

12 January 2021

Health and Care Professions Council response to the General Pharmaceutical Council's consultation on managing concerns about pharmacy professionals: our strategy for change

1. About us

We welcome the opportunity to respond to this consultation.

The Health and Care Professions Council (HCPC) is a statutory regulator of healthcare and psychological professions governed by the Health Professions Order 2001. We regulate the members of 15 professions. We maintain a register of professionals, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a professional may not be fit to practise. Our role is to protect the public.

2. Response to the consultation

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

a. 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

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

There are a couple minor amendments/clarifications that may assist, but overall we fully support the thrust of the aims as stated.

In relation to Strategic Aim 2, and the reference to 'fair', HCPC has received feedback from its Equality, Diversity and Inclusion Forum members that this word is not favoured in this context and is perhaps something difficult to objectively measure performance on. This is because it is unlikely for FTP process/outcomes to be perceived as 'fair' by the registrant involved. The important part is the inclusivity and freedom from discrimination and bias. This feedback has stimulated our thinking around this, as it is commonly used in this context by many regulators.

In relation to Strategic Aim 3, some additional wording to aid clarity and understanding of who's 'perception' this refers to – is it GPHC's, registrants, service users, or all of the above?

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

a. If yes, which of the following strategic outcomes need additions and/or amendments? (Please tick all that apply – see list above)

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

In relation to bullet point one, while we fully support the intention of this outcome, we feel that the use of the word 'any' may be a little ambitious given it aims for pharmacy professionals to get *any* support they may need to help them meet standards. 'Any' is probably unachievable given the context in which they practice and the potential financial implications?

Additionally, we suggest that a reference to 'wellbeing' be included, e.g. get support to help them meet our standards and other issues affecting ability to meet these, such as their wellbeing.

In relation to bullet point two, we recommend caution in the wording given that FTP action may still need to take place, and because evidence of genuine insight and remorse will be required – wouldn't want to risk interpretation that acknowledgement of mistake alone will always suffice. Therefore, perhaps the aim should be a little wider and include 'acknowledge *and address* any mistakes...'

In relation to bullet point four – While we think we understand the intention behind the wording, ‘deal with the cause of the regulatory concern’, there’s perhaps a risk of misinterpretation here, if taken too far. What about instances where it is proven that the cause of the referral/complaint is not the fitness to practise of the registrant but instead a systems/employer issue (e.g. staffing shortages) for example. It may not always be possible for a professions’ regulator to address.

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.

The proposed test seems very sensible and the areas of enquiry appropriate. We would suggest that some additional clarity and information surrounding the following could potentially be of benefit:

- the difference between an enquiry and an investigation
- clear time frames and criteria for the activities that would take place in each stage
- criteria to help determine if the proposed test is met

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.

We have selected 'neither agree nor disagree' because it is difficult to provide a definitive response with the relatively limited amount of information provided on page 14 about when and how these reflective statements would be used. We note that the draft says that:

'The professional can submit the piece either as part of their revalidation or separately depending on timing.'

But believe that further clarity is required about the proposed process and what it would entail, eg if not as part of revalidation, then when? And, what enforcement mechanism would this attract – if a registrant doesn't provide the reflective statement does it instigate FTP process? There may be unintended consequences and potential problems with asking registrants to write a reflective piece as a way of resolving a concern. It would be helpful if there was further information about how the integrity and quality of this information would be assessed, and how you would take it into account if you get future fitness to practise concerns.

While we of course agree with the importance of reflective practice, we have some concern around using it outside of the formal FTP process which attracts certain protections for the registrant. Managing concerns outside of a formal process can raise human rights issues for the registrant themselves. The formal processes are there to ensure fairness, transparency and protection for the registrant and so we would suggest the ability for a registrant to provide a reflective piece is managed within the formal process to ensure those protections exist.

The ability for the registrant to do this is probably there already – all registrants have an opportunity to respond to concerns and encouraging them to provide any evidence of reflection, remediation etc is achievable. Like the HCPC, GPHC may want to give registrants and their representatives the confidence and ability to share these insights at a much earlier stage in the process – they usually come at the end and after a finding.

We would also highlight the issues raised surrounding support and advice for registrants when things go wrong, and the disparity of experience for those who do not have legal representation and those without pastoral/supervisory support, professional body and/or trade union membership. GPHC will of course be familiar with the issues raised around reflective practice following the reviews instigated following recent gross negligence manslaughter convictions, which will be important to consider in the context of this proposal. The continuing degree of anxiety, fear and concern amongst health and care professions surrounding reflective practice, may risk the efficacy of this proposal in practice. It's important it isn't perceived as being a tick box exercise.

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.

The HCPC would caution about the value/benefit and appropriateness of mediation. The HCPC has mediation in its legislative framework as an option for resolving concerns. We have previously undertaken pilots to assess the benefits of mediation and we found that the fundamental role of mediation doesn't align well with the current set up/function of professional regulators. It was not an effective way for us to resolve FTP concerns and parties to HCPC cases were not very receptive to exploring mediation as an option. Furthermore, we found that the suitable types of cases would be those that were at the lower end of the spectrum and might not meet the threshold for FTP investigation in any event, in which case, it raised concerns for us about the proportionality of the impact on the individuals involved.

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.

These 'promises' are clear, deliver what you have set out in the strategic aims and appear to be at the right level.

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

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

HCPC has selected 'yes', however we have based this response in understanding derived from the learning of other regulators including the GMC and NMC and the substantive research and data analyses that they have undertaken which demonstrates the disproportionate impact of their FTP processes on registrants with particular protected characteristics. It seems highly likely that the experiences of their registrants will be replicated across the health and care professions, in our view. This said, further work needs to be done to understand what the specific barriers are and how they can be mitigated/addressed. This is highly complex and is unfortunately not as simple as we might hope – there are many compounding factors that affect the experiences of registrants and individual registrants do not present with just one protected characteristic in isolation; intersectionality is highly important to consider here.

There are some very general conclusions that can be drawn from existing research (of which GPHC will be aware). However, such general conclusions should be considered cautiously, be substantiated with evidence, and viewed through the lens of the lived experiences of GPHC registrants specifically. It would appear that lack of legal representation impacts the severity of FTP hearing outcome and the degree of case progression (likely that those represented may have cases closed at an earlier stage of the process). Additionally, it would appear that BAME health and care professionals are less likely to have legal representation (and other important sources of support, such as peer, pastoral and employer support) than their white counterparts. There are many factors to be considered here, including complex cultural factors, that will influence experiences and outcomes. Therefore identification of specific barriers will require careful consideration backed up by evidence.

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.

HCPC believes that there is a place for remote hearings post-pandemic, and they have the potential to encourage participation and engagement (subject to the EDI considerations outlined below).

Our feedback and experience with stakeholders to date suggests they may be more suited for review hearings or some IOA hearings, and simple substantive hearings e.g. no witnesses, registrant not engaged.

HCPC has also been conducting remote hearings due to COVID 19 restrictions and we have provided some details of our Equality Impact Assessment which may be of relevance here.

We identified that the move to remote hearings (alongside other changes) had the potential to impact upon:

- the public, including service users and colleagues in health and care;
- registrants;
- health and care providers, professional bodies and consumer groups; and

HCPC employees and partners.

We made an assessment against the protected characteristics as follows:

Age - Lack of access to the internet may impact on the ability of older people to engage with hearings where relevant.

Disability - (includes physical and mental health conditions)- Access to participation in hearings is also likely to be impacted by having to use virtual or teleconferencing methods.

We did not identify additional impacts for the other protected characteristics, however we did identify that lack of access to the internet may also impact on the ability of people who are socio-economically disadvantaged to engage with hearings where relevant. Our usual mechanisms by which we offer support to vulnerable parties during the FTP process is also limited due to the closure of our phone lines and hearings centres.

We also considered the impact on those across the four countries of the UK and concluded that whilst the government restrictions on all but essential travel and social contact apply to the whole of the UK there is no current impact on four country diversity. This may change should the current restrictions be lifted at a different rate and/or in different ways across the four countries when we resume business as usual.

In order to address/mitigate the identified impact, we put in place some additional measures including:

- We have published a Statement of Approach to FTP Investigations and Hearings during COVID-19 on our website. Our approach is reviewed monthly and input is sought from FTP Forum representatives on any changes. Support available for registrants has been shared with the Forum.
- We continue to meet regularly with the Directors of FTP group to ensure we take an approach that is consistent across the sector, allowing for different registrant groups and legislative requirements.

- Outgoing phone calls are being made to particularly vulnerable parties whilst we can ensure staff are supported to make challenging phone calls whilst working remotely.
- The team that handle general enquiries are frequently updated on the FAQs and other support and guidance available to parties at this time so these can be signposted to relevant parties as appropriate.

In terms of potential benefits - A potential benefit may arise for those registrants not within the locality of the hearing facilities/may avoid extensive travel/cost associated.

Remote hearings may benefit those who have a personal preference or with mental health conditions for not attending which may reduce impact of stress and anxiety.

The use of remote hearings may reduce length of time taken to hearing, which may also have a positive impact on reduction of stress and anxiety for all involved.

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 understand and recognise the potential perceived benefits to such statements from members of the public, and value the importance of ensuring that complainants and their families are involved in all investigatory processes when things go wrong. There are currently issues throughout the processes of investigation (starting locally with the employer) with patients and family members feeling as though they are not a genuine and valued contributor to investigations, in practice. By the time that the case has reached the registrant's regulator the complainant and/or their family may have experienced what they would describe as complete exclusion and a lack of communication. This can of course compound and entrench issues (such as feeling as though their voices have not been heard) that could have been resolved much earlier on in the processes.

However, that said, we are also of the view that there are many potential challenges and risks associated with personal experience statements being taken into account when deciding what regulatory action is suitable. These challenges and risks would need to be addressed before they should be introduced.

The biggest risk is around fairness for the registrant and whether using these statements might impact the outcome unduly. Bias of decision makers is inevitably at risk; unconscious bias is well evidenced and while mitigating training can be

delivered, it would not protect against risk of bias that would satisfy most defence representatives.

FTP cases do not require actual harm (a clear distinction from civil negligence) and so there is a question as to whether registrants who are involved in cases where actual harm has occurred would suffer a disproportionate impact in the outcome of their case with these statements, to those where they were lucky enough for harm to not have been incurred (often as the result of another health and care professional or other safety measure preventing the harm).

Even where there are cases involving complainants (not employer/colleague referrals) not all individuals involved would want to provide these statements; so again, these registrants may be perceived to have benefitted in comparison to those where they are not used.

Additionally, some will inevitably struggle with the purpose of the statements; as is currently seen in understanding of the purpose of the FTP process overall, not as punishment, but as an assessment of fitness to practise at that point in time. We are slightly concerned that the provision of the statement could be misleading to statements and cause further issues with managing expectations about the purpose of FTP. Just because an individual does/doesn't feel that a registrant 'deserves' a sanction, doesn't mean that the facts would or wouldn't be found proven at hearing and registrant's fitness to practise would/would not be found to be impaired. This could impact on protection of the public if the statement is given too much weight or is at odds with the findings of the FTP panel.

There are other areas of the process that would also require clarification before implementation, such as whether the registrant would be provided with the opportunity to respond to the statement, make corrections, and in what format.

This proposition seems to replicate existing process of obtaining witness statements and providing a defence to allegations and doesn't appear to address what would replace the important protections associated with the formal existing process.

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?

A range of methods would be needed and it may be helpful to canvass feedback at various stages of the investigation, so that any feedback can be acted upon before the conclusion. Surveys for those involved as they move through the process, interviewing a sample as they conclude the process, and a means for staff to easily record feedback for analysis as they go. Quite often someone will give their case manager or hearing clerk feedback in person, during a telephone call or in written correspondence and this can be very valuable too.

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.

Our response here is tentative because of the use of the word 'significant'. This implies that more weight could be given to this factor in comparison to other unidentified factors. In our view, the context in which the professional is working and other human factors should be identified and taken account at decision points, alongside all other important factors. We understand that this is currently the approach of most, if not all regulators but there has been recent debate around the degree to which it is (for example the reviews of gross negligence manslaughter).

Having investigators equipped with the knowledge and skills to identify and assess that information will be helpful in making robust and proportionate decisions. Registrants should, therefore, be encouraged and empowered to provide any information about context that might be relevant at an early stage and this should form part of the overall evidence and information considered by the decision-makers.

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?

No, not beyond the existing support measures that most regulators already have in place.

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 (Age and Disability)**
- Yes - both positive and negative impact
- No impact
- **Don't know (other characteristics)**

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.

We have selected negative impact (Question 23) in relation to the proposal to introduce reflective statements and personal experience statements, which we hypothesize, may increase stress and anxiety for registrants, particularly those with pre-existing mental health conditions.