Report on the responses to the Draft Premises Standards for a Retail Pharmacy Business at or from a Registered Pharmacy

Contents

1. About the Pharmaceutical Society of Northern Ireland

1.1 The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

1.2 Our primary purpose is to ensure that practising pharmacists in Northern Ireland are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

1.3 It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

2. About the Consultation

2.1 With commencement of The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (hereafter called the 2016 Order) the Pharmaceutical Society NI will:

i. be obliged to set new Premises Standards for the safe and effective practice of pharmacy, at a retail pharmacy business at or from a registered pharmacy, and its associated premises; and
ii. have new powers to enforce these new Premises Standards, in the interest of public protection.

2.2 These new legislative provisions have yet to be commenced in Northern Ireland.

2.3 In accordance with the Principles and Standards of the Code (2016)[1] every retail pharmacy at or from a registered pharmacy, and its associated premises, must provide a safe and quality service from a properly managed, safe and secure working environment; thereby assuring the delivery of safe and effective pharmacy services to patients and the public.

[1] THE CODE - Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland, 2016

2.4 The proposed Premises Standards are a shift away from the previous Premises Standards produced in 2010[2] which were a prescriptive and detailed checklist approach to compliance. The proposed new Standards reflect an 'outcomes based' approach; where the Pharmacy Owners are accountable for using their professional judgement to evidence compliance, and have in place the correct management systems and processes, to facilitate the delivery of high quality outcomes for patients and the public.

3. Consultation Engagement

3.1 **Pre-Consultation engagement:** A number of pre-consultation meetings were held with stakeholders, including the Department of Health NI, Community Pharmacy Northern Ireland and the Pharmacy Forum NI. Further engagement was held with the five Health and Social Care Trusts in Northern Ireland.

3.1 **Correspondence with key stakeholders**: All registrants, including superintendents, and key stakeholders were emailed along with details of the consultation and instructions on how to respond.

3.2 **Website:** The consultation document and the draft premises standards were available to download from the website along with a response form between Monday 2 October 2017 to 12 noon on Monday 27 November 2017.

4. Purpose of Report – approach and analysis

4.1 This report provides a summary of the responses to the consultation on the Draft Premises Standards for a Retail Pharmacy Business at or from Registered Pharmacy held from 2 October 2017 to 12 noon on Monday 27 November 2017.

4.2 The consultation document was based on seven questions relating to the Draft Premises Standards, with space provided for respondents to make further comments in relation to the relevant question. The analysis primarily summarises general qualitative themes, responses and issues – highlighted areas of agreement and diversity of opinion.

4.3 A number of respondents provided detailed analysis of particular Principles and related Standards. A table cross referencing responses to each Principle and Standard has been created in Appendix 1. The body of the main report

[2] http://www.psni.org.uk/wp-content/uploads/2012/09/community_pharmacy_premises_standards-2015.pdf

has therefore focused largely on thematic responses and more general comments.

4.4 Due to the relatively low response rate a brief qualitative analysis of responses to each question is provided and a breakdown by individuals/organisations is provided in Appendix 2.

4.5 No differential weighting was given to responses, and all responses were read and considered. Comments and points from individuals were considered alongside the views of organisations. Where the views of a particular organisation were considered to be particularly relevant to a question or issue this has been highlighted in the report.

4.6 In the report, comments and direct quotes are attributed to the consultee category to which they fit i.e. individual pharmacist. With regards to organisations, we have in most instances directly attributed comments/quotes.

5. Consultation Document

5.1 The Consultation document outlined how to respond to the consultation; outlined and explained the seven consultation questions; and provided a rationale for the proposed Draft Premises Standards for a Retail Pharmacy Business at or from Registered Pharmacy.

5.2 Consultees were asked the following questions and were provided with space to make further comments on each question and in general.

1. Is sufficient clarity given about the Premises that need to be registered with the Pharmaceutical Society NI?
   Yes
   No
   Unsure

2. Is it clear where the accountability for meeting the Premises Standards rests?
   Yes
   No
   Unsure

3. The document has been structured by stating the main Principle, the Standards associated with the Principle, and finally some examples of Compliance Indicators. Does this structure work?
   Yes
   No
   Unsure

The Principles

4. There are five Principles which relate to the Standards set out in The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, are the Principles clear?
   Yes
   No
   Unsure

5. Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Principles need to be added?
   Yes
   No
   Unsure

The Standards

6. The Standards are grouped under five Principles. Are the Standards clear?
   Yes
   No
   Unsure

7. Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Standards need to be added?
   Yes
   No
   Unsure

6. Respondents

6.1 The Pharmaceutical Society NI received 9 responses. One response was made in an individual capacity and eight were made on behalf of organisations. Of the responses made on behalf of organisations, five were made by Pharmacy Representative Bodies, one was made on behalf of a Health and Social Care Organisation, and two were made by private companies. The one individual response was made by a pharmacist.

7. Overview of Main Findings

Question 1: Is sufficient clarity given about the Premises that need to be registered with the Pharmaceutical Society NI?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**2 (22.2%)**	**1 (11.1%)**	**0**
Question 2: Is it clear where the accountability for meeting the Premises Standards rests?			
Yes	**No**	**Unsure**	**Did not answer**
5 (55.6%)	**3 (33.3%)**	**1 (11.1%)**	**0**
Question 3: The document has been structured by stating the main Principle, the Standards associated with the Principle, and finally some examples of Compliance Indicators. Does this structure work?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**1 (11.1%)**	**2 (22.2%)**	**0**

Question 4: There are five Principles which relate to the Standards set out in The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, are the Principles clear?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**2 (22.2%)**	**1 (11.1)**	**0**
Question 5: Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Principles need to be added?			
Yes	**No**	**Unsure**	**Did not answer**
1 (12.5%)	**7 (87.5%)**	**0**	**1**
Question 6: The Standards are grouped under five Principles. Are the Standards clear?			
Yes	**No**	**Unsure**	**Did not answer**
3 (37.5%)	**3 (37.5%)**	**2 (25%)**	**1**
Question 7: Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Standards need to be added?			
Yes	**No**	**Unsure**	**Did not answer**
2 (25%)	**6 (75%)**	**0**	**1**

8. Responses to Question 1

Question 1: Is sufficient clarity given about the Premises that need to be registered with the Pharmaceutical Society NI?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**1 (11.1%)**	**2 (22.2%)**	**0**

Premises

8.1 One respondent (Boots UK) answered 'No' to Question 1, stating that they did not think sufficient clarity was given concerning the exactitude of the specific Premises that need to be registered with the Pharmaceutical Society NI. Boots UK provided the following additional comment:

No formal definition is given in the documents relating to which premises – there is merely a statement that this applies to "registered pharmacy premises.

There is a lack of clarity as to what might constitute "associated premises" – what is the nature and purpose of such premises? What is their relationship, especially in terms of location or proximity to the full registered premises? What types of activity can be carried out in such premises – storage only? Will they be inspected at the same time as the full premises? Which or what standards apply to them?

8.2 Two respondents stated that they were 'Unsure' as to whether sufficient clarity was given about the Premises that need to be registered with the Pharmaceutical Society NI. Both respondents that answered 'Unsure' provided additional comments.

8.4 The Health and Social Care Board (HSCB) raised concerns regarding the use of the term registered pharmacy, retail pharmacy business and associated premises in the draft Standards and the consultation document, the HSCB response went on to state:

There is a need to be consistent in the terminology used and we would suggest having a consistent approach i.e. referring to registered pharmacy throughout the document after defining the parameters of how the standards might apply beyond the registered pharmacy…. Further clarity is required on this point.

8.5 The Guild of Healthcare Pharmacists (The Guild) provided the following additional comment:

These standards need to be read and understood by patients and service users so it would be essential to include in the glossary definitions for a 'registered pharmacy' and a 'retail pharmacy business'.

8.6 Of the six respondents that answered 'Yes' to Question 1, one respondent provided a substantive additional comment.

Additional Services

8.7 The National Pharmacy Association (NPA) stated:

Sufficient clarity has been provided about the premises that need to be registered with the Pharmaceutical Society NI. It may be useful to clarify if services that are delivered by pharmacists outside of the registered premises e.g. through 'flu vaccination clinics or involvement with Building Community Pharmacy Partnership (BCPP) will be included.

9. Responses to Question 2

Question 2: Is it clear where the accountability for meeting the Premises Standards rests?			
Yes	**No**	**Unsure**	**Did not answer**
5 (55.6%)	**3 (33.3%)**	**1 (11.1%)**	**0**

9.1 Three respondents did not think it was clear where the accountability for meeting the Premises Standards rests, all were organisations.

The responsibility of staff

9.2 The Pharmacy Defence Association (PDA) stated:

[W]e have a concern that some of the standards appear to be worded such that they would, in practice, set additional standards for employee pharmacists rather than owners or superintendents. For example:

- *5.3 Staff must act with professionalism and in the best interest of patients*
- *5.4 Staff must comply with the laws and regulations that affect their professional practice and be accountable for any acts and/or omissions*
- *5.6 Staff must ensure that incentives or targets do not compromise their professional judgement, in the interests of the health, safety or wellbeing of patients and the public.*

The standards should set expectations for pharmacy owners in relation to the conditions they create which enable pharmacists to deliver safe patient care, rather than setting additional expectations for pharmacists.

9.3 The PDA went on to make the following recommendation:

Where the proposed standards are written such that they appear to set additional standards for employee pharmacists and other pharmacy staff, these should be rewritten as a requirement of the pharmacy owner. For example, they may be prefaced with "Pharmacy owners must create working conditions in which pharmacists are enabled and supported to…"

Power to hold Superintendents to account

9.4 In response to Question 2 and in the foreword to its consultation response, the PDA also raised the issue of the specific powers the Pharmaceutical Society NI has to hold superintendents to account for breaches of the premises standards, with pharmacy owners only being "*held to account for breaches in limited circumstances – where it is found that they are unfit to carry on the business*". The PDA extrapolated on this point in its foreword by stating: "*The PSNI has not set out the circumstances in which it would levy sanction against a pharmacy owner for the failure to meet the proposed premises standards*". Further recommending that "*The PSNI must make clear the circumstances in which it is prepared to remove pharmacies from the register for a breach of premises standards*".

9.5 The HSCB made a similar point when providing the following additional comment:

Throughout the document there appears to be joint responsibility between the Pharmacy Owner and the Superintendent. Consideration needs to be given in relation to who has the responsibility. For example, for health and safety requirements, the Pharmacy Owner will have prime responsibility. For certain professional elements, it may be the Superintendent.

9.6 The National Pharmacy Association (NPA) also made a similar point:

[W]e remain unclear on where ultimate accountability for meeting the premises standards rests. There is no indication of what individual responsibilities the owner and superintendent have, or what action can be taken if compliance with standards are poor. Should it be the case that these will be determined by the current legislation review by the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board then it would be helpful to reference the interim position until legislation is implemented.

9.7 The one respondent that answered 'Unsure' to Question 2, raised similar issues; the Guild stated:

The standards state that it is the responsibility of Pharmacy Owner and Superintendent Pharmacist to make sure that the Standards are met. It is necessary for purposes of clarity to further explain the relationship between the Pharmacy Owner and Superintendent in terms of this responsibility.

9.8 The Guild went on to reference the wording of the GPhC's Premises Standards as helpful in delineating the relationship between the Pharmacy Owner and Superintendent in terms of responsibility.

9.9 Five respondents answered 'Yes' to Question 2, with three providing additional comments.

Inspections

9.10 Medicare stated:

We welcome the aim to provide greater autonomy for the pharmacy owner/Superintendent Pharmacist to evidence the delivery of patient-centred pharmacy services. We would welcome the aim of the inspection approach to be one that promotes compliance and builds public confidence. Where Action Plans would be necessary for "poor" compliance, we would suggest that it is imperative from the outset of any new inspection process, that consistency of approach by individual inspectors would be crucial.

Rebalancing legislation and any new detail regarding the pharmacy superintendent and owners of pharmacy premises should be taken into consideration.

9.11 Whilst Boots UK said:

The statements read as if all pharmacies have one owner and a superintendent. They should make it clearer that the "owner" could be a body corporate or its Board of Directors and that the body doesn't have to based or registered in Northern Ireland (only its premises and superintendent)

9.12 The theme of inspections was raised by CPNI in its introductory response, which accompanied its answers to the Questions. It stated:

CPNI regularly takes calls from contractors seeking clarity on current inspection and assessment processes. We have some concern with the marked overlap between this set of new draft Premises Standards, the HSCB Assurance Framework and the draft Clinical Governance Framework which will be discussed within new community pharmacy contract negotiations. To ensure the inspection process is clear and efficient for both inspectors and pharmacy owners it will be important to:

- *Avoid duplication wherever possible, developing a pragmatic approach to inspections/assessments*
- *Ensure that a common approach is adopted so that where overlaps occur they are inspected/assessed using a common set of indicators*
- *Ensure that inspectors/assessors adopt a standardised, objective approach*
- *Ensure that inspectors/assessors are fully aware of the remit of all other professional inspections/ assessments carried out in community pharmacy*
- *Ensure that all compliance indicators are realistic and measureable*
- *Ensure that inspection/assessments processes are clear and transparent with pharmacy owners/superintendent pharmacists fully informed of the remit of each inspection process, with a series of supporting documents produced which clearly describe the approach and inspection/assessment criteria (similar to the GPhC's Inspection Decision Making Framework, Prototype Inspection Model Template)*

Implementation

9.13 Related to the issue of inspections CPNI considered it important that the timeframe for implementation of the final new premises standards is "*realistic and achievable with sufficient time given to allow for planning, training and preparation of support material for both inspectors and pharmacy owners/superintendents. Transparent processes with trained inspectors adopting a standardised approach across a network of fully informed pharmacy owners will be essential components for successful implementation*".

10. Responses to Question 3

Question 3: The document has been structured by stating the main Principle, the Standards associated with the Principle, and finally some examples of Compliance Indicators. Does this structure work?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**1 (11.1%)**	**2 (22.2%)**	**0**

10.1 One respondent (PDA) answered 'No' to Question 3, providing an additional comment the PDA stated:

Compliance Indicators

In terms of structure, we do not see a problem with having specific principles and a number of standards associated with each. However, we note that the compliance indicators are only intended as examples of how pharmacy owners and superintendents can demonstrate compliance with the standards,

but will not be absolute requirements and will be removed from the final version of the premises standards

10.11 Going on to say:

The PSNI must consider whether the standards in pharmacies could ever be deemed acceptable if any of the above examples [of compliance indictors] *could not be demonstrated. By not including these stipulations as part of the standards, we are concerned that it may be sending a message that it will accept shortcomings in these areas.*

More Prescriptive

10.12 This response corresponds with the PDA's foreword to its consultation response, where it stated:

Due to the commercial focus of some community pharmacy owners, Standards for Registered Pharmacy Premises must be detailed and prescriptive in nature, setting out exactly what is expected by the regulator. In this way, meaningful premises inspections can be conducted. The standards may require particular outcomes, but should at the same time be prescriptive about important aspects of practice which allow those outcomes to be achieved.

10.13 Of the two respondents that answered 'Unsure' to question 3, one provided an additional comment.

10.14 Boots UK stated:

Repetition

The layout broadly works but it is extremely repetitive (especially the compliance indicators in relation to the standards). In many cases the compliance indicators merely state "show you are meeting the standard by doing the standard" which does not add any useful clarity.

Undefined Terms

Terms such as "accessible", "associated premises" and "staff" are undefined and open to wide interpretation.

It is unclear that patients and members of the public will find these broad generalities useful in deciding whether pharmacies are meeting the expected standards.

10.15 Of the six respondents who answered 'Yes' four provided additional comments.

Consistent Inspections and Additional Guidance

10.16 Four of those respondents referenced the need for additional guidance in relation to compliance indicators and any inspection regime.

10.17 CPNI stated:

Yes this is a reasonable structure providing it is supplemented by supporting documentation which clearly describe inspection processes, full details of Compliance Indicators, what is expected under each criteria and examples of evidence which may be required (similar to the GPhC's Inspection Decision Making Framework, Prototype Inspection Model and Action Plan Template)

10.18 Whilst the NPA stated:

We welcome the examples of the compliance indicators provided but suggest that additional guidance will be required by registrants in order to prepare for an inspection under the revised standards.

10.19 The HSCB stated:

We understand that the compliance indicators will not be included in the final document and, therefore, feel it will be difficult for the pharmacy owner or superintendent to know what is required to meet the standards – will there be further guidance on this?

10.20 Whilst Boots said:

…[A] clear set of published compliance indicators should be made available for use by inspectors in order that those inspecting and those to be inspected can be assured of a fair and consistent approach.

The importance of taking account of experiences of colleagues in GB cannot be overstated, both in relation to pharmacists' experiences of inspections when the new style of GPhC inspections were introduced and inspectors/GPhC learning as a result of the issues which arose and how the approach evolved as the regulator gained new insights as a result of the implementation and roll-out and feedback it received.

Composition and Language

10.21 In relation to the composition of the Principles the HSCB stated:

The structure works but consideration needs to be given to the composition of Principles, Standards and Indicators. In particular, the standard should state one specific, measurable issue. There are many standards that appear to have two or more objectives. A number of standards use the words 'as appropriate' or 'properly' – these are not sufficiently specific unless additional

guidance is given. Standards should be as objective as possible – where there is subjectivity, clarity will be required e.g. clean, safe, secure, confidential, quiet – these are all open to interpretation.

There appears to be a degree of overlap in certain standards e.g. 3.6 and 3.7; 5.1 and 5.2. By splitting out the key elements of the standard required, this might help reduce the potential overlap.

11. Responses to Question 4

Question 4: There are five Principles which relate to the Standards set out in The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, are the Principles clear?			
Yes	**No**	**Unsure**	**Did not answer**
6 (66.7%)	**2 (22.2%)**	**1 (11.1)**	**0**

11. 1 Six respondents agreed that the five Principles, which relate to the Standards, are clear.

11.2 Of the six respondents that answered 'Yes' two provided additional comments.

11.3 Of the two respondents that answered 'No' both provided additional comments the one respondent that answered 'Unsure' also provided an additional comment.

11.4 A number of respondents did not directly answer Question 4, in relation to the clarity of the Principles and instead took the opportunity to provide feedback on the general suitability and appropriateness of the content of the Principles. This feedback has been broken down by Principle and Standard in Appendix 1.

Responsibility

11.5 The Four respondents that provided additional comments to Question 4, focused on the clarity of the Principles and on where responsibility lies for meeting the Principles and Standards.

Principle 5

Staff

11.6 Three respondents raised issues with the reference to 'Staff' in Principle 5, with the PDA again questioning the appropriateness for the reference to 'Staff' when employees will have no legal responsibility under the Standards, with the HSBC making a general query as to where responsibility lies under the wording, whilst the NPA's response somewhat contradicted this opinion by stating that the phrase 'appropriate authority' in relation to staff 'implies a passive involvement'.

11.7 For example the PDA stated:

Our view is that Principle 5 – Staff is written such that it appears to prescribe requirements of employee staff members and not pharmacy owners.

11.8 The HSCB also referred to Principle 5 in this regard stating:

It is unclear if this relates to all staff employed by the pharmacy, those employed to deliver pharmacy services or just professionally registered staff.

11.9 The NPA further stated:

The principle states that staff should have "appropriate authority" to competently provide pharmacy services. This phrase implies a passive involvement, and in line with the Standards defined it may be more appropriate to use the phrase "to empower staff members to competently provide pharmacy services" which encourages staff to actively engage in the effective provision of services.

Principle 2

Responsible Pharmacist

11.10 In relation to Principle 2 Boots stated:

The superintendent pharmacist/owner in applying the standards under this principle would direct what would be expected in branches, but it would be important that the Responsible Pharmacist (RP) also ensured these standards were met on a day to day basis. Should the role of RP be mentioned within the standards document in this regard?

11.11 The NPA focused on the collective responsibility of the team in relation to Principle 2 stating:

11.12 As it is currently worded this principle suggests that only the pharmacy owner and superintendent have responsibility for the working environment of the pharmacy. However, we believe that this is a collective responsibility and that each team member can contribute to hygienic and secure premises suitable for quality patient care.

12. Responses to Question 5

Question 5: Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Principles need to be added?			
Yes	**No**	**Unsure**	**Did not answer**
1 (12.5%)	**7 (87.5%)**	**0**	**1**

12.1 The one respondent that answered 'Yes' to Question 5 provided an additional comment:

12.2 The Pharmacy Forum NI provided additional information, which related to other Principles and information that needed to be added. They also provided some additional comments which related to the content and nature of the Principles and Standards themselves; these comments have been added to Appendix 1.

12.3 Of those comments relating directly to whether any other Principles or information need to be added the Pharmacy Forum NI Stated in relation to Standard 1.3:

We agree with the principle that staff should have defined roles and be clear about their responsibilities. However, we would suggest that the standard should also encompass the requirement for staff development and contingency plans, for business and service continuity.

12.4 Of those respondents that answered 'No' to Question 5 two provided additional comments

Virtual Service Provision

12.5 The HSCB raised the issue of further IT developments stating:

The development of pharmacy practice will see further use of IT – the principles could be applied to virtual service provision but further consideration may need to be given.

13. Responses to Question 6

Question 6: The Standards are grouped under five Principles. Are the Standards clear?			
Yes	**No**	**Unsure**	**Did not answer**
3 (37.5%)	**2 (25%)**	**3 (37.5%)**	**1**

13.1 Both respondents that answered 'No' to Question 6 provided additional comments. The three respondents that answered 'Unsure' to Question 6 provided additional comments and one respondent that answered 'Yes' provided an additional comment. Some of the themes substantive themes emerging from the comments are outlined below. All comments which relate to a specific Standard have also been placed in Appendix 1.

Standard 3.4: Medicine Use Reviews and smoking cessation figures

13.2 A number of respondents raised issue with the inclusion of Medicine Use Reviews and smoking cessation figures as examples of measuring patient outcomes in Standard 3.4

13.3 The PDA stated:

A measurable patient outcome could be, for example, an acceptable proportion of asthma patients with a satisfactory peak flow reading when assessed at the pharmacy, or a certain proportion of diabetic patients whose blood sugar level was within the target range. The number of MURs conducted, or smoking cessation figures, are not patient outcomes.

13.4 Going on to say:

Not only could it portray a lack of understanding of patient outcomes, but the PSNI appears to have proposed that MUR targeting become an expected part of pharmacy practice, when other healthcare authorities have taken steps to prevent such behaviour on the part of employers.

13.5 This issue was also raised by the HSCB, the NPA, Medicare and Boots UK.

Standard 5.4: Scope for Ethical Decision Making

13.6 The PDA raised a concern that the wording of Standard 5.4, namely that 'staff must comply with the laws and regulations that affect their professional practice and be accountable for any acts and/or omissions' , "leaves no scope for ethical decision making and precludes professional judgement which

would lead to any action not in accordance with the law". The PDA went on to recommend that the Premises Standards leave scope for pharmacists to use ethical reasoning and professional judgement.

Access NI Checks

13.7 The NPA sought clarity on whether it is appropriate for all pharmacy staff to be subject to Access NI checks, referencing that current guidance from DoH in respect of the definition of regulated activity, as specified under the Safeguarding Vulnerable Groups Order 2007, does not require all pharmacy staff to undergo this check. This issue was also raised by Pharmacy Forum NI.

Additional Guidance

Stock Management

13.8 The NPA suggested that additional guidance would be beneficial in a number of areas relating to the proposed standards. This included Guidance in relation to Standard 3.3 specifically concerning stock management issues, outside of the pharmacist's control.

Information Governance

13.9 The NPA considered further Guidance is required in relation to Standard 4.3, noting it correlates with GPhC's Standard 5.3, however, the GPhC's Standard 5.3 is accompanied by a wider Information Governance Framework.

Staff Training

13.10 In relation to Standards 5.1 and 5.2 the NPA stated that it would be useful to owners and superintendents to have guidance on training and competencies for individual roles. This issue was also raised by the Pharmacy Forum NI and the HSCB.

13.11 All detailed comments on individual standards are included in Appendix 1.

14. Responses to Question 7

Question 7: Reflecting on the activities related to the safe and effective practice of pharmacy at a retail pharmacy business at or from a registered pharmacy, do any other Standards need to be added?			
Yes	**No**	**Unsure**	**Did not answer**
2 (25%)	**6 (75%)**	**0**	**1**

14.1 Both respondents that answered ‘Yes’ to Question 7 provided additional comments:

Appropriate Staffing Levels

14.2 Both the Guild and the PDA recommended that the Premises Standards include a standard on appropriate staffing levels.

14.3 The Guild suggested additional standards on sourcing and stocking medications, IT a Standard on access for patients with special needs/vulnerability.

14.4 The PDA recommended additional Standards relating to an onus on employers to address concerns raised by staff to ensure staff feel empowered to raise concerns in a way that is consistent with a culture of openness, honesty and learning.

14.4 The PDA further recommended standards on appropriate breaks and rest period for staff and the physical safety of staff and the protection from violence.

The Council of the Pharmaceutical Society NI considered this consultation report at its meeting of 04 June 2018 along with proposed changes to the draft Premises Standards.

The Council of the Pharmaceutical Society NI approved new premises Standards on 05 June 2018.

Appendix 1

Table 1: Comments relating to specific Principles and Standards	
Standard	**Comment**
1.1 The risks associated with pharmacy services must be identified through appropriate risk assessment.	**NPA:** *We suggest amending this to "risks must be identified and managed through appropriate risk assessment" in order to encourage owners and superintendents to provide supporting evidence of taking action in response to required amendments*
	Medicare: *Standard 1.1: Refers to appropriate risk assessment. We would suggest more clarity is required on what would be deemed "appropriate" to give clarity to superintendents/owners and inspectors.*
	CPNI: In our view the language and framing of this Principle around safeguarding the public is better reflected in the GPhC version. This version also makes clearer what exactly is required, for example, PSNI 1.1 *"The risks associated with pharmacy services must be identified through appropriate risk assessment."* Compared to GPhC 1.1 *"The risks associated with providing pharmacy services are identified and managed."* Our overriding advice is to keep it simple and explain what exactly is required, this will remove subjectivity and improve compliance.
1.3 Staff must have clearly defined roles and be clear about their accountabilities.	**NPA:** *We support the standard to provide defined roles and clear accountabilities for staff. However, we advocate that this standard should extend to the requirement for staff development and implementation of contingency plans to manage business and service continuity.*
	Pharmacy Forum NI: *We agree with the principle that staff should have defined roles and be clear about their responsibilities. However, we would suggest that the standard should also encompass the requirement for staff development and contingency plans, for business and service continuity.*
1.5 All records must be managed accurately, clearly and be legibly written and attributable	**Boots:** *Use of "legibly written" suggests handwritten rather than electronic documents*
	CPNI: "*All records*" is not well defined and "*attributable*" may not always be feasible, for example an entry in a

	PMR at present cannot be attributed to a single staff member. We would suggest as alternative wording, *"All necessary records for the safe provision of pharmacy services are kept and maintained."*
1.6 Information must be managed confidentially to protect the dignity and privacy of patients and the public who receive pharmacy services	**CPNI:** This needs to be specific to pharmacy services, as an alternative form of wording we suggest, *"Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services."*
1.7 Vulnerable individuals, including adults and children must be safeguarded.	**NPA:** *We seek clarity on whether it is appropriate for all pharmacy staff to be subject to Access NI checks? Current guidance from DoH in respect of the definition of regulated activity as specified under the Safeguarding Vulnerable Groups Order 2007 does not require all pharmacy staff to undergo this check. Implementation of a standard that requires Access NI checks on all staff is likely to carry a significant workload and cost burden. We suggest that a requirement to ensure that all staff receive relevant training in safeguarding is added.*
	Pharmacy Forum NI: *In supporting the requirement that vulnerable individuals, including adults and children, must be safeguarded, the Pharmacy Forum would suggest that it may not be necessary for all pharmacy staff to be subject to Access NI checks.* *While it is likely to be appropriate for those staff with access to patient records, or who perform certain functions, such as delivery drivers, there will be other staff for which the process may be unnecessary. This includes counter staff that are not working alone or unsupervised.* *It is important to note that the requirement that all staff be subject to Access NI checks is also contrary to the guidance issued by the Department of Health in respect of the definition of regulated activity (adults), as specified under the Safeguarding Vulnerable Groups Order 2007* *Additionally, carrying out Access NI checks on all staff is likely to have significant financial implications.*

	Under these circumstances, we feel that the issuing of supplementary guidance or a clear definition of regulated roles would be appropriate
	Medicare: *Would welcome clarity on what level of "training" would be acceptable for particular groups of staff Feedback on "compliance indicator: have appropriate skill mix of staff to offer the range of services": Consideration needs to be given to the "normal" circumstances and staff complement, but also when urgent of unforeseen circumstances arise. Recruitment challenges and other circumstances can arise that may not be within the control of the owner/pharmacy superintendent.*
Principle 2 The Pharmacy Owner and Superintendent must ensure that the working environment of the registered pharmacy, and its associated premises is suitable to assure the safe and effective provision of pharmacy services to patients and the public.	**Boots:** *Lack of clarity around "associated premises". The statement that pharmacies should "present a professional image" could be open to wide interpretation.*
2.4 Premises must protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services	**Pharmacy Forum NI:** *The guidance in respect of this standard, suggests the requirement for a consultation room as well as a quiet area. This could prove difficult for pharmacies to put in place, particularly in smaller premises. Guidance and examples in this area, in respect of achievable outcomes, would therefore be useful. Additionally, in keeping with several other areas within the requirements, there is a link to the Pharmaceutical Services contract. The Pharmacy Forum would suggest collaboration, to ensure a single standard.*

2.5 Premises must be appropriate for the provision of quality patient care.	**Pharmacy Forum NI:** *The Pharmacy Forum considers this requirement to be subjective and would seek further clarification from the Pharmaceutical Society on the definition of "appropriate" in this context. We would also suggest that vignettes in respect of how this standard would be evidenced, would be essential.*
	Medicare: *"Premises must be appropriate for the provision of quality patient care" would be open to interpretation of superintendent pharmacist/owner and the inspector. So if an action plan was to result with an item relating to this standard, what would reasonable and feasible expectations be?*
Principle 3 The Pharmacy Owner and Superintendent must ensure the delivery of accessible, professional and quality patient-centred services to patients and the public	**Boots:** *Lack of definition of "accessible" – is this just physical access?*
	CPNI : *There was one notable divergence in PSNI Principle 3 which specifically "relates to the patient and public experience", whereas GPhC Principle 4 relates to the "the way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public."* *GPhC includes the relevant aspects of patient and public experience within Principle 1 "The governance arrangements safeguard the health, safety and wellbeing of patients and the public." this is framed differently to PSNI's Principle which "relates to governance arrangements for registered pharmacies including arrangements for managing and monitoring the sale and effective provision of pharmacy services at, or from registered pharmacies." Thus by framing this Principle differently PSNI omit GPhC Standard 1.4 "Feedback and concerns about the pharmacy, services and staff can be raised by individuals and organisations, and these are taken into account and action taken where appropriate." Instead PSNI create their new proposed Principle 3.* *While CPNI understands and values the patient and public experience we do not believe this warrants a Principle in its own right within a set of Premises Standards, particularly when this element is not only already currently reflected within the HSCB Assurance Framework but additionally contractors are anticipated to have new obligations within the new*

	Clinical Governance Framework. What PSNI describe under this proposed draft Principle 3, alongside other existing/new obligations would be overly onerous on pharmacy owners. For this reason CPNI suggests adopting a similar approach to GPhC by including key Standards pertaining to the patient and public experience within appropriate Principles and replacing PSNI Principle 3 with GPhC Principle 4, including its related Standards.
3.3 Provide an appropriate stock of medicines and medical devices	**Pharmacy Forum NI:** *In light of quotas put in place by a number of Pharmaceutical Companies on the supply of drugs, we would seek guidance on how shortages and quotas, outside contractor control, will be considered in relation to this standard and requirement.*
	Medicare: *"Provide an appropriate stock of medicines and medicinal devices" would appear to be open-ended and difficult to assess by an external inspector. Is this relating to actual stock maintained on shelves or obtainable within a reasonable timeframe?*
3.4 Measure and evaluate patient outcomes to demonstrate commitment to quality service provision, for example, number of Medicines Use Review (MURs), or smoking cessation figures	**PDA:** *A measurable patient outcome could be, for example, an acceptable proportion of asthma patients with a satisfactory peak flow reading when assessed at the pharmacy, or a certain proportion of diabetic patients whose blood sugar level was within the target range. The number of MURs conducted, or smoking cessation. Page 12 of 14 figures, are not patient outcomes. It is extraordinary that this has been included in the premises standards. Not only could it portray a lack of understanding of patient outcomes, but the PSNI appears to have proposed that MUR targeting become an expected part of pharmacy practice, when other healthcare authorities have taken steps to prevent such behaviour on the part of employers.*
	HSCB: *Disagree that the number of MURs is an indicator of patient outcomes / quality service provision. The smoking cessation figures would be an indicator of compliance rather than stated within the objective.*

	Medicare*: Measuring outcomes e.g. number of MURS – we would like to suggest that the impact an MUR has had on a patient would be a measure and not simply the number done.*
	Boots: *The standard talks about measuring "outcomes" but refers as examples to two "outputs" (ie, numbers of MURs and smoking cessation). It would be best to avoid making references to specific services that might be changed, renamed or withdrawn in the lifetime of the document.*
3.5 Respond to constructive patient and public feedback on service provision	**PDA:** *This requirement, if it is retained, must surely be to respond to any patient and public feedback on service provision where the patient expects a response. The manner in which patients and the public provide feedback cannot be prescribed by the PSNI in premises standards applicable to pharmacy owners and superintendents; patients cannot always be expected to be constructive in their feedback in order to obtain a response.*
	Medicare: *This would imply that a public satisfaction survey would need to be conducted/required as evidence. We would welcome clarity on what an inspector would consider appropriate i.e. would pharmacies need to proactively seek views, capture that information, assimilate this and produce a summary report for example annually? If so, time required to meaningfully conduct this activity needs to be factored in.*
3.6 Ensure and effective complaints procedure is available	**Medicare:** *Complaints procedure – this is already captured in other legislation/standards e.g. RP, and evaluated by means of Community Pharmacy Assurance Framework visits and declarations.*
3.7 Respond quickly and appropriately to any complaint about care or service, and take appropriate action	**Medicare:** *"Respond quickly" is open to interpretation, and we would suggest "in a timely manner' or "in accordance with company policies" may be alternative ways to word this. Consultation document definition of Superintendent includes "A superintendent is intended to be the professional lead within a company*

	and is responsible for ensuring that all pharmacy staff meets the premises standards of PSNI"
4.3 Equipment and facilities must be used in a manner that protects the privacy and dignity of the patients and public who receive pharmacy services.	**Pharmacy Forum NI:** *We would welcome some specificity on Information Governance Requirements pertaining to pharmacy.*
	NPA: *The NPA notes that this standard correlates to standard 5.3 from GPhC. However, within the GPhC this standard is defined by a wider Information Governance framework, and so we suggest that further guidance is required to allow pharmacies achieve this standard.*
5.1 Staff must be suitably qualified and skilled for the safe and effective provision of pharmacy services provided.	**Pharmacy Forum NI:** *The Pharmacy Forum is of the view that it would be helpful if the training requirements for staff and the competency requirements for their respective roles were clearly stipulated by the Pharmaceutical Society.*
	NPA: *The NPA are concerned that standards 5.1 and 5.2 are duplicated. Within these standards it would be useful to owners and superintendents to have guidance on training and competencies for individual roles.*
	Medicare: *5.1 and 5.2 are similar standards. To assist superintendent pharmacists, it would be important that PSNI provides clear and unambiguous guidance on training and competencies for roles within the pharmacy team. Note for reference, that under Principle 2 of GPhC "Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public", an indicator is "Staff are trained in accordance with the published GPhC policy".*
	CPNI: *In our opinion Standards 5.1 and 5.2 overlap significantly in terms of staff qualifications and skills. In the equivalent GPhC Standards 2.1 and 2.2 these are better defined with 2.1 relating to the number of suitably qualified staff and 2.2 relating to staff working within their competencies or under appropriate supervision. We recommend rewording PSNI Standards 5.1 and 5.2 in the same way to remove duplication. Similarly we*

	prefer the wording of GPhC Standards 2.3 – 2.6, which essentially reflect the same elements of PSNI Standards 5.3 – 5.6 just in a softer, more positive tone, this is particularly the case in Standard 2.6 compared to 5.6.
5.4 Staff must comply with the laws and regulations that affect their professional practice and be accountable for any acts and/or omissions	**PDA: T***his stipulation is similar to one included in the GPhC's Standards for Pharmacy Professionals – that pharmacists and pharmacy technicians "must keep to the relevant laws". [12] It leaves no scope for ethical decision making and precludes professional judgement which would lead to any action not in accordance with the law. For example, it may mean that a dying cancer patient is refused a supply of diamorphine due to a technical error on a prescription, where the pharmacist may otherwise have used professional judgement in relation to all of the circumstances and made a decision to supply. The inclusion of this requirement may mean that the PSNI itself would have some degree of accountability were any harm to come to a patient as a result of following it.* ***Recommendation*** *The PSNI must ensure that its premises standards leave scope for pharmacists to use ethical reasoning and professional judgement.*
	Boots: *Lack of definition of "staff". Staff are not generally responsible for setting incentives or targets. This should apply to pharmacy owners, superintendents or other senior management.*

Appendix 1

Respondents*	
Name	**Organisation/Job Type**
Guild of Healthcare Pharmacists	Pharmacist Representative Body
Pharmacist Defence Association	Pharmacist Representative Body
Pharmacy Forum NI	Pharmacist Representative Body
Community Pharmacy NI	Pharmacist Representative Body

National Pharmacy Association	Pharmacist Representative Body
Health and Social Care Board	Health and Social Care
Medicare Pharmacy Group	Business
Boots UK	Business

*Note we received one response from an individual pharmacist who requested that their name not be listed.