

Issue: March 2016



STANDARDS AND GUIDANCE ON THE RESPONSIBLE PHARMACIST REGULATIONS



PROFESSIONAL STANDARDS AND GUIDANCE ON THE RESPONSIBLE PHARMACIST REGULATIONS

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, as well as some general background for contextual understanding
- **Mandatory Professional Standards** for all registered pharmacists in Northern Ireland; and
- **Good Practice Guidance** (indicated by the word 'should', 'might', 'may', 'would', 'will' and 'could') which the pharmacist should seek to follow in all normal circumstances.

Serious or persistent failure to follow either the Legal Requirements or Professional Standards 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 and underpinning legal and professional requirements, including the Professional Standards and Guidance outlined in this document.

This document should therefore be read in conjunction with:

- Section 30 of the Health Act 2006
http://www.opsi.gov.uk/acts/acts2006/pdf/ukpga_20060028_en.pdf
- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008
http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

- The Department of Health’s Guidance on the Responsible Pharmacist regulations

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_095570

and,

- The Pharmaceutical Society NI’s, *The Code – Professional standards of conduct, ethics and performance for pharmacists in Northern Ireland* (2016)

1. THE RESPONSIBLE PHARMACIST

LEGAL REQUIREMENTS AND GENERAL BACKGROUND

The Health Act 2006 requires each registered pharmacy premises to have a Responsible Pharmacist in charge in order to operate lawfully (the one pharmacy/one pharmacist rule). 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.

Current legislation, regulations and Professional Standards permit any pharmacist registered with the Pharmaceutical Society of Northern Ireland to be a Responsible Pharmacist in Northern Ireland.

Department of Health Guidance defines the Responsible Pharmacist as “the pharmacist in charge of a registered pharmacy on any day and at any time. Only one pharmacist may be responsible for a pharmacy at any one time.”

MANDATORY PROFESSIONAL STANDARDS

The Responsible Pharmacist must:

- 1.1. Establish the scope of his role and responsibilities and take reasonable steps to clarify any ambiguities or uncertainties with the pharmacist (or other delegated person)² in a position of authority.
- 1.2. Take all reasonable steps to establish the roles and responsibilities of other members of staff and clarify any ambiguities and uncertainties.

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.

- 1.3. 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.

2. PHARMACY PROCEDURES

LEGAL REQUIREMENTS AND GENERAL BACKGROUND

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 for which the Responsible Pharmacist is legally and professionally accountable.

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

1. Arrangements to ensure that medicinal products are:-
 - Ordered;
 - Stored;
 - Prepared;
 - Sold by retail;
 - Supplied in circumstances corresponding to retail sale;
 - Delivered outside the pharmacy; and,
 - 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;
- (c) The responsible pharmacist; and
- (d) Pharmacy staff.

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 anytime.

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 and any changes are documented accordingly (see 2.7)

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

Document Control Systems

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.

GOOD PRACTICE GUIDANCE

- 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 change of the Pharmacy Procedures as soon as possible.

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

⁴ For example, an area manager

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

3. THE PHARMACY RECORD

LEGAL REQUIREMENTS AND GENERAL BACKGROUND

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. Legislation requires the Pharmacy Record be maintained by the Pharmacy Owner for a period no less than 5 years.

MANDATORY PROFESSIONAL STANDARDS

- 3.1 The Responsible Pharmacist must ensure the Pharmacy Record is accurate and contemporaneous⁵ and amendments are initialled and dated.

Pharmacy Owners must ensure:

- 3.2 appropriate back-ups are made of an electronic Pharmacy Record; and,
- 3.3 computer based records are safeguarded from being tampered with or being inadvertently over-written.

⁵ Originating, existing, or happening during the same period of time e.g. Notifications to the Record such as when the Responsible Pharmacist signed out should not be made the day afterwards, but at the time of the occurrence.

4. ABSENCE⁶ FROM THE PHARMACY

LEGAL REQUIREMENTS AND GENERAL BACKGROUND

The Responsible Pharmacist Regulations (2008) enable a registered pharmacy to continue to operate for the sale of General Sales List medicines 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.

However, if another pharmacist(s) remains present in the pharmacy during the absence of the Responsible Pharmacist all medicines (GSL, P and POM) can be sold or supplied and advice provided, under the procedures which were established or adopted by the (absent) Responsible Pharmacist. In such a scenario, the absent Responsible Pharmacist will continue to remain accountable for the safe and effective running of the pharmacy unless another pharmacist signs on to become the Responsible Pharmacist and makes an entry in the Pharmacy Record to this effect.

In order for absence from the pharmacy premises to be permitted, the Responsible Pharmacist regulations (2008) require that the Responsible Pharmacist be able to return with reasonable promptness and remain contactable by pharmacy staff during his absence or arrange for another pharmacist to provide advice in his absence. The regulations also state these arrangements must be made prior to 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

- 4.1 In his absence, the Responsible Pharmacist must ensure that GSL medicines sales are only delivered to the public by members of staff who have received as a minimum, formal medicines counter assistant training⁷.

⁶ Absence is described in Department of Health guidance as meaning "periods when the responsible pharmacist is away from the registered pharmacy premises whilst remaining responsible for the safe and effective running of the pharmacy"

⁷ Medicines counter assistant training currently approved by the Pharmaceutical Society of Northern Ireland are: the Cambridge Counterpart course; Buttercups Training; and Pharmacy Interact (NPA). The following in-house courses are also approved: Lloyds, Tesco, Alliance, Boots and Co-op. For any other courses pharmacists are advised to contact the Pharmaceutical Society of Northern Ireland in relation to their content and standard.

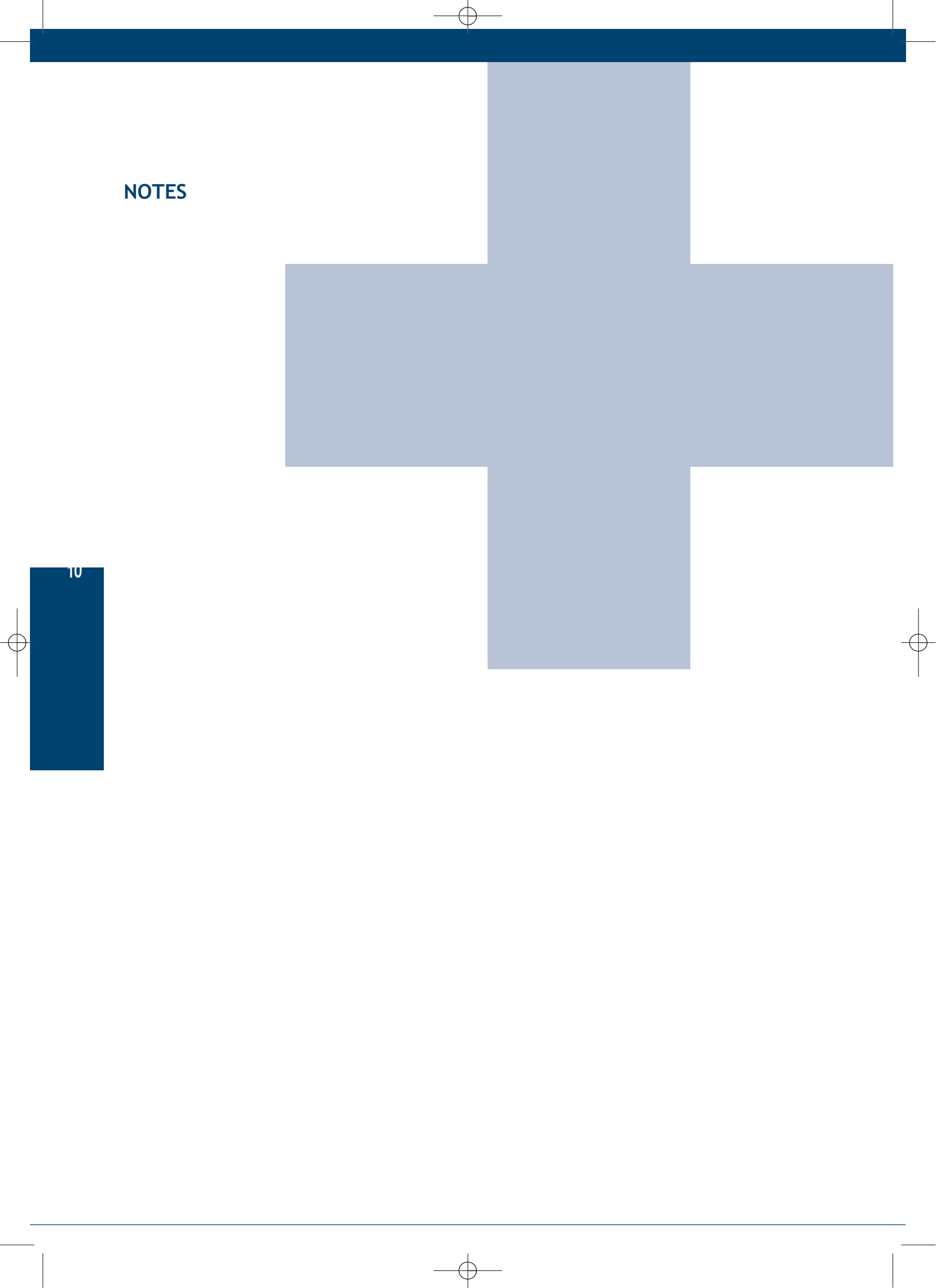
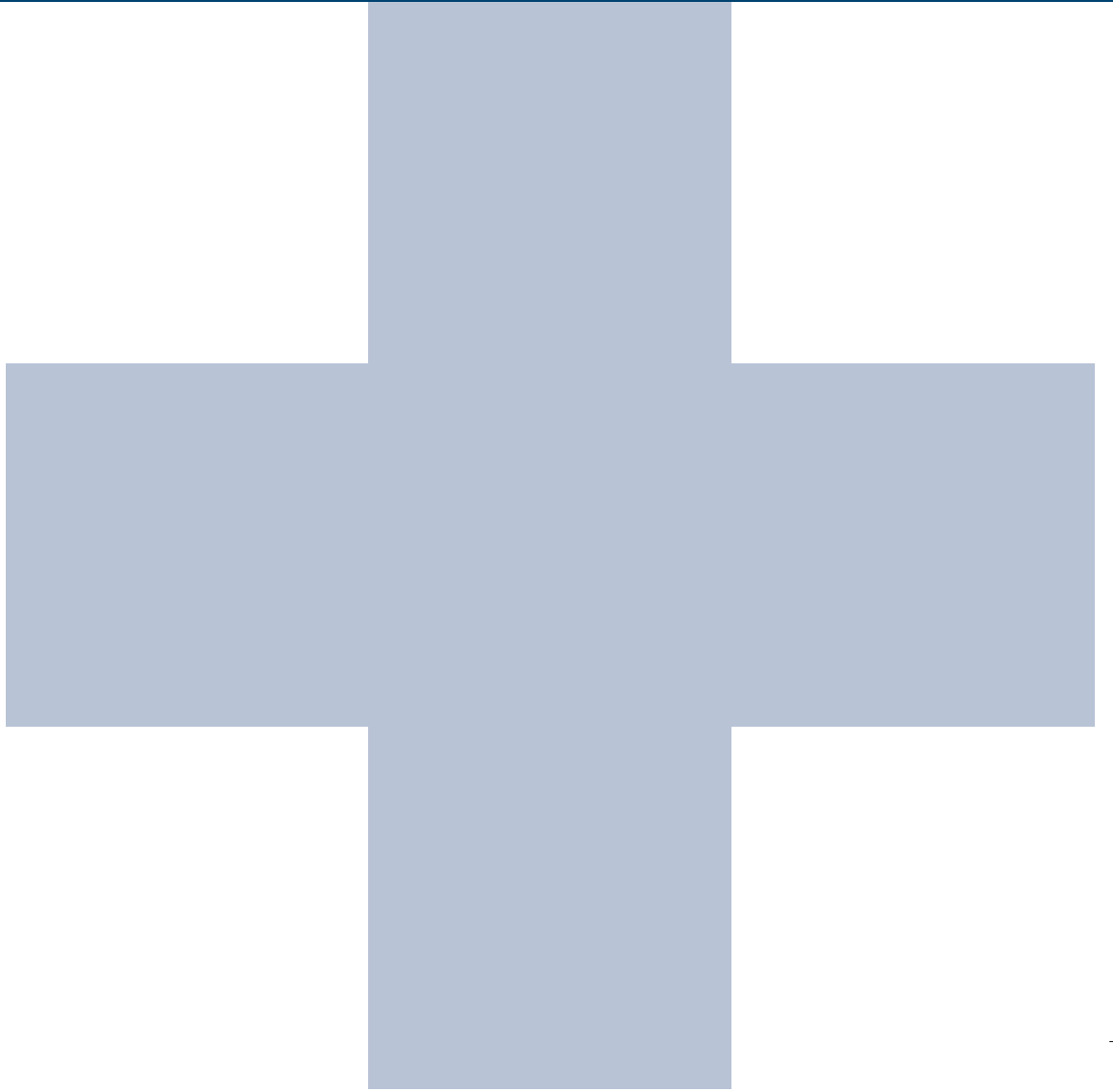
GOOD PRACTICE GUIDANCE

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 and whether any other pharmacist is currently present.

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

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