Response to the General Pharmaceutical Council consultation: 'Managing concerns about pharmacy professionals: Our strategy for change'

January 2021

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

2.1 We welcome the opportunity to comment on the General Pharmaceutical Council's (GPhC) consultation on its strategy for dealing with concerns about pharmacy professionals. Our response is in two parts: general comments about the proposals, and answers to any specific questions. We have only provided a response to the questions we felt we had sufficient information to respond to.

2.2 We welcome all the strategic aims, which would if successful address many of the challenges facing regulators of rising case loads, and perceptions of fitness to practise as an overly punitive process, at a time when professionals are under acute pressure.

2.3 We support the approach taken by the GPhC with this strategy, and in particular the ambitious focus on learning from the findings of recent enquiries to make the process more accessible, less adversarial, and more focused on prevention and collaborative working. We were pleased also to note the ambitions relating to addressing discrimination and bias in the process, and supporting candour when things have gone wrong.

2.4 We note the references to our work on learning from the Nursing and Midwifery Council's (NMC) handling of the Morecambe Bay cases, our report on public confidence, and the fitness to practise chapter of *Right-touch reform*. We were particularly pleased to see that the Strategy took on board many of the concerns we identified in the Morecambe Bay cases, particularly in respect of the aspects of the FtP process that can undermine its patient safety purpose, such as long delays, and overly adversarial approaches.

2.5 There are nonetheless some aspects of the strategy that we wish to question, suggest changes to, or hear more about before we can give them our support. You will note that our most substantive concerns relate to the first Strategic Aim, and the lack of clarity about the proposals to remove some cases from the formal fitness to practise routes, and their legislative basis.

3. Legislative bases and wider public interest

3.1 It would have been helpful for the Strategy to be anchored more explicitly within the GPhC's legislation. Without such references, it is hard to understand whether and how the proposals fit within the scope of the GPhC's existing powers and duties.

3.2 More specifically, we recommend that the Strategy place more weight on the need for fitness to practise decisions to maintain public confidence and uphold professional standards.

3.3 We appreciate that there is a fine line to be drawn between blame or punishment, and accountability, and we support the focus of Strategic Aim 3. The role of fitness to practise is to keep the public safe from risky practitioners, but also to hold registrants to account for actions, practice, or behaviour that could undermine public confidence or professional standards. The role of the regulator in this respect is subject to interpretation,[1] and can appear unnecessarily punitive.

3.4 Nonetheless, the over-arching objective gives the GPhC a clear duty to uphold these wider public interest limbs, the principles of which were established in case law even long before the objective was put in place for all regulators (with the exception of the PSNI) and the Authority. As the document reads currently, we feel there is a risk that action may not be taken in cases that engage primarily the public interest limbs.

3.5 Under Stategic Aim 1, we would have welcomed reference to all three limbs of public protection in the list of factors to be considered at the initial enquiry stage. There are a number of other points in the document where there is an emphasis on addressing risks to patients, but no apparent consideration of the need to maintain public confidence or professional standards. Where the public interest is mentioned on page 15 in relation to voluntary removal, there is a lack of clarity over what it entails (see below).

[1] Our work on public confidence identified a lack of consensus on the application of the public confidence limb of the regulators' over-arching objective. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/how-is-public-confidence-maintained-when-fitness-to-practise-decisions-are-made.pdf?sfvrsn=c8c47420_0

4. Strategic Aim 1: Keeping patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns.

Clarity about the new thresholds and outcomes outside formal processes

4.1 For the purposes of understanding what is being proposed, we would have welcomed greater clarity about:

- Whether the GPhC intends to amend or retain its current threshold for action, both formal or informal, against registrants
- Within this overall threshold, which cases the GPhC considers should no longer meet the GPhC's threshold for *formal* action.

4.2 We would have liked to see clear articulations of the thresholds at the different stages, and their bases in legislation. In due course, we would want to see detailed guidance about how these thresholds should be applied.

4.3 We also have a number of questions about the proposals to manage more cases using outcomes outside the formal processes. In our 2018/19 performance review, we expressed concerns about pre-Investigating Committee undertakings (which have since been renamed 'voluntary agreements') and informal guidance issued by the GPhC. Our primary concern is that the use of such informal processes could affect the transparency, consistency and fairness of the process.

4.4 We suggest the GPhC give consideration to the following:

- If a concern does not warrant investigation through the formal process, on what legitimate basis can the GPhC take action through an informal process?
- Has the GPhC considered, or taken legal advice on, whether it has a legitimate basis on which to request and store information when it is not doing so under a formal process, particularly when the information is about a registrant's health?
- How will the GPhC make the distinction between a formal and informal process clear and unambiguous for registrants and complainants? In particular, the status of the case (open or closed), how the information may be used by the GPhC in future, should further concerns be raised, and the consequence(s) of not engaging with what is described as a voluntary process.
- How will the use of outcomes outside the formal process uphold professional standards and maintain confidence in the profession?
- How will the GPhC assess whether a reflective piece or voluntary agreement has sufficiently addressed the matters of concern so as to no longer be a risk to public protection (all three limbs)? What are the options if it doesn't, and can the case be brought back into formal channels? We assume that while the ambition is for 'only the most serious concerns to reach a hearing', this will be partly dependent on whether a registrant accepts any consensual outcome proposed.

- Given there is an imbalance of power in the relationship between a regulator and its registrants, how will the GPhC ensure that registrants do not feel obliged to agree to voluntary measures in cases that would otherwise be closed?

Preliminary enquiries and reflective statements

4.5 It would have been helpful to gain a better understanding of what might be involved in the preliminary enquiry process, and the extent of the investigations that could be carried out here. On the face of it though, we are concerned that attempting to establish risk of repetition, patterns of behaviour, and sufficiency of evidence at this early stage may be premature. We would not wish to see cases being closed, for example, on either an absence of evidence of risk of repetition or patterns of behaviour, or on inconclusive evidence of insight and remediation.

4.6 We made similar comments when responding to the NMC's consultation on its new FtP strategy in 2018,[2] in which we also noted that:

- it is more difficult to assess insight at the early stages of a case without hearing directly from the registrant and when the facts are not yet established
- care needs to be taken over what assistance/guidance the registrant is given to remediate and how far this goes
- steps independently taken by a registrant to remediate go some way to demonstrate a genuinely insightful and reflective approach and carry particular weight.

4.7 We also caution against placing too much weight on outcomes of third-party investigations. The fact that employers or the police decide to take no action can be a relevant indicator of the seriousness of the matter, but it should not be used as a blanket reason for closing cases at the enquiry stage. The GPhC's remit, standards, and methods are different to those of employers, or indeed the police. In line with what was said by the Court of Appeal in Bawa Garba,[3] we would expect a regulator to take its own view of whether to take action based on the nature and severity of the incident and whether it has the potential to call into question the registrant's fitness to practise, rather than a finding by another body not to take action in response to that incident.

4.8 Reflective statements could be a valuable tool, and we welcome the intention to bring revalidation tools into the fitness to practise processes where appropriate. The GPhC may want to guard against the obvious risk that such statements might become too standardised to give a reliable impression of the registrant's genuine insight. It is also worth bearing in mind that some cases may require evidence that the reflections are actually embedded in practice.

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[2] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2018/professional-standards-authority-response-to-the-nmc-consultation-on-ensuring-patient-safety-enabling-professionalism.pdf?sfvrsn=fa397220_4

[3] Bawa-Garba v The General Medical Council & Ors [2018] EWCA Civ 1879 (13 August 2018). See here at paragraph 76.

4.9 We bring this up in these general comments, as we are seeing what appears to be an emerging trend across regulators of thresholds that encourage cases to be closed before the regulator has gained its own independent understanding of the facts.

4.10 These comments link to concerns we have expressed in the past about the GPhC's processes and decision-making in the early stages: in addition to the issues we raised about the threshold criteria in the 2017 consultation, our 2018/19 performance review found that the GPhC was not complying with its own triage guidance when making triage decisions (in particular, it was considering factors beyond those set out in its guidance)

4.11 In our 2019/20 performance review, we had some fundamental queries about the robustness of the GPhC's triage process and new processes that were being piloted that allowed for remediation and insight to be considered at triage. We indicated we would be closely monitoring the GPhC's ongoing redesign of its triage function.

4.12 It would be helpful if the GPhC could share with us how it intends to address these issues through the new Strategy.

Voluntary removal and mediation

4.13 We support the use of voluntary removal in limited circumstances, where doing so is compatible with both the three limbs of public protection, and the regulators' own legislation.[4]

4.14 In particular:

- There will be some matters which are so serious that the public interest requires a hearing
- It is important that the registrant accepts all the facts and that impairment is established in respect of those
- The regulator must be in a position to assess whether the concerns will persist if the registrant decides to return to practice, and ensure that sufficient information about the concerns is available for the restoration process
- The more serious the conduct involved, the more exceptional the circumstances will need to be before voluntary removal becomes appropriate.

4.15 With respect to possible reasons for needing to hold a hearing rather than opt for voluntary removal, we suggest that this could be better explained than currently on page 15. There may be public protection reasons for needing to refer a case to a hearing, given that the alternative of voluntary removal is not a formal fitness to practise outcome, and therefore would not be on public record in the same way. Public interest reasons for referring to a hearing cover both the upholding of professional standards and the need to maintain public confidence. It would have been helpful to see all three reasons clearly spelled out. Finally, it is not clear what is meant by 'serious personal issue', which

[4] We have encountered some ambiguity in this respect with other regulators.

could cover any number of concerns that might require airing at a full hearing or a more robust regulatory response; some cases involving serious mental health issues might also need to be referred to formal channels for similar reasons.

4.16 We would also urge caution in considering the use of mediation. It is a helpful concept in resolving civil disputes (particularly family ones) and assisting parties to move forward and reach a solution. However, our review of the fitness to practise function published as part of *Right-touch reform*[5] did not identify a place for mediation.

4.17 The purpose of fitness to practise is to protect the public, acting in the public interest – it is not to resolve disputes or complaints. This is demonstrated by the fact that the referrer is not a party to the complaint, and neither do regulators act on behalf of the referrer. In addition, there have been concerted efforts by the regulators and ourselves in recent years to move away from the terminology of complaints, to make it clearer to the public that regulation is not about resolving disputes, or finding redress.

4.18 The regulators we oversee receive a large number of complaints that do not give rise to concerns about the registrant's practice or behaviour that engage the three limbs of public protection. A number of these could no doubt be resolved through mediation, but we do not see it as the regulator's role to resolve them in this way. Encouraging better local resolution of complaints, and working with the GPhC inspectorate function to raise standards of complaints management would be preferable. This fits with the view we originally set out in *Right-touch regulation*,[6] that where possible, problems are best addressed close to where they occur.

4.19 It is also the role of the GPhC to set out and publish clear threshold criteria that make sense to members of the public, to reduce the number of complaints they receive that do not have the potential to engage the three limbs of public protection. Finally, we suggest that the proposed improvements to communications with referrers may also help to reduce numbers of complaints that do not give rise to concerns about a registrant's fitness to practise. Managing referrers' expectations from the outset about the possible outcomes of the process is an important part of the regulator's role.

Impacts

4.20 Some idea of the volume of cases the GPhC would divert from fitness to practise proceedings to non-formal routes, along with those that might not proceed to an investigation at all, would have been helpful to understand the impact of what is being suggested.

4.21 One of these impacts, which we feel should have been mentioned in the document is that cases that would in future be dealt with through alternative mechanisms would cease to fall under the Authority's section 29 (s.29) jurisdiction. The purpose of our powers is to identify, in cases that meet the

[5] Available at: Right-touch reform - a new framework for assurance of professions (professionalstandards.org.uk)
[6] Available at: Professional Standards Authority - Right-touch regulation

threshold for action on registration, outcomes that are insufficient to protect the public, and appeal them in order that corrective action may be taken. The fact that an outcome is reached by consent with the registrant in no way implies that it cannot be insufficient, and therefore has no bearing on the need for our powers to cover consensual outcomes that have met the threshold for regulatory action. Depending on where the new threshold for formal action lies, assuming it is changing, we would be concerned if cases we currently can appeal were being removed from our jurisdiction without this being made clear to stakeholders, and without a clear understanding of the impact and potential patient safety risks.

Interaction with employers and system regulation

4.22 We agree that it is appropriate for the GPhC to consider whether a concern indicates a wider or underlying system failure as there may be cases where a concern indicates a FtP issue as well as a systems issue. It would be helpful to have clarity on how the FtP strategy will interact with, or be considered alongside, the GPhC's approach to regulating pharmacies, particularly how the GPhC will decide which route is the appropriate one to take action through or when it will be appropriate to take action through both. When we audited the GPhC as part of the 2018/19 performance review, we highlighted a number of cases where decision-making in this regard appeared inconsistent.

4.23 We support the GPhC's commitment to working with employers to improve local resolution and understanding of when to make a referral to the GPhC. We would however caution against the risk of becoming over-reliant on employers' investigations. This risk may be mitigated by having clear criteria or guidance for circumstances where the risk is more appropriately managed by the regulator, for example where a registrant has changed employer or is a locum, and by being clear on the types of cases that can be resolved locally and those which the GPhC would expect to take forward.

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

5.1 We welcome and support all aspects of this Strategic Aim.

5.2 The GPhC has recognised the importance of the timing of taking personal experience statements into account and we support the GPhC's intention to gain a better understanding of the wider implications and appropriateness of their use. We also highlight the importance of ensuring that parties are provided with clear information about how a personal experience statement fits into a fitness to practise rather than a complaints process. In our aforementioned response to the NMC's FtP Strategy consultation we indicated that a statement from the complainant about the impact of the registrant's actions may be relevant where cases are dealt with outside a panel hearing.

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

6.1 In our response to the NMC's consultation we acknowledged that context may mitigate particular errors but should not distract from investigating the individual actions of the registrant. There will be cases where a registrant's fitness to practise may still be impaired even taking context into account. The GPhC's strategy does not set out how it will assess context to ensure that a consistent and transparent approach is taken.

7. Questions

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

7.1 Strongly agree

2. Is there anything missing from the strategic aims, or anything that should be changed?

7.2 **No.**

3. Considering the full set of strategic outcomes on page 12, to what extent do you agree or disagree that these are appropriate?

7.3 **Neither agree nor disagree.**

7.4 We agree with some of them. Our feedback on the outcomes is as follows:

- We suggest that under the second outcome (being open and honest), it might be more accurate to say 'if they acknowledge any mistakes quickly, this ~~will~~ *may* minimise the need for a fitness to practise investigation~~.~~, *or lead to a less serious fitness to practise outcome.'*
- As previously mentioned, we do not agree that 'only the most serious concerns' should reach a hearing, given the limited options the GPhC has for alternative means of disposal, and the fact that disputed cases would always need to be referred for adjudication by a panel.
- We would have liked to see some reference to the over-arching objective here to highlight that fitness to practise outcomes must, above all else, fulfil the three limbs.

4. Is there anything missing from the strategic outcomes, or anything that should be changed?

7.5 **Yes**.

7.6 See above.

5. Have we identified appropriate areas of enquiry?

7.7 **No**.

7.8 See above.

6. To what extent do you agree or disagree that the proposed test is appropriate?

7.9 **Neither agree nor disagree**.

7.10 This test appears appropriate on the face of it, but how it might work in practice would depend on a number of other factors:

- Would the information taken into account at this stage (as set out in the list of points of enquiry) give decision-makers enough evidence to make a fully informed, safe decision (see concerns set out above)?
- We have already noted that the list of enquiries includes an evidential threshold, which we would regard as premature at this stage (see above), but it is not clear how this would feed into the test which is focused on potential grounds for investigation.
- In line with our comments about thresholds at the different stages, it is not clear how this test would enable decision makers to determine whether information should be referred for formal or informal action, or simply closed.

8. 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. To what extent do you agree or disagree that this is an appropriate and effective outcome for some concerns?

7.11 Agree.

9. Please explain your response

7.12 See above.

10. To what extent do you agree or disagree that mediation can play a role in resolving concerns about pharmacy professionals?

7.13 Strongly disagree

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

7.14 See above.

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

a. disadvantage anyone?

7.15 Don't know

b. present any risks to a fair hearing?

7.16 Don't know

c. have benefits for those involved?

7.17 Don't know.

16. Please explain your response

7.18 We have not studied the impacts of remote hearings on the above, but we have considered our position on their use during the Covid emergency. Outside an emergency situation, it would be important for virtual hearings to be used in appropriate circumstances, and for the GPhC to ensure that transparency and accessibility can be maintained through facilitating public access. Please see our guidance for considerations which we would expect to apply both within and outside the emergency situation. [7] We will be returning to this guidance in March this year, to understand whether there is new evidence to feed into our thinking in this area.

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

7.19 Yes

18. Please explain your response

7.20 See above.

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?

7.21 Agree.

21. Please explain your response

7.22 See above.

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?

7.23 Our Performance Reviews have identified communication with parties through the fitness to practise process as a weakness for two years running. Our most recent report acknowledges that progress in this area has been negatively affected by the pandemic, and we welcome the focus in this Strategy on clear, timely communication with referrers.

7.24 We also support the intention to use feedback from parties who have been involved with the process to identify areas for improvement.

8. Further information

8.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

[7] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/authority-guidance-for-regulators-on-fitness-to-practise-hearings-during-the-covid-19-pandemic-(september-2020).pdf?sfvrsn=78d67620_4

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