

Draft Premises Standards for a Retail Pharmacy Business at or from a Registered Pharmacy

- **a consultation on the draft standards**

Monday 2 October 2017 – Monday 27 November 2017

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About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists and registered pharmacies in Northern Ireland.

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.

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, and the standards for registered pharmacy premises;
- maintaining a publicly accessible Register of pharmacists and pharmacy premises;
- handling concerns about the fitness to practise of pharmacists, acting as a complaints portal and acting to protect the public; and
- ensuring high standards of education and training for pharmacists in Northern Ireland.

Overview

We are consulting on new Premises Standards for a retail pharmacy business at or from a registered pharmacy, and its associated premises for eight weeks from **Monday 2 October 2017 to 12 noon on Monday 27 November 2017**.

In preparation for commencement of new legislation¹ we are making changes to the regulation of pharmacy retail pharmacy business at or from a registered pharmacy and its associated premises, which will make a positive contribution to the health and wellbeing of patients and the public. With the expansion of pharmacy roles and changes to the way in which pharmacy services are being operated, these new Premises Standards are intended to provide further assurance to patients and the public, accessing pharmacy services, that patient safety is paramount.

Whilst we currently publish Pharmacy Premises Standards; in future, we want to simplify these to make them less prescriptive and more focussed on patient outcomes. Pharmacy Owners and Superintendents will be given autonomy to validate the services they provide to patients and the public.

The proposed new Premises Standards are categorised under five Principles. The Principles are all equally important, and cover the following matters:

1. governance arrangements
2. working environment at a retail pharmacy business at or from a registered pharmacy and its associated premises
3. patient and public experience of pharmacy services
4. condition of the equipment and facilities
5. staff, including training and arrangements for defining roles and accountabilities.

After initial engagement with a range of pharmacy professionals we have developed an approach, which is intended to give transparency and quality assurance to patients and the public accessing pharmacy services.

The consultation document is presented in two sections, these are:

- 1. What this consultation is about** – this section explains what we do now and the proposals for new Premises Standards. It sets out the greater autonomy and responsibility on Pharmacy Owners and Superintendents to ensure adherence to the Standards. It references the current pharmacy inspection model, and details the sanctions to be applied by the Statutory Committee where there are breaches of the Standards.

¹ Article 5A of the Pharmacy (Northern Ireland) Order 1976 which was inserted by Article 13 of the Pharmacy (Premises, Standards, Information Obligations, etc.) Order 2016

- 2. How can I respond to this consultation?** – this explains how individuals and organisations can record their views during the consultation period. A list of consultation questions is provided.

Section 1: What this consultation is about

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.

This new legislative framework supports high quality patient care, improved patient safety and promotes the development of pharmacy practice. These new legislative provisions have yet to be commenced in Northern Ireland.

In accordance with the Principles and Standards of the Code (2016)² 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.

The new Premises Standards are a shift away from the previous Premises Standards produced in 2010³ which were a prescriptive and detailed checklist approach to compliance. These new Standards reflect an ‘outcomes based’ approach; where the Pharmacy Owners and their staff 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.

Accountability for meeting the Premises Standards, which are all equally important, will rest with the Pharmacy Owner or the Superintendent Pharmacist in the case of a registered pharmacy being owned by a body corporate.

² [THE CODE - Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland, 2016](#)

³ http://www.psn.org.uk/wp-content/uploads/2012/09/community_pharmacy_premises_standards-2015.pdf

Who should be interested in the Standards

The Premises Standards are of relevance not only to Pharmacy Owners and Superintendents, but also to patients and the public so they can understand what they should expect from visiting or accessing pharmacy services via a retail pharmacy business at or from a registered pharmacy, and its associated premises.

The Inspection Regime

The Department of Health NI has enforcement powers and duties under, the Medicines Act 1968, the Misuse of Drugs Act 1971, the Poisons (Northern Ireland) Order 1976, Regulations made under the Health Act 2006 and the Veterinary Medicines Regulations. These enforcement duties and powers relate to the sale and supply of medicinal products from a retail pharmacy business at or from a registered pharmacy, and its associated premises.

The Pharmaceutical Society NI does not employ its own pharmacy inspectorate; investigations and inspections are independently conducted by an arms-length pharmacy inspectorate (known as the Medicines Regulatory Group ('MRG')) in the Department of Health (DoH), Belfast, as defined in the Pharmacy (Northern Ireland) Order 1976.

The inspection model for registered pharmacies and its associated premises will continue to focus on a risk-based approach to inspection; focussing on prioritising inspections for registered pharmacies considered at higher risk to patients and the public; either because of the services they provide or where patient safety is in doubt.

The MRG inspectorate informs the Pharmaceutical Society NI where there are significant breaches of standards or where public safety is at some risk.

Sanctions

The 2016 Order has added to the sanctions available to the Statutory Committee of the Pharmaceutical Society NI in relation to pharmacy owners.

- Firstly, it enables the Statutory Committee to remove entries from the premises part of the register or to disqualify a pharmacy owner for breaches of the premises standards.
- Secondly, sanctions may be applied not only to pharmacy owners that are bodies corporate but also to pharmacy owners that are partnerships or individual pharmacists.
- Thirdly, sanctions may be applied in relation to breaches of premises standards where the Statutory Committee is satisfied that the pharmacy owner is unfit to carry on the relevant business safely and effectively.

The 2016 Order aligns the disciplinary provisions and sanctions for Pharmacy Owners in respect to breaches of pharmacy Premises Standards, with those for

individual registrants involved in fitness to practise cases. This consultation does not address these disciplinary provisions and sanctions.

Section 2: How can I respond to this consultation?

How do I take part?

In this consultation, we are seeking views from a wide range of individuals and organisations including patients and the public, pharmacy professionals including Pharmacy Owners, Superintendents, professional and representative bodies.

The consultation questions have been constructed to seek your views on the Principles and the Standards.

Please Note the example compliance indicators will not be included in the final Premises Standards document. The example compliance indicators have been added to assist readers in understanding the Principles and Standards only.

Your responses to the consultation questions will help inform and finalise the Pharmacy Premises Standards. Please fill in the forms provided to assist us in processing your responses.

Accessibility of information

You can find the draft and all documents relating to the consultation on the Pharmaceutical Society NI website:

<http://www.psni.org.uk/publications/consultations/>

If you are having difficulties accessing the documentation or you need us to make adjustments to be able to respond to this consultation, please contact us and we will do our best to address the issue.

If you wish your response to remain confidential you should indicate this in your response and the Pharmaceutical Society NI will generally respect this request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000.

Consultation process

This **eight week** consultation starts on **Monday 2 October 2017 and closes at 12 noon on Monday 27 November 2017**. Responses should preferably be returned electronically to consultations@psni.org.uk and hard copy responses may be sent to Mark Neale at: Draft Premises Standards for a Retail Pharmacy Business at or from a Registered Pharmacy 2017

Pharmaceutical Society of Northern Ireland
73 University Street
Belfast
BT7 1HL

For further information on this consultation please contact Mark Neale at consultations@psni.org.uk or telephone 02890326927.

Report on the consultation

Once the consultation period ends, a report analysing the consultation responses will be produced.

Basic approach/lay out of the Draft Premises Standards Document

A copy of the draft Standards we are consulting upon can be found here:

<http://www.psni.org.uk/publications/consultations/>

The draft Premises Standards contains **five mandatory Principles** which set a clear regulatory framework for pharmacy practice to enable continuous improvement in pharmacy service provision. They touch on every aspect of pharmacy practice, including good governance arrangements, working environment, equipment and facilities at a registered pharmacy and associated premises, patient and public experience of pharmacy services, as well as staff roles, training, and accountability.

A key feature of these draft Premises Standards is a shift away from a prescriptive approach to a more patient-centred and outcomes-based approach. The five Principles are supported by **27 Standards** which are clear indicators for quality improvement. The Principles and Standards are all of equal importance. It is up to each registered Pharmacy Owner and Superintendent to evidence how their retail pharmacy business at or from a registered pharmacy, and its associated premises, is performing in relation to the Standards, and this will provide a basis to monitor progress and take corrective action.

A number of **compliance indicators** provide examples of how the Standards can be met. These indicators are for guidance only and are not meant to be an exhaustive list. Whether you use these or another approach, evidence must be provided that the Standards have been met. Please note the compliance indicators will not be included in the final Premises Standards document after consultation ends.

The inspection model is operated by the MRG at the Department of Health, Belfast; questions relating to inspection are not addressed in this consultation.

Consultation Questions

We would welcome any views you may wish to submit on the questions outlined below. **It is important that you provide reasons for your answers, where possible, so the Council of the Pharmaceutical Society NI can understand the rationale for your views.** We have provided a response template to complete, which is available on the website: <http://www.psnl.org.uk/publications/consultations/>

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