Response to the General Pharmaceutical Council consultation on revised threshold criteria

March 2017

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 voluntary 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 nine health and care professional regulators and report annually to Parliament on their performance
- 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 on guidance

2.1 We welcome the opportunity to respond to this consultation from the General Pharmaceutical Council (GPhC) on their revised threshold criteria. We recognise that the GPhC's intention in updating the threshold criteria is to ensure they are in line with the revised standards for pharmacy professionals, which are due to be published in May of this year.

2.2 Threshold criteria form an important part of the case handling process and can be a useful tool for those making decisions on which cases to refer on, and for complainants and registrants in understanding the basis on which cases move to the Investigating Committee (IC) stage. It is positive that the GPhC are seeking feedback on their proposed changes to the criteria.

2.1 We welcome regulators reviewing their approach to fitness to practise, looking at options for taking forward only the most serious cases, and disposing of cases consensually where appropriate. However, within the confines of the current legislation, there are limited and defined ways to dispose of cases transparently and accountably. Regulators need to respect the boundaries set by their legislation and the case law.

2.2 We welcome the inclusion of the over-arching objective and three limbs of public protection, which are helpful in framing the criteria around the purpose of regulation. However, it would be helpful if this was placed more prominently

and it was made clearer that this should come before wider public interest considerations when considering whether to refer the case on to the Investigating Committee.

2.3 We recognise the GPhC's ambition to give Case Workers more discretion to close cases when it may not be in the wider public interest for the case to go to the IC. However, we have some concerns about the potential impact of some of the changes proposed, in particular the reference to assessment of insight and remediation and the test of proportionality which may result in risks to public protection and may damage public perception of the GPhC as a regulator. Our comments overlap to some extent with the view put forward in the last GPhC performance review on the revised IC guidance, which also included a reference to a proportionality test.

2.4 Our concerns in relation to the revised threshold criteria fall into three main areas:

- The clarity of the revised criteria and transparency in how they will be applied
- The risk of cases which may meet the real prospect test being closed prematurely, potentially resulting in public protection risks
- A lack of scrutiny and transparent oversight of decisions being made.

Clarity and transparency of decision-making

2.5 In our view, the wording of the revised standards, with the use of a double negative (e.g. the registrar will **not** refer a case to the IC if: it does **not** present an actual or potential risk to patient safety) will be difficult for members of the public and registrants to understand. Whilst we understand from the GPhC that the revised criteria have been phrased in this way so that they align more closely with the wording of their legislation, further consideration should be given to whether this wording is sufficiently clear.

2.6 The criteria as currently drafted appear to duplicate the different considerations relating to public risk and public protection. On page 12 in 1.6. three of the criteria seem to paraphrase the three limbs of public protection (risk to patient or public safety, confidence in the profession, and failure to meet the standards); on page 13 under the public interest considerations in 1.10, the three strands are stated again explicitly. Then in 1.11 – is the decision 'sufficient to protect the public' appears to reiterate the same consideration.

2.7 It is not clear how the conduct, behaviour and health criteria, will interact with the public interest considerations such as assessment of insight and proportionality and the types of cases that would be likely to be referred on to the IC. We are also unsure why competence is not specifically referenced alongside conduct and behaviour, and health.

2.8 We note that the GPhC produced guidance to go with the current criteria, however the consultation document as drafted does not give sufficient detail on application of the revised criteria. Any guidance produced should outline the process to be followed in applying the different parts of the criteria to

ensure that public protection is at the centre of decisions made. It would also be useful for any guidance to be clear that the threshold criteria will be applied after an investigation. In order to fully assess how the criteria should be applied, it would also be necessary to have alongside them guideline cases or categories of cases. At the moment, it is unclear what types of cases may be closed down at this stage.

2.9 The reference to proportionality is not clearly explained and the term not defined; therefore it is difficult to tell how it would be applied. As currently framed, this could result in a perception of lack of transparency from members of the public, who may feel that the GPhC is putting registrants' interests above the public interest.

2.10 The consultation document refers to the registrar's power to close a case and issue advice to the registrant. This appears to have some overlap with the power to issue warnings to registrants at IC stage. However, it is unclear what status advice issued by the registrar would have. Whilst the GPhC would retain information from a previous investigation as 'soft intelligence' we have concerns about the transparency of this to the public who would not be aware of advice issued. It may also make it more difficult for a Panel to build a picture of a pattern of behaviour if a registrant has a further complaint made against them.

Public protection risks

2.11 We are concerned that as currently drafted, the revised threshold criteria may allow cases to be closed prematurely with the potential to result in public protection risks.

2.12 The proposals suggest that the registrar may be able to close cases which meet some or all of the initial conduct and health criteria if they feel that the registrant has demonstrated insight and/or carried out appropriate remedial action. Whilst we are told by the GPhC that this discretion is intended to be used in cases where the harm caused or risk of harm is low, we believe that introducing consideration of these elements, specifically the points in 1.11, appears to move aspects of the realistic prospect test to an earlier stage in the process.

2.13 We have previously put forward the view that establishing insight from a registrant is essential ahead of any disposal of a case outside of a formal panel hearing, therefore we believe that the reference to 'showed remorse **or** insight [our bold]' is inappropriate.

2.14 Furthermore, accurate assessment of insight without hearing from the registrant or any witnesses in person can be challenging. Moving this consideration to this stage in the process places a large responsibility on the Case Worker to be able to assess insight, largely based on written evidence and risks cases being closed which should properly proceed to a public hearing.

2.15 The introduction of a further test of proportionality may create an additional hurdle to cases being referred which otherwise meet the criteria for referral. Proportionality is not defined in the consultation document and this makes it

unclear how it might be applied at this stage when the decision is binary – to refer or not to refer a case to the IC. Taking a more proportionate approach would suggest that the public can be protected through alternative means. However, as the powers of the registrar at this stage are limited to issuing advice, this would suggest that that there are unlikely to be adequate alternatives to referral to IC. It would be useful to understand how consideration of proportionality will be balanced against the wider public interest of holding a public hearing when there is a real prospect of the registrant's fitness to practice being found impaired.

2.16 As highlighted, we are supportive of a proportionate approach to regulation in general and welcome regulators reviewing their approach to fitness to practise, looking at options for taking forward only the most serious cases, and disposing of cases consensually where appropriate. However, within the confines of the current legislative framework, there are limited and defined ways to dispose of cases transparently and accountably. Regulators need to respect the boundaries set by their legislation and the case law.

Lack of scrutiny and transparency of proceedings

2.17 As highlighted, the criteria outlined under 1.11 appear to mirror aspects of the realistic prospect test which, under the GPhC rules currently sits with the Investigating Committee (rule 9 (7)(a)). The effect of the changes proposed could therefore be to bring the realistic prospect test forward in the process to a decision made by GPhC staff behind closed doors. In our view this raises issues of transparency and due process. Whilst IC hearings are also carried out in private, the IC's role and proceedings are governed by legislation and decisions made by the IC have clear legal status. From our understanding decisions made by the registrar at this stage would have no such legal status and could make it more difficult to challenge decisions made not to refer a case on.

2.18 In addition, we are concerned that the effect of applying the revised threshold criteria could be to remove cases, where there is a real prospect of a panel finding impairment, from the additional safeguard of the Authority's Section 29 oversight powers. If the registrar has the discretion to close cases based on an assessment of insight or where their view is that referral would be disproportionate, even when initial health or conduct criteria have been met then this risks the closure of potentially serious cases at an earlier stage in the process with no external scrutiny.

2.19 We have raised similar concerns in relation to the power of the IC (and for some regulators Case Examiners) to agree undertakings with registrants at IC stage, in cases where the realistic prospect test may be met. Moving this assessment and discretionary power to close cases to an even earlier stage in the process is a cause for concern and may result in a lack of oversight of GPhC decision making in this area.

3. Consultation questions

3.1 *Question 1. The Pharmacy Order 2010 allows us to have threshold criteria, which help us decide whether a case should be referred to the investigating committee. Do you think the proposed threshold criteria are clear and understandable?*

3.2 No – see our general comments.

3.3 The move from 15 to six threshold criteria does not in itself raise any specific concerns providing the proposed criteria are capable of covering the full range of types of cases the GPhC may deal with. We are unsure why competence is not specifically referenced alongside conduct and behaviour, and health.

3.4 We note that the third criterion under conduct and behaviour refers to 'a serious or persistent failure to meet any of the standards for pharmacy professionals'. The standards for pharmacy professionals are not yet finalised, however assuming no further major changes will be made to these, this should allow any cases not covered by the other criteria to be picked up under this criterion.

3.5 However, as previously highlighted the current 'double-negative' wording of the criteria may be confusing to the public and registrants and this may need to be reviewed to ensure clarity. As noted in our general comments, the criteria also appear to duplicate the different considerations relating to public risk and public protection.

3.6 We would suggest that in paragraph 1.6 of the document, it may be helpful to amend to: 'The registrar will not usually refer a case to the IC if…' to avoid the perception that the registrar has fettered their powers of discretion.

3.7 In the fourth bullet point of paragraph 1.6 it may be helpful to amend to: 'It does not show that the honesty or integrity of the registrant has been called into question'.

3.8 In relation to the conduct and behaviour criteria under 1.6, it may be helpful to include reference to 'values' and 'attitudes' of pharmacy professionals.

3.9 For the health criteria under 1.6, it may be useful to refer to 'current and/or future risk of harm'.

3.10 In paragraph 1.7 we would suggest it should refer to 'the alleged behaviour and actions of the registrant' and it may also be useful to refer to 'omissions' as well as actions.

3.11 We welcome the inclusion of the over-arching objective and three limbs of public protection, which are helpful in framing the criteria around the purpose of regulation but would like to see it made clearer that these considerations should be at the heart of decisions on referral.

3.12 *Question 2. The criteria are used by decision-makers within the GPhC who are involved in investigating concerns to decide whether the case should be referred to the investigating committee. Do you think how we apply the criteria in practice is clear?*

3.13 No – see our general comments.

3.14 Further clarity is needed on how the conduct, behaviour and health criteria interact with the public interest considerations, specifically the assessment of registrant insight and remediation. For example, if there is a serious element of harm in a case would this guarantee referral to the IC despite the fact the Case Worker thinks that the registrant has shown sufficient insight and remediated? Examples of types or categories of case which would or would not be referred would be helpful. It would also be useful to explain the criteria as a hierarchy or sequence of decisions, or perhaps to illustrate with a decision-tree.

3.15 It should be made clear that establishing insight is essential if cases are to be closed outside of a public hearing. Clarity is also needed on how Case Workers will be able to effectively assess insight at this stage in the process as this may be challenging without access to the full range of evidence and the ability to hear directly from the registrant and other witnesses.

3.16 The concept of proportionality also needs to be more clearly defined, in particular, how this will be balanced against the wider public interest of holding a public hearing when there is a real prospect of the registrant's fitness to practice being found impaired. The criteria would benefit from further guidance for example with guideline cases to illustrate what would be considered proportionate in conjunction with the public interest considerations.

3.17 *Question 3. These criteria give us a framework to make sure we make proportionate, fair and consistent decisions in all investigations. Do you think the proposed threshold criteria will make sure the right cases are referred to the investigating committee?*

3.18 See our general comments.

3.19 The criteria as framed suggest that the GPhC is moving elements of the real prospect test and consideration of impairment to an earlier stage in the process. These are currently powers reserved to the Investigating Committee and laid out in legislation.

3.20 Whilst it is currently unclear what the effect will be on cases being referred, we feel there is a risk of the right cases not being referred either through an inaccurate assessment of insight or a mistaken view that referral would not be proportionate. There is also a risk that patients may be dissuaded from making a complaint if they do not see the criteria as clear or the process for referral as transparent.

3.21 *Question 4. Do you have any other comments on the proposed criteria?*

3.22 See our general comments.

3.23 We have concerns that disposing of more potentially serious cases earlier on in the process, particularly those where there is a real prospect of finding impairment, could remove cases which would usually come under the additional safeguard of our Section 29 powers of oversight. It may also make it difficult for us to assess the quality of decision making under our Performance Review powers. This could lead to a lack of scrutiny of cases closed at this stage.

3.24 *Question 5. Are there any aspects of the proposed criteria that could have a negative impact on patients, members of the public, pharmacists, pharmacy technicians, or any other groups?*

3.25 See our general comments.

3.26 We would suggest that there is a potential for a negative impact if patients are dissuaded from making complaints due to the way the criteria are framed. There could also be a detrimental effect on public safety if cases which should be referred are inappropriately closed.

3.27 *Question 6. Do you have any comments on the potential impact of the criteria?*

3.28 Even if a direct impact on public protection does not transpire as described in the previous answer, there could be a negative effect on public confidence in the GPhC if there is a perception that cases are being prematurely closed for the benefit of the registrant.

4. Further information

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

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