June 2016

Pharmacists' Defence Association Response to the General Pharmaceutical Council's Consultation on Standards for Pharmacy Professionals

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the pharmacists' defence association

Contents

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 25,000 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

Executive Summary

The General Pharmaceutical Council (GPhC) has a legal duty to set the standards of conduct, ethics and performance for GPhC registrants. It is consulting on standards to replace the existing 'Standards of Conduct, Ethics and Performance' and has chosen the name 'Standards for Pharmacy Professionals' for the replacement. It has developed nine standards, focused on the areas it says are necessary to deliver safe and effective care. The standards are accompanied by introductory text. Each individual standard is supplemented by an explanation of what it means and examples of responsibilities set by that standard under the heading 'Applying the standard'.

Revision of the standards provides the opportunity to enhance public safety and provide pharmacists with clear professional requirements which reflect modern pharmacy practice.

Our recommendations are:

01. That the standards apply *at all times* and that they apply *not only during working hours* are proposals that will need to be re-visited. The expectations outside of a working environment must be different to those within it. It is recognised, however, that it will still be necessary for fitness to practice committees to consider certain actions taken outside of a working environment. As an alternative, a statement should be included in the introductory text to the effect that any behaviour which brings or may bring the profession into disrepute may be considered as a fitness to practice issue by the GPhC. *(Page 08)*

02. We welcome simplicity as a concept for the standards, but this does not necessarily mean using fewer words. The GPhC *has* used fewer words, but a delicate balance must be struck when taking such an approach. It comes with the responsibility to ensure those words are appropriate, sufficient and avoid unintended consequences and that the standards remain fit for purpose. We do not believe that the proposed standards are fit for purpose in their current form, because the appropriate balance has not been achieved. A significant amount of work is needed to address this. The GPhC should revise the standards in light of the feedback from this consultation and consult on them again at a later stage, before implementing any changes to the current Standards of Conduct, Ethics and Performance. *(Page 09)*

03. The GPhC should consider a similar, consistent approach when setting the Standards of Conduct, Ethics and Performance to that taken in its Standards for Registered Pharmacies. On occasion, sanctions may need to be applied for a breach of the standards. However, it must be recognised that there will be variation in the degree to which the standards will be upheld, and even a breach in absolute terms should not necessarily be met with a sanction. *(Page 09)*

04. Separate standards for superintendent pharmacists and pharmacy owners should be issued prior to updating the standards of conduct, ethics and performance for GPhC registrants. In addition, a requirement should be added as a preface to the updated standards of conduct, ethics and performance (the proposed new standards) to the effect that superintendents and pharmacy owners must ensure that pharmacists working within the organisation for which they are responsible are supported and enabled to meet the standards. *(Page 09)*

05. In the text preceding the standards, to reduce the risk of the standards being applied inappropriately, a paragraph should be included to the effect that *due to the limited wording and lack of context to the examples provided in the 'Applying the standard' section, it will not always be appropriate for registrants to uphold each of the examples as they are written. (Page 10)*

06. 'Make patients your first concern' should be retained in the standards, but reworded to 'Make patients your first concern as a registrant'. *(Page 10)*

07. The Pharmacy Order 2010 creates a legal obligation for the GPhC to set standards relating to the conduct, ethics and performance of registrants. If the same set of standards are to be applied to pharmacists and pharmacy technicians, in the interests of public safety, the term 'pharmacy professionals' should be replaced with 'registrants'. Where specifically required, the standards should make the distinction between pharmacists and pharmacy technicians. *(Page 12)*

08. With a view to assuring public safety, to ensure the appropriate use of the noun 'profession' and its derivatives such as 'professional judgement', references in the standards to 'professional judgement' should be replaced with 'judgement'. Alternatively, it should be made clear that the term 'professional judgement' only applies to pharmacists. *(Page 12)*

09. The title 'Standards of Conduct, Ethics and Performance' should continue to be used in accordance with the wording used in the Pharmacy Order 2010. *(Page 12)*

10. The word 'patient' should be used in the standards rather than 'person' as it better conveys the importance of the individual as a recipient of healthcare and embraces the ethos and attitude that the pharmacy sector has, and should continue to have, towards recipients of its services. *(Page 12)*

11. Point 4 of the introduction to the standards currently reads 'It is the attitudes and behaviours of pharmacy professionals in their day-to-day work which make the most significant contributions to patient safety and the quality of care.' This is the GPhC's view and not an unequivocal fact, so should be rewritten. We suggest the following wording: 'The GPhC's view is that the attitudes and behaviours of pharmacy professionals in their day-to-day work make a significant contribution to patient safety and the quality of care.' *(Page 13)*

12. Point 12 of the 'Applying the standards' section (which follows the introductory text but precedes the standards themselves) should be rewritten so that it does not create a risk to the public by obviating the need to use professional judgement and ethics. It must avoid setting the simple requirement of pharmacists to 'keep to the relevant laws'. *(Page 13)*

13. To increase the applicability of the standards, to assure public safety appropriately and to avoid inappropriately subjugating the behaviour of pharmacy students and diminishing their formative experiences, separate codes of conduct to the code applied to GPhC registrants should be established for pharmacy students (undergraduates), pre-registration trainee pharmacists and trainee pharmacy technicians. *(Page 14)*

14. Standard 9 should be reworded to 'registrants must demonstrate leadership appropriate for a healthcare setting and their position'. *(Page 15)*

15. For Standard 1, the example given in the 'Applying the standard' section which reads 'recognise and value diversity, and respect cultural differences – making sure that every person is treated fairly whatever their values and beliefs' should be replaced with 'work to ensure the practice of pharmacy reflects the needs of a diverse patient base'. *(Page 16)*

16. For Standard 1, the example given in the 'Applying the standard' section which reads 'recognise their own values and beliefs but do not impose them on other people' should be reworded to 'recognise their own values and beliefs and exercise conscience, but do not foist these values and beliefs on other people'. *(Page 16)*

17. For Standard 1, the example given in the 'Applying the standard' section which reads 'tell relevant health professionals, employers or others if their own values or beliefs prevent them from providing care, and refer people to other providers' should be reworded to 'tell relevant health professionals and employers if their own values or beliefs prevent them from providing care'. This would avoid inadvertently creating the mistaken belief among registrants that they must inform *patients* that their values or beliefs prevent them from providing care. *(Page 16)*

18. For Standard 2, the example given in the 'Applying the standard' section which reads 'contact, involve and work with local and national organisations' should be reworded to 'contact, involve and work with local and national organisations when necessary and appropriate'. (Page 16)

19. The GPhC should place a greater emphasis upon ensuring that employers provided the necessary staffing levels to enable pharmacists to make the use of patients records a core element of practice. *(Page 17)*

20. References to body language and tone of voice should be removed from the standards. *(Page 17)*

21. To avoid commoditizing CPD and creating the wrong approach to it, for Standard 4, the example given in the 'Applying the standard' section which reads 'Carry out a range of relevant continuing professional development (CPD) activities' should be reworded to: 'carry out a range of relevant activities which contribute to their ongoing development as a registrant'. *(Page 17)*

22. The 'Applying the Standard' section of Standard 5 should be revised to ensure it is clear that non-pharmacist GPhC registrants such as pharmacy technicians are not expected to make clinical decisions. *(Page 18)*

23. For Standard 5, the example given in the 'Applying the standard' section which reads 'declare any personal or professional interests and manage conflicts of interest' should be reworded to: 'declare and manage any personal or professional conflicts of interest as appropriate'. *(Page 18)*

24. For Standard 6, the example given in the 'Applying the standard' section which reads 'are polite and considerate' should be qualified. It should be reworded to: 'are polite and considerate in the workplace as appropriate to the circumstances'. *(Page 18)*

25. For Standard 7, the example given in the 'Applying the standard' section which reads 'work in partnership with the person when considering whether to share information, except where this would not be appropriate' should be reworded to: 'work in partnership as necessary with the person when considering whether to share information, except where this would not be appropriate or necessary'. *(Page 19)*

26. To avoid isolating whistleblowers, confusing the concepts of whistleblowing and candour and increasing the risk to the public, for Standard 8, the text in the 'Applying the standard' section which reads 'At the heart of this standard is the requirement to be candid with the person concerned, and with colleagues and employers' should be reworded to: 'The purpose of this standard is twofold. It sets the requirement to be candid with the patient and with colleagues and relevant authorities. It is also about raising concerns to the relevant authority.' *(Page 19)*

27. For Standard 8, the example given in the 'Applying the standard' section which reads 'raise a concern, even when it is not easy to do so' should be reworded to: 'raise concerns with the relevant authority, even when it is not easy to do so, within an organisation or external to it as appropriate'. *(Page 20)*

28. For Standard 8, the example given in the 'Applying the standard' section which reads 'say sorry, provide an explanation and set out to put things right when things go wrong' should be reworded to: 'seek to understand the facts of what happened when things go wrong, accept when they have made mistakes and endeavour to learn from them'. *(Page 20)*

29. For Standard 8, the example given in the 'Applying the standard' section which reads 'reflect and act on feedback or concerns, thinking about what can be done to prevent the same thing happening again' should be reworded to: 'reflect on feedback or concerns, taking action as appropriate and taking steps where necessary to reduce the risk of the same thing happening again'. *(Page 21)*

30. For Standard 9, the example given in the 'Applying the standard' section which reads 'demonstrate effective team working' should be removed in order to avoid its misuse and unintended consequences (such as the inappropriate sanctioning or removal of a pharmacist from the register). *(Page 21)*

31. For Standard 9, the example given in the 'Applying the standard' section which reads 'contribute to the training and development of the team' should be reworded to: 'make appropriate contributions to the training and development of the pharmacy team'. *(Page 21)*

32. For Standard 1, 'make sure that all their work, or work that they are responsible for, is covered by appropriate professional indemnity cover' should be included as an example in the 'Applying the standard' section. *(Page 22)*

33. For Standard 5, 'balance competing legal and professional responsibilities, acting in the best interests of the patient' should be included as an example in the 'Applying the standard' section. *(Page 22)*

34. For Standard 5, 'raise concerns with the relevant authority about conditions which impair or prevent them from complying with the standards' should be included as an example in the 'Applying the standard' section. This is different to our recommendations relating to Standard 8 since it explicitly refers to working conditions. *(Page 22)*

35. For Standard 7, 'share information with other health professionals when necessary and appropriate in the interests of the patient' should be included as an example in the 'Applying the standard' section. *(Page 23)*

36. As a priority, the GPhC should issue guidance covering the following areas of practice:
    - Staffing levels
    - Managing organisational goals and targets and other workplace pressures
    - Developing, Implementing and Maintaining Standard Operating Procedures

    (Page 25)

37. As a secondary priority, the GPhC should also issue guidance covering the following areas of practice:
    - Risk assessment
    - Use of care records
    - Acting as role models
    - Making contributions to training
    - Safe delegation
    - Monitoring one's practice/CPD
    - Managing conflicts of interest
    - Social media
    - Duties of managers and those in positions of authority
    (Page 25)

The Consultation Document

As a general principle, we recommend that questions in a consultation such as this be asked in an entirely neutral manner. Commencing questions with leading wording such as 'do you agree' could lead to acquiescence bias.[1,2,3,4] This may mean that the responses obtained will not truly represent respondents' views. We provided the same feedback in our response to the 'Draft Amendments to Rules: The GPhC (Registration) Rules 2010, The GPhC (Fitness to Practise and Disqualification etc.) Rules 2010 and The GPhC (Statutory Committees and their Advisers) Rules 2010' consultation.

Consultation Response

Introduction

Our overall impression is that the new standards are highly corporatized, set unrealistic expectations of GPhC registrants, represent a significant departure from right-touch regulation and place a burdensome expectation of perfection, uniformity and blandness of character that would be difficult for a body of professionals to achieve. We believe that the standards will lead to unintended consequences including risks to public safety and the isolation of whistleblowers.

The wording of the new standards is reminiscent of the language used by large corporate employers and is somewhat Orwellian in nature. One could easily conclude that the thrust and the wording used have been influenced to a greater extent by the responses provided by corporate employers to previous GPhC initiatives, such as the responses given to the patient-centred professionalism discussion, than they have by input from pharmacists who do not have business interests.

We view the new standards as Orwellian because the GPhC has introduced the concepts of regulating explicitly the body language, tone of voice and the words used by registrants. It has also said that registrants must meet these standards at all times, not only during working hours. These were not features of the current 'Standards of Conduct, Ethics and Performance'. In that context, in addition, it has greatly extended the concept of regulating politeness and the consideration registrants give to others, as well as registrants' duty of care to patients' representatives, carers, other healthcare workers and colleagues in employment. This is facilitated in part by the use of the word 'person' rather than 'patient' and as a consequence of the wording used within the standards themselves.

01. Recommendation

*That the standards **apply at all times** and that they apply **not only during working hours** are proposals that will need to be re-visited. The expectations outside of a working environment must be different to those within it. It is recognised, however, that it will still be necessary for fitness to practice committees to consider certain actions taken outside of a working environment. As an alternative, a statement should be included in the introductory text to the effect that any behaviour which brings or may bring the profession into disrepute may be considered as a fitness to practice issue by the GPhC.*

Employers' and Pharmacy Owners' Use of the Standards

The proposed standards could be interpreted in an employer's favour, to any end that suits them, in almost any situation. It has become commonplace for employers to quote breaches of GPhC standards in employment matters. We believe that employers will use these uncompromising standards to make inappropriate referrals to the GPhC for fitness to practice consideration and that, more frequently still, they will use them to support their own disciplinary processes.

The GPhC has facilitated the potential for abuse of the standards by employers because it has effectively provided them with a tool which will allow them to treat pharmacists in whatever way they choose. Against the backdrop of unrealistic standards, employers will have little difficulty labelling any failure on a pharmacist's part as a 'fitness to practice' issue, regardless of whether it is relevant to the safe and appropriate practice of pharmacy.

We have long held the view (and the GPhC has also heard it from others) that the GPhC ought to use its powers under Schedule 1, paragraph 6 of the Pharmacy Order 2010 to provide guidance specifically to owners of pharmacy businesses. Whilst it is prepared to set such uncompromising standards for registrants, it has repeatedly failed (and continues to fail) to do that on matters which have a significant impact on patient and public safety, such as appropriate staffing levels, targeting and professionalism generally. This should be done before implementing any changes to the standards applicable to individual pharmacists.

Given the nature of the standards and the GPhC's apparent unwillingness to tackle large corporate employers in any meaningful way on matters of public safety, it is unsurprising that many pharmacists are of the view that the GPhC is afraid to tackle large employers and that its authority and oversight is being displaced by theirs. It seems to have accepted, without reservation, suggestions from corporate employers as to how it should regulate pharmacists.

Number of Standards

During the consultation period, in presentations given in relation to the new standards, the GPhC has repeatedly asserted that the current 57 standards (under 7 headings) has been reduced to 9 new standards. The examples given in the 'Applying the standard' section will be interpreted by fitness to practice committees, employers, individuals pursuing civil claims and courts of law literally, as they are written and to the interpreter's own ends. There are 55 examples under the 9 different standards, so in fact the GPhC has made no reduction in the *number of expectations* it has set.

02. Recommendation

*We welcome simplicity as a concept for the standards, but this does not necessarily mean using fewer words. The GPhC **has** used fewer words, but a delicate balance must be struck when taking such an approach. It comes with the responsibility to ensure those words are appropriate, sufficient and avoid unintended consequences and that the standards remain fit for purpose. We do not believe that the proposed standards are fit for purpose in their current form, because the appropriate balance has not been achieved. A significant amount of work is needed to address this. The GPhC should revise the standards in light of the feedback from this consultation and consult on them again at a later stage, before implementing any changes to the current Standards of Conduct, Ethics and Performance.*

Impact on Pharmacists and Consistency with the Premises Standards

The GPhC's Standards for Registered Pharmacies result in a grading of either poor, satisfactory, good or excellent following a GPhC inspection. In those outcomes, the GPhC recognises that premises vary in their performance against the applicable standards; the standards are not interpreted in absolute terms. A failure to meet one or more of the standards may result in a 'Satisfactory' or 'Good' rating; this is not in itself a sanction, but merely an indication of the degree to which the standards have been upheld.

The proposed new standards for individuals take an altogether different approach. They would subjugate pharmacists to a life of intolerable servility through the application of an overly-restrictive regulatory ligature on their every action. They represent a significant departure from right-touch regulation. In implementing standards of this nature, we believe the Council will have increased the risk to the public. We do not believe that to be its intention.

03. Recommendation

The GPhC should consider a similar, consistent approach when setting the Standards of Conduct, Ethics and Performance to that taken in its Standards for Registered Pharmacies. On occasion, sanctions may need to be applied for a breach of the standards. However, it must be recognised that there will be variation in the degree to which the standards will be upheld, and even a breach in absolute terms should not necessarily be met with a sanction.

Superintendents and Pharmacy Owners

We understand that the 'Standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority'[5] have been repealed (though we can find no evidence of this in the public domain). Superintendents have been given an enforceable responsibility for ensuring that the Standards for Registered Pharmacies are met. We would also like to see responsibilities set out within the standards of conduct, ethics and performance for superintendents and pharmacy owners to ensure that other pharmacists are supported to meet them.

We are awaiting the outcomes of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme, which may result in separate standards being introduced for superintendent pharmacists, but will not result in standards for pharmacy owners.[6]

04. Recommendation

Separate standards for superintendent pharmacists and pharmacy owners should be issued prior to updating the standards of conduct, ethics and performance for GPhC registrants. In addition, a requirement should be added as a preface to the updated standards of conduct, ethics and performance (the proposed new standards) to the effect that superintendents and pharmacy owners must ensure that pharmacists working within the organisation for which they are responsible are supported and enabled to meet the standards.

Applications of the Standards

The new standards will be used in employer-mediated disciplinary and performance management and legal proceedings, where they are less likely to be used appropriately in the way the Council has intended. We believe that the standards will also lead to an increase in the number of public complaints to the Council which are not relevant to the practice of pharmacy. When expectations are put in to writing by an authority such as the GPhC, they are often interpreted literally, favourably to the party interpreting them. We have given examples of the problems this causes in our responses to other questions.

In the foreword to the standards, the GPhC must explain that in the event of scrutiny as to whether a pharmacist has upheld them, all circumstances must be considered and that, due to the limited wording and lack of context to the examples provided in the 'Applying the standard' section, it will not always be appropriate to uphold each of the examples as they are written.

05. Recommendation

In the text preceding the standards, to reduce the risk of the standards being applied inappropriately, a paragraph should be included to the effect that ***due to the limited wording and lack of context to the examples provided in the 'Applying the standard' section, it will not always be appropriate for registrants to uphold each of the examples as they are written.***

Make Patients your First Concern

The first standard in the current 'Standards of Conduct, Ethics and Performance', standard 1.1, is 'make patients your first concern'. We would like to see this retained in the current standards, but appropriately qualified to reflect the fact that this duty arises as part of the work of a registrant.

06. Recommendation

'Make patients your first concern' should be retained in the standards, but reworded to 'Make patients your first concern as a registrant'.

The Difference between Pharmacists and Pharmacy Technicians

The proposed new standards continue to use the term 'pharmacy professionals' to refer to both pharmacists and pharmacy technicians. We believe that there is a distinction in the expectations of patients and the public with respect to the attitudes and behaviours of the two groups of registrants and the trust and confidence placed in each.

We must therefore reiterate the issues we raised in our response to the 'patient-centred professionalism' consultation conducted by the GPhC in 2015.[7] The PDA has long been concerned that in pharmacy, the terminology and the thinking behind the phrases 'acting professionally' and 'being a professional' has become almost interchangeable. This is not at all helpful.

In reality, 'professionalism' is distinct from 'being a professional'. The use of the word 'professional' as an adjective (being professional) is altogether different to its use as a noun (being *a* professional) and carries different meanings. A sixteen-year-old receptionist or a fast food server with no qualifications whatsoever could, with good manners and a little organisational knowledge, seem to act professionally in a relatively simple customer transaction. He or she could hardly be described as being 'a professional' or belonging to 'a profession'. Likewise, it would be a misuse of the English language to say that he or she had exercised 'professional judgement'. The term 'professional judgement' is used to refer to those individuals who belong to a profession.[8,9]

We hope that all staff members of pharmacies throughout the UK should be able to act professionally when facing a patient, but this does not mean that they could or should each be described as being 'a professional'. Neither can the notion that a register of personnel which is created on a particular day mean that all those appearing on that register from that day on have become professionals.

Yet this is an issue that plagues pharmacy. In 2010, as a result of an initiative driven by civil servants, an administrative register of pharmacy technicians was created. This in itself would not be a problem as such, but since that day, there has been confusion about what it means to be *'a professional'* in pharmacy. Increasingly, pharmacy technicians, without sufficient justification, are being described as professionals or members of a profession. That this confusion has been allowed to emerge is, we believe, because the register of pharmacy technicians was a keen policy construct of the civil service.

The register of pharmacy technicians did not emerge through a robust and traditional process of professional consciousness being gradually built up layer by layer over a period of time and in response to changes in healthcare requirements. It was not developed by a group with highly specialist skills, expert knowledge and rigorous high-level training that led to the emergence of a professional group, represented by a strong leadership body, who could represent and articulate its ambitions (as is the case with doctors, nurses and pharmacists). It therefore should not be considered, in terms of public safety assurance, as a group whose registration confers anything like the same protection to the public as does a professional group that emerged through the more traditional route over a period of centuries, alongside the development of pharmacy.

What exists instead is one profession, formed by pharmacists over many generations and in the traditional way, and a distinctly separate register of pharmacy technicians that was created by government edict. Consequently, many of those on this register are separated by great differences in training, experience, capability and, most importantly of all, by widely differing ambitions. Pharmacy technicians have not joined a profession in the common sense of the word; rather, they came to work as usual and on one particular day, it became a requirement for their names to be entered onto a register. As such, the register 'joined them'.

This is an extremely important concept to consider, especially when the debate about skill mix and how it relates to public safety is considered. The aim should be to identify the roles that pharmacy technicians might undertake to allow the development of pharmacy service provision, with a view to improving the benefits that patients derive from those services. It should be about learning what makes the very best pharmacy technicians so good, then recognising and overcoming the challenges that would bring the rest up to that standard - which could then be quality-assured.

It is also about recognising and understanding the significant differences between pharmacy technicians in the hospital setting - where standards have been developed over many years with the support of senior hospital pharmacists - and those in the community setting, where pharmacy technician development has been held back by a lack of investment by some community pharmacy employers. Ultimately the debate should be about how best to develop professionalism and high standards amongst such a large and disparate group in a way that benefits patients. There appears to be a reluctance to take such an approach.

The pharmacy civil service, pharmacy organisations, representative bodies and in particular the GPhC must not only understand the difference, but they must consciously apply this knowledge and act in a way and in a context which ensures it does not diminish public safety when policy on pharmacy workforce and skill mix is being developed.

The notion that someone who appears on a register and who can act in a professional manner should automatically be considered to be a professional is a fallacy and is a concept that creates risks to the public, especially when it is applied to the provision of healthcare.

This is a problem of which senior officials at the GPhC are fully aware. During a debate at the Royal Pharmaceutical Society Conference in September 2014, the GPhC Chairman talked about the fact that the GPhC had created a register of pharmacy technicians. He explained, however, that a large proportion of the pharmacy technicians on that register had joined it through a grand-parenting arrangement and had not undergone further training since. As a result, there were some very variable standards amongst pharmacy technicians on the register. He explained that it was therefore not possible for the regulator to take a blanket view and to recommend what roles should be undertaken by registered pharmacy technicians.

It is because of the differences in training, qualifications and experience that the GPhC register of *pharmacists* lists those who are superintendents and those who are not, whilst the register of pharmacy technicians includes no such annotation. We are pleased that the GPhC continues to draw this distinction, but it is testament to the fact that there *is* a difference between the two groups.

It would be helpful if in future these concerns were reflected much more robustly and transparently in discussion papers and other statements made by the pharmacy regulator. Unless these concerns are discussed openly, they cannot be resolved. In particular, the GPhC, in the language it uses in its policy papers, consultation/discussion documents and in the approach that it takes, should not give the public and other important stakeholders the impression that the professional credentials of pharmacists are comparable to those of pharmacy technicians.

07. Recommendation

The Pharmacy Order 2010 creates a legal obligation for the GPhC to set standards relating to the conduct, ethics and performance of registrants. If the same set of standards are to be applied to pharmacists and pharmacy technicians, in the interests of public safety, the term 'pharmacy professionals' should be replaced with 'registrants'. Where specifically required, the standards should make the distinction between pharmacists and pharmacy technicians.

08. Recommendation

With a view to assuring public safety, to ensure the appropriate use of the noun 'profession' and its derivatives such as 'professional judgement', references in the standards to 'professional judgement' should be replaced with 'judgement'. Alternatively, it should be made clear that the term 'professional judgement' only applies to pharmacists.

Title of the Standards

We are disappointed by the loss of the word 'ethics' from the title of the standards, since the use of ethics in decision making is a fundamental part of a pharmacist's role.

The Pharmacy Order creates a legal obligation for the GPhC to 'set standards relating to the conduct, ethics and performance expected of registrants'. With this in mind, we make the following recommendation.

09. Recommendation

The title 'Standards of Conduct, Ethics and Performance' should continue to be used in accordance with the wording used in the Pharmacy Order 2010.

Patient vs. Person

In many instances, the GPhC has chosen to use the term 'person' rather than 'patient' in the standards. The word 'patient' means a recipient of healthcare. As opposed to words such as 'person' and 'customer' (a word more often used in corporate retailing environments), it conveys the importance of the individual as a recipient of healthcare and embraces the ethos and attitude that the pharmacy sector has, and should continue to have, towards recipients of its services. It was used repeatedly in the foreword of the consultation document by the GPhC and continues to be used in some cases within the standards. It is used in legislation such as the Pharmacy Order 2010 and in other NHS regulations, guidance and policies.

10. Recommendation

The word 'patient' should be used in the standards rather than 'person' as it better conveys the importance of the individual as a recipient of healthcare and embraces the ethos and attitude that the pharmacy sector has, and should continue to have, towards recipients of its services.

Questions

1. The introduction should set the context and make clear who the standards apply to, and how they should be applied by pharmacy professionals.

Is the introduction clear?

NO

1a. What else, if anything, should be added to or removed from the introduction?

INTRODUCTION POINT 4

Point 4 of the introduction states 'It is the attitudes and behaviours of pharmacy professionals in their day-to-day work which make the most significant contributions to patient safety and the quality of care.' This is the GPhC's belief, not an unequivocal fact. The workplace environment and other factors also make significant contributions to patient safety and in many instances (especially when they are deficient) are even more important, but the standards are notably silent on this point.

11. Recommendation

Point 4 of the introduction to the standards currently reads 'It is the attitudes and behaviours of pharmacy professionals in their day-to-day work which make the most significant contributions to patient safety and the quality of care.' This is the GPhC's view and not an unequivocal fact, so should be rewritten. We suggest the following wording:

'The GPhC's view is that the attitudes and behaviours of pharmacy professionals in their day-to-day work make a significant contribution to patient safety and the quality of care.'

INTRODUCTION POINT 12

The *'Applying the standards'* section follows the introduction but is distinct from the *'Applying the standard'* section provided under each of the nine proposed standards.

We are concerned about point 12 in the 'Applying the standards' section of the introduction. It reads 'the standards and supporting explanations do not cover the legal duties pharmacy professionals have, as all pharmacy professionals must keep to the relevant laws.' Our view is that this statement is incompatible with the use of professional judgement and ethics and with other statements in the consultation document. For example, point 14 in the 'Applying the standards' section states 'there will be times when pharmacy professionals are faced with conflicting legal and professional responsibilities' and in the 'Applying the standard' section under standard 5 it states 'professional judgement includes managing competing legal and professional responsibilities'.

Any wording from the GPhC to the effect that pharmacists must follow the law without the need to use professional judgement and ethics could place the public at significant risk. It is important not to undermine the importance of the law, but to recognise that pharmacists must also apply professional ethics.

12. Recommendation

Point 12 of the 'Applying the standards' section (which follows the introductory text but precedes the standards themselves) should be rewritten so that it does not create a risk to the public by obviating the need to use professional judgement and ethics. It must avoid setting the simple requirement of pharmacists to 'keep to the relevant laws'.

2. The present standards for pharmacy professionals already apply to all pre-registration trainee pharmacists and pharmacy technicians.

We also intend to ask all pharmacist and pharmacy technician students to meet the standards for pharmacy professionals, rather than having a separate student code of conduct.

Do you agree with this approach?

NO

2a. If you do not agree with this proposal, please explain why.

Pharmacy students will not necessarily be working in a pharmacy or have an employer. Therefore, any reference to the 'person' within the standards (which is defined at point 10 of the 'Applying the standards' section as 'the person receiving care') would have little relevance to pharmacy students. Similarly, references to employers, records of care, consent, working with local and national organisations, safeguarding, CPD, professional decision making, practicing only when fit to do so, organisational incentives and targets and task delegation are likely to be of no or limited relevance to pharmacy students.

For the standards to be applicable to both pharmacy students and GPhC registrants, both the standards themselves and the corresponding text on applying each standard would have to be made so generic that they would become meaningless and irrelevant to both groups. One size cannot fit all; a separate student code of conduct must be maintained.

It must be remembered that pharmacy students have not yet qualified as professionals. The group includes those who have just left school or college and those who, for various reasons, will fail to qualify as a pharmacist.

The standards set expectations, not aspirations. By virtue of the fact that they dictate how a registrant *must* behave, they are also enabling; since registrants *must* comply with them, they are enabled and in fact required to behave in accordance with them.

An individual who works at a fast food retailer could become a trainee dispensing assistant immediately upon commencing employment in certain community pharmacies. The person may qualify as a 'trained' dispensing assistant within a period of three to six months. He or she could then immediately enrol as a trainee pharmacy technician. The Council proposes to apply the new standards to students, trainee pharmacy technicians and pre-registration students.

We believe that this proposal may cause confusion. If pre-registration pharmacists, pharmacy students, pharmacy technicians and trainee pharmacy technicians are told that the standards apply to them, they may believe that they are entitled to call themselves 'pharmacy professionals'. If they are told that they are expected to meet the standards, they may also believe that they are expected to 'use their judgement to make clinical and professional decisions' (standard 5). This would introduce a significant risk to public safety. A lay person may identify a headache and decide to take paracetamol to treat it, but it would hardly be appropriate to refer to it as a clinical decision.

Applying the same standards of conduct, ethics and performance to pharmacy students as well as to pharmacists would subjugate student behaviour and thereby diminish their formative experiences at University. Students whose body language, tone of voice and politeness was subject to improper controls at all times of the day and night might well hesitate to join student protests or become politically active. Their intellectual exploration and the formation of their world-views and personalities could thereby be inhibited. As a result, students might become less 'rounded' as pharmacists, adversely affecting their interactions with patients and the public in the communities they serve.

13. Recommendation

To increase the applicability of the standards, to assure public safety appropriately and to avoid inappropriately subjugating the behaviour of pharmacy students and diminishing their formative experiences, separate codes of conduct to the code applied to GPhC registrants should be established for pharmacy students (undergraduates), pre-registration trainee pharmacists and trainee pharmacy technicians.

The nine standards for pharmacy professionals

3. Are the standards clear?

NO

3a. What, if anything, is unclear?

They are clearly written insofar as the wording is comprehensible, but each of the standards requires explanation as to its meaning and many require extensive revision.

4. Are there any standards you do not agree with? (If so, please explain)

YES

As already set out in the introduction, we believe that the standards need to be extensively rewritten as they do not set realistic expectations for pharmacy practice.

Standard 9

It is notable that the concept of leadership has been introduced by these draft standards. It does not exist explicitly in the current standards.

Any standard or explanation in the 'Applying the standard' section will be used at an employer's discretion against a pharmacist and interpreted by the employer in a way which is most favourable to them. Those in pursuit of civil claims will do the same. As a result, we have concerns with various standards and with the associated 'Applying the standard' sections. Standard 9, which focuses on leadership, provides a useful opportunity to illustrate the issues.

'Leadership' has many different meanings and connotations. An employer will be able to argue that any shortcomings they perceive in a pharmacist's actions in or out of work – such as their behaviours, words, body language, tone of voice or performance against targets - are a failure of the pharmacist's leadership and therefore constitute a breach of the standards. The same is true of the example 'demonstrate leadership so that everyone in the pharmacy team understands the need to maintain a person's privacy and confidentiality' in the 'Applying the standard' section of standard 7.

Further, in a team of people, not all of them can function simultaneously as the principal leader. The current wording may lead to confusion and conflict in this regard as to which registrant, in a given scenario, was the leader; due to the wording of the standards, each would be required to demonstrate leadership.

14. Recommendation

Standard 9 should be reworded to 'registrants must demonstrate leadership appropriate for a healthcare setting and their position'.

5. Are there any other standards that you think are missing?

NO

(If so, please explain)

N/A

Applying the standards

Each standard is supported by a section called 'applying the standards' [note: It is in fact called 'Applying the standard'; a separate section called 'Applying the standards' follows the introductory text]. These sections explain why the standard is important, and gives examples of the types of attitudes and behaviours that pharmacy professionals should demonstrate.

6. Do you think the section 'applying the standards' is useful in helping you to understand the standards?

NO

In principle the 'applying the standard' sections would be useful, but we believe that they need to be extensively rewritten as they do not set realistic expectations for pharmacy practice.

7. Do you think the 'applying the standards' sections are clear and easy to understand?

NO

8. What is unclear? Please say which standard or standards you mean, and explain why you think there is a problem with the 'applying the standard' section.

Standard 1

The example requirement 'recognise and value diversity, and respect cultural differences – making sure that every person is treated fairly whatever their values and beliefs' should be removed. It should be unnecessary to explain that every person should be treated fairly *whatever their values and beliefs* and in fact might imply an assumption of bigotry. We expect that the GPhC's thinking may well have been in the context of healthcare and the treatment of patients. Consequently, if this example were retained, the term *'every patient'* would say enough. Further, it is beyond the remit of the regulator to mandate that registrants 'recognise and value diversity' in all aspects of their lives. Whilst we recognise the importance of such behaviour and believe that it is the behaviour expected of all members of a civilised society, we take the view that it is well beyond the scope of a healthcare regulator to place such demands upon its registrants.

15. Recommendation

For Standard 1, the example given in the 'Applying the standard' section which reads 'recognise and value diversity, and respect cultural differences – making sure that every person is treated fairly whatever their values and beliefs' should be replaced with 'work to ensure the practice of pharmacy reflects the needs of a diverse patient base'.

The wording of the example requirement 'recognise their own values and beliefs but do not impose them on other people' should be revisited. In its current form, any registrant who was also a religious functionary such as a priest, rabbi or imam, would arguably be breaching the standards.

It should not be necessary for pharmacists to tell patients if their own beliefs prevent them from providing care. In the PDA's experience this has led to very difficult conversations in the past, requiring the pharmacist to explain why this was the case. A patient may then conclude that the pharmacist was imposing his/her beliefs upon them. It should be sufficient for the registrant to say that he/she does not provide a particular service.

16. Recommendation

For Standard 1, the example given in the 'Applying the standard' section which reads 'recognise their own values and beliefs but do not impose them on other people' should be reworded to 'recognise their own values and beliefs and exercise conscience, but do not foist these values and beliefs on other people'.

17. Recommendation

*For Standard 1, the example given in the 'Applying the standard' section which reads 'tell relevant health professionals, employers or others if their own values or beliefs prevent them from providing care, and refer people to other providers' should be reworded to 'tell relevant health professionals and employers if their own values or beliefs prevent them from providing care'. This would avoid inadvertently creating the mistaken belief among registrants that they must inform **patients** that their values or beliefs prevent them from providing care.*

Standard 2

The example 'contact, involve and work with local and national organisations' must be revised. Pharmacists do not need to do this in all circumstances in order to provide safe and effective patient care. For example, it should not be necessary to contact local and national organisations each time a prescription is presented to a pharmacy. If the wording is left as it is, however, it may be used inappropriately in fitness to practice and other legal proceedings and employer-mediated disciplinaries and performance management processes.

18. Recommendation

For Standard 2, the example given in the 'Applying the standard' section which reads 'contact, involve and work with local and national organisations' should be reworded to 'contact, involve and work with local and national organisations when necessary and appropriate'.

We support wholeheartedly the concept of making the use of patients records a core element of pharmacy practice. We support the example 'make and use records of the care provided'. We believe that pharmacists should be able to do this routinely for every patient in order to provide safe and effective patient care. However, due to the current poor staffing levels and working environments in many community pharmacies, such a requirement would be difficult (and potentially impossible) to meet at this time unless the GPhC made a significant investment in tackling staffing shortages in community pharmacy. We would urge the GPhC to make this a priority.

19. Recommendation

The GPhC should place a greater emphasis upon ensuring that employers provided the necessary staffing levels to enable pharmacists to make the use of patients records a core element of practice.

Standard 3

The text in the 'Applying the standard' section includes the sentence 'Body language, tone of voice and the words pharmacy professionals use all contribute to effective communication'. The consultation document also states explicitly that the standards will be used to demonstrate continuing fitness to practice.

Body language varies between cultures and the same gesture can convey different meanings to people dependent on their background. The same gesture could mean different things to different people or may be interpreted in different ways.[10]

We are also aware that pharmacists are often required to work in extreme situations, sometimes dealing with aggressive and even violent patients. There must be a recognition that the body language and tone of voice used by pharmacists will change depending on circumstances.

We are concerned about how the GPhC will regulate body language and tone of voice and that this standard will lead to inappropriate application in fitness to practice and other legal proceedings and in employer-mediated disciplinaries and performance management processes. We hope that the Council will continue to recognise that inappropriate sanctions may place the public at risk – for example by removing a pharmacist who provides an outstanding service to the public but who, for a brief moment, exhibited what the GPhC deemed to be the wrong body language.

20. Recommendation

References to body language and tone of voice should be removed from the standards.

Standard 4

The example 'Carry out a range of relevant continuing professional development (CPD) activities' needs to be revised. The approach to CPD should be that a pharmacist undertakes activities which in retrospect can be used to demonstrate that he or she has developed professionally. It then becomes an activity which can contribute to a person's CPD record. Calling such an activity 'a CPD activity' appears to commoditize CPD, suggesting that only specified activities would contribute to CPD. It alludes to an exercise undertaken purely to satisfy a regulatory requirement. This may lead to the wrong approach to CPD.

21. Recommendation

To avoid commoditizing CPD and creating the wrong approach to it, for Standard 4, the example given in the 'Applying the standard' section which reads 'Carry out a range of relevant continuing professional development (CPD) activities' should be reworded to:

'carry out a range of relevant activities which contribute to their ongoing development as a registrant'.

Standard 5

The 'Applying the Standard' section includes the wording 'People expect pharmacy professionals to use their professional judgement' and 'people receive safe and effective care when pharmacy professionals use their judgment to make clinical and professional decisions…'. The GPhC intends to apply the standards to both pharmacists and pharmacy technicians, and it is proposed that the standards will also be applied to pre-registration trainee pharmacists and pharmacy students (we disagree with this approach). This section should therefore be reworded.

As we have already set out, the standards are enabling as well as setting expectations. In our view the wording will cause confusion and will lead pharmacy technicians, pharmacy students and pre-registration trainee pharmacists to believe they are expected to make clinical decisions and to exercise professional judgement.

As such, the wording creates a serious and substantial risk to public safety. We understand that pharmacy students and pre-registration trainee pharmacists need to develop their clinical knowledge and in doing so will need to consider what clinical decision they *would* make once qualified as a pharmacist. However, they do not make such decisions unchecked *until and unless* they become qualified as a pharmacist and should not be expected to do so, in the interests of public safety.

22. Recommendation

The 'Applying the Standard' section of Standard 5 should be revised to ensure it is clear that non-pharmacist GPhC registrants such as pharmacy technicians are not expected to make clinical decisions.

Since the standards will be used in legal proceedings, including in fitness to practice proceedings, the example 'declare any personal or professional interests and manage conflicts of interest' requires rewording. It is not always appropriate to declare personal interests – it depends on the circumstances. It would not, for example, be appropriate for a pharmacist to tell every patient who enters a pharmacy that he or she has an interest in football or in a particular team.

23. Recommendation

For Standard 5, the example given in the 'Applying the standard' section which reads 'declare any personal or professional interests and manage conflicts of interest' should be reworded to:

'declare and manage any personal or professional conflicts of interest as appropriate'.

Standard 6

We are concerned about the example 'are polite and considerate'. The consultation document states that 'the standards also need to be met at all times, not only during working hours'. Pharmacists deal with a variety of situations both within the scope of pharmacy practice and outside of it. In work this could include, for example, challenging a shoplifter. Outside of work, the possibilities are endless; it may include responding to an abusive spouse, removing an intruder from his or her property or preventing physical harm to himself, herself or to a family member. Like any other person, pharmacists may use swear words or tell rude jokes in their private lives – and they would judge when it was appropriate to do so. The standards set by the GPhC may be interpreted literally, favourably to the party interpreting them. They may be used in fitness to practice and other legal proceedings or by employers. They could even be used by professional adversaries; for example, the RPSGB code of conduct for council members was used in such an inappropriate way by political adversaries on numerous occasions. By using this wording without limitation, the Council leaves pharmacists open to inappropriate challenges to their professionalism. This in turn creates a risk to the public – that a pharmacist committed to serving the public in a dedicated and professional manner could be inappropriately sanctioned or even removed from his or her position, depriving the public of access to such an individual.

24. Recommendation

For Standard 6, the example given in the 'Applying the standard' section which reads 'are polite and considerate' should be qualified. It should be reworded to:

'are polite and considerate in the workplace as appropriate to the circumstances'.

Standard 7

The example 'work in partnership with the person when considering whether to share information, except where this would not be appropriate' needs to be revised. It may be *appropriate* to have a discussion about sharing information, but it may not be *necessary*. For example, consider the situation in which a patient's representative enters a pharmacy and asks for a repeat prescription to be dispensed. During the discussion, the representative informs the pharmacist that the patient has run out of one of his or her medicines but it is not included on the prescriptions. Whilst it may be *appropriate* to phone the patient to say 'do you mind if I speak with the GP to inform them you have run out of your medicines', it may not be *necessary*. The patient and their representative would both be persons receiving care, using the definition given in the standards. The presentation of the prescription would likely imply consent to deal with an issue such as that described above.

25. Recommendation

For Standard 7, the example given in the 'Applying the standard' section which reads 'work in partnership with the person when considering whether to share information, except where this would not be appropriate' should be reworded to:

'work in partnership as necessary with the person when considering whether to share information, except where this would not be appropriate or necessary'.

Standard 8
Whistleblowing – Standard 8

The explanation in the 'Applying the standard' section states 'At the heart of this standard is the requirement to be candid with the person concerned, and with colleagues and employers.' We are concerned that the Council has chosen this wording. The Council speaks of *'how we as a society have learnt from tragic failures of care – such as those at Mid Staffordshire Foundation Trust, the Vale of Leven in Scotland, and the Abertawe Bro Morgannwg University Health Board hospitals in Port Talbot and Bridgend in Wales'* in the consultation document. We take the view that the wording in this 'Applying the standard' section is inconsistent with any positive learning from such events. The GPhC risks portraying a limited understanding of concepts such as whistleblowing and candour.

The GPhC's guidance on raising concerns states that the concern must be raised to *'the relevant authority'*. The most similar standard from the current Standards of Conduct, Ethics and Performance, which these new standards will seemingly replace, is *'Make the relevant authority aware of any policies, systems, working conditions, or the actions, professional performance or health of others if they may affect patient care or public safety. If something goes wrong or if someone reports a concern to you, make sure that you deal with it appropriately'.* The 'relevant authority' may include an employer, the GPhC, a defence association, an organisation which supports whistleblowers such as Public Concern at Work, any prescribed body named under the Public Interest Disclosure Act (PIDA) or the free press in certain circumstances.

The wording in the 'Applying the standard' section narrows and limits the Council's previous definition of 'the relevant authority', in these standards, to the person concerned, colleagues and employers. It omits to mention the 'relevant authority' and does not provide any examples other than 'colleagues' and 'employers' which would indicate any intention that concerns may be raised other than to these two groups. In choosing such wording, the Council may suppress concerns from pharmacists and prevent them from being raised outside of their own employing organisation. Therefore, we believe in its current form the 'Applying the standard' section results in a significant increase in risk to the public and will likely lead to a diminution of whistleblowing culture. We believe it will isolate whistleblowers by removing the external option for whistleblowing that the Council should provide as a prescribed body under PIDA and as a regulator.

The wording 'At the heart of this standard is the requirement to be candid with the person concerned, and with colleagues and employers' also attempts to amalgamate (and thereby diminishes) the concept of whistleblowing / raising concerns with the duty of candour in the event of a dispensing error. Whistleblowing and candour are two distinctly different concepts and must not be confused.

26. Recommendation

To avoid isolating whistleblowers, confusing the concepts of whistleblowing and candour and increasing the risk to the public, for Standard 8, the text in the 'Applying the standard' section which reads 'At the heart of this standard is the requirement to be candid with the person concerned, and with colleagues and employers' should be reworded to:

'The purpose of this standard is twofold. It sets the requirement to be candid with the patient and with colleagues and relevant authorities. It is also about raising concerns to the relevant authority.'

The example 'raise a concern, even when it is not easy to do so' should be reworded to emphasize that the 'relevant authority' should be contacted – internal to the organisation or external to it as appropriate.

27. Recommendation

For Standard 8, the example given in the 'Applying the standard' section which reads 'raise a concern, even when it is not easy to do so' should be reworded to:

'raise concerns with the relevant authority, even when it is not easy to do so, within an organisation or external to it as appropriate'.

Professionalism – Standard 8

The PDA deals routinely with calls from pharmacists expressing concerns about the approach taken by employers to their professionalism. This includes instances in which employers have placed pressure on pharmacists to apologise for a dispensing error – including writing a letter of apology – before a full investigation of the error has been carried out; on occasion it has later transpired that the pharmacist was not involved at all.

The example 'say sorry, provide an explanation and set out to put things right when things go wrong' needs qualification.

28. Recommendation

For Standard 8, the example given in the 'Applying the standard' section which reads 'say sorry, provide an explanation and set out to put things right when things go wrong' should be reworded to:

'seek to understand the facts of what happened when things go wrong, accept when they have made mistakes and endeavour to learn from them'.

Feedback – Standard 8

The example 'reflect and act on feedback or concerns, thinking about what can be done to prevent the same thing happening again' needs to be revised. Not all feedback is valid, so whilst it may be appropriate to *listen* to it and *reflect* upon it, it may not be appropriate to *act* upon it. For example – if an employer said 'you should be doing more Medicines Use Reviews on those patients whether they need them or not, that is the business target, for each one you don't do we lose £28', the employer's position would not be appropriate. The pharmacist may need to counsel the employer with respect to the inappropriateness of their approach – but ultimately that approach might not change. The pharmacist in this case would need to 'challenge poor practice and behaviours' but that is covered by a different example in the 'Applying the standard' section.

There may not have been anything that the pharmacist should have done differently in light of the feedback they have been given and therefore there may be no further personal action needed. However, we envisage that, given the wording of this example, this would be difficult to argue in an employment, civil, criminal or fitness to practice situation where an imbalance of power existed.

To further illustrate the point, in our response to the consultation 'Patient-Centred Professionalism in Pharmacy', we provided feedback to the GPhC that referring to pharmacy technicians as 'pharmacy professionals' presented risks to public safety. The GPhC may have reflected on that feedback, but it has not acted upon it to any extent apparent to us; it has named the standards 'Standards for Pharmacy Professionals' with a view to applying them both to pharmacists and to pharmacy technicians and has seemingly invited pharmacy technicians to use 'professional judgement' and to make clinical decisions (see our comments relating to standard 5 of the consultation document). The GPhC is of course entitled not to act on our feedback if it has good reason to believe it is invalid.

Similarly, in December 2015 we responded to the GPhC consultation on 'Draft Amendments to Rules: The GPhC (Registration) Rules 2010 The GPhC (Fitness to Practise and Disqualification etc.) Rules 2010, and The GPhC (Statutory Committees and their Advisers) Rules 2010'. In that consultation response we pointed out that starting consultation questions with the words 'do you agree' created biased questions and could lead to responses which do not truly reflect respondents' views. We said that consultation questions should be asked in an entirely neutral manner. The GPhC has continued to commence questions with 'do you agree' in this consultation, so has not acted on our feedback to any extent apparent in this consultation document.

The GPhC may have disagreed with our feedback. It is not always necessary to *act* on feedback received.

In addition, it may not be possible to *prevent* the same thing happening again, but only to *reduce the risk* of it happening again.

29. Recommendation

For Standard 8, the example given in the 'Applying the standard' section which reads 'reflect and act on feedback or concerns, thinking about what can be done to prevent the same thing happening again' should be reworded to:

'reflect on feedback or concerns, taking action as appropriate and taking steps where necessary to reduce the risk of the same thing happening again'.

Standard 9

The example 'demonstrate effective team working' needs to be qualified. A pharmacist may work in a role involving line management and in any case may need to challenge the performance of others. For example, he or she may need to challenge a non-pharmacist line manager or the performance of a dispensing assistant whose practice presents a risk to patients.

In some instances, individuals may take exception to the pharmacist's view or how they managed the situation. In a line management role, a pharmacist may, for example, need to refuse a holiday request, manage a redundancy consultation or decline a request for flexible working. In this case, the affected individual might believe that the pharmacist was not demonstrating effective team working and had therefore breached the standards. In our view it would be inappropriate to leave this example worded in this way since it leaves pharmacists exposed to inappropriate interpretations of the standards.

30. Recommendation

For Standard 9, the example given in the 'Applying the standard' section which reads 'demonstrate effective team working' should be removed in order to avoid its misuse and unintended consequences (such as the inappropriate sanctioning or removal of a pharmacist from the register).

The example 'contribute to the training and development of the team' needs to be qualified. 'The team' may take various definitions. It could be defined by an employer as 'the group of people who work in the store' and the employer may therefore choose to compel pharmacists to support the development of make-up artists, cashiers, managers and others. Like the word 'leadership', 'effective team working' may be subject to inappropriate interpretation.

31. Recommendation

For Standard 9, the example given in the 'Applying the standard' section which reads 'contribute to the training and development of the team' should be reworded to:

'make appropriate contributions to the training and development of the pharmacy team'.

9. *Are there any examples that it would be useful to include in the sections 'applying the standards'?*

YES

Although the consultation document does not ask for this explicitly as it does with other questions, we anticipate that you would like us to articulate which examples we believe are missing.

Standard 1

In late 2015, the GPhC conducted a consultation entitled 'Draft Amendments to Rules: The GPhC (Registration) Rules 2010, The GPhC (Fitness to Practise and Disqualification etc.) Rules 2010 and The GPhC (Statutory Committees and their Advisers) Rules 2010', which included proposals to implement statutory requirements for registrants to have appropriate indemnity arrangements in force. We are surprised that indemnity insurance has not been mentioned in these standards. Standard 7.9 of the current 'Standards of Conduct, Ethics and Performance' says 'Make sure that all your work, or work that you are responsible for, is covered by appropriate professional indemnity cover'. Professional indemnity cover is important to provide public assurance and confidence in the profession and the services it receives.

32. Recommendation

For Standard 1, 'make sure that all their work, or work that they are responsible for, is covered by appropriate professional indemnity cover' should be included as an example in the 'Applying the standard' section.

Standard 5

As part of their practice, pharmacists need to consider the applicable laws and the professional duties set out in the standards. Providing patient-centred care will sometimes involve taking actions which knowingly break the law in the interests of patient safety. For example, a prescription may be presented late at night to a pharmacist for diamorphine for a terminally ill patient. If the prescription has a minor technical error rendering it illegal, but the prescriber's intentions are still clear, the pharmacist has to decide whether to make the supply, considering the circumstances. If the failure to make the supply would put the patient at risk of harm (such as prolonged suffering), and there were no reasonable alternatives to secure a correction to the prescription without causing undue delay, the pharmacist may decide to make the supply.

Similarly, supplies against faxed prescriptions for care homes are common but have no legal basis. Pharmacists often make supplies in the knowledge that a legally valid prescription does exist and will be acquired in due course.

33. Recommendation

For Standard 5, 'balance competing legal and professional responsibilities, acting in the best interests of the patient' should be included as an example in the 'Applying the standard' section.

The former RPSGB 'Standards of Professional Performance' included the stipulation that pharmacists must ensure that 'they do not work in conditions that do not enable them to comply with the key responsibilities of a pharmacist'. Given the poor working conditions prevalent nationally across the sector at this point in time (e.g. poor staffing levels and targeting due to commercial imperatives) if pharmacists were to comply with that, the pharmacy service in many areas of the UK would come to an abrupt halt. However, a similar example would support pharmacists to challenge poor working conditions.

34. Recommendation

For Standard 5, 'raise concerns with the relevant authority about conditions which impair or prevent them from complying with the standards' should be included as an example in the 'Applying the standard' section. This is different to our recommendations relating to Standard 8 since it explicitly refers to working conditions.

Standard 7

The 1997 report of the 'Review of Patient-Identifiable Information', chaired by Dame Fiona Caldicott ('the Caldicott Report'), made a number of recommendations for regulating the use and transfer of patient-identifiable information between NHS organisations in England and to non-NHS bodies. These were called the Caldicott principles. In 2013 the Caldicott2 Review Panel revised the Caldicott Principles and recommended that they should be adopted and promulgated throughout the health and social care system. A 7th Caldicott principle was added. The 7th Caldicott principle is 'The duty to share information can be as important as the duty to protect patient confidentiality'.[11]

As we have already set out, the wording of the example 'work in partnership with the person when considering whether to share information, except where this would not be appropriate' needs to be revised. However, we also take the view that a further example is required in the 'Applying the standard' section.

> ***35. Recommendation***
>
> *For Standard 7, 'share information with other health professionals when necessary and appropriate in the interests of the patient' should be included as an example in the 'Applying the standard' section.*

The new standards and their explanations make clear that a pharmacy professional's personal values and beliefs must be balanced with the care they give people who use pharmacy services. [The following wording was removed from the question as it was initially proposed: 'We do not want to impose a belief system on pharmacy professionals, and equally a pharmacy professional should not impose their own beliefs on any person who receives care. For example, a pharmacy professional's own beliefs may prevent them from selling emergency hormonal contraception. They should demonstrate compassion, and help the person asking for care by directing them to another appropriate healthcare provider.']

10. Do you agree with our approach?

YES

We do agree with the approach as set out in this question but have made comments about the relevant examples of the 'applying the standard' section of standard 1 in our response to question 8.

11. If you do not agree with this approach, please explain why.

N/A

12. Do you have any other comments

We have already made other relevant comments as an introduction to our response as we felt this was an appropriate way of setting the context to, and structure of, our response. Please consider the comments under the heading 'Introduction' in this document as a response to this question.

Equality analysis

We believe the focus of the standards on delivering person-centred care should have positive implications for people. We have not identified any implications that would discriminate against or unintentionally disadvantage any individuals or groups.

13. Are there any aspects of the standards that could have a negative impact on patients, members of the public, pharmacists, pharmacy technicians, or any other groups?

YES

We have highlighted these within our responses. We are particularly concerned about areas of the standards which we believe increase the risk to public safety relative to the current standards, including the isolation of whistleblowers.

14. If you have any comments on the potential impact of the standards, please give these in the box below.

Our comments about the potential impact of the standards have been included in our responses to the questions asked and in the 'Introduction' section of this document. Please consider the 'Introduction' section as a response to this question.

15. We plan to review and update our guidance in the following areas:

- ***Raising concerns: explains how pharmacy professionals should raise concerns that they have***
- ***Consent: explains the principles of consent***
- ***Confidentiality: explains the steps to take to protect the confidential information obtained in the course of professional practice***
- ***Maintaining clear sexual boundaries: explains the importance of maintaining clear sexual boundaries, and explains the responsibilities pharmacy professionals have***
- ***Balancing personal beliefs and the care of patients: what pharmacy professionals need to do if their religious or moral beliefs affect the provision of pharmacy services to patients and the public***

Do you agree with the areas we have identified?

NO

We believe that additional guidance is needed in other areas (see our response to question 16). We take the view that the GPhC's time would be better spent on such additional guidance as a priority.

We also hold the view that you should not take a majority of 'Yes' responses to this question as an indication that you should continue as planned. Respondents will not necessarily *disagree* with the GPhC's plans to review the guidance mentioned, so given the choice of 'Yes' or 'No', might choose 'Yes'. However, they might prefer that the GPhC produce other guidance first.

16. What other support, if any, do you think pharmacy professionals need?

In later 2015/early 2016, the PDA conducted a survey of its members. It received 2,849 responses.

- 53% of respondents believed that at least half of the time there were not enough suitably qualified and skilled staff for the safe and effective provision of the pharmacy services provided.
- 46% of respondents found that at least half of the time they were in a position whereby commercial incentives or targets had compromised the health, safety or wellbeing of patients and the public, or the professional judgement of staff.
- 59% of respondents reported that at least half of the time they found themselves in positions where they believe financial cutbacks imposed by their main employer had directly impacted upon patient safety.

The Council claims to have learned from the Francis inquiry. The report published following the inquiry included several findings and recommendations which are relevant to the provision of adequate staffing levels and workplace pressure. Whilst it focused on nursing, it would be a mistake to conclude that the findings and recommendations were not also applicable to pharmacy. These include:

- *The procedures and metrics produced by NICE should include evidence-based tools for establishing the staffing needs of each service. These measures need to be readily understood and accepted by the public and healthcare professionals.*
- *The professional voice needs to be strengthened… the advice of the […] director should be obtained and recorded in relation to the impact on the quality of care and patient safety of any proposed major change in […] staffing or facilities.*
- *The NHS Litigation Authority should introduce requirements with regard to observance of the guidance to be produced in relation to staffing levels, and require […] to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration.*

- *Commissioning arrangements should require the boards of provider organisations to seek and record the advice of its […] director on the impact on the quality of care and patient safety of any proposed major change to […] staffing arrangements or provision facilities, and to record whether they accepted or rejected the advice, in the latter case recording its reasons for doing so.*[12]

We take the view that these issues are not being adequately addressed or uncovered by GPhC premises inspections and as a result, a significant risk to the public is being allowed to persist on a national scale. Since issues with staffing levels and inappropriate workplace pressure are clearly an issue for a large number of pharmacists, we would like to see the Council issue guidance on these matters (as well as improving the inspections process to ensure it identifies and addresses these issues).

Work done in a pharmacy is completed or initiated by human hand. The field of *methods time measurement* examines and uses international standard times for human movements. Every step of a Standard Operating Procedure (SOP) could be associated with a time to carry out that step. SOPs and changes to them determine the staffing levels required in a pharmacy. The Council has responsibility for regulating Responsible Pharmacists and has issued guidance for that group. The Responsible Pharmacist regulations include the requirement for pharmacists to establish pharmacy procedures. The Council should therefore, in our view, provide guidance as to how to determine the appropriate staffing levels required to ensure those procedures can be followed.

Further, some large employers set company-wide SOPs and mechanisms for changing them which seek to prevent individual pharmacists from making changes without head office approval. Compliance is pursued rather than concordance. We would therefore like to see guidance from the Council on Developing, Implementing and Maintaining Standard Operating Procedures.

36. Recommendation

As a priority, the GPhC should issue guidance covering the following areas of practice:

- *Staffing levels*
- *Managing organisational goals and targets and other workplace pressures*
- *Developing, Implementing and Maintaining Standard Operating Procedures*

37. Recommendation

As a secondary priority, the GPhC should also issue guidance covering the following areas of practice:

- *Risk assessment*
- *Use of care records*
- *Acting as role models*
- *Making contributions to training*
- *Safe delegation*
- *Monitoring one's practice/CPD*
- *Managing conflicts of interest*
- *Social media*
- *Duties of managers and those in positions of authority*

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