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## Pharmacists' Defence Association Response to the General Pharmaceutical Council's Consultation on Revised Threshold Criteria

| representing **your** interests |

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## About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 26,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

### The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

## Summary of Proposals

The GPhC is consulting on revised threshold criteria, which will use to decide whether to refer cases to the Investigating Committee (IC) where a registrant's fitness to practice is in question.

The PDA supports the *simplification* of the criteria. However, we do have some significant concerns, which are detailed in this response.

The consultation runs from 14 December 2016 to 7 March 2017.

## The PDA's recommendations are:

- To avoid the use of double and triple negatives and to make them easier to understand, the threshold criteria should be rewritten using positively-worded statements and the stipulation that referral to the IC will occur if **any** of the criteria **are** met.
- The criterion *"it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession"* should be changed to *"it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession or the practice of pharmacy"*.
- The criterion *"it does not present an actual or potential risk to patient or public safety"* must be reworded to *"it did not and does not present an unmitigated risk to public safety"*.
- The GPhC should make clearer the circumstances in which a pharmacist would and would not be referred to the IC as a result of this criterion, by providing examples to illustrate good and bad decision-making and risk mitigation.
- To provide assurances about the consistency of application of the threshold criteria, the GPhC must provide detailed guidance on how the criteria will be applied and issue public reports on the subject, nature and trends of concerns referred – and not referred – to the investigating committee, and the reasons for the decisions. These should be in statistical / thematic form, and must not identify individuals.
- The GPhC must establish threshold criteria for referral to the Investigating Committee, applicable to pharmacy owners and superintendents, where 'there has been a serious or persistent failure to meet any of the standards for registered pharmacies'. The Investigating Committee must establish a process for dealing with such failures – considering whether they would warrant either fitness to practice proceedings, suspension or removal of the pharmacy from the register and/or prosecution and a fine.

## The Consultation Document

We appreciate that the way the consultation questions are phrased has improved in that the questions do not commence with 'do you agree' (or similar), as has previously been the case.

The rationale for the negative wording of the threshold criteria can be found in the GPhC council meeting papers of December 2016 – to align with the provision in the Pharmacy Order 2010.<sup>[1]</sup> This was not explained in the consultation document. We highlighted a similar situation in response to the GPhC's consultation on 'sampling continuing professional development records for review'.<sup>[2]</sup> It would be helpful if, rather than having to read through council meeting papers, all information relevant to GPhC consultations could be included in the consultation documents.

# Consultation Response

## 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?*

### NO

Whilst we support the simplification of the threshold criteria for referral to the investigating committee (IC), we do have some concerns about the proposed wording.

The current threshold criteria describe the circumstances in which the registrar **will** refer a case to the investigating committee, whilst the proposed new criteria describe the circumstances in which it **will not**. As such, the proposed criteria are written in the negative sense; all the criteria must be met to **avoid** referral to the IC. This results in the use of double (and in one case triple) negative clauses, which will require careful interpretation if they are to be applied correctly.

On first reading, the proposed new criteria are not as easy to understand as the existing, which may cause confusion. It seems that the GPhC's desired outcome, stated in the consultation document, will not be achieved: *"We also want to make sure the revised threshold criteria are accessible and easily understood by a wide range of stakeholders, not just people who use them as part of their work. This includes anyone who has raised a concern, or has had a concern raised about them."* Although we note the GPhC's desire to align them with the provision in the Pharmacy Order 2010, it has operated since 2010 with criteria worded in the positive sense, and in our view should continue to do so.

#### Recommendation

To avoid the use of double and triple negatives and to make them easier to understand, the threshold criteria should be rewritten using positively-worded statements and the stipulation that referral to the IC will occur if any of the criteria are met.

Under "Conduct and behaviour", the second criterion is that *"it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession"*. Recognising that the regulatory framework will apply to those who are not professionals and that its reach may be extended in the future, we make the following recommendation.

#### Recommendation

The criterion *"it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession"* should be changed to *"it has not undermined, and is unlikely to undermine, confidence in the pharmacy profession or the practice of pharmacy"*.

We are concerned about the criterion *"[the registrant's conduct and behaviour] does not present an actual or potential risk to patient or public safety"*. A risk could be defined as "the chance that an adverse effect will occur". An "actual risk" is the same as a "risk" and a "potential risk" (to public safety) could be defined as "the possibility that the chance of an adverse effect on public safety will develop in the future (but has not yet developed)". In the event of any complaint, it may be impossible for a registrant to prove that his or her conduct or behaviour *does not* present a *potential* risk to patient or public safety. The term *potential risk* appears to set an unreasonably low threshold for referral to the IC, which could divert the GPhC's resources unnecessarily from matters of greater importance to public safety.

Indeed, risk is inherent in the practice of pharmacy. Trying to achieve the best outcomes for patients inevitably results in occasional mistakes; the ability to learn from mistakes and put that learning in to practice is an important factor in the development of a pharmacist.

What may be important in determining whether a pharmacist should be referred to the IC is the process by which he (or she) comes to a decision, the measures he puts in place to mitigate risk and how he incorporates learning from experience in to his practice.

In addition, this criterion does not provide for the consideration of events in the past. A registrant’s conduct and behaviour may have been so egregious in the past as to have presented a risk to public safety – and even harmed it – but may be unlikely do so in the future (e.g. because the registrant wishes to leave the register). It might be necessary for the purposes of upholding public confidence in pharmacy that the registrant be held to account for his or her actions. However, given its current wording, the criterion would result in some significant cases not being referred to the IC.

**Recommendation**  
 The criterion “it does not present an actual or potential risk to patient or public safety” must be reworded to “it did not and does not present an unmitigated risk to public safety”.

**Recommendation**  
 The GPhC should make clearer the circumstances in which a pharmacist would and would not be referred to the IC as a result of this criterion, by providing examples to illustrate good and bad decision-making and risk mitigation.

**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?**

**NO**

The way in which the GPhC currently applies the criteria in practice is unclear. We are aware of a number of significant decisions in which the criteria have, in our view, been incorrectly applied by the GPhC.

The new proposed criteria will be used by decision-makers within the GPhC in deciding whether to refer a case to the IC. They are framed to allow the registrar flexibility in how a decision is made and we appreciate that there will inevitably be some degree of subjectivity. However, this process must be open, transparent and consistent. We are concerned that a registrant subjected to the process, and where applicable a person who makes a complaint, will not be able to see clearly the rationale for referral to the IC, or absence thereof. We are also concerned that the process may be applied inconsistently.

**Recommendation**  
 To provide assurances about the consistency of application of the threshold criteria, the GPhC must provide detailed guidance on how the criteria will be applied and issue public reports on the subject, nature and trends of concerns referred – and not referred – to the investigating committee, and the reasons for the decisions. These should be in statistical / thematic form, and must not identify individuals.

**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?**

**NO**

The new proposed criteria cannot account for how they will be applied in practice. This relies upon the proper and proportionate application of the criteria by the GPhC.

Significant issues with the GPhC's investigatory processes remain. It is our experience that often, a failure to meet the GPhC's standards, particularly those relating to conduct, ethics and performance, is not solely the result of the actions of a single individual. Environmental factors may be causative. People in positions of authority and pharmacy owners may make decisions that materially contribute to standards being compromised and put patients at risk. In a number of cases where it was identified, during investigation of the original complaint or in a subsequent fitness to practice hearing, that a senior manager, pharmacy superintendent or pharmacy owner contributed to the issues at hand or his / her fitness to practice was in question, the GPhC has not broadened its investigations to include such individuals. Since its inception, the GPhC has consistently failed to hold such persons to account for their role. The public will continue to endure the risks and consequences of the GPhC's failure to act in this regard.

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

The introduction to the proposals in the consultation document, in the Overview section, states "As the regulator, our main role is to protect, promote and maintain the health and safety of people who use services from pharmacy professionals **or from registered pharmacies**" (emphasis added). The standards within registered pharmacies are determined by individuals – to the greatest extent by pharmacy owners, pharmacy superintendents and chief pharmacists, but also by senior managers within larger organisations. It is of great concern, therefore, that the threshold criteria, whilst referring to failures to meet the 'Standards for Pharmacy Professionals', say nothing of a failure to meet the GPhC's Standards for Registered Pharmacies. There are no other threshold criteria applicable to such failures which would result in referral to the IC. This is a considerable gap in the GPhC's governance and approach.

The Pharmacy Order 2010 gives the GPhC the power to create standards necessary for the safe and effective practice of pharmacy, which must be met by pharmacy owners and superintendents.

It allows improvement notices to be served where these are not met, and the pharmacy owner may face a fine of up to level 5 on the standard scale (currently unlimited) as a result. The GPhC may also suspend or remove the pharmacy from the register.<sup>[3]</sup> We have a substantial body of evidence that the policies and practices of certain pharmacy owners have resulted in working conditions which make the safe practice of pharmacy extremely difficult and in some cases unfeasible.

Whilst the GPhC issued 771 sanctions against individuals in 2015/16, the PDA is not aware of a single case of a pharmacy facing a fine or suspension or removal from the register. In fact, the GPhC's annual report for 2015-16 showed that 526 "action plans" were agreed with "pharmacies" following inspections, but makes no mention of sanctions or even the prospect of such. Again, the GPhC's focus in this part of the report was on registrants rather than pharmacy owners, even though the Standards for Registered Pharmacies state "Responsibility for meeting the standards lies with the pharmacy owner", who is often not a registrant.<sup>[4] [5]</sup>

**Recommendation**

The GPhC must establish threshold criteria for referral to the Investigating Committee, applicable to pharmacy owners and superintendents, where ‘there has been a serious or persistent failure to meet any of the standards for registered pharmacies’. The Investigating Committee must establish a process for dealing with such failures – considering whether they would warrant either fitness to practice proceedings, suspension or removal of the pharmacy from the register and/or prosecution and a fine.

Again, the GPhC has not sought to hold pharmacy owners to account at this juncture, for their contribution to the care and safety of patients and the public. If it fails to take the opportunity presented by the renewal of the threshold criteria, in our view the GPhC will be propagating its failure to fulfil its stated ‘main role’ to the proper extent.

**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?**

We particularly value the inclusion of a “public interest” criterion in deciding whether a case will be referred to the IC. If it is applied appropriately, this could reduce unnecessary referrals to the IC, and should mean that cases of significant public interest will be more likely to be referred.

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

**OUR COMMENTS HAVE BEEN MADE IN RESPONSE TO THE OTHER QUESTIONS.**

## References

- 1 General Pharmaceutical Council, "Meeting of Council," 8 December 2016. [Online]. Available: [http://www.pharmacyregulation.org/sites/default/files/2016-12-08\\_council\\_papers\\_for\\_website\\_thurs\\_am.pdf](http://www.pharmacyregulation.org/sites/default/files/2016-12-08_council_papers_for_website_thurs_am.pdf).
- 2 Pharmacists' Defence Association, "GPhC CPD Sampling Consultation," 2 November 2016. [Online]. Available: <https://www.the-pda.org/gphc-cpd-sampling-consultation/>.
- 3 "The Pharmacy Order 2010," 2010. [Online]. Available: [http://www.legislation.gov.uk/ukdsi/2010/9780111487358/pdfs/ukdsi\\_9780111487358\\_en.pdf](http://www.legislation.gov.uk/ukdsi/2010/9780111487358/pdfs/ukdsi_9780111487358_en.pdf).
- 4 General Pharmaceutical Council, "Annual fitness to practise report & annual accounts 2015/16," 2015/16. [Online]. Available: [https://www.pharmacyregulation.org/sites/default/files/pdf/gphc\\_annual\\_report\\_2015-16.pdf](https://www.pharmacyregulation.org/sites/default/files/pdf/gphc_annual_report_2015-16.pdf).
- 5 General Pharmaceutical Council, "Standards for Registered Pharmacies," September 2012. [Online]. Available: <https://www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf>.

[www.the-pda.org](http://www.the-pda.org)

The Pharmacists' Defence Association  
The Old Fire Station  
69 Albion Street  
Birmingham  
B1 3EA  
Contact information  
General Enquiries: 0121 694 7000  
Fax: 0121 694 7001  
Web: [www.the-pda.org](http://www.the-pda.org)  
Email: [enquiries@the-pda.org](mailto:enquiries@the-pda.org)

