

Amendments to the personal control and supervision requirements of the Medicines Act 1968

Background

The Health Bill received Royal Assent on 19 July 2006 and became the Health Act 2006. The Health Act 2006 makes amendments to the personal control and supervision requirements of the Medicines Act 1968. The amendments establish the overarching requirements for the preparation, sale and supply of medicines from registered pharmacy premises. The detail of the parameters and conditions of the requirements (e.g. parameters for the responsible pharmacist's absence from the pharmacy; restrictions on delegation of supervision) and exceptions to the requirements (e.g. circumstances where a pharmacist may be responsible for more than one pharmacy) will be contained in regulations to be made under the Act.

The Department of Health Consultation on the content of the responsible pharmacist regulations was launched on 24 October 2007. The closing date for responses was the 20th January 2008.

The Society wrote to all branch secretaries to advise of the launch of the consultation and encourage responses to be made directly to the Department of Health. Members of Council and staff have also attended branches, who have requested a speaker, to discuss the consultation and possible outcomes from the regulations.

The Society response was considered in the first instance by the Health Act Working Group (HAWG), chaired by Martin Astbury. The HAWG made recommendations to the Law and Ethics Committee (LEC), who in turn presented their recommendations to Council at their meeting in December. Council agreed the response in public business at its December meeting.

In making recommendations to LEC, views and input was sought from the three sector groups (Veterinary Pharmacists Group, Hospital Pharmacists Group and the Community Pharmacists Group). In addition, all three national boards input were also sought.

How we came to our position

In arriving at this policy, the Society's Council has sought to ensure that patient safety is not compromised by the content of these regulations. This is followed by Councils recognition and strong belief that a unique selling point of pharmacies is that members of the public can seek expert advice about their medicines and health without the need for appointment. It would be of concern to the Society if this important quality service were to be lost. When considering the provisions of the responsible pharmacist Regulations the Council has sought to ensure that the current quality framework that is in place in all registered pharmacy premises is not lost.

Council strongly opposes any attempt to make the responsible pharmacist Regulations overly burdensome, but recognises the need for certain important safeguards that need to be put in place to assure the quality and safety of service provision. Council has been vociferous in its response that breaches of the Regulations surrounding the responsible pharmacist provisions should not result in the potential for criminal prosecution.

The Society's Council has stated in its response that:

- A pharmacist must only be responsible for one pharmacy at any one time. However **IF**, Regulations were to be drafted to permit a Responsible Pharmacist to be responsible for more than one pharmacy this should only be in truly exceptional circumstances, or where the Responsible Pharmacist is responsible for the pharmacy in which they are based and for 1 automated machine.
- The maximum period of absence allowed during the time the pharmacy is open is **2 hours**.

For the reasoned arguments behind the policy below, please see the RPSGB response to the content of the responsible pharmacist regulations: www.rpsgb.org

Responsible Pharmacist (RP)

1. Pharmacy procedures

- Pharmacy owners and superintendent pharmacists must have responsibility to
 - Ensure safe systems of working and SOPs are in place
 - Ensure systems are in place so that staff are suitably trained and competent to undertake tasks in accordance with SOPs
 - Ensure the continued presence of an adequate number of appropriately trained staff.
 - Ensure staff are aware of personal responsibilities and limits of competence and authority.
 - Ensure staffing arrangements can deliver a safe service.
 - Define delegation arrangements.
 - Define both the circumstances and provide the means by which the professionally accountable pharmacist is to be contacted
 - Ensure clinical governance and audit arrangements provide appropriate risk assessment and adequate records etc.
- The responsible pharmacist must be satisfied that
 - Tasks are delegated to suitably trained, competent staff working within clearly defined SOPs.
 - Support staff are aware of their personal responsibilities and limits of competency.
 - There are clear protocols defining the circumstances for which a pharmacist needs to have personal involvement or direct oversight.
 - Incident reporting and complaints procedures are in place.
 - Robust SOPs are in place and adhered to, but procedures for a specific pharmacy should not be subject to change each time the responsible pharmacist changes, unless there is good reason.
- The approach to pharmacy procedures must be balanced. There is a need to achieve some consistency in the content of pharmacy procedures but there must still be flexibility in their application.
- It is important that the flexibility allows an incoming responsible pharmacist to amend the pharmacy procedures to comply with their statutory duty to secure the safe and effective running of the pharmacy. The RPSGB does not believe that the flexibility should result in the responsible pharmacist changing procedures unless it is necessary to adhere to their statutory duty and therefore secure patient safety.
- Pharmacy procedures should be maintained either electronically or on paper.
- Pharmacy procedures must be readily available and accessible.
- Regulations should not specify the format used for setting out pharmacy procedures.

- A responsible pharmacist must not have to sign off to say they have checked and are content with the pharmacy procedures.
- On taking responsibility for a pharmacy, the responsible pharmacist must assess the need for the procedures to be reviewed and amend the procedures where necessary. However this requirement should not be in regulation, but should be covered by professional guidance.
- Guidance is a more appropriate means of providing information and advice on the review of procedures
- Professional guidance should require procedures to be reviewed at least annually and that procedures should be signed and dated to indicate that they have been reviewed.
- The requirement for procedures to be reviewed annually must not detract from the need for procedures to be reviewed in response to changes or incidents.
- The Superintendent or Pharmacy Owner should sign a yearly declaration to state that appropriate procedures are in place.
- There should be a requirement, in guidance, for any amendment made to the pharmacy procedure to be recorded, with the reason for the amendment.
- Types of procedures that need to be covered in SOPs in relation to sale and supply of medicines are outlined in **Appendix 1**.

2. Pharmacy records

- The pharmacy record must contain, in Regulation:
 - Name and registration number of the RP
 - Date and time at which the RP assumes responsibility for the pharmacy
 - Date and time at which the RP is absent from the pharmacy
 - Date and time at which the RP ceases to have responsibility for the pharmacy
- In addition, the RPSGB proposes that the reason for absence must also be recorded.
- The record should be maintained on paper or electronically.
- Regulations should require the pharmacy record to be kept for a minimum of 5 years from the date on which an entry is made or in line with other regulations appropriate to the sector of practice.

3. Absence from the pharmacy

- An RP must only be absent from the pharmacy when having a rest break or undertaking professional services.
- Regulations should specify the need for the RP to be able to justify their absence but professional guidance should exemplify what is justifiable.
- The total length of absence permitted in the regulations should be specified per pharmacy premises rather than per responsible pharmacist.
- The minimum presence of the RP should not be specified in Regulation.
- The pharmacy must have an RP for **substantially more than half** of the time the pharmacy is open.
- **IF** however the regulations are to specify a minimum period of presence, this must be **75%** of the time the pharmacy is open.
- The maximum period of absence allowed during the time the pharmacy is open is **2 hours** (If there were two RP during the working day, and the first had been absent for 2 hours, the second RP would not be able to be absent)
- The Regulations should specify that the RP must be able to return to the pharmacy with reasonable promptness.

- Reasonable promptness must not be defined in Regulations. Professional guidance can advise more generally on this topic.
- The Regulations should specify that the RP must be readily contactable during any period of absence.
- Regulations must not specify how the RP is to be readily contactable. Professional guidance can advise on the manner in which an RP remains contactable.
- The RP must arrange, in advance, for another pharmacist to provide advice where the RP cannot remain contactable.
- The manner in which this is arranged should not be specified in Regulation. This is more appropriate for professional guidance.

4. Qualifications and Experience

- All pharmacists must be eligible to be the responsible pharmacist, so far as securing the safe and effective running of the pharmacy, at the point of joining the register.
- As currently, a newly qualified pharmacist is competent to be in sole charge of a pharmacy
- Extra competencies (e.g. leadership and management competencies) are needed for the responsible pharmacist to be absent or be responsible for more than one pharmacy.
- Confirmation of the additional competencies will have to be part of the consideration of the changes to supervision.
- The ability of a pharmacist to undertake the role of the responsible pharmacist must not be based on specific lengths of time on the register.
- As a result of requiring extra competencies to be absent or be responsible for more than one pharmacy, there may be a need to annotate the register. This will need to be looked at when supervision provisions are considered in the future.
- It is proposed that the RPSGB assesses competency
- There must be no minimum period of experience in the relevant pharmacy sector.
- Prior to undertaking a role, a pharmacist must consider their competency and the requirements of the Code of Ethics.
- The RPSGB does not agree that the regulations should specify a minimum period of experience before taking the role of the responsible pharmacist where a pharmacist has not practised for three or more years.

5. One pharmacy/One Responsible Pharmacist

- A pharmacist must only be responsible for one pharmacy at any one time, but if Regulations were to be drafted to permit a Responsible Pharmacist to be responsible for more than one pharmacy this should only be in truly exceptional circumstances, or where the Responsible Pharmacist is responsible for the pharmacy in which they are based and for 1 automated machine.
- A temporary pharmacy, for example at a festival, should not constitute a truly exceptional circumstance.
- The automated machine scenario should be considered separately to other truly exceptional circumstances.
- Regulations must not specify a pharmacist's capacity to exercise their statutory duty. This is implicit in the Health Act 2006.
- Regulations must not specify that certain staff must be employed in the pharmacy in order for a RP to be responsible for more than one pharmacy.
- The time limit for which a RP can be responsible for more than one pharmacy must be the same as the limits on absence.

- The RPSGB must be notified where a RP is responsible for more than one pharmacy.
- The RPSGB does not need to be notified prior to a RP being responsible for more than one pharmacy, i.e. the notification could be retrospective.
- The number of pharmacies that a responsible pharmacist may be responsible for is one. **IF** however, Regulations were to be drafted to permit a Responsible Pharmacist to be responsible for more than one pharmacy this only be two pharmacies.
- The two pharmacies do not need to be owned/ managed by the same company.

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6. Supervision by the RP in a pharmacy where s/he is not the RP.

- This should not be a routine activity, and should only occur for temporary periods in clearly defined circumstances.
- An audit trail and clear lines of accountability must exist.
- There must be a limit on the number of pharmacies a Responsible Pharmacist can supervise. A pharmacist can only supervise activities in one pharmacy at any one time.
- When a responsible pharmacist supervises the activities undertaken at another pharmacy, only activities that do not require their personal supervision may continue in the pharmacy they are responsible for.
- There should not be a specific time limit on how long this supervision can last but a Responsible Pharmacist should not be supervising another pharmacy for prolonged periods of time.
- The two pharmacies do not need to be part of the same company.

7. Preparing for the change

- A 12 month time period is necessary to prepare for the introduction of the responsible pharmacist regulations.
- The RPSGB supports a phased approach to the provisions of the Health Act 2006.
- There are some areas, such as absence, that cannot be fully considered without considering the proposed changes to supervision.
- Further guidance to support the regulations is needed.
- The RPSGB envisages that any further professional guidance, whether mandatory or good practice should be provided by the Society in the form of standards and good practice documents.

Supervision

The Department of Health is taking a phased approach to the implementation of the Health Act. First they will consider the responsible pharmacist regulations, and at a later stage will consider supervision.

The Society's existing policy was used as the starting point for discussions. Council agreed the recommendations of the Health Act Working Group in October 2006, and the consolidated Council policy can be found in below.

8. Conditions to be met in order for a sale or supply of a pharmacy or prescription only medicine to be considered as having occurred under the 'supervision' of the pharmacist

- Supervision should be redefined as the identification of circumstances where a pharmacist's intervention is required and systems should provide for that intervention (either in person or remotely).
- Pharmacists should be able to delegate the supervision of sale/supply of certain P and POMs to registered pharmacy technicians provided robust SOPs are in place and no further pharmacist intervention is required. (i.e. permit supply of dispensed prescriptions and sale of certain P medicines when the pharmacist is absent)
- The pharmacist must still professionally assess every prescription.
- Legislation should make provision for pharmacists to delegate supervisory duties, but must not confer others the authority to supervise unless they have been authorised to do so by the responsible pharmacist.
- Supervision of certain activities must not be delegated e.g. supply of CDs, sales of medicines of abuse.
- Supervision must only be delegated to registered technicians who are appropriately trained and competent.
- It is not appropriate for others to supervise (e.g. nurses, accredited healthcare assistants) unless they are a suitably competent registered health professional.
- SOPs must set out the activities that must be undertaken by the pharmacists and the activities that, if not undertaken by a pharmacist, must be undertaken by a pharmacy technician.
- SOPs must define the activities that require pharmacist intervention.

9. The conditions that must be met in order for a section 10 activity (preparation of medicinal products) to be considered as having occurred under the 'supervision' of the pharmacist

- Supervision of section 10 activities must only be delegated to registered pharmacy technicians who meet a specified competency framework.
- Supervision must only be delegated if the activities are deemed not to require a pharmacist's intervention.
- The pharmacist must approve the formula for the product that is being prepared under S10, but once a formula has been approved it does not need to be re-approved on every occasion that the product is made.
- Other tasks, e.g. record keeping, labelling etc can be undertaken by appropriately trained members of staff.
- The pharmacist is responsible for ensuring that standards and safe systems are in place to enable the delegated member of staff to undertake the other S10 activities.
- The pharmacist is responsible for ensuring that the person they delegate S10 activities to has the necessary competence.

10. The circumstances in which supervision could be met when the pharmacist is not on the premises (remote supervision)

- Only pharmacists should be able to supervise remotely.
- Pharmacists must have access to all relevant information that they would have if present in the pharmacy e.g. PMR etc and must have enough information to make an appropriate assessment.
- SOPs would need to cover
 - how the pharmacist can be contacted
 - how patients can obtain advice from the pharmacist
 - what to do in an emergency
- Remote supervision must not remove the need for a responsible pharmacist
- The pharmacy that is being remotely supervised must request supervision from the pharmacist that remotely supervises.
- It is the responsibility of the Responsible Pharmacist to have systems and procedures in place for the pharmacy that is being remotely supervised e.g. for what situations they will need to request remote supervision.
- The pharmacist that is going to supervise remotely can only supervise a single activity in 1 pharmacy at any given time.
- If there were to be a specific number of pharmacies that could be supervised remotely there would need to be some evidence based analysis on which to base such a decision.
- A standard audio link (e.g. telephone) is not appropriate for remote supervision.
- A pharmacist can only supervise remotely when there is a registered member of staff in the pharmacy.
- Regulations should not specify a restricted list of tasks that can be supervised remotely.
- Consideration needs to be given to the implications of remote supervision of CD supplies.

11. Supervision- pharmacists need only clinically assess new prescriptions, or those which have materially changed

- RPSGB policy is that pharmacists must still professionally assess every prescription.
- Prescriptions which 'have not materially changed' will be difficult to define.
- The fact that a repeat prescription has not changed may in itself indicate a problem

It is proposed that procedures would need to cover, as a minimum:

- Arrangements for the safe, secure and effective ordering, storage, preparation, dispensing, sale or supply, delivery (delivery will include the handing over of a pharmacy medicine to a patient or carer either in the pharmacy or as part of a pharmacy's arrangements for delivery of medicines to, for example, a patient's home) and disposal of medicines
- Arrangements that demonstrate adherence to the legislative framework relating to the supply of controlled drugs
- Activities that may be undertaken by specified pharmacy staff and the level of training/qualification/competence required to undertake these tasks
- Record keeping
- Arrangements for the provision of advice to patients and the public on the sale of medicines by the pharmacist and pharmacy staff, including general sales list (GSL) medicines, and when pharmacy staff should seek the advice or the involvement of the pharmacist.
- Arrangements when the responsible pharmacist is absent from the pharmacy
- Arrangement for recording amendments to the procedures
- Arrangements for responding to complaints and adverse incidents relating to the sale and supply of medicines from the pharmacy
- Arrangements for the transfer of responsibility for the pharmacy from the responsible pharmacist to an incoming responsible pharmacist.