

# Professional Standards and 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, The 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 Pharmaceutical Society of Northern Ireland is similarly under discussion.

This document does not give detailed guidance on the 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, and the responsible pharmacist regulations made under section 72A of the 1968 Act.

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

The responsible pharmacist is the pharmacist appointed to secure the safe and effective running of the pharmacy in relation to the sale and supply of medicines. At any one time there can only be one responsible pharmacist for a registered pharmacy premises.

### STANDARDS

The Act requires each registered pharmacy premises to have a responsible pharmacist in order to operate lawfully. 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 is required to establish, if not already established, maintain and review pharmacy procedures. Appendix A lists the minimum information to be included in pharmacy procedures that must be in place, as required in the regulations.

Where this document refers to pharmacy procedures, these are currently known as standard operating procedures. The standards in this section apply to those procedures detailed in Appendix A.

In this section, reference to an **amendment** to a procedure 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. Where amended, the procedure must revert to its original content once the change in circumstance is resolved.

In this section, a **review** is where you reevaluate the content of the current procedure to ensure that it is still applicable and workable. Review must be in accordance with the standards below, or following an incident in the pharmacy which indicates that it may no longer be operating safely and effectively, 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 the minimum areas information required in the pharmacy procedures that must be in place.

In addition, you ensure that:

- 2.1** the procedures are being operated in the pharmacy and the requirement for amendment or review is assessed by you.
- 2.2** it is clear to staff on duty which procedures are in operation on the day.
- 2.3** adequate back ups of the content of pharmacy procedures are maintained.
- 2.4** pharmacy procedures must be applicable at all times under normal circumstances;

### Establishing the pharmacy procedures

- 2.5** if you are the responsible pharmacist who is responsible for establishing the pharmacy procedure(s), these are:
  - 2.5.1** marked with the date of preparation.
  - 2.5.2** marked with the date it is due for review.

### The amendment of pharmacy procedures

- 2.6** in the event that you make a temporary amendment to the pharmacy procedure, an audit trail is maintained to identify:
  - 2.6.1** what procedures are currently in place;
  - 2.6.2** what procedures were previously in place;
  - 2.6.3** the responsible pharmacist who amended or reviewed the procedures and date on which any changes were made.

## The review of pharmacy procedures

- 2.7** the procedures are reviewed at least once every two years, and at any time that an incident or event occurs which indicates that the pharmacy is not running safely and effectively
- 2.8** any changes to the procedures, following their review, are notified to the person in position of authority as soon as it is reasonably practicable.
- 2.9** an audit trail is maintained to identify:
  - 2.9.1** what procedures are currently in place;
  - 2.9.2** what procedures were previously in place;
  - 2.9.3** the responsible pharmacist who reviewed the procedures and date on which any changes were made.

### 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 not be dependant on the presence and ways of working 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 complete the pharmacy record, as required in the Act, is a criminal offence that could result in prosecution. Appendix B sets out the minimum information to be included in the pharmacy record, as required by the regulations. In addition, you must:

- 3.1** ensure the record is accurate and contemporaneous
- 3.2** make appropriate back-ups of an electronic record to ensure the record is available at the premises
- 3.3** safeguard a paper based record by initialling and dating any amendments to an entry made in the record
- 3.4** ensure that any alterations to the electronic record 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 remain contactable with pharmacy staff where this is practical. You must also be able to return with reasonable promptness. You must return with reasonable promptness, where in your opinion this is necessary to secure the safe and effective running of the pharmacy. If you cannot remain contactable, you must arrange for another pharmacist to provide advice throughout the period of absence or for any time during that period that you are out of contact. You must exercise your professional judgment in deciding whether to be absent from the pharmacy.

### Good practice

- You should record your reason for absence.
- You should wherever possible, plan your absence in advance of leaving the pharmacy.
- 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 with the pharmacy, for example a pager or mobile telephone and any risks in being able to remain contactable, for example where travelling through areas with poor mobile phone reception.

## APPENDIX A

The regulations require that the pharmacy procedures must provide information on the following:

- 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.

- 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 regulations require the following details to be included in the pharmacy record:

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

<sup>1</sup> At this time a responsible pharmacist cannot be responsible for more than one pharmacy premises.

### Guidance that supports this document

We have produced documents or guidance bulletins on the following which should be considered in conjunction with these standards:

- Code of ethics for pharmacists and pharmacy technicians
- Professional standards and guidance for pharmacists and pharmacy technicians in positions of authority

You can download these documents and more copies of this document from our website ([www.rpsgb.org](http://www.rpsgb.org)) or you can telephone us on 020 7735 9141.

### 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's legal and ethical advisory service on 020 7572 2308, or email [leadvice@rpsgb.org](mailto:leadvice@rpsgb.org).