



**Royal  
Pharmaceutical  
Society**  
of Great Britain

## **Consultation on the draft professional standards and regulatory guidance for the Responsible Pharmacist**

### **BACKGROUND**

In 2004, the Government published a consultation titled 'Making Better Use of the Pharmacy Workforce'. Responses to this consultation supported the need for legislative changes to allow pharmacists and pharmacy owners to make better use of the skills and training of all those working in pharmacies to pursue a greater clinical role and improve access to medicines.

### **CURRENT LEGISLATION: MEDICINES ACT 1968**

The Medicines Act 1968 is concerned with all aspects of the sale and supply of medicines; it does not legislate for other pharmacy activities such as diagnostic testing, smoking cessation or other clinical services provided within the pharmacy.

In order to lawfully conduct a retail pharmacy business there must currently be a pharmacist in personal control. In addition, the sale and supply of Pharmacy (P) medicines and Prescription Only Medicines (POM) must be under the supervision of pharmacist. The Medicines Act does not define supervision; however NHS legislation requires a pharmacist to directly supervise the supply of all medicines.

### **HEALTH ACT 2006**

The Health Act 2006 (primary legislation) makes changes to the personal control requirements of the Medicines Act, with the detailed requirements set out in secondary legislation i.e. in Regulations.

The Health Act replaces the term personal control with that of a responsible pharmacist. Therefore every registered retail pharmacy must have a 'responsible pharmacist'. Where the pharmacy is operating without a responsible pharmacist, it must close for the sale and supply of medicines. If there is more than one pharmacist working in the pharmacy, only one may be the responsible pharmacist at any one time.

For the first time, primary legislation sets out a statutory duty for the responsible pharmacist to secure the safe and effective running of the pharmacy.

In exercising this statutory duty, the Health Act outlines a requirement for the responsible pharmacist to establish (if they are not already established), maintain and keep under review procedures for safe working, and keep a record of the pharmacist responsible for the pharmacy at any one time. There is also a statutory duty on the pharmacy owner to ensure the responsible pharmacist properly maintains the pharmacy record.

The Health Act also enables ministers to set out in regulations the ability of the responsible pharmacist to be absent from the pharmacy.

The supervision requirements will be considered at a later stage.

## **RESPONSIBLE PHARMACIST REGULATIONS**

The Responsible Pharmacist regulations were laid on 29 October 2008, and come into force on the 1 October 2009. They set the quality framework for the safe and effective operation of the pharmacy, which will underpin any proposed changes to supervision. The responsible pharmacist regulations cover areas including pharmacy procedures, pharmacy records and absence from the pharmacy. These areas are described in further detail below:

### **PHARMACY PROCEDURES**

Pharmacy procedures must be reviewed regularly and as a minimum, they must cover the following:

- arrangements to secure 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;
- the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;
- the 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;
- the keeping of records about the matters *mentioned above*;
- arrangements which are to apply during the absence of the responsible pharmacist from the premises;
- steps to be taken when there is a change of responsible pharmacist at the premises;
- the procedure which is to be followed if a complaint is made about the pharmacy business;
- 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
- the manner in which changes to the pharmacy procedures are to be notified to the staff.

### **PHARMACY RECORDS**

As a minimum, the following details must be recorded:

- the responsible pharmacist's name;
- 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:
  - o The date of absence
  - o The time at which the absence commenced
  - o The time at which they returned
  - o If they have been the responsible pharmacist for more than one premises, this fact

The person carrying on the pharmacy business, for example the owner of the pharmacy must keep the pharmacy record for a period of five years. Failure to

comply with the requirement to maintain, and preserve the pharmacy record is a criminal offence and could result in prosecution.

Both pharmacy procedures and records can be recorded electronically, in writing or both, and the regulations state that both must be available at the premises for inspection by:-

- the person carrying on the business;
- the superintendent, if any;
- the responsible pharmacist; and
- pharmacy staff.

#### **ABSENCE FROM THE PHARMACY**

The regulations enable the responsible pharmacist to be absent from the pharmacy for a maximum of 2 hours, during the operational hours of the pharmacy between midnight and midnight.

The regulations detail that in order for a responsible pharmacist to be absent they must remain contactable and be able to return with reasonable promptness. If however, this is not possible another pharmacist must be available to provide advice.

Where a responsible pharmacist has been appointed, the regulations make it explicit that GSL medicines can continue to be sold in the absence of that responsible pharmacist. However, until changes have been made to the supervision requirements, only GSL medicines can be sold in their absence, unless a second pharmacist is present to supervise the sale and supply of POMs and P medicines.

One area in which your views are sought is surrounding the absence of the responsible pharmacist from the pharmacy. The responsible pharmacist has a statutory duty to secure the safe and effective running of the pharmacy, regardless of the reason for absence and whether or not this reason is recorded.

Firstly you are asked to consider whether there is a need for specific regulatory guidance to be issued on the circumstances in which a responsible pharmacist may be absent from the pharmacy or whether this should be left to the pharmacist's professional discretion. You should consider whether absence from the pharmacy for reasons other than professional matters may undermine public confidence in the profession.

Secondly, your views are sought regarding the need to record the reason for absence. The current draft standards state that the responsible pharmacist needs to record the reason for absence only where this is unplanned, for example they have to unexpectedly visit a patient in their own home. Do you feel it is necessary to record the reason for absence in all circumstances, only in certain situations or never at all?

The Society has drafted Professional Standards and Regulatory Guidance for the Responsible Pharmacist that will expand on requirements of the Code of Ethics (this document can be viewed in Appendix 1). It is intended that this document will outline the mandatory professional standards and provide good practice guidance for Responsible Pharmacists. The document will advise the profession of the standards that they must achieve and will form part of the Society's regulatory framework.

#### **Consultation**

The Society is holding an eight week consultation with the membership, stakeholders and others to seek views on the content of the Professional Standards and

Regulatory guidance for the Responsible Pharmacist. Please let us have your views by Friday 6<sup>th</sup> March. There are two ways of responding:

**By post**

Please complete the questionnaire and send it to: Priya Sejjal, Head of Professional Ethics, RPSGB, 1 Lambeth High Street, London SE1 7JN

**Online**

Please complete the questionnaire online at the RPSGB website [www.rpsgb.org](http://www.rpsgb.org)

**Further information**

If you would like further information please contact: Priya Sejjal, Head of Professional Ethics, RPSGB, 1 Lambeth High Street, London SE1 7JN

As well as consulting on the professional standards and regulatory guidance for the responsible pharmacist, we are also running a second consultation on amendments to the standards for pharmacists and pharmacy technicians in positions of authority. These standards are being amended due to the introduction of the responsible pharmacist regulations. A separate consultation document to comment on these changes can be found online at: [www.rpsgb.org](http://www.rpsgb.org). Alternatively hard copies are available to download at [www.rpsgb.org](http://www.rpsgb.org)

If you would like further information please contact:

Priya Sejjal, Head of Professional Ethics, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London, SE1 7JN

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# Professional Standards and Regulatory Guidance for Responsible Pharmacists

## About this document

The Code of Ethics sets out seven principles of ethical practice that you must follow as a pharmacist. It is your responsibility to apply the principles to your daily work, using your judgement in light of the principles.

The Code of Ethics says that you must **'Make the care of patients your first concern'**. In meeting this principle you are expected to:

- Provide a proper standard of practice and care to those for whom you provide professional services
- Be satisfied as to the integrity and quality of products to be supplied to patients
- Maintain timely, accurate and adequate records and include all relevant information in a clear and legible form.
- Undertake regular reviews, audits and risk assessments to improve the quality of services and minimise risks to patient and public safety.

As the responsible pharmacist for a registered pharmacy, you have both a professional and a legal duty to comply with the requirements of the Medicines Act 1968 and the regulations made under the Act, Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. This document expands on the principles of the Code of Ethics to explain your professional responsibilities when acting in your capacity as the responsible pharmacist. It is designed to meet the Society's obligations under the Pharmacists and Pharmacy Technicians Order 2007 and other relevant legislation.

From 2010 the current regulatory responsibilities of the Royal Pharmaceutical Society will, be transferred to the General Pharmaceutical Council, the arrangements for which are currently under discussion at the time of writing. The regulatory role of the PSNI is similarly under discussion.

This document does not give detailed guidance on legal requirements, but you must ensure you comply with relevant legislative requirements. The UK Health Departments have produced factual guidance on the Health Act 2006 amendments to the Medicines Act 1968, including the responsible pharmacist regulations.

Where this document refers to 'the Act' this is the Medicines Act 1968 as amended by the Health Act 2006. Where this document refers to 'the regulations' these are the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. This document does not detail all the requirements of the Act or the regulations, but will reference these where appropriate.

## Status of this document

Principle 6.6 of the Code of Ethics states that you must comply with legal requirements, mandatory professional standards and accepted best practice guidance.

This document contains:

- Mandatory professional standards (indicated by the word 'must') for all registered pharmacists; and
- Guidance on good practice (indicated by the word 'should') which you should follow in all normal circumstances.

If a complaint is made against you the Society's fitness to practise committees will take account of the requirements of the Code of Ethics and underpinning documents, including this one. You will be expected to justify any decision to act outside its terms.

## **1. THE RESPONSIBLE PHARMACIST**

### **STANDARDS**

The Act requires every registered pharmacy premises to have a responsible pharmacist in order to operate lawfully.<sup>1</sup> As the responsible pharmacist, the Act requires you to secure the safe and effective running of the pharmacy. In complying with this legal duty and exercising your professional judgement, you must:

- 1.1 establish the scope of your role and responsibilities and take all reasonable steps to clarify any ambiguities or uncertainties with the pharmacist in a position of authority or other delegated person
- 1.2 not undertake work that is outside of your competency

## **2. PHARMACY PROCEDURES**

To comply with the Act, the responsible pharmacist has a statutory duty to establish, if not already established, maintain and review pharmacy procedures. Appendix 1 lists the pharmacy procedures that must be in place, as detailed in the regulations.

In this section, an amendment is intended to mean a temporary change to the procedure due to a change in the pharmacy's circumstances, for example a member of staff is off sick or a power failure. The procedure must revert to its original content once the change in circumstance is resolved.

A review is where you reevaluate the content of the current procedure to ensure that it is still applicable and workable. This must be in line with the standards below, or following an incident, for example a near miss.

### **STANDARDS**

The pharmacy procedures form part of the quality framework for the safe and effective running of the pharmacy. Pharmacy procedures must be fit for purpose, and reflect the day to day running of the specific pharmacy premises. The regulations set out what pharmacy procedures must be in place. In addition, you must make sure that:

- 2.1 the procedures are being operated and should assess the need for these to be reviewed
- 2.2 if you are the responsible pharmacist who is responsible for establishing the pharmacy procedure(s), it is:
  - 2.2.1 marked with the date of preparation
  - 2.2.2 marked with the date it is due for review
- 2.3 procedures are reviewed at least once every two years, as indicated by the date of review, and at any time that an incident or event occurs where patient safety could be compromised
- 2.4 you sign and date the procedure to indicate it has been amended or reviewed

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<sup>1</sup> At a future date, the Government intends to bring into force regulations enabling a pharmacist to be responsible for a maximum of two registered pharmacy premises, subject to complying with the circumstances and conditions set out in the regulations. It is intended that this would be in exceptional circumstances.

2.5 you notify the person in a position of authority of the review and any consequential changes to the pharmacy procedure, as soon as is reasonably practicable

2.6 version control is in place, such that the content of the procedures available to the staff are those they should be working to on that day

2.7 a log of amendments to the procedures is maintained

2.8 adequate back ups of the content of pharmacy procedures are maintained

#### **GOOD PRACTICE**

- All members of staff involved in the sale and supply of medicines should read and comply with the pharmacy procedures
- Pharmacy procedures should be applicable at all times under normal circumstances; they should not be dependant on the presence of the responsible pharmacist under whose authority they were established
- You should record the reason for the review or amendment

### **3. PHARMACY RECORD**

#### **STANDARDS**

*Failure to maintain and retain the pharmacy record, as required in the regulations, is a criminal offence that could result in prosecution.* Appendix B sets out the minimum content of the pharmacy record, as required by the regulations. You must:

3.1 ensure the record is accurate and contemporaneous

3.2 make appropriate back-ups of an electronic record

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

3.4 ensure that computer records are safeguarded from tampering and over writing. Any alterations to the computer record must identify when and by whom the alteration was made.

### **4. ABSENCE FROM THE PHARMACY**

The regulations enable the pharmacy to continue to operate for the sale and supply of medicines for a maximum of two hours during the operational hours of the pharmacy between midnight and midnight without the presence of a responsible pharmacist, subject to specified conditions. The regulations require you to be able to return with reasonable promptness and remain contactable with pharmacy staff. If you cannot remain contactable, you must arrange for another pharmacist to provide advice. You must:

#### **STANDARDS**

4.1 arrange for another pharmacist to provide advice in advance of your absence from the pharmacy, where you cannot remain contactable or return with reasonable promptness

4.2 ensure that planned absence from the pharmacy is notified to patients in advance

4.3 record the reason for any unplanned absence

#### **GOOD PRACTICE**

- You should consider the length of time it will take for you to travel to and from the pharmacy to the alternative destination, in considering your ability to return with reasonable promptness.
- You should consider what would be the most appropriate means to remain contactable, for example a pager or mobile telephone

## **APPENDIX A**

Pharmacy procedures must cover the following:

- arrangements to secure 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 ofin a safe and effective manner.
- the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;
- the 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;
- the keeping of records about the matters *mentioned above*;
- arrangements which are to apply during the absence of the responsible pharmacist from the premises;
- steps to be taken when there is a change of responsible pharmacist at the premises;
- the procedure which is followed if a complaint is made about the pharmacy business;
- 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
- the manner in which changes to the pharmacy procedures are to be notified to the staff.

## **APPENDIX B**

The following details must be recorded:

- the responsible pharmacist's name;
- 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:
  - o The date of absence
  - o The time at which the absence commenced
  - o The time at which they returned
  - o If they have been responsible pharmacist for more than one premises, this fact<sup>1</sup>

<sup>1</sup> At a future date, the Government intends to bring into force regulations enabling a pharmacist to be responsible for a maximum of two registered pharmacy premises, subject to complying with the circumstances and conditions set out in the regulations. It is intended that this would be in exceptional circumstances.