

HEALTH ACT, SKILL MIX AND RESPONSIBLE PHARMACIST

TIMELINES

The changes to the Medicines Act do not come into effect until the **1st October 2009**. The Society is in the process of preparing professional standards and regulatory guidance for responsible pharmacists which will be subject to public consultation in Jan 2009. In addition, we will continue to look at other support tools for the profession.

For background information to these changes, please see the end of this document. Until the changes detailed below come into effect you must continue to operate as you currently do.

AFTER 1ST OCTOBER 2009

Every registered retail pharmacy will have to have a 'responsible pharmacist'. Where the pharmacy is operating without a responsible pharmacist, it must close for the sale and supply of medicines. Where there is more than one pharmacist working in the pharmacy, only one is to be the responsible pharmacist at any one time. Therefore, if you employ two pharmacists to work at the same, you will need to be clear who the responsible pharmacist is.

There will be a statutory duty for the responsible pharmacist to secure the safe and effective running of the pharmacy.

The responsible pharmacist will have:

- 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.
- to display a notice with the name of responsible pharmacist, their registration number and the fact that they are in charge of the pharmacy.

There will also be a statutory duty on the pharmacy owner to ensure the responsible pharmacist properly maintains the pharmacy record.

1. PHARMACY PROCEDURES: AFTER 1ST OCTOBER 2009

Pharmacy procedures will have to be reviewed regularly and as a minimum, they will have to 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 on 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 below*;
- 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.

2. PHARMACY RECORDS: AFTER 1ST OCTOBER 2009

As a minimum, the following details will have to 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 will have to keep the pharmacy record for a period of five years. Failure to comply with the requirement to maintain, and preserve the pharmacy record is the only aspect of the responsible pharmacist regulations that could result in a criminal offence.

Both pharmacy procedures and records can be recorded electronically, in writing or both, and pharmacy procedures and the pharmacy record will have to be available at the premises for inspection by:-

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

3. ABSENCE FROM THE PHARMACY: AFTER 1ST OCTOBER 2009

The regulations will enable the responsible pharmacist to be absent from the pharmacy for a maximum of 2 hours, during the operational hours of the pharmacy, in a 24 hour cycle from midnight to midnight.

In order for the 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 contactable and available to provide advice.

Finally, GSL medicines will be able to be sold in the absence of the responsible pharmacist. However, if there is no appointed responsible pharmacist then GSL medicines cannot be sold.

ROLE OF THE SUPERINTENDENT PHARMACIST

The role of the superintendent is to continue as it currently does. Therefore, pharmacies carried on by a body corporate will still be required to have a

superintendent pharmacist. The responsible pharmacist, where they are not the superintendent pharmacist, will remain subject to the directions of the superintendent pharmacist.

BACKGROUND TO THESE CHANGES

In 2004, the Government published a consultation titled 'Making Better Use of the Pharmacy Workforce'. Responses to this consultation supported the need for legislative change 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. The intention therefore, was to enable pharmacists to pursue a greater clinical role:

- within the pharmacy;
- in the same location adjacent to the pharmacy and
- elsewhere (for example a care home or patient home etc).

The Government initially focused on amending the supervision requirements of the Medicines Act 1968, however, when they began to look at supervision, they realised that personal control was also interpreted as requiring physical presence of the pharmacist in the pharmacy. This interpretation means that currently General Sale List medicines can only be sold in a pharmacy when the pharmacist is present even though pharmacist presence is not necessary for other retail outlets. So the focus shifted to include personal control.

Initially, the Government will introduce the concept of the responsible pharmacist. The responsible pharmacist changes are largely mandatory and will set the quality framework on which the changes to supervision can be built. The amendments to supervision will follow, and are intended to be enabling.

In October 2007, the Department of Health launched a consultation to seek views on the content of the responsible regulations. The responsible pharmacist regulations will contain much of the detail outlined in the Health Act, in respect of the responsible pharmacist. Amendments to supervision will take place at a later stage, and a separate consultation will be held on these changes.

Based on the responses received to the consultation, the responsible pharmacist regulations have been drafted. The *Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008*, referred to throughout this document as the Responsible Pharmacist Regulations were laid on the 29th October 2008, and do not come into effect until 1st October 2009.

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 of Pharmacy (P) 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 supervise directly the supply of all medicines.