

Consultation on the amendments to the standards for pharmacists and pharmacy technicians in positions of authority

BACKGROUND

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 RESPONSIBLE PHARMACIST

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.

The Society is currently running a consultation on new professional standards and regulatory guidance for responsible pharmacists. The background to the consultation explains in further detail the role of the responsible pharmacist. Further details can be found under the link 'consultations' on the Society website: www.rpsqb.org

PHARMACISTS AND PHARMACY TECHNICIANS IN POSITIONS OF AUTHORITY

The interlink between the responsible pharmacist and pharmacists or pharmacy technicians in positions of authority is of great importance. The extent to which the standards for pharmacists and pharmacy technicians in positions of authority apply to the responsible pharmacist will be dependant upon the specific role and responsibilities which the responsible pharmacist has been employed to undertake.

The standards for pharmacists or pharmacy technicians in a position of authority have been amended to take account of the introduction of the responsible pharmacist regulations. We are seeking your views on whether the changes made are appropriate and sufficient.

In order to assist, you may find the following three situations useful to consider as you consider this consultation.

Imagine the following three situations:

Pharmacist A is a superintendent pharmacist who employs a responsible pharmacist, pharmacist B.

Pharmacist A will need to comply with the standards for pharmacists and pharmacy technicians in positions of authority.

Pharmacist B will need to comply with the professional standards and guidance for responsible pharmacists.

Pharmacist A whilst not working as the responsible pharmacist will still need to be aware of the responsible pharmacist standards and the responsible pharmacist will need to comply with the standards for pharmacists and pharmacy technicians depending on their roles and responsibilities.

Pharmacist A is both the pharmacy owner and responsible pharmacist. Pharmacist A will have to comply with both the standards for pharmacists and pharmacy technicians on positions of authority, and also the professional standards and guidance for responsible pharmacists.

Pharmacist A is the pharmacy owner, and works three days a week in the pharmacy they own. On the other days, Pharmacist A employs a variety of locums to be the responsible pharmacist.

The locum pharmacists will need to comply with the professional standards and guidance for responsible pharmacists, and apply the standards for pharmacists and pharmacy technicians in positions of authority depending on their roles and responsibilities.

The standards for pharmacists and pharmacy technicians have been in effect since 1 August 2007. Your views are welcome on the document as a whole, however in order to highlight the areas where changes are being proposed the original standards have been amended using 'tracked changes'.

Draft Professional Standards for Pharmacists and Pharmacy Technicians in Positions of Authority

About this document

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

The Code of Ethics says that you must **'Take responsibility for your working practices'** and sets out what you are expected to do when applying this principle in practice.

This document expands on the principles of the Code of Ethics to set out your professional responsibilities if you are in a position of authority. It is designed to meet the Society's obligations under the Pharmacists and Pharmacy Technicians Order 2007 and other relevant legislation.

The term 'position of authority' encompasses the wide range of managerial responsibilities pharmacists and pharmacy technicians undertake, including managing a pharmacy, pharmacy team or department, being a superintendent pharmacist or pharmacy owner, or managing services in a hospital, trust or other field of practice such as industry or academia. The standards in this document are intended to apply to all practice settings. As pharmacists and pharmacy technicians take on management responsibilities to varying degrees, the ability to put into effect parts of this document will depend on the authority your position gives you and the area of practice in which you work.

If you have overall responsibility for the provision of pharmacy services within your organisation (for example, if you own a registered pharmacy premises, are a superintendent pharmacist, or are a chief pharmacist), you must ensure that all the standards set out in this document are met. Where you have delegated the day-to-day implementation of any of the standards you retain overall responsibility for ensuring that the standards are met.

If you are a pharmacist or pharmacy technician with other management responsibilities, for example, ~~if you have management responsibilities for a group of pharmacies or staff within your organisation, you must ensure that the standards in this document are met wherever it is your responsibility and within your power to do so. Where it is not, you must raise awareness of any problems with those who are in a position to make change.~~

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If you are the responsible pharmacist, as defined in the Medicines Act, you must ensure that you also comply with the professional standards and guidance for responsible pharmacists. The extent to which the standards in this document apply to you will be dependant upon the specific role and responsibilities that you have been employed to undertake.

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▼ This document does not detail legislative requirements, but when in a position of authority you must comply with the legislative and contractual requirements, such as NHS terms of service, relevant to your management responsibilities.

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 pharmacy technicians in positions of authority.

You must follow the standards where it is your responsibility and within your power to do so.

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.

Sections 1-9 of this document are applicable to all practice settings. Sections 10 and 11 outline requirements specific to registered retail pharmacies.

1. Accepting positions of authority

STANDARDS

You must accept work only where you have the skills and competence for the tasks to be performed. When taking on any position of authority you must:

- 1.1 establish the scope of your role and responsibilities and clarify any ambiguities or uncertainties about where your responsibilities lie.
- 1.2 have the necessary knowledge, skills and experience, including sufficient language competence, to undertake the role.
- 1.3 be able to comply with your legal and professional obligations and manage effectively the activities you are responsible for.
- 1.4 keep up to date with and observe the laws, statutory codes and professional obligations relevant to your particular responsibilities.
- 1.5 declare to the relevant person or authority any interests that could be perceived to influence your judgement in financial or commercial dealings which impact on patient care or public safety.

2. Policies and procedures

STANDARDS

You must ensure that all legal and professional requirements are observed in relation to the pharmaceutical aspects of the business or professional services you manage. It is essential that appropriate policies and procedures are established, maintained and reviewed. Policies and procedures must be made readily available to relevant staff. There must be clarity on areas of responsibility and clear lines of accountability must exist.

If you are a pharmacy owner, superintendent pharmacist or pharmacy manager in a hospital, trust, or other field of practice you have overall responsibility for setting out the standards and policies for the provision of pharmacy services by your organisation. If you are a pharmacist or pharmacy technician with management responsibilities for the day-to-day running of one or more departments or pharmacy premises, you must ensure that policies and procedures are appropriate for the particular department or premises you are responsible for.

You must, as appropriate to your particular management responsibilities, ensure that:

- 2.1 policies and standard operating procedures to ensure the safe and effective provision of pharmacy services in accordance with relevant legal and professional requirements are in place, maintained and regularly reviewed.
- 2.2 clear lines of accountability exist and a retrievable audit trail of the health professional taking responsibility for the provision of each pharmacy service is maintained.
- 2.3 appropriate policies for the number and required experience levels of staff for the business or department(s) you manage are in place and are made known to relevant staff.
- 2.4 suitable arrangements are in place when members of staff are off duty and effective handover procedures are followed.
- 2.5 there are systems to identify and manage risks to patients, the public and those you employ. There must be procedures to deal with incidents that pose a threat to patient, public or employee safety and to review practices in light of such incidents.
- 2.6 procedures are in place to record errors or near miss incidents, notify the person responsible, and review procedures as appropriate.
- 2.7 procedures respect and protect confidential information about patients and employees in accordance with current legislation, relevant codes of practice and professional guidelines.
- 2.8 systems are in place to ensure that the supplier and the quality of any medicines, devices and pharmaceutical ingredients obtained are reputable.
- 2.9 appropriate security measures are in place to protect stocks of medicinal products, devices, and pharmaceutical ingredients, especially those which may be at particular risk of theft or abuse.
- 2.10 any advertising and promotional activity you authorise for professional services or medicinal products complies with appropriate advertising codes of practice, professional guidance and the law.

3. Pharmacy premises and facilities

STANDARDS

The pharmacy premises, department or facilities you manage must enable safe systems of work and be appropriate to the professional services being provided. You must ensure that:

- 3.1 the pharmacy premises, department or facilities you are responsible for do not bring the pharmacy profession into disrepute.
- 3.2 all relevant statutory requirements and regulations are complied with.
- 3.3 any part of the premises from which professional services are provided is readily identifiable and well maintained.
- 3.4 medicines, pharmaceutical ingredients, devices and other stock at the pharmacy premises or facilities are stored under conditions appropriate to the nature and stability of the product concerned.

4. Responsibilities to those you employ, manage or lead

STANDARDS

You must make sure that those you employ, manage or lead, including temporary staff and locums, are not prevented or hindered from performing their professional and legal duties. You must ensure that:

- 4.1 the views, beliefs and rights of those you employ, manage or lead are respected and protected.
- 4.2 financial or other targets do not compromise the professional services you and your staff provide.
- 4.3 those you employ, manage or lead:

- are aware of and are able to comply with their professional and legal responsibilities, ~~and that systems are in place to facilitate this.~~
- are able to exercise their professional judgement in the best interest of patients and the public;
- understand their individual roles and responsibilities, including the activities and decisions which have and have not been delegated to them;
- are provided with the information necessary to enable them to perform their duties safely and effectively;
- are not required to undertake tasks that they are not competent and trained, or being trained, to do;
- have appropriate supervision, either through close personal supervision (trainee staff, for example) or, where legislation permits and the staff are appropriately trained and qualified, through a managed system with clear reporting structures.

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- 4.4 working conditions and practices are lawful and resources, facilities and equipment enable staff to provide services to professionally accepted standards.
- 4.5 staff are able and encouraged to take appropriate rest breaks. When agreeing working hours and rest breaks with employees you must take into account legislative requirements, individual requirements for breaks and the needs of patients.

5. Employing others

STANDARDS

Individuals who are employed or engaged to provide pharmacy services, including temporary staff and locums, must be suitable for the role given to them. If you employ or engage pharmacists, pharmacy technicians or other pharmacy staff (including trainees and students), or if you have overall responsibility for their employment within your organisation, you must be satisfied that:

- 5.1 appropriate checks are carried out before employment commences and that adverse findings do not make employing or engaging the individual untenable. Depending on the remit and responsibilities of the role this may include inquiries about previous criminal convictions, verification of professional registration status and checks on any conditions or limitations on practice.
- 5.2 the individual to be employed has or will undertake appropriate training to attain the skills, knowledge and competency, including sufficient language competence for their role.
- 5.3 reliable references are sought and provided.
- 5.4 the requirements of the Code of Ethics are taken into account when making decisions relating to the conduct of pharmacists, pharmacy technicians, pre-registration trainees or student pharmacy technicians.
- 5.5 the Society is informed if there is concern that the professional competence or fitness to practise of a pharmacist, pharmacy technician, pre-registration trainee or student pharmacy technician may compromise patient care or public safety.
- 5.6 there is co-operation with investigations or inquiries into the fitness to practise of anyone you employ and the impact of any findings and decisions on the employee's role and responsibilities are taken into account.

6. Training and development

STANDARDS

Pharmacists, pharmacy technicians and other staff must have the appropriate knowledge, skills and competence for the roles they undertake and must be provided

with training and development opportunities to strengthen and improve these. Where you employ, manage or lead others you must ensure that:

- 6.1 individuals have access to the training they need and undertake any accredited training requirements relevant to their duties in a timely manner.
- 6.2 you take steps to satisfy yourself that the pharmacists and pharmacy technicians you employ, manage or lead are aware of their obligation to undertake continuing professional development relevant to their professional duties, and are supported to meet this requirement.
- 6.3 staff who seek assistance because they do not feel able to carry out their professional work are reasonably and effectively supported.
- 6.4 the progress and performance of staff, particularly trainees, is regularly reviewed with honest and constructive feedback.
- 6.5 when training pre-registration trainees or student pharmacy technicians:
 - the trainee is fit to practise throughout their training contract,
 - the training meets the development needs of the trainee and provides the necessary range of experiences of professional practice,
 - the trainee is appropriately supervised and monitored by their pre-registration tutor or supervisor and their performance is honestly and impartially evaluated,
 - pre-registration training is provided in approved premises and the Society is notified when such training is being provided.

7. Enabling others to raise concerns

STANDARDS

It is important that those you employ, manage or lead, including temporary staff and locums, are able to raise concerns about risks to patients or the public. Appropriate systems need to be in place to deal with these concerns. You must make sure that:

- 7.1 there is an appropriate and effective mechanism for staff to raise concerns about risks to patients or the public, including concerns about inadequate resources, policies and procedures, or problems with the health, behaviour or professional performance of others.
- 7.2 staff have ready access to information on how to raise concerns, and who they should be raised with.
- 7.3 staff who raise genuine concerns are appropriately supported and protected.
- 7.4 systems are in place to investigate concerns promptly, fully and fairly, and appropriate records are maintained of any investigations and action taken.
- 7.5 concerns which cannot be addressed at a local level are referred to senior management and/or the appropriate authority, such as a regulatory body.

Further information and advice on raising concerns can be found in the Society's guidance document 'Raising concerns- guidance for pharmacists and registered pharmacy technicians' (www.rpsgb.org).

8. Handling complaints

STANDARDS

All complaints about individuals, activities or services under your managerial control must be dealt with in an appropriate and professional manner. Where applicable, NHS complaints procedures must be followed. If you are in a position of authority you must be satisfied that:

- 8.1 ~~systems are in place to enable~~ complaints ~~to be dealt with~~ promptly, constructively and honestly.
- 8.2 those you employ, manage or lead, including temporary staff and locums, are familiar with the complaints procedure.
- 8.3 complainants receive a timely and constructive response and are informed about the way in which the complaints process will proceed.

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- 8.4 anyone being investigated is treated fairly and individuals who are being asked to account for their conduct are made fully aware of the allegations made against them.
- 8.5 appropriate records are maintained of any complaints received and the action taken.

9. Indemnity arrangements

STANDARDS

All pharmacists and pharmacy technicians have a responsibility to ensure that their professional activities are covered by adequate professional indemnity arrangements. Where you employ or engage pharmacists, pharmacy technicians or other staff you must ensure that:

- 9.1 all professional activities undertaken by you or under your control are covered by adequate professional indemnity cover.
- 9.2 those you employ or engage are aware of the extent of the professional indemnity cover provided to them.

10. Superintendent pharmacists and responsible pharmacists for a registered pharmacy premises

Superintendent pharmacists and responsible pharmacists have statutory functions detailed in the Medicines Act 1968. The specific professional requirements for pharmacists undertaking these statutory roles and the relationship between the two roles are explained below.

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Superintendent pharmacists

STANDARDS

As a superintendent pharmacist you are required to manage the keeping, preparing, dispensing and sale or supply of medicinal products by a registered retail pharmacy business owned by a body corporate. You have a responsibility to set the overarching standards and policies for the pharmaceutical aspects of the business. You must ensure that all legal and professional requirements are adhered to and must respond appropriately to any systems failures or concerns that may arise. The role of superintendent pharmacist is a key position carrying full time responsibility and accountability within a company.

You must be satisfied that you have sufficient resources, authority and influence within your organisation to comply with your legal and professional responsibilities. You must also make sure that the members of the board of the body corporate are aware of and understand your responsibilities. As superintendent pharmacist, you retain overall professional accountability for the pharmaceutical aspects of the business even if you are employed for fewer hours than the pharmacy business operates. If you are employed as a superintendent pharmacist on a part time basis, or are not resident in the UK it is very unlikely that you will be able to comply adequately with the legal and professional responsibilities of this role.

You must ensure that the responsible pharmacist is supported to fulfil their legal and professional responsibilities and appropriate systems are in place to deal with concerns raised by the responsible pharmacist.

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Responsible Pharmacist

STANDARDS

Where a pharmacy premises is owned by a body corporate, the superintendent pharmacist is required to set the overarching standards and policies for the pharmacy

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business. As the responsible pharmacist of a particular pharmacy at any given time, you must secure the safe and effective running of that pharmacy for the sale and supply of medicinal products, as required by the Medicines Act 1968. You are responsible for ensuring appropriate procedures for the pharmacy while you are the responsible pharmacist. Where model procedures have been agreed by the pharmacy owner or superintendent pharmacist you must ensure that they are implemented and amended or reviewed where necessary within the pharmacy you are assuming responsibility for. You must ensure that you exercise your professional judgment in complying with your statutory duty to secure the safe and effective running of the pharmacy and that you comply with the standards detailed in the professional standards and regulatory guidance for responsible pharmacists.

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11. Bodies Corporate

STANDARDS

Where a body corporate owns a pharmacy business, a superintendent pharmacist must be appointed to manage the pharmaceutical aspects of the business. The Society expects members of the board of a body corporate to consider and act on the advice of the superintendent pharmacist when dealing with the requirements of the pharmaceutical parts of the business. The superintendent pharmacist needs to be provided with the necessary support and resources to carry out his or her legal and professional obligations as detailed in this document.

The Society must be notified in writing of any changes to the address or ownership of a registered pharmacy premises, or superintendent pharmacist of a body corporate.

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 responsible pharmacists
- Professional standards and guidance for the sale and supply of medicines
- Professional standards and guidance for patient confidentiality
- Raising concerns- guidance for pharmacists and registered pharmacy technicians
- Rest breaks (Law and Ethics Bulletin)

You can download these documents and more copies of this document from our website (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.