



A consultation paper

Professional Standards and Guidance for Pharmacists in Northern Ireland on the Responsible Pharmacist Regulations

2009

Foreword from the Registrar:

What the Responsible Pharmacist regulations mean for you.

Is your pharmacy practice ready for 1 October 2009?

Forty years after the enactment of the 1968 Medicines Act, legislation governing the accountability of pharmacists for the sale and supply of medicines in a registered pharmacy premises is in the midst of fundamental change.



Put simply, the enactment of the Responsible Pharmacist regulations on 1 October this year marks the most dramatic shift in registered pharmacy premises control in Northern Ireland in two generations. It is therefore imperative that all pharmacists in such premises familiarise themselves with this new legislation and take steps to be compliant.

Up until now personal accountability in registered pharmacy premises has been governed by the 1968 Medicines Act requirement that a pharmacist be in 'personal control'. This has been commonly defined as necessitating the physical presence of the pharmacist in a pharmacy to ensure safe systems and supervision of work. However, following review by Government, "personal control" was replaced in the Health Act 2006 with a new requirement that all registered pharmacy premises have a 'Responsible Pharmacist' accountable for securing "the safe and effective running" of the pharmacy. Further statutory regulations were passed by Parliament in 2008: The Medicines (Pharmacies)(Responsible Pharmacist) Regulations 2008 SI No. 2789 (hereafter referred to as "the Responsible Pharmacist Regulations"). The Professional Standards and Guidance contained in this consultation build on these legal requirements.

This consultation is the first of a series of communications from the Pharmaceutical Society of Northern Ireland to registrants in 2009 in relation to the Responsible Pharmacist regulations. Others to follow include live roadshow events and presentations.

Please give this consultation your full consideration. Your views on appropriate mandatory professional standards and good practice guidance for pharmacists are important to us.

I look forward to receiving your responses by Monday 27 April and hope to see you shortly at one of our forthcoming Responsible Pharmacist information events across Northern Ireland, details of which are on our website and the following section.

A handwritten signature in black ink that reads "Brendan Kerr".

Brendan Kerr MPSNI
Registrar and Head of Professional Services

5 ways of preparing for the Responsible Pharmacist Regulations (which come into force on 1 October 2009)

- First** Study the Responsible Pharmacist Regulations included within this documentation as Appendix 3
- Second** Read and respond to this consultation on the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance on the Responsible Pharmacist regulations, using the response form in Appendix 1
- Third** Check your own understanding of how the new requirements under the Responsible Pharmacist regulations and Professional Standards and Guidance will impact on your daily practice. Consider what changes may be required to your regular processes and conduct after 1 October 2009.
- Fourth** Consider what active steps may need to be taken by you in advance of 1 October 2009. This might include:
- a. reviewing the use of information technology in your practice in relation to the development and maintenance of the Pharmacy Procedures and the Pharmacy Record;
 - b. how you will display to the public who is the responsible pharmacist for those premises (and indicate their absence if necessary), and:
 - c. supplementary training or information required by you or other pharmacy staff e.g. through the Northern Ireland Centre for Pharmacy Learning and Development, or other training provider
- Fifth** Attend one of the forthcoming information days on the Responsible Pharmacist Regulations being held province wide by the Pharmaceutical Society of Northern Ireland. These are taking place at are taking place at the following times and venues:
1. Thursday 26th March 2009 at 7.15pm in the Glenavon Hotel, Cookstown
 2. Monday 30th March 2009 at 7.15pm in The Lodge Hotel, Coleraine
 3. Thursday 2nd April 2009 at 7.15pm in 73 University Street, Belfast

The Code of Ethics (2009) for Pharmacists in Northern Ireland

In June 2009 a revised version of the Pharmaceutical Society of Northern Ireland Code of Ethics and Practice will be launched, referred to in this document as the Code of Ethics (2009).

The Draft Professional Standards and Guidance for Pharmacists in Northern Ireland on the Responsible Pharmacist Regulations therefore refers to, and should be read in reference to, the Code of Ethics (2009), available on the Code of Ethics section of the PSNI website <http://www.psni.org.uk/professionals/code-of-ethics.php>

The Code of Ethics for Pharmacists (2009) in Northern Ireland states:

As a pharmacist registered with the Pharmaceutical Society of Northern Ireland you must:

1. Make the safety and welfare of patients your prime concern
2. Respect and protect confidential information
3. Show respect for others
4. Exercise professional judgement in the interests of patients and public
5. Encourage patients (and/or their carers as appropriate) to participate in decisions about their care
6. Maintain and develop professional knowledge and competence
7. Act with honesty and integrity
8. Provide a high standard of practice and care at all times.

Principle 6.6 of the 2009 Code of Ethics for pharmacists in Northern Ireland states that the pharmacist must comply with legal requirements, mandatory professional standards and accepted best practice guidance.

Draft Professional Standards & Guidance

The Responsible Pharmacist



STATUS OF THIS DOCUMENT

This document describes:

- **Legal Requirements** as laid out in the Health Act 2006 and the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008
- **Mandatory professional standards** for all registered pharmacists; and
- **Guidance on good practice** (indicated by the word 'should', 'might', 'may', 'would', 'will' and 'could') which the pharmacist should follow in all normal circumstances.

Serious or persistent failure to follow this guidance will put a pharmacist's registration at risk. The pharmacist must therefore, be prepared to explain and justify his actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society of Northern Ireland's Fitness to Practise process will take account of the requirements of the Code of Ethics and underpinning documents, including this one. The pharmacist will be expected to justify any decision to act outside its terms.

1. THE RESPONSIBLE PHARMACIST

LEGAL REQUIREMENTS

The Health Act 2006 requires every registered pharmacy premises to have a Responsible Pharmacist in order to operate lawfully. The Act requires the Responsible Pharmacist¹ to secure the safe and effective running of the pharmacy at all times.

Under the terms of the Act, a notice must also be conspicuously displayed on the premises stating the name and registration number of the Responsible Pharmacist at that time.

MANDATORY PROFESSIONAL STANDARDS

In addition, the Responsible Pharmacist **must**:

- 1.1. Establish the scope of his role and responsibilities and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacist² (or other delegated person) in a position of authority.

¹ In keeping with legal terminology and to avoid unnecessary confusion, the Responsible Pharmacist will be referred to as "he" in the personal sense throughout this document.

² This may be the pharmacy owner, superintendent or their authorised deputy.

- 1.2. Take all reasonable steps to establish the roles and responsibilities of other members of staff and clarify any ambiguities and uncertainties.
- 1.3. Not undertake any work that is outside of his competency
- 1.4. Take all reasonable steps to prevent members of staff working under his supervision from working beyond their competency

Question 1:

Are the standards relating to the definition, role and duties of responsible pharmacist outlined in section 1 of the Standards document clear and concise?

Question 2:

Are there any professional standards relating to the (a) definition, (b) role and (c) duties of the Responsible Pharmacist which should be added to or removed?

2. PHARMACY PROCEDURES

LEGAL REQUIREMENTS

To comply with the Responsible Pharmacist Regulations, the Responsible Pharmacist has a statutory duty to establish, maintain and review Pharmacy Procedures.

The Pharmacy Procedures form part of the quality framework for the safe and effective running of the pharmacy.

As a minimum, the regulations state that Pharmacy Procedures **must** cover the:

1. Arrangements to ensure that medicinal products are:-
 - o Ordered;
 - o Stored;
 - o Prepared;
 - o Sold by retail;
 - o Supplied in circumstances corresponding to retail sale;
 - o Delivered outside the pharmacy; and,
 - o Disposed of,In a safe and effective manner.
2. Circumstances in which a member of the pharmacy staff, who is not a pharmacist, may give advice about medicinal products;
3. Identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform specified tasks relating to the pharmacy business;
4. Maintenance of records about the matters mentioned above;
5. Arrangements which are to apply during the absence of the responsible pharmacist from the premises;

6. Steps to be taken when there is a change of responsible pharmacist at the premises;
7. The procedure which is to be followed if a complaint is made about the pharmacy business;
8. The procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner; and
9. The manner in which changes to the pharmacy procedures are to be notified to the staff

These are the **minimum legal** requirements as set out in the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. Pharmacies may obviously wish to develop additional Pharmacy Procedures.

Procedures must by law be recorded in written or electronic form.

Pharmacy Procedures must also be available at the premises for inspection by—

- (a) the person carrying on the pharmacy business;
- (b) the superintendent, if any(8);
- (c) the responsible pharmacist; and
- (d) pharmacy staff.

Additionally, regulations state that Pharmacy Procedures must be reviewed regularly

MANDATORY PROFESSIONAL STANDARDS

In addition to the legal requirements above, the Responsible Pharmacist **must** ensure that:

Pharmacy Procedures and members of staff

- 2.1 All necessary steps are taken to ensure Pharmacy Procedures are operated accordingly by members of staff
- 2.2 Members of staff are competent to perform the tasks required of them in the Pharmacy Procedures
- 2.3 Pharmacy Procedures define which tasks individual staff members are competent to perform in the absence of the responsible pharmacist
- 2.4 Pharmacy staff are aware of what Pharmacy Procedures are in place at any time

The Regular Review of Pharmacy Procedures

- 2.5 Pharmacy Procedures are regularly reviewed to ensure they are fit for purpose and reflect the day to day running of the specific pharmacy premises,

2.6 Review of the Pharmacy Procedures occurs every two years as a minimum or at any time that an incident occurs which may potentially have led to a compromise of patient safety

There is a Document Control System

2.7 There is a system of document control³ to make clear:

- What Pharmacy Procedures are currently in place;
- What Pharmacy Procedures have previously been in place during any given period of time;
- The Responsible Pharmacist who amended or revised the Pharmacy Procedures and the date at which the amendment or revision was made and the date it is valid until.

Question 3:

Are the standards relating to the Pharmacy Procedures clear and concise?

Question 4:

Are there any professional standards relating to the Pharmacy Procedures which should be added or removed?

Question 5:

In relation to the circumstances in which a member of the pharmacy staff who is not a pharmacist may give advice about medicinal products, should the professional regulator set standards in relation to the experience or qualification to be achieved by such persons?

Question 6:

Should there be further professional standards in relation to the Pharmacy Procedures detailing the arrangements which are to apply during the absence of the responsible pharmacist from the premises?

GOOD PRACTICE

- A record of all induction and training received by pharmacy staff in the Pharmacy Procedures should be maintained and available for review by the Responsible Pharmacist.
- Pharmacy procedures should not be dependant on the presence of the Responsible Pharmacist under whose authority they were established.
- The Responsible Pharmacist should notify the superintendent, owner or delegated person in a position of authority⁴ of any review or update of the Pharmacy Procedures as soon as possible.

The Responsible Pharmacist should record the reason for his review or amendment of the Pharmacy Procedures

³ Recording and saving a document and detailing the time period which it relates to. This is also referred to as version control

⁴ E.g. an area manager

Question 7:

Are the good practice guidance points relating to the Pharmacy Procedures listed here clear and concise?

Question 8:

Are there any good practice guidance points relating to the Pharmacy Procedures which should be added or taken from the Guidance?

3. THE PHARMACY RECORD

LEGAL REQUIREMENTS

It is a legal requirement of the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 that a record ('The Pharmacy Record') is maintained of:

- The name of the Responsible Pharmacist;
- Their registration number;
- The date and time at which the Responsible Pharmacist became the Responsible Pharmacist;
- The date and time at which the Responsible Pharmacist ceased to be the Responsible Pharmacist;
- In relation to absence from the premises by the Responsible Pharmacist:
 - The date of absence
 - The time at which the absence commenced
 - The time at which they returned to the premises

Failure to maintain and retain the pharmacy record, as required in the regulations is a criminal offence that may result in prosecution.

MANDATORY PROFESSIONAL STANDARDS

The Responsible Pharmacist **must**:

3.1 ensure the record is accurate and contemporaneous

3.2 make appropriate back-ups to an electronic record

3.3 initial and date any amendments that are made to a paper based pharmacy record

3.4 ensure that computer based records are safeguarded from tampered with or being inadvertently over-written. any alterations to the computer record must identify when and by whom the alteration was made.

Question 9:

Are the standards relating to the pharmacy record clear and concise?

Question 10:

Are there any standards relating to the pharmacy record which should be added or removed?

4. ABSENCE FROM THE PHARMACY

LEGAL REQUIREMENTS

The Responsible Pharmacist Regulations (2008) enable a registered pharmacy to continue to operate for the sale and supply of General Sales List medicines (only) for a maximum of two hours in a twenty four hour period (midnight to midnight) without the presence of a Responsible Pharmacist, subject to specified conditions.

The Medicines Act 1968 (as amended by the Health Act 2006) requires the Responsible Pharmacist to secure the safe and effective running of the pharmacy at all times. The supply of 'Pharmacy only' and 'Prescription Only Medicines' is not permitted during the Responsible Pharmacist's absence.

In order for absence from the pharmacy premises to be permitted, the Responsible Pharmacist regulations (2008) require the Responsible Pharmacist to be able to return with reasonable promptness and remain contactable by pharmacy staff during his absence.

If the Responsible Pharmacist is unable to remain contactable during a period of absence he must arrange for another pharmacist to provide advice.

MANDATORY PROFESSIONAL STANDARDS

Prior to any absence from the pharmacy, the Responsible Pharmacist **must**:

4.1 make arrangements to ensure that either:

- he is contactable and able to return with reasonable promptness; or
- another pharmacist is available to provide advice in his absence.

4.2 be satisfied that the pharmacy will continue to operate safely and effectively in their absence

Question 11:

Are the standards relating to absence from the pharmacy clear and concise?

Question 12:

Are there any standards relating to absence from the pharmacy which should be added or removed?

GOOD PRACTICE

Prior to being absent from the pharmacy premises:

- The Responsible Pharmacist should consider the practicality of remaining contactable and consider the distances involved in returning with reasonable promptness
- The Responsible Pharmacist should consider what would be the most appropriate means by which he remains contactable during the period of absence

- The Responsible Pharmacist should put into place measures which reasonably prevent unauthorised access to P and POM medicines during his absence.
- Alongside the legal requirement for a pharmacy premises to display to the public who is the Responsible Pharmacist at any given time, the display should also make clear if the Responsible Pharmacist is currently absent.

Question 13:

Is the good practice guidance relating to absence from the pharmacy clear and concise?

Question 14:

Are there any additional good practice guidance relating to absence from the pharmacy which should be added or taken from the Guidance Document?

Documents supporting the Standards and Guidance

The Pharmaceutical Society of Northern Ireland's Standards and Guidance Document on the Responsible Pharmacist Regulations should be read in conjunction with:

- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 SI No. 2789⁵
- The Medicines Act 1968 (as amended by the 2006 Health Act)
- The Pharmaceutical Society of Northern Ireland's 2009 Code of Ethics

These documents are available on the Pharmaceutical Society of Northern Ireland website.

Other sources of Society advice

Further information or advice on the professional or legal obligations of the pharmacy profession can be obtained by contacting the Society at 028 9032 6927 or by e-mail ethics@psni.org.uk.

⁵ http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1