and could have an impact on the volume of concerns that would need to be investigated. It is not clear from the information available if this is intentional. We apply a threshold test of 'whether the concern raised suggests that the doctor's fitness to practise is currently impaired.'

8. The GPhC propose introducing a reflective piece as a way of managing some concerns outside the formal processes. For example, the professional might be asked how they intend to deal with some shortcomings in performance. The professional can submit the reflective piece as part of revalidation or separately depending on timing (page 14). To what extent do you agree that this is an appropriate and effective outcome for some concerns?

Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know
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9. Please explain your response.

As currently described your proposal is not clear on the distinction between reflection for continuous professional development purposes and evidence of insight and remediation which is

relevant to considering fitness to practise concerns. Therefore, it's difficult to provide feedback on the proposals.

Reflection and being [a reflective practitioner](#) are important features of continued professional development for healthcare professionals and form part of our model of revalidation for doctors. Within the context of revalidation, we ask doctors to reflect on the supporting information they have collected and what it says about their practice, using local appraisals as a supportive and developmental forum at which to discuss their reflections. Reflection through appraisal should form part of an ongoing process of continual improvement rather than a point in time exercise.

Reflection should not substitute or override other processes that are necessary to discuss, record and escalate significant events and serious incidents. It should also not substitute fitness to practise processes where the concern raised would meet the threshold for investigation. There are some cases referred to us which don't reach the threshold for investigation but where we will exercise our discretion to notify the doctor and their Responsible Officer (RO) or employer of the concerns identified, with the expectation they will be considered as part of the doctor's annual appraisal; however, once we've notified the doctor's RO or employer we don't have direct involvement or oversight of the doctor's personal reflection.

Doctors' personal reflections are fundamental to professionalism and as such, should be protected. When we are investigating concerns, we do not ask for doctors' personal reflective records. We agree that evidence of insight and remediation is key in assessing the risk that a doctor poses to public protection and can influence how we need to respond to a concern about their fitness to practise. However, when requesting evidence of insight and remediation we are clear it is for the doctor to decide the form that information should take.

We're also mindful that a review into gross negligence manslaughter in healthcare published in 2018 by Sir Norman Williams recommended that regulator's power to require information from individuals as part of a fitness to practise investigation should expressly exclude reflective practice material. The Department of Health and Social Care (DHSC) accepted this recommendation and is seeking to introduce it as part of legislative reforms to the GMC's Medical Act. We understand that this will also apply to other health and social care regulators in time and therefore, this might be something that you want to consider in relation to how sustainable the proposed model will be. If it will be sustainable, you may want to consider what involvement you have in any process that sits outside the formal fitness to practise procedures and / or set an expectation of the process you want registrants to follow to give pharmacy professionals confidence to fully engage in personal reflection.

10. Our discussions with stakeholders, including our work looking at other regulators, showed that mediation could play a role in resolving concerns. To what extent do you agree 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
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11. Please explain your response including, if it is appropriate, what form you think the mediation should take.

We're not clear from the limited information provided in the consultation document how you consider mediation fits within your regulatory remit or at what stages of the fitness to practise process you would seek to use it.

We understand mediation is a mechanism used for dispute resolution and allows parties to negotiate on issues and reach a compromised outcome. We can see that there may be some benefit in using mediation outside of the fitness to practise process. For example, we're aware that the GDC provide the '[Dental Complaints Service](#)' which offers assistance in resolving private complaints. However, we understand this is only available where the complaint does not reach the threshold for a fitness to practise investigation.

We don't think mediation would be appropriate in fitness to practise cases where there is a current risk to public protection. Given that our purpose is to protect the public, we don't consider we're able to facilitate negotiations between individual doctors and complainants, or enter into negotiations with doctors, about the outcome of fitness to practise investigations.

We know from [research](#) we commissioned that patients come to us when they've been unable to resolve concerns elsewhere and are often looking for an apology. This is an area where it may be more appropriate to use a model involving mediation. You may also want to consider ways to facilitate dialogue between your registrants and members of public at a local level, before a complaint is made to you which could provide an alternative to providing mediation services directly.

12. To make sure we put people at the heart of what we do, we are proposing a number of service promises (pg. 17-18) that set out what you should expect from us. Do you think our service promises give you clear expectations of the service you will receive from us?

Yes	No	Don't know
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13. Please explain your response.

We agree the service promises you've set out in the strategy will provide clear expectations of the services that the GPhC will provide. Our [patient charter](#) for patients, relatives and carers sets out similar messages and our corporate strategy for 2021-25 places an emphasis on improving our understanding of people's experiences to make our interactions with all those we work with better.

14. Do you think that people who share one or more protected characteristics set out in the Equality Act 2010 encounter specific barriers in fitness to practise processes because of that characteristic?

Yes	No	Don't know
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14a. Please explain, including any measures to remove these barriers.

Specific barriers in fitness to practise processes relating to protected characteristics can include individuals being unable to raise their concern due to formats that are inaccessible and difficulty in responding to concerns we are investigating due to a physical or mental illness. We seek to remove these barriers in different ways and have provided some specific examples below which we hope are helpful.

We ensure that reasonable adjustments are offered throughout the fitness to practise processes in line with our [reasonable adjustments policy](#).

The quickest and easiest way for most people to raise a concern with us is via our online form. However, if using the online form isn't possible, we provide an accessible word version, a form for people with a learning disability and can offer a telephone service. We also have a support advocacy framework to meet specific needs for a small number of individuals. The aim of this is to help patients and members of the public engage with us when raising a concern.

We know from our [Fair to Refer research](#) that certain groups of doctors have a higher rate of referral to our fitness to practise process. To tackle the overrepresentation of certain groups in our processes, we have taken steps to implement the recommendations of the research in our own processes and to influence others within the wider healthcare system. For example, part of our [Supporting a Profession Under Pressure programme](#) aims to work with healthcare providers to tackle the impact of system pressure on medical practice that detrimentally impact certain groups of doctors and result in concerns raised. We also publish data and advocate early intervention to address the factors that generate the referral patterns we see. We do this through our outreach teams, who work with doctors and healthcare providers, to learn about the environments doctors are working in and support employers to manage concerns at a local level, where appropriate.

We provide some support services for doctors who are going through our fitness to practise processes. We commission the BMA's [Doctor Support Service](#) to provide an emotional peer support service and the MPTS offer the [Doctor Contact Service](#) which provides support during a hearing, particularly for those who are attending a hearing alone or are unrepresented. We also undertook a significant programme of work on how to improve our engagement with vulnerable doctors. For example, introducing communication plans to understand the impact of any vulnerability and what that means for how we should communicate with doctors.

All our staff, including those involved in fitness to practise decision making, will complete mandatory equality, diversity and inclusion E-learning, face to face training and refresher training every two years to support decision makers to make decisions objectively and fairly. Our tribunal

members also receive bespoke training which includes looking at sample cases to explore issues in more detail.

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

15a. Disadvantage anyone?

Yes	No	Don't know
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15b. present any risks to fair hearings?

Yes	No	Don't know
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15c. have benefits for those involved?

Yes	No	Don't know
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16. Please explain your response.

The MPTS is currently running both virtual and in-person hearings to meet our statutory duty to protect the public by holding hearings where it is fair and safe to do so. The MPTS guidance on [Deciding how to hold hearings from August 2020](#) sets out the factors that will be taken into account when making decisions on whether to hold remote or in-person hearings. We believe that longer term remote hearings can continue to be used and conducted in such a way that any potential disadvantages or risks to fair hearings are overcome in most cases. However, it's important that any decision to hold a remote or in-person hearing is made based on the individual circumstances of each case.

We've identified several significant benefits of using remote hearings, such as:

- there is more flexibility for attendees and when listing witnesses,
- there are financial savings on both accommodation and travel for all those involved in appearing at hearings,

- they may reduce the stress of witnesses giving evidence, in particular for vulnerable witnesses. However, it's still important to make sure that witnesses are supported sufficiently when giving evidence remotely.

When developing our current approach to the use and management of virtual hearings, we've considered a range of risks which may mean that a specific hearing should be held in person to ensure its smooth running or fairness of the proceedings. These include:

- where the hearing bundle will be extensive, or where physical evidence will be presented,
- representation status - we recognise that doctors who are unrepresented can find the fitness to practise process particularly stressful and virtual hearings could increase feelings of isolation and reduce the doctors' understanding of the process,
- the possibility that tribunals and legal representatives may find it more difficult to undertake in depth examination and cross examination of a witness remotely leading to detrimental conclusions about the quality of witness evidence and credibility of the accounts given.

We also think it's possible for some hearings to go ahead with some participants taking part remotely, while others attend in-person. However, there may be some circumstances in which a remote hearing is not appropriate at all, for example if an individual cannot access a computer or internet, and in these cases the option for an in-person hearing should remain.

A specific challenge to running remote hearings is technical difficulties which can cause delays in hearings and result in sound/video glitches which may impact on the effective management of the hearing. We have found this can be mitigated by providing guidance to MPTS staff, tribunal members, parties and witnesses on participating in remote hearings. Test calls with tribunal members, the doctor and their representative to confirm that the software and their equipment works correctly are also helpful.

As running remote hearings is relatively new for all healthcare regulators, we will be continuing to evaluate and apply learnings from our own approach to using remote hearings.

17. The GPhC wants to understand wider implications and appropriateness of using personal experience statements (page 19) at all stages of the FtP process including during an investigation, at an investigating committee or at a fitness to practise hearing. Do you think that we should take personal experience statements into account when deciding what regulatory actions is suitable?

Yes	No	Don't know
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18. Please explain your response.

Our understanding is that personal experience statements are frequently used in criminal court cases to give a victim a voice and put them at the centre of proceedings. The focus of our fitness to practise process is the protection of the public and not punishment or obtaining justice for an individual. Therefore, their purpose and the weight attached to them would need to be considered and applied appropriately when deciding what regulatory action is suitable.

Capturing the patient's views and experience during the fitness to practise process is important. We gather this from the complainant in either written form or through meetings we offer to patients and complainants during the process. We also obtain witness accounts where appropriate and keep all complainants and witnesses up to date as the case progresses.

While the impact on a patient of the circumstances giving rise to the concern can be a relevant consideration, it's not determinative of current impairment and/or the appropriate outcome. Therefore, we don't routinely obtain personal experience statements as part of, or in addition to, taking witness statements.

When making an assessment of the overall risk a doctor poses to public protection, our [Sanctions Guidance](#) suggests that tribunals can take into account any actual harm suffered and the risk of harm when considering impairment and what sanction, if any, to impose.

Given the specific purpose of fitness to practise proceedings, it would be useful to consider how to position the routine use of personal impact statements so that it minimises any confusion for patients and members of the public about the regulator's role and their expectation of how their statement will impact decisions made. You might also want to consider if there are any fairness considerations to explore, such as inconsistent use, if they can only be obtained in some, but not all, cases.

19. 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. What methods have been / 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 use several methods for obtaining feedback from individuals involved in our fitness to practise processes, including: surveys, feedback questionnaires / forms and face to face meetings / observations. Some specific examples are set out below.

We have a dedicated complaints service within our fitness to practise directorate, as well as a corporate complaints team. Both routinely review feedback we receive from individuals involved in our fitness to practise processes. Our corporate complaints team produce quarterly complaints reports that are presented to senior management and used to identify business improvement opportunities, for example, improving the tone of voice of some letters we send.

Our patient liaison service offers meetings to complainants to explain and answer questions about what happens when we investigate a doctor and how we decide the outcome. We also offer to

meet with complainants again after we've made a decision – either at the end of an investigation or after a tribunal hearing. Following each meeting we send the complainant a link to a survey for them to complete. The survey asks a range of questions, such as how they found our communication and whether they felt they were treated with dignity and respect at all stages of our process.

Where an individual gives witness evidence at a hearing, we debrief with them immediately afterwards and this also acts as an opportunity for them to give feedback on their experiences.

The MPTS provides the [doctor contact service](#) which provides confidential support for doctors attending a hearing and provides them with information about the hearing process. Doctors can provide direct feedback to staff or complete a feedback questionnaire. The MPTS also provides resources for doctors about tribunal hearings and at the end of the document there is a link to a survey for them to complete. The aim is to check if the resources are helpful and identify any gaps in the support provided.

With the introduction of remote hearings because of the pandemic, MPTS staff have directly observed virtual hearings to ensure that in addition to the feedback received from operations staff and other users, we could directly observe the experience for the parties and identify learning points to improve processes further.

We have also undertaken doctor and patient surveys in the past to ask for feedback on our fitness to practise processes, correspondence during the investigation and support services for those going through the investigation process. We also routinely seek feedback from other customers, including medical defence organisations, through our regular meetings with them.

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
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21. Please explain your response.

All concerns raised with us about a doctor's fitness to practise are considered on a case by case basis and our decision makers routinely consider the context in which a doctor was working at the time the matters giving rise to the concern occurred. This includes the circumstances that existed at the time and the extent to which they impacted on the events and actions raised in the concern.

A specific example of how important it is to consider context is the circumstances of the Covid-19 pandemic, which has placed unprecedented demands on our social structures and healthcare systems. In turn, it has created significant and unfamiliar challenges for all healthcare staff, including doctors, in delivering safe and effective healthcare. As such, we developed [guidance](#) for our decision makers that weigh up various factors as they relate to each specific case to determine

whether the doctor poses a risk in the future, keeping in mind our overarching objective to protect the public.

22. 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. 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 have recently updated our signposting materials and we achieved this by working with other bodies that deal with complaints. This included updating: our internal 'signposting toolkit' for staff, a 'Fitness to Practise' factsheet for staff and the public that provides an explanation of our fitness to practise processes, updating letters and other material we send to members of the public which explains our fitness to practise processes, and 'lines to take' about our role for our staff when they are engaging externally with patient and public facing organisations to improve consistency.

We are also developing relationships with organisations who support patients and the public. Our primary objective in doing so is to improve understanding by these organisations about our role and our fitness to practise processes. These organisations then can support people in raising their concerns with the most appropriate organisation first. We are also working closely with patient representative groups to make sure we incorporate patient input and feedback into our projects and any future reforms to our fitness to practise processes.

23. 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. 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
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24. 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. 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 – both positive and negative impact	No impact	Don't know
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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.

Based on the information provided in the consultation, we believe that the proposals could have both positive and negative impacts on individuals or groups sharing any of the protected characteristics in the Equality Act 2010. We've given some specific examples below which we hope are helpful.

Your proposal to make more enquiries when you first receive a concern is similar to our provisional enquiries process (referred to above). We recently undertook an equality analysis as part of our work to expand our use of provisional enquiries and we expect that a positive impact will be that we will make more robust decisions earlier in our fitness to practise process. Depending on the proportion of referrals and types of complaints you receive, it's possible that your proposal could help reduce disadvantages faced by your registrants with protected characteristics who are currently overrepresented in your fitness to practise procedures.

A number of your proposals are considering the use of restorative approaches to fitness to practise concerns e.g. use of mediation and reflective pieces. These may have a negative impact on groups of registrants who are less likely to engage with restorative approaches or meet the criteria for this type of disposal as they usually require acceptance, and therefore insight, of some form. From [research](#) we've undertaken, we're aware that some groups may have difficulty acknowledging mistakes and demonstrating insight for a variety of reasons, including cultural differences, which might be a barrier to accessing different outcomes and disadvantage some registrants.