General Pharmaceutical Council

Council meeting 14 June 2012 06.12/C/01

Public business

# Summary report on the GPhC consultation 'Modernising Pharmacy Regulation'

**Purpose**

To brief the Council on our recent consultation and provide a draft summary report for consideration

**Recommendations**

**The Council is asked to note the wide ranging engagement activities undertaken and the process for capturing, collating and analysing the feedback.**

**The Council is asked to agree:**

i. **the summary consultation document for publication; and**

ii. **the list of issues for further consideration, set out in paragraph 6, in advance of the Council's consideration of revised standards and the full consultation report for approval.**

## 1.0 Introduction

1.1. In our consultation document, *Modernising Pharmacy Regulation: draft standards for registered pharmacies*, Council acknowledged that what was proposed represented a significant change in the way in which registered pharmacies, and the services they provide, would be regulated in future.

1.2. Given the significance and scale of what was proposed, we recognised that a thorough consultation would be required which would build on pre-consultation engagement work we carried out in 2011.

1.3. Our public consultation ran from 8 February to 7 May 2012 and the summary report is attached to this paper.

1.4. The aims of the consultation were to:

i. Raise awareness of the proposed changes with all our key interest groups including patients and the public; individuals and representative organisations within pharmacy; NHS and regulatory bodies across Great Britain;

ii. Ensure our proposals were tested appropriately with these audiences and that feedback was received on both the general approach and detail within the three main sections of the consultation document; and,

iii. Identify specific issues or areas which need further consideration before we present the Council with standards for approval and proposals for implementation.

## 2.0 How we generated feedback

2.1. We designed our approach to the consultation based on acknowledged best practice in engagement and consultation. This included seeking external advice from the Consultation Institute[1] on our draft consultation document, particularly the formulation of the consultation questions. We also commissioned the Institute to provide training for GPhC staff members in facilitation to enhance the quality of our consultation events.

2.2. We also used the services of Community Research[2] to assist with our deliberative events with patients and the public.

2.3. We undertook an ambitious and wide ranging consultation exercise, seeking to use a range of techniques to secure both formal and informal feedback. These tools included:

- Use of enhanced web technology and social media: this involved establishing a dedicated website (www.registeredpharmacies.org), online promotion of our events and an online questionnaire to assist collection of feedback. We promoted the consultation and drove traffic to the dedicated website from a

[1] www.consultationinstitute.org
[2] http://www.communityresearch.co.uk

range of social media platforms, including facebook and twitter. We also sought third parties to promote the consultation.

- Holding GPhC-facilitated consultation events: we held more than 20 events across all three countries within Great Britain with pharmacy organisations in both the NHS hospital sector and community which were led by senior GPhC staff. These included a national launch attended by key industry and professional bodies in pharmacy, and key stakeholder events in England, Scotland and Wales

- Working with third party representative groups: we attended a number of events held by third parties, such as Local Practice Forums and Local Pharmaceutical Committees

- Hosting deliberative events with patients and the public: we held four events with patients and the public using external expert facilitators and our trained GPhC facilitators

- Ensuring full GB-wide coverage: We undertook a full range of consultation events and activities in each of the three GB countries, England, Scotland and Wales.

## 3.0 Who we heard from

3.1. The consultation process generated responses from a large number of organisations and individuals.

3.2. We hosted, or participated in, 35 events at which we considered themes across each of the three main sections of the consultation document. We captured feedback on our proposed approach and encouraged attendees to respond more fully either as individuals or as part of an organisation response, through the online consultation questionnaire.

3.3. We held three deliberative workshops with patients and the public in Cardiff, Edinburgh and London, and met with patients and the public in Liverpool, to facilitate discussion and generate feedback.

3.4. In total there were 456 responses to the consultation. Of these 350 were from individuals and 106 from organisations, 70 of which were pharmacy organisations.

3.5. Responses were received from each of the countries in the United Kingdom.

## 4.0 How we have collated the feedback and analysed the responses

4.1. We have attempted to utilise best practice in managing consultation responses. Our approach has been informed by guidance from the Consultation Institute and

recognises that it is important that all feedback, whether it be from an individual or a large representative organisation is given full consideration. Steps we have taken to ensure the process is robust include:

- presenting the statistics in a clear and consistent manner throughout the summary report
- ensuring that these statistics include both online and paper based responses
- that those who were reviewing and coding responses were from a different policy team to those responsible for drafting the consultation document
- reviewing all the responses to the qualitative, open questions so that each response was coded in order to identify themes
- following this coding approach consistently for all responses received which either didn't seek to answer questions directly or included more discursive feedback. This approach allows us to highlight recurrent themes which emerged in response to each question.
- all comments, including those from individuals and not part of a wider theme have been captured for further consideration as part of our review of the draft standards as has feedback from all of the consultation events.

## 5.0 What we heard during the consultation process

5.1. This paper is not intended to list nor summarise all the feedback we received. Although the feedback on each of the proposals within the three main sections of the consultation document is positive, the scale of the feedback is such that final conclusions cannot be drawn and it would be premature to ask Council to agree a final report, including feedback, on the consultation.

5.2. We propose that this would be done alongside Council's consideration of revised standards for registered pharmacies.

5.3. However, there are certain themes which we have already identified as needing further consideration before the standards are finalised and can be presented for approval to Council.

## 6.0 Issues for further consideration

6.1. As part of our analysis of the consultation responses and feedback received during the consultation process, we have identified a number of issues we think need further consideration. Our review of responses may lead to identification of other issues but our preliminary view is that the following are all issues which would benefit from further analysis and consideration:

i. Registration criteria: a number of responses raised questions about the registration criteria and our interpretation of the relevant sections of the Medicines Act 1968. We have already sought external legal advice to provide additional assurance that final proposals reflect a sound interpretation of the law in this area

ii. Presentation and drafting of the standards and compliance indicators: we have received a range of suggestions about the presentation and drafting of the standards and compliance indicators which we think should be considered

iii. How we work with other regulators: there was a significant amount of feedback about the need to work with other regulatory bodies, such as the MHRA and national inspection bodies across GB, and local NHS commissioning organisations. We think further work should be undertaken to ensure we reduce any risk of duplication of information and monitoring requirements or regulatory gaps.

iv. How professional duties and regulatory requirements in relation to medicines legislation can best be met: we received feedback about a range of issues related to medicines legislation. We will need to set out our response to the issues raised in our final report, including how we propose to take these issues forward. These include, but are not limited to, issues such as adherence to the medicines licensing regime, meeting supervision requirements in relation to supply of Prescription Only and Pharmacy medicines as well as exemptions provided to registered pharmacies in Section 10 of the Medicines Act 1968.

## 7.0 **Communications implications**

7.1. We have undertaken a detailed and thorough consultation. We received a large amount of feedback indicating a desire for further wide-ranging communications and engagement work to sit alongside the publication of final agreed standards before they are fully enforced.

7.2. We also recognise that we will need to communicate the results of further work to update our inspection model to take into account the new standards and approach to compliance and enforcement.

7.3. We have already identified further guidance required to sit alongside the proposed standards; further communications will be required as this is drafted and finalised.

7.4. Finally, the standards for registered pharmacies, as set out in the Pharmacy Order 2010, will also need to be set out in rules. There are further statutory obligations to consult on these rules.

## 8.0 Equality and diversity implications

8.1 We sought, through the pre-consultation engagement activities and the formal consultation period, to access as wide a range of audiences as possible. Activities included working with patient representative groups as well as deliberative events with the public. We are currently drafting an equalities impact assessment consistent with our responsibilities as set out in the Equalities Act 2010.

## 9.0 Resource implications

9.1 There are limited resource implications associated with the publication of the consultation summary report.

9.2 However, there is likely to be some additional resource requirement associated with seeking external legal advice which we expect to be met from existing budget allocations.

## 10.0 Risk implications

10.1. We have mitigated some of the risks associated with the implementation of a new approach to regulation by holding such a thorough and wide-ranging consultation.

10.2. However, we intend to provide further assurance to Council in relation to the legal framework for our proposed registration criteria.

10.3. There are further reputation risks if we do not consider feedback provided through the consultation and subsequently communicate clearly our reasons for either agreeing with feedback provided or why we disagree with the feedback and what, if anything, we propose to do in response.

## Recommendations

**The Council is asked to note the wide ranging engagement activities undertaken and the process for capturing, collating and analysing the feedback.**

**The Council is asked to agree:**

**i. the summary consultation document for publication; and**

**ii. the list of issues for further consideration, set out in paragraph 6, in advance of Council's consideration of revised standards and the full consultation report for approval.**

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*6 June 2012*

# Consultation summary report

## Modernising pharmacy regulation: A consultation on the draft standards for registered pharmacies



June 2012

# Contents

## Section 1: About this consultation

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland and Wales by upholding standards and public trust in pharmacy.

Our principal functions include:

- approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises;
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns; and
- establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies.

Our public consultation, *Modernising Pharmacy Regulation,* was held for 13 weeks from 8 February 2012 and set out how we intend to modernise pharmacy regulation with the publication of draft standards for registered pharmacies. It explained our proposed model for registering pharmacies and described the pharmacy services that an owner must provide for premises to be eligible for registration as a pharmacy. It also set out the our proposals for how we will make sure that pharmacies are delivering the outcomes required by the new standards, and the action we will take if the standards are not being met.

The consultation document was structured in three main sections which set out a number of questions. The sections were as follows:

- **Registration:** an overview of which premises we intend to register.

- **Standards:** the draft standards we are proposing for registered pharmacies.

- **Compliance and enforcement:** a description of how we plan to secure compliance against the proposed standards and our approach to enforcement activity.

**Background and approach**

This consultation document was informed by extensive pre-consultation engagement activities and a number of small deliberative focus group style events aimed at ensuring that the document was accessible and clear for the wide range of interested parties we wished to receive feedback from. We also sought external advice on our proposed approach from the Consultation Institute[3] who provided training for GPhC staff in consultation event facilitation. We also used the services of Community Research[4] to assist with our deliberative events with patients and the public.

We recognised that the new legislative requirements placed upon, and powers provided to, the General Pharmaceutical Council in relation to standards for registered pharmacies and securing compliance represents a significant change from what pharmacy is used to in Great Britain. In undertaking this

[3] www.consultationinstitute.org
[4] http://www.communityresearch.co.uk

consultation it was important that we reached as wide a range of individuals and organisations as possible including patients and the public, pharmacy professionals, professional and representative bodies as well as NHS and regulatory bodies with an interest.

Given the potential scale of change proposed we undertook an ambitious and wide ranging consultation exercise, seeking to use a range of techniques to secure both formal and informal feedback. These tools included:

- Use of enhanced web technology and social media: this involved establishing a dedicated website (www.registeredpharmacies.org), online promotion of our events and an online questionnaire to assist collection of feedback

- Holding GPhC facilitate consultation events: we held a number of events across all three countries within Great Britain with pharmacy organisations in both the NHS hospital sector and community which were led by senior GPhC staff

- Working with third party representative groups: we attended a number of events held by third parties, such as Local Practice Forums and Local Pharmaceutical Committees

- Hosting deliberative events with patients and the public: we held a number of events with patients and the public using external expert facilitators as well as trained GPhC facilitators.

- Ensuring full GB-wide coverage: We undertook the full range of consultation events and activities in each of the three GB countries, England, Scotland and Wales

Further detailed breakdown of how we used some of these techniques is set out below.

**Consultation events**

We held 35 consultation events with a wide range of key stakeholders, including local practice forums, local pharmaceutical committees, primary care commissioning organisations, professional bodies and other representative organisations, superintendent pharmacists, pharmacy owners, and health councils, across England, Wales and Scotland.

These events provided an opportunity to engage with our stakeholders in a meaningful way about the proposed standards for registered pharmacies as well as our proposed approach to compliance and our decision-making process on enforcement. The events also provided an

opportunity for us to encourage key organisations to promote the consultation via their networks and website.

A summary of the key points raised at the stakeholder events is included at the end of each section of this report.

**Patient and Public events**

As part of the consultation process we held three deliberative workshops in Cardiff, Edinburgh and London. The objective of the workshops was to gather feedback from a broadly representative mix of members of the public with regard to the draft standards and the proposed approach to compliance and enforcement. We also attended an engagement event hosted by Liverpool Local Involvement Network

(LINK). These events were deliberative and included wide ranging discussions about service delivery issues as well as this consultation. For that reason, feedback from these events has been summarised and reported separately at the end of this report.

**Using this report**

Given the large number of responses received, we have used a systematic approach to capturing feedback and ensuring we take full account of all responses.

Responses to the quantitative questions have been analysed and are presented throughout the report. These include those submitted through the online questionnaire and those submitted in hard copy format. Breakdowns giving further detail are presented in Appendix A.

Responses to the qualitative, open questions were all considered and each response was coded in order to identify themes. We also followed this coding approach for responses received which either didn't seek to answer questions directly or included more discursive feedback. Each of these responses has been reviewed and feedback coded to ensure this report reflects the views we heard. This approach allows us to highlight recurrent themes which emerged in response to each question.

In addition to the key themes presented here we received many comments and suggestions, some representing strongly held views, which, even if they were heard from small numbers of respondents, we will be considering as we develop our proposals for decision by Council in September 2012. We also received many constructive suggestions about the wording, presentation and measurability of the standards and compliance indicators which will all be taken into account and inform our development of the standards.

This report attempts to report back on what we heard through the consultation, present key statistics about views on each question and to draw out themes where these have been identified. We intend to publish a full report, with our response to the issues raised here, later in the year.

## Section 2: Who we heard from

Overall, we received 456 responses to the consultation. This figure includes all those who answered to any of the consultation questions as well as a number of responses which didn't directly respond to the consultation questions but provided more general comments. All issues raised in these have been fully taken into account and, where applicable, incorporated into this report.

In presenting the quantitative consultation questions, the percentages may not always add to a 100% due to rounding. In some instances, the total number of responses is very small and as such percentages are best read in conjunction with the total numbers. A summary of all quantitative questions, with responses broken down to individuals and organisations, can be found in appendix A. Background information about the respondents is presented below.

| | |
|---|---|
| **Total number of respondents:** | **456** |

| **Individual respondents** | | |
|---|---|---|
| Pharmacy professionals | | 317 |
| *Of whom:* | | |
| *Pharmacists* | *298* | |
| *Pharmacy technicians* | *19* | |
| Members of the public | | 20 |
| Other | | 13 |
| **Total individual respondents** | | **350** |

| Countries of individual respondents | | |
|---|---|---|
| England | **275** | (79%) |
| Wales | **20** | (6%) |
| Scotland | **40** | (11%) |
| NI | **3** | (1%) |
| Other or not specified | **12** | (3%) |

| Organisations responding | |
|---|---|
| **Total respondents** | **106** |

Over a hundred organisations responded to the consultation. All organisations that provided their name are listed in appendix B.

## Section 3: Registering a pharmacy with us – response summary

**What we proposed**

Our proposed model for registering pharmacies is based on a two stage approach – an eligibility to register test followed by a compliance test. The eligibility test is based on the legal definition of a pharmacy business and the legal requirements for the sale or supply of pharmacy and prescription only medicines. The compliance test is based on the GPhC standards for registered pharmacies being met. We also set out the circumstances which would lead us to place conditions on the registration of a pharmacy.

**What we heard**

| **Q1** | **Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?** |
|---|---|

| | | |
|---|---|---|
| Yes | **72%** | (301) |
| No | **12%** | (49) |
| Unsure | **16%** | (68) |
| Total | 100% | (418) |

The majority of respondents (72%) felt that the proposals provided sufficient clarity about the premises that need to be registered.

| **Q2** | **Do you have any comments or observations about the proposed two stage test for registration or renewal of registered pharmacies?** |
|---|---|

There were a large number of positive comments in support of the proposed approach. Respondents said that the proposals were good, clear and sensible.

A significant number of respondents disagreed with the GPhC's decision not to register pharmacies that sell or supply medicines solely for animal use. Some respondents questioned the GPhC's interpretation of the legislation covering this issue.

Respondents wanted clarity about the circumstances in which the GPhC would register a hospital pharmacy. In particular, clarification was sought on what is meant by "the supply of medicines in a hospital made in the course of the business of that hospital".

A number of respondents queried where responsibility lies for the regulation of dispensing doctors as that is outside the remit of the GPhC.

| Q3 | **The document sets out three situations where we think it may be appropriate to impose conditions on registered pharmacies. In what, if any, other situations should conditions be applied?** |
|---|---|

Respondents suggested a range of situations where it might be appropriate for the GPhC to impose conditions on registered pharmacies. Situations most frequently mentioned were temporary premises established during a re-fit of registered premises or because of damage to premises e.g. following a flood or fire; and situations where temporary premises are established in an emergency situation or following a natural disaster.

| Q4 | **Do you have any other comments or observations to make with regard to these specific proposals?** |
|---|---|

A wide range of comments were received on the issue of internet pharmacies and what our response to them should be. Some respondents suggested that internet pharmacies should be subject to greater regulatory control and some that they should be part of a different regulatory process. Some respondents suggested that internet pharmacies should meet the same standards as other registered pharmacies, others suggested that a different set of standards should apply to internet pharmacies.

A number of respondents re-iterated the view that the GPhC should reconsider its proposal not to register premises that sell or supply medicines solely for animal use. Some respondents questioned the rationale behind this decision; others questioned the GPhC's interpretation of legislation in this area. It was also suggested that if the GPhC no longer registers such premises the Veterinary Medicines Regulations will need to be amended to define a new category of premises. If this is the case it was suggested that the GPhC and Veterinary Medicines Directorate (VMD) agree a period of transition to allow a suitable registration and inspection regime to be put in place.

A number of respondents registered their disagreement with the document not including a specific requirement that Pharmacy (P) medicines should not be available for self selection. This issue was raised in response to a number of questions throughout the consultation.

**Feedback from stakeholder events**

The stakeholder events provided an opportunity to discuss our proposals with a wide range of organisations and individuals. The key themes relating to the proposed registration criteria and process were:

- Concerns were expressed that dispensing doctors are not subject to the same regulatory processes as registered pharmacies
- Clarity was sought about the circumstances in which a hospital pharmacy will be registered with the GPhC
- Opposition was expressed to the GPhC proposal not to register premises that sell or supply medicines solely for animal use
- Concerns were expressed about ensuring that 100 hour pharmacies are staffed adequately
- Clarity was sought about the regulation of internet pharmacies
- Further clarification was sought about the types of temporary premises which would be registered by the GPhC.

## Part 4: Standards for registered pharmacies – response summary

**What we proposed**

The proposed standards are designed to ensure that patients and the public are properly protected. They are outcome focused and designed so that pharmacy owners and superintendent pharmacists are able to use their professional judgment to decide how best to meet our standards for their pharmacy.

The purpose of the standards is to create and maintain the right environment, both organisational and physical, for the safe and effective practice of pharmacy. Responsibility for meeting the standards lies with the pharmacy owner. If the registered pharmacy is owned by a 'body corporate' the superintendent pharmacist also carries responsibility along with the company.

As well as meeting our standards, the pharmacy owner and superintendent pharmacist must make sure they comply with all relevant legislation, regulatory standards and legal requirements. We also expect them to be familiar with all associated guidance, including our compliance guidance.

The standards are grouped under five principles. The principles are equally important and must be met. Under each principle we set out the standards and examples of how compliance with each standard could be demonstrated.

**Principle 1:** The governance arrangements safeguard the health, safety and wellbeing of patients, the public and members of staff.

**Principle 2:** Staff are empowered and competent to safeguard the health, safety and wellbeing of patients, the public and members of staff.

**Principle 3:** The premises where pharmacy services are provided, and any associated premises, are safe and suitable.

**Principle 4:** The management of medicines and medical devices safeguards the health, safety and wellbeing of patients and the public.

**Principle 5:** The equipment and facilities that available are safe and suitable.

**What we heard**

| Q5 | Is it clear where the responsibility for meeting the standards lies? |
|---|---|

| | | |
|---|---|---|
| Yes | **71%** | (240) |
| No | **17%** | (56) |
| Unsure | **12%** | (41) |
| Total | 100% | (337) |

The majority of respondents (71%) felt that it was clear where responsibility for meeting the standards lies.

| Q6 | What is unclear? |
|---|---|

In particular respondents were not clear about where the responsibilities of the Responsible Pharmacist lie in relation to those of the owner or superintendent. Respondents also questioned how the GPhC would assess who is responsible for what between the owner and the superintendent.

| Q7 | The introduction to the standards should set the context and clarify and explain how the standards are relevant to different audiences. What else if anything should be added to the introduction? |
|---|---|

Again, respondents sought clarity about where responsibility lies for meeting the standards between the owner and superintendent; some also questioned how responsibility for meeting the standards will fit with the role of the Responsible Pharmacist. It was suggested that the GPhC could publish further information or examples to illustrate where responsibilities would lie in different scenarios.

| Q8 | **The standards are grouped under five main principles. Under each principle there are three sections – the principle itself, the standards that relate to that principle and examples of how compliance would be shown. Does the structure work well?** |
|---|---|

| | | |
|---|---|---|
| Yes | **77%** | (246) |
| No | **9%** | (29) |
| Unsure | **14%** | (46) |
| Total | 100% | (321) |

The majority of respondents (77%) felt that the structure works well.

| Q9 | **How could it be improved?** |
|---|---|

Many comments were made relating to the structure and content of the standards. Recurring comments and themes included:

- The standards are too vague
- The link between each standard and the compliance indicators which relate to it should be made clearer
- The compliance indicators should be more specific and measurable
- The language used should be more specific and terms should be defined
- Further detail, including examples or case studies illustrating how the standards could be met, is needed.

| Q10 | **Are the standards under each principle clear?** |
|---|---|

| | **Principle 1** | **Principle 2** | **Principle 3** | **Principle 4** | **Principle 5** |
|---|---|---|---|---|---|
| Yes | **80%** | **77%** | **80%** | **81%** | **82%** |
| No | **10%** | **13%** | **13%** | **10%** | **9%** |
| Unsure | **9%** | **9%** | **7%** | **9%** | **9%** |
| Total responses | (278) | (275) | (270) | (270) | (275) |

The majority of respondents felt that the standards are clear.

**Q11 What is unclear?**

The main theme of comments in response to this question was the need for better definition of terms. For example the standards and compliance indicators use terms such as 'suitable' 'appropriate' 'reputable' and 'regular'. There was a desire from some for the GPhC to be more specific about the meaning of these terms in each context.

Comments were also made that the standards were considered to be too vague and the compliance indicators rely too much on subjective assessment.

**Q12 Is anything missing from the standards under each principle?**

| | Principle 1 | Principle 2 | Principle 3 | Principle 4 | Principle 5 |
|---|---|---|---|---|---|
| Yes | **13%** | **16%** | **14%** | **14%** | **11%** |
| No | **60%** | **61%** | **64%** | **63%** | **66%** |
| Unsure | **26%** | **23%** | **22%** | **23%** | **24%** |
| Total responses | (257) | (250) | (242) | (243) | (254) |

The majority of respondents (between 60 – 66%) felt that nothing was missing from the standards.

**Q13 What standards should be added?**

**What standards should be added?**

A range of suggestions was made in response to this question. The most common suggestions were:

- Include a standard relating to minimum rest breaks
- Include further reference to raising concerns and 'whistleblowing'
- The requirements relating to consulting rooms should be more specific
- Ensure that P Medicines are not available for self-selection

In addition, similar comments were made in response to this question as to earlier ones; that the standards are considered vague, that the compliance indicators should be more measurable and that more clarity is required as to where responsibility for meeting the standards lies.

| Q14 | Are the compliance indicators clear? |
|---|---|

| | | |
|---|---|---|
| Yes | **56%** | (150) |
| No | **27%** | (71) |
| Unsure | **17%** | (46) |
| Total | **100%** | (267) |

Just over half of respondents (56%) thought the compliance indicators were clear. A total of 44% thought they were not clear or were unsure.

| Q15 | What is unclear? |
|---|---|

The majority of respondents to this question expressed concerns about how the compliance indicators could be measured. Many comments were made about the language and terms used; respondents requested better definition of terms and clarity about how compliance with the indicators could be demonstrated. Comments were also made about how the compliance indicators are presented, with suggestions that it needs to be clearer which standards the compliance indicators relate to.

| Q16 | The indicators are examples only and do not represent a complete list of everything that might indicate compliance with the standards. What if any additional or alternative indicators would it be helpful for us to include here? |
|---|---|

A range of comments and suggestions were made in response to this question with no clear trends emerging. Respondents made general comments about the need for compliance indicators to be more specific and measurable and the need for more detail and guidance about how to comply.

| Q17 | To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework? |
|---|---|

| | | |
|---|---|---|
| Agree | **54%** | (145) |
| Neutral | **25%** | (67) |
| Disagree | **13%** | (35) |
| Unsure | **8%** | (21) |
| Total | 100% | (268) |

Just over half the respondents (54%) agreed that the standards and compliance indicators provide pharmacies with a clear and useable framework. 13% disagreed while 33% were either neutral or unsure.

| Q18 | What, if any, further support tools or information would pharmacy owners or superintendent pharmacists need to be able to meet these standards? |
|---|---|

Almost half the respondents to this question said that further guidance would be needed to help owners and superintendents to meet the standards. A number of suggestions were made about the types of guidance/support tools which should be made available including:

- Examples of good practice
- A compliance toolkit
- Clarity on where responsibility lies
- Guidance on how the GPhC defines risk
- Guidance on how conflicts will be resolved
- Listing or signposting other legislation/regulations
- Guidance on skill mix/staffing levels

| Q19 | What if any concerns do you have about the practical implications of implementing these standards in registered pharmacies? |
|---|---|

Respondents expressed concern about the timescale for implementation of the proposed changes. Some expressed the view that the timescale suggested is too short. Others suggested that there should be a transition phase to allow pharmacies time to ensure that they have the systems and processes in place to comply with the standards.

The need for a consistent approach from the inspectors and the need for further guidance about how to comply with the standards were raised.

Comments were made about the lack of clarity about where responsibility for meeting the standards lies and how the role of the Responsible Pharmacists sits within this.

**Feedback from stakeholder events**

The proposed standards and compliance indicators were discussed at each of the stakeholder events.

The key concern raised at these meeting was the potential for duplication and overlap with monitoring requirements from other regulatory bodies and NHS organisations. It was suggested that the GPhC should liaise with relevant organisations to try to eliminate duplication.

There was also concern expressed that the standards are too vague and that there is a need for better definition of terms used in the standards and compliance indicators.

There were also a range of positive comments broadly welcoming the approach being proposed by the GPhC.

## Section 5: Securing compliance and our approach to enforcement – response summary

**What we proposed**

The consultation document set out the GPhC's current thinking and direction of travel as we continue to explore how best to inspect and regulate registered pharmacies in a way that is proportionate and based on risk.

Our focus will be on supporting people to meet the standards rather than an adversarial enforcement approach. We recognise that pharmacy owners, superintendents and registrants may require additional information about how best to achieve and demonstrate compliance, particularly as what we are proposing is to move away from a prescriptive rules based approach to outcome focused standards.

We will support compliance by visiting and inspecting registered pharmacies. We believe a robust inspection model is needed to protect patients, support compliance with the proposed standards and enable us to make a decision based on what we see during the inspection and evidence presented to us by the owner or superintendent.

We want to hear feedback from this consultation before we develop and test our new inspection model. It is also possible that there will be a need for additional guidance on compliance for specific areas.

**What we heard**

| | |
|---|---|
| **Q20** | **Our current view is that there will be a need for additional guidance on compliance for certain specific areas either because of the complexity of process or where the model of service may be new or technology based. Potential guidance includes:**<br>• **Compliance guidance for pharmacy owners operating an internet pharmacy**<br>• **Compliance guidance for registered pharmacies working under an exemption from MHRA licensing requirements.**<br>**To what extent do you agree or disagree with our assessment that compliance guidance will be needed in these areas?** |

| | | |
|---|---|---|
| Agree | **75%** | (203) |
| Neutral | **17%** | (46) |
| Disagree | **4%** | (11) |
| Unsure | **3%** | (9) |
| Total | 100% | (269) |

The majority of respondents (75%) agreed with our assessment that compliance guidance will be needed on internet pharmacies and those working under an exemption from MHRA licensing requirements.

| | |
|---|---|
| **Q21** | **Are there any other areas where you believe compliance guidance will be required?** |

A number of respondents suggested that the GPhC should produce compliance guidance relating to all standards. It was also suggested that examples of good practice should be shared and that guidance should be prioritised according to risk to patients and public protection.

A number of respondents requested that the GPhC produce guidance to clarify the circumstances in which a hospital pharmacy would be registered in future.

| | |
|---|---|
| **Q22** | **We cannot fully develop our approach to compliance until the standards have been finalised; therefore this section of the consultation document broadly sets out current thinking. Do you have any comments or observations about the broad approach described?** |

There were a large number of positive comments broadly welcoming the GPhC's proposed approach to compliance. Respondents commented that this approach is in line with that of other regulatory bodies. It was also commented that the proposed approach gives flexibility to pharmacy owners to take account of their individual premises and circumstances, whilst ensuring that inspection and action is taken based on the identified risks to users of pharmacy services.

There were some comments about the importance of ensuring a consistent approach from GPhC inspectors and ensuring that there is no duplication with NHS monitoring requirements.

| | |
|---|---|
| **Q23** | **We recognise that everyone, in particular pharmacy owners and superintendent pharmacists, will need support to familiarise themselves with the new standards and get ready for the new approach to regulating registered pharmacies in the transition phase. What can we do to make sure the transition is as straightforward as possible?** |

A significant number of respondents suggested that the best way of ensuring a straightforward transition would be through clear and continuing communication between the GPhC and stakeholders.

In addition, respondents suggested that the GPhC should produce compliance guidance and that a long lead in time is required to ensure that registered pharmacies are able to comply with the standards.

| | |
|---|---|
| **Q24** | **Do you have any further comments to make about the proposals in this consultation?** |

A wide range of comments were made in response to this question. A small number of respondents expressed concern that there is potential for overlap with monitoring requirements from NHS organisations and other regulatory bodies.

**Feedback from stakeholder events**

The proposed approach to compliance and enforcement was discussed at each of the stakeholder meetings.

A range of issues was raised including the need for clarity around how the GPhC will define risk, and the possibility of duplication with NHS and other regulators' monitoring requirements. A number of concerns and questions around the proposed reporting process were raised including questions about whether there would be a chance for registered pharmacies to appeal or rectify situations before the publication of inspection reports.

## Public and patient involvement

As part of the consultation process there were four deliberative workshops with patients and public in Cardiff, Edinburgh, Liverpool and London. A range of issues were discussed including service delivery issues as well as those related to this consultation.

In general the standards relating to staff and premises were considered to be appropriate and reflect what patients would expect. The most important aspects of the standards with regard to overall management were those relating to confidentiality.

The proposal for a more risk-based approach was cautiously welcomed and there was a strong preference that inspections should be mostly or entirely unannounced. There was virtually unanimous agreement that reports of inspections should be published. In addition to an indication of compliance with GPhC's standards, it was felt that inspection reports could usefully include information covering a range of issues including the types of services offered, hygiene and cleanliness, confidentiality and numbers of complaints. Participants felt that reports should include recommendations for improvement and that the views of the public should also be included.

There was a divergence in views with regard to the proposal that pharmacists would have more discretion about where medicines would be placed within the pharmacy. Some thought the existing rules regarding placement of medicines should remain in place, with others believing that allowing pharmacists greater discretion in placing certain medicines for self-selection would be a positive step forward.

There was a strong feeling from patients and the public that the standards should be widely promoted and that the existence and role of the GPhC needs to be more widely understood.

**Appendix A**
**Consultation statistics**

**Q1 Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?**

All responses

| | | |
|---|---|---|
| Yes | 72% | 301 |
| No | 12% | 49 |
| Unsure | 16% | 68 |
| Total | 100% | 418 |

Individuals

| | | |
|---|---|---|
| Yes | 71% | 243 |
| No | 11% | 38 |
| Unsure | 18% | 60 |
| Total | 100% | 341 |

Organisations

| | | |
|---|---|---|
| Yes | 75% | 58 |
| No | 14% | 11 |
| Unsure | 10% | 8 |
| Total | 100% | 77 |

**Q5 Is it clear where the responsibility for meeting the standards lie?**

All responses

| | | |
|---|---|---|
| Yes | 71% | 240 |
| No | 17% | 56 |
| Unsure | 12% | 41 |
| Total | 100% | 337 |

Individuals

| | | |
|---|---|---|
| Yes | 74% | 194 |
| No | 13% | 35 |
| Unsure | 13% | 34 |
| Total | 100% | 263 |

Organisations

| | | |
|---|---|---|
| Yes | 62% | 46 |
| No | 28% | 21 |
| Unsure | 9% | 7 |
| Total | 100% | 74 |

**Q8 The standards are grouped under five main principles. Under each principle there are three sections - the principle itself, the standards that relate to that principle and examples of how compliance would be shown. Does this structure work well in your view?**

All responses

| | | |
|---|---|---|
| Yes | 77% | 246 |
| No | 9% | 29 |
| Unsure | 14% | 46 |
| Total | 100% | 321 |

Individuals

| | | |
|---|---|---|
| Yes | 77% | 189 |
| No | 9% | 21 |
| Unsure | 15% | 37 |
| Total | 100% | 247 |

Organisations

| | | |
|---|---|---|
| Yes | 77% | 57 |
| No | 11% | 8 |
| Unsure | 12% | 9 |
| Total | 100% | 74 |

**Q10 Are the standards under principle 1 clear?**

All responses

| | | |
|---|---|---|
| Yes | 80% | 223 |
| No | 10% | 29 |
| Unsure | 9% | 26 |
| Total | 100% | 278 |

Individuals

| | | |
|---|---|---|
| Yes | 81% | 176 |
| No | 10% | 22 |
| Unsure | 9% | 19 |
| Total | 100% | 217 |

Organisations

| | | |
|---|---|---|
| Yes | 77% | 47 |
| No | 11% | 7 |
| Unsure | 11% | 7 |
| Total | 100% | 61 |

**Q10 Are the standards under principle 2 clear?**

All responses

| | | |
|---|---|---|
| Yes | 77% | 212 |
| No | 13% | 37 |
| Unsure | 9% | 26 |
| Total | 100% | 275 |

Individuals

| | | |
|---|---|---|
| Yes | 81% | 173 |
| No | 11% | 23 |
| Unsure | 8% | 18 |
| Total | 100% | 214 |

Organisations

| | | |
|---|---|---|
| Yes | 64% | 39 |
| No | 23% | 14 |
| Unsure | 13% | 8 |
| Total | 100% | 61 |

**Q10 Are the standards under principle 3 clear?**

All responses

| | | |
|---|---|---|
| Yes | 80% | 215 |
| No | 13% | 35 |
| Unsure | 7% | 20 |
| Total | 100% | 270 |

Individuals

| | | |
|---|---|---|
| Yes | 81% | 172 |
| No | 12% | 25 |
| Unsure | 7% | 15 |
| Total | 100% | 212 |

Organisations

| | | |
|---|---|---|
| Yes | 74% | 43 |
| No | 17% | 10 |
| Unsure | 9% | 5 |
| Total | 100% | 58 |

**Q10 Are the standards under principle 4 clear?**

All responses

| | | |
|---|---|---|
| Yes | 81% | 218 |
| No | 10% | 28 |
| Unsure | 9% | 24 |
| Total | 100% | 270 |

Individuals

| | | |
|---|---|---|
| Yes | 83% | 174 |
| No | 10% | 20 |
| Unsure | 7% | 15 |
| Total | 100% | 209 |

Organisations

| | | |
|---|---|---|
| Yes | 72% | 44 |
| No | 13% | 8 |
| Unsure | 15% | 9 |
| Total | 100% | 61 |

**Q10 Are the standards under principle 5 clear?**

All responses

| | | |
|---|---|---|
| Yes | 82% | 225 |
| No | 9% | 24 |
| Unsure | 9% | 26 |
| Total | 100% | 275 |

Individuals

| | | |
|---|---|---|
| Yes | 83% | 177 |
| No | 8% | 18 |
| Unsure | 9% | 19 |
| Total | 100% | 214 |

Organisations

| | | |
|---|---|---|
| Yes | 79% | 48 |
| No | 10% | 6 |
| Unsure | 11% | 7 |
| Total | 100% | 61 |

**Q12 Is anything missing from the standards under principle 1?**

All responses

| | | |
|---|---|---|
| Yes | 13% | 34 |
| No | 60% | 155 |
| Unsure | 26% | 68 |
| Total | 100% | 257 |

Individuals

| | | |
|---|---|---|
| Yes | 13% | 26 |
| No | 58% | 118 |
| Unsure | 29% | 60 |
| Total | 100% | 204 |

Organisations

| | | |
|---|---|---|
| Yes | 15% | 8 |
| No | 70% | 37 |
| Unsure | 15% | 8 |
| Total | 100% | 53 |

## Q12 Is anything missing from the standards under principle 2?

All responses

| | | |
|---|---|---|
| Yes | 16% | 40 |
| No | 61% | 152 |
| Unsure | 23% | 58 |
| Total | 100% | 250 |

Individuals

| | | |
|---|---|---|
| Yes | 15% | 30 |
| No | 59% | 118 |
| Unsure | 26% | 51 |
| Total | 100% | 199 |

Organisations

| | | |
|---|---|---|
| Yes | 20% | 10 |
| No | 67% | 34 |
| Unsure | 14% | 7 |
| Total | 100% | 51 |

## Q12 Is anything missing from the standards under principle 3?

All responses

| | | |
|---|---|---|
| Yes | 14% | 33 |
| No | 64% | 155 |
| Unsure | 22% | 54 |
| Total | 100% | 242 |

Individuals

| | | |
|---|---|---|
| Yes | 13% | 24 |
| No | 62% | 118 |
| Unsure | 26% | 49 |
| Total | 100% | 191 |

Organisations

| | | |
|---|---|---|
| Yes | 18% | 9 |
| No | 73% | 37 |
| Unsure | 10% | 5 |
| Total | 100% | 51 |

## Q12 Is anything missing from the standards under principle 4?

All responses

| | | |
|---|---|---|
| Yes | 14% | 33 |
| No | 63% | 153 |
| Unsure | 23% | 57 |
| Total | 100% | 243 |

Individuals

| | | |
|---|---|---|
| Yes | 15% | 28 |
| No | 59% | 112 |
| Unsure | 26% | 50 |
| Total | 100% | 190 |

Organisations

| | | |
|---|---|---|
| Yes | 9% | 5 |
| No | 77% | 41 |
| Unsure | 13% | 7 |
| Total | 100% | 53 |

## Q12 Is anything missing from the standards under principle 5?

All responses

| | | |
|---|---|---|
| Yes | 11% | 27 |
| No | 66% | 167 |
| Unsure | 24% | 60 |
| Total | 100% | 254 |

Individuals

| | | |
|---|---|---|
| Yes | 10% | 20 |
| No | 63% | 126 |
| Unsure | 27% | 53 |
| Total | 100% | 199 |

Organisations

| | | |
|---|---|---|
| Yes | 13% | 7 |
| No | 75% | 41 |
| Unsure | 13% | 7 |
| Total | 100% | 55 |

## Q14 Are the compliance indicators clear?

All responses

| | | |
|---|---|---|
| Yes | 56% | 150 |
| No | 27% | 71 |
| Unsure | 17% | 46 |
| Total | 100% | 267 |

Individuals

| | | |
|---|---|---|
| Yes | 59% | 121 |
| No | 22% | 45 |
| Unsure | 19% | 38 |
| Total | 100% | 204 |

Organisations

| | | |
|---|---|---|
| Yes | 46% | 29 |
| No | 41% | 26 |
| Unsure | 13% | 8 |
| Total | 100% | 63 |

**Q17 To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework?**

All responses

| | | |
|---|---|---|
| Agree | 54% | 145 |
| Neutral | 25% | 67 |
| Disagree | 13% | 35 |
| Unsure | 8% | 21 |
| Total | 100% | 268 |

Individuals

| | | |
|---|---|---|
| Agree | 53% | 112 |
| Neutral | 27% | 57 |
| Disagree | 13% | 27 |
| Unsure | 8% | 17 |
| Total | 100% | 213 |

Organisations

| | | |
|---|---|---|
| Agree | 60% | 33 |
| Neutral | 18% | 10 |
| Disagree | 15% | 8 |
| Unsure | 7% | 4 |
| Total | 100% | 55 |

**Q18 Our current view is that there will be a need for additional guidance on compliance for certain specific areas either because of the complexity of process or where the model of service may be new or technology based. Potential guidance includes:**
**• Compliance guidance for pharmacy owners operating an internet pharmacy**
**• Compliance guidance for registered pharmacies working under an exemption from MHRA licensing requirements.**
**To what extent do you agree or disagree with our assessment that compliance guidance will be needed in these areas?**

All responses

| | | |
|---|---|---|
| Agree | 75% | 203 |
| Neutral | 17% | 46 |
| Disagree | 4% | 11 |
| Unsure | 3% | 9 |
| Total | 100% | 269 |

Individuals

| | | |
|---|---|---|
| Agree | 75% | 154 |
| Neutral | 19% | 39 |
| Disagree | 4% | 8 |
| Unsure | 2% | 5 |
| Total | 100% | 206 |

Organisations

| | | |
|---|---|---|
| Agree | 78% | 49 |
| Neutral | 11% | 7 |
| Disagree | 5% | 3 |
| Unsure | 6% | 4 |
| Total | 100% | 63 |

**Appendix B:**

Organisations that responded to the consultation (only those that provided their name are listed)

1 Accountable Officers' Network Scotland Working Group
2 All Wales Chief Pharmacists Committee
3 Aneurin Bevan Community Health Council
4 Association of the British Pharmaceutical Industry
5 Berkshire LPC
6 Birmingham Local Pharmaceutical Committee
7 Blackbay Ventures Ltd T/A Chemistree
8 Board of Community Health Councils in Wales.
9 Bolton Local Pharmaceutical Committee
10 British Pharmaceutical Students' Association
11 Broughton Park Pharmacy Ltd
12 Calder Pharmacy
13 Cardiff and Vale of Glamorgan Community Health Council
14 Care Quality Commission
15 Collins & Butterworth Ltd
16 Community Pharmacy Scotland
17 Community Pharmacy Tees (Cleveland Local Pharmaceutical Committee)
18 Cornwall and Isles of Scilly Local Pharmaceutical Committee
19 County Durham & Darlington Local Pharmaceutical Committee
20 David Stearne Ltd trading as David Stearne Pharmacies
21 Department of Health
22 Devon Local Pharmaceutical Committee
23 Dispharma Retail Ltd
24 Dorset Local Pharmaceutical Committee
25 East & SE England Specialist Pharmacy Services
26 East Riding & Hull and South Humber LPCs
27 East Sussex LPC
28 Gateshead & South Tyneside LPC
29 General Optical Council
30 Guild of Healthcare Pharmacists
31 Hampshire & IOW Local Pharmaceutical Committee

32 Healthcare Improvement Scotland
33 Howells and Harrison (Southend) Limited
34 Hutchison Health Care Ltd
35 Independent Pharmacy Federation
36 Institute of Pharmacy Management
37 Kent Local Pharmaceutical Committee
38 Kingston and Richmond Local Pharmaceutical Committee
39 L. Rowland and Co. (Retail) Ltd. t/a Rowlands Pharmacy
40 Leyes Lane Pharmacy
41 Liverpool Local Involvement Network
42 Lloydspharmacy
43 M.D. & A.G. Burdon Ltd
44 Masons Chemists
45 Medicines and Healthcare products Regulatory Agency
46 MedicX Pharmacy
47 National Patient Safety Agency
48 National Voices
49 Natural Health Pharmacy
50 NHS Ayrshire & Arran Pharmacy Directorate
51 NHS Calderdale
52 NHS Education for Scotland
53 NHS Employers
54 NHS Grampian
55 NHS Greater Glasgow and Clyde Area Pharmaceutical Committee
56 NHS Hertfordshire
57 NHS Highland Area Pharmaceutical Committee
58 NHS Lanarkshire
59 NHS National Services Scotland
60 NHS Protect
61 NHS Scotland
62 NHS Tayside
63 Nuffield Health
64 Numark
65 Nutricia Homeward
66 Oxfordshire Local Pharmaceutical Committee
67 Patients Association

68 Perrigo (Galpharm)
69 Pharmaceutical Society of Northern Ireland (PSNI)
70 Pharmaceutical Society Northern Ireland Professional Forum
71 Pharmacy Defence Association (PDA)
72 Pharmacy Plus
73 Pharmacy Voice
74 Pharmacy2U
75 Primary Care Pharmacy Group (Scotland)
76 Quincewood Ltd
77 R M Jones (Pharmacy) LLP
78 Royal College of General Practitioners
79 Royal Pharmaceutical Society
80 Scottish National Acute Pharmacy Sevices Networking Group (NAPS)
81 Shil Pharmacy
82 SHIP PCT cluster
83 South Staffordshire Local Pharamceutical Committee
84 Sunderland LPC
85 Sure Health Limited
86 Surrey Local Pharmaceutical Committee
87 Swindon and Wiltshire Local Pharmaceutical Committee
88 T.Mclean and Sons
89 The Dispensing Doctors' Association
90 The NHS Pharmaceutical Quality Assurance Committee
91 The Pharmaceutical Services Negotiating Committee
92 UK Medicines Information
93 Veterinary Medicines Directorate
94 Veterinary Pharmacy Forum
95 Welsh Pharmaceutical Committee
96 West Sussex Local Pharmaceutical Committee