

Consultation on revised threshold criteria

Analysis of consultation responses

Introduction

1. This report sets out the analysis of responses to our consultation on revised threshold criteria. It follows the structure of the formal consultation document and questionnaire, and summarises the key issues and themes that emerged in the consultation responses.

About the consultation

2. The consultation was open for twelve weeks, beginning on 13 December 2016 and ending on 7 March 2017. To ensure we heard from as many individuals and organisations as possible an online survey was available for individuals and organisations to complete during the consultation period, and we organised a number of engagement events aimed at pharmacy professionals, patients and members of the public held across Great Britain.

Survey responses

3. We received 68 survey responses to the consultation. Of those who submitted a response, 19 were from organisations and 49 from individuals, including registrants, a pre-registration trainee and a member of the public. The vast majority of individual respondents (48, around 94 per cent) identified themselves as a pharmacy professional. Around 80 per cent (38) of those describing themselves as “pharmacy professionals” were pharmacists, while around 19 per cent (9) were pharmacy technicians.
4. We also heard from a patient group, law firms, professional and representative bodies (including pharmacy organisations and healthcare regulators) and several pharmacy multiples.
5. It should be noted that while there were 68 responses to the quantitative, questions (with a yes/no answer in response), the number of responses were much lower to the qualitative, open questions. The full list of organisations responding to the consultation can be found in appendix A.

Engagement events

6. Recognising the technical nature of this consultation, engagement events were a critical part of our consultation activities and were particularly useful in reaching those groups who were less likely to respond to the consultation via the online form, including individual patients and members of the public. The questions in the online survey were used as a structure for discussion in our engagement events.
7. We held five events across Great Britain, including three focus groups and two stakeholder events. We also held a number of individual meetings with key stakeholders, including the Professional Standards Authority, to hear their views on the consultation. A full list of the events held during the consultation is included in appendix B.

Our approach to analysis

8. The great majority of responses were submitted through SmartSurvey using the formal consultation questionnaire. Responses to the questions (with a yes/no answer in response) have been reported giving both the numbers of responses as well as percentages.
9. A coding framework was developed to identify different issues and themes coming up in responses, to identify patterns as well as the prevalence of ideas, and to help structure our analysis. The framework was built bottom up through an iterative process of identifying what emerged from the data, rather than projecting a framework set prior to the analysis on the data.
10. Open questions were analysed using this coding framework. The qualitative nature of the responses here meant that we were presented with a variety of views, and rationales for those views. Responses were carefully considered and coded through the iterative analysis process.
11. The main issues and themes are presented in this report in the narrative under each relevant question. Finally, the coding frame was used to analyse both responses to the formal consultation survey, as well as notes from meetings and events, and other responses that we received.

What we heard

12. Overall, the proposed criteria were received very positively throughout. The feedback across both the survey responses and engagement events was very similar with the majority supporting the proposals. A small number of respondents expressed less positive views. They felt the criteria were either unclear, too broad or open to interpretation. Some offered solutions for how they could be improved, including detailed guidance, training for GPhC staff and reframing the criteria in the positive.
13. In response to several questions, we heard similar, repeated, views on some issues, for example the clarity of the criteria, so we have grouped these under the relevant question to avoid repetition. Also, a range of respondents to the consultation, as well as several at focus groups, highlighted a desire for explanatory materials including a decision process map that sets out the sequence or hierarchy of decisions and examples of case studies that could help define more clearly how the new criteria would work in practice.
14. We also heard feedback on a number of areas that were outside the immediate scope of the consultation including general comments GPhC investigatory processes and the accountability of non-registrant staff. We will consider these, and other issues raised that were outside the scope of this consultation, under relevant project streams.
15. The next section presents key issues and themes raised under each consultation question and follows the order of the questionnaire.

Clear and understandable

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?

Yes	50	75%
No	17	25%
Total	67	100%

Please explain why

The majority of respondents, including those at focus groups and engagement events, believed the criteria were clear and understandable. They were thought to be fair, simple, succinct and reflected the expectations of the GPhC and the public. However, a small number of these respondents also thought the criteria were ambiguous in parts and believed the wording in relation to the health aspect required further clarification. A few respondents welcomed how the criteria focused on the behaviours and actions of registrants. Further, the inclusion of a public interest test was seen as a positive measure. The increase in transparency of the process was also welcomed by one organisation and another regulator. Some hoped the criteria would improve standards in pharmacy by setting out the behaviours expected of registrants.

A number of respondents believed the criteria were too broad, subjective, and that they could be potentially confusing and result in inconsistent decision making. The most common reason for the confusion was the fact the proposed criteria were expressed in the negative. Others believed that training for GPhC staff and additional guidance was required to explain certain aspects of the proposed criteria and address potential risks to decision-making.

Finally, a number of comments and suggestions for improvement to the criteria were proposed. It was widely believed that reframing the criteria in the positive would aid understanding and make the criteria more straightforward to apply.

Applying the criteria in practice

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?

Yes	49	74%
No	17	26%
Total	66	100%

Please explain why

We were encouraged that the majority of respondents, and those that attended focus groups and stakeholder events, believed it was clear how the criteria would be applied in practice. They thought the decision-making process was clearly set out and simpler than the current criteria. A small number of those that responded positively also commented on some areas where clarity could be further improved such as what criteria needs to be met in order to for a case to be referred to an Investigating Committee and case studies to improve understanding. A law firm thought it would be an improvement if the criteria stated that a case will only be referred when the evidence supports it.

Many respondents who thought the criteria were unclear also believed it was equally unclear how they were to be applied in practice. Some respondents thought certain aspects within each of the criteria required further explanation such as *potential risk* or *in the public interest*. Others required clarity around whether all criteria needed to be met before a case is referred to the Investigating Committee.

Some respondents thought public confidence was at risk if decision making is poor and believed further information on who was making decisions, and the qualifications of those decision makers, was needed. One organisation was concerned that the revised threshold criteria may allow cases to be closed prematurely and therefore potentially result in a risk to public protection. It was also concerned with how proportionality and insight would be assessed in the process, the latter particularly against the wider public interest. It also raised concerns on how the public interest would interact with the criteria.

Some respondents commented on how 'harm' is considered. Some agreed that it is right to focus not on the harm itself but on the circumstances in which the harm arose. Others were concerned that the proposed criteria do not include express references to harm. For example, some felt that this could lead to all dispensing errors being referred to the Investigating Committee, as they could all be considered as a potential risk to patient safety.

Others who had concerns believed additional guidance would help all stakeholders understand how the criteria would be applied.

Proportionate, fair and consistent decisions

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?

Yes	50	76%
No	16	24%
Total	66	100%

Please explain why

A significant majority of responses from the survey, alongside feedback from focus groups and stakeholder events, were in support that the right cases would be referred to the Investigating Committee. Many respondents felt the criteria were flexible, fair and that a range of factors, including individuals who have shown insight and learned from the incident, would be taken into account. However, many of those that agreed also felt that guidance was needed to ensure consistent decision-making.

A number of organisations, and some pharmacy professionals, thought the criteria could lead to inconsistent decision-making. This was on account of them being too broad and subjective. Many thought training for individuals applying the criteria, and regular review of decisions, was necessary to address any potential inconsistencies in decision-making. In contrast, some respondents thought that the proposed changes would reduce the amount of time it takes for the Investigating Committee to resolve concerns, would allow the Investigating Committee to devote more time to the right cases and therefore would improve decision-making. Some respondents welcomed the inclusion of a public interest consideration as it could reduce unnecessary referrals to the Investigating Committee.

One organisation believed the simplification of the criteria could be problematic and that the proposed criteria may not capture the full range of issues that registrants present the GPhC with. Another organisation was concerned that the proposed changes could result in the realistic prospect test (a test which is used at the Investigating Committee stage) being brought forward in the process, which would raise issues of transparency and due process. The same organisation also had concerns that the proposed criteria could remove cases from the process early with no external scrutiny. They also highlighted a potential 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.

Other comments

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

Some respondents sought clarity over why changes were being proposed in the first place whilst others highlighted the operational impact that the changes would have in their line of work e.g. training/formal education for pre-registration trainees. Others had queries about the impact the changes would have more generally. For example, some respondents queried how cases were assessed and by whom whilst others spoke positively of how proposed changes to the criteria would align the new standards for pharmacy professionals. Another respondent thought the proposed approach would reduce the amount of time it takes for the Investigating Committee to resolve concerns.

Equality analysis

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?

Yes	12	19%
No	51	81%
Total	63	100%

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

In response to this question many respondents reiterated key points from their earlier answers, including comments that the criteria are clear and well set out. Some added that the impact depended on the accompanying guidance and how that will ensure consistent decision-making. Some respondents thought there may be an impact on public confidence, and confidence in the GPhC, if incorrect decisions are taken under the new criteria or cases are closed prematurely. Similarly another organisation stated that the criteria need to be clear and applied fairly or there will be a risk to public confidence.

One organisation believed that the proposed threshold criteria is likely to increase the length of an investigation, and the resources required to carry it out, in some cases and this may have a negative impact on those directly affected by the investigation. One respondent was concerned it could lead to an increase in fear of prosecutions and under reporting of incidents.

Appendix A: Organisations that responded

Action against Medical Accidents

Blake Morgan LLP

Charles Russell Speechlys LLP

BLM

Professional Standards Authority

Royal Pharmaceutical Society

Association of Pharmacy Technicians UK

General Optical Council

National Pharmacy Association

Boots Pharmacists' Association

Pharmacy Voice

Pharmacists' Defence Association

Community Pharmacy Scotland

Celesio UK

Boots UK

Rowlands Pharmacy

Area Professional Pharmaceutical Committee NHS Ayrshire & Arran

University of Bradford

Northumberland, Tyne and Wear NHS Foundation Trust/Guild of Healthcare Pharmacists

Appendix B: GPhC engagement events

Events: Focus groups and stakeholder engagement events

Patient and public focus group - Cardiff

Stakeholder engagement event - Cardiff

Patient and public focus group - Glasgow

Stakeholder engagement event - Glasgow

Patient and public focus group - London