

# Pharmacy Act 2007: Understanding your role

## (ICCPE / PSI / HSE joint educational session Spring 2009)

### PSI / ICCPE taskforce

A joint PSI/ICCPE taskforce has been set up to advise the ICCPE and the PSI Registrar/CEO on how best to effectively collaborate with and support pharmacists during the implementation of key sections of the Pharmacy Act 2007. This taskforce, in conjunction with HSE pharmacists, held 12 meetings around the country as part of the ICCPE Spring programme, at which the PSI gave a presentation on the roles and responsibilities of the superintendent and supervising pharmacists, and the implications of 'Section 18' regulations. Along with ICCPE tutors and

HSE pharmacists, workshops/discussions on a number of case study scenarios were facilitated to further understanding of these requirements through a practical exploration of the responsibilities and requirements of the new legislative framework. The first session was followed in all locations by a second workshop, facilitated by ICCPE tutors, on self-audit processes using the PSI Pharmacy Practice Guidance Manual as a tool for this process.

The PSI presentation given as part of the ICCPE Spring programme 2009 is published here in a reader-friendly format.

### Introduction

The Pharmacy Act 2007 has brought significant changes to the way the profession is regulated in Ireland and to the roles and responsibilities of pharmacists. It has introduced a professional management structure through the roles and responsibilities of the superintendent pharmacist and the supervising pharmacist and provides for the adoption of a statutory Code of Conduct for pharmacists.

### Pharmacy Act 2007 – three phase commencement process

The Pharmacy Act 2007 is being commenced in three phases. The first phase was commenced on 22 May 2007 and provided for the establishment of the PSI with a broad range of functions and duties (and the dissolution of the old body of the same name). It also provided for the establishment of a new Council with a non-pharmacist majority.

In preparation for the second phase of commencement, the PSI developed a number of statutory rules and a draft Code of Conduct for pharmacists, which were subject to public consultation during 2008. The five statutory rules related to Registration, Retail Pharmacy Business Registration, Council, Education and Training and Fees, and are intended to set out in greater detail the procedures and requirements which will be operated by the PSI in carrying out its various functions under the provisions of the Act.

In addition, the PSI developed a Pharmacy Practice Guidance Manual (PPGM), which was disseminated to all pharmacies in the country via the Roadshow meetings held during the summer of 2008, to inform pharmacy owners and supervising pharmacists of the new regulatory environment which would pertain once the registration of pharmacies was introduced. The PPGM was a self-audit tool to allow individual owners and pharmacists audit and evaluate their own practices, and feedback was welcomed.

In preparation for the second phase, the Department of Health and Children developed draft regulations under Section 18 of the Pharmacy Act 2007 to govern the operation of retail pharmacy businesses.

### Second phase of commencement process

The second phase of the Pharmacy Act 2007 was commenced on 29 November 2008, and included Parts 4, 5, 7 and 8 of the Act. Part 4 pertains to the new pharmaceutical registration systems– the registration of retail pharmacy businesses, and continued registration for pharmacists and pharmaceutical assistants. Part 5 relates to Offences, primarily relating to the operation of retail pharmacy businesses, Part 7 provides for new powers of investigation and enforcement of the PSI and Part 8 relates to miscellaneous provisions, primarily the revocation of old legislation, including the old Pharmacy Acts.

### Final phase of commencement process

The remaining Part of the Act, Part 6 which relates to complaints, inquiries and discipline, is expected to be commenced in 2009, and this Part provides for 'fitness to practise' and 'fitness to operate' systems. This Part also includes Sections 63 and 64, which concerns economic relationships with doctors, etc.

A further provision of the Act to be implemented is the requirement for Continuing Professional Development (CPD) for pharmacists. The PSI has commissioned a review of international CPD models and it is envisaged that the report of this review will be presented to Council before the end of 2009, with a view to initiating pilot rollout during 2010. It should be noted that in applying for the registration of a retail pharmacy business, the pharmacy owner/superintendent pharmacist undertakes to make appropriate arrangement for CE and CPD for the pharmacists they employ.

### Registration of Retail Pharmacy Businesses

Part 4 of the Pharmacy Act 2007 outlines a number of conditions that pertain to the registration of a retail pharmacy business. Some conditions are comparable to the system pertaining under the old legislation, while some are new.

- Ownership: pharmacist, a partnership of pharmacists, a corporate body or a representative of a deceased pharmacist;
- The retail pharmacy business must be under the personal control of a superintendent pharmacist (new) – the role of superintendent pharmacist is a new requirement under the Act;
- At each premises, there must be a supervising pharmacist in whole-time charge of carrying on the business;
- The sale and supply of medicinal products in the retail pharmacy business must be by or under the personal supervision of a pharmacist (new) – this requirement involves a subtle updating of Irish medicinal product legislation to the EU norm, whereby the 'default' position in relation to the supply of medicinal products is now 'by or under the personal supervision of a pharmacist in a pharmacy', as opposed to the previous situation where supply was controlled by virtue of a medicinal product being listed on a schedule attached to regulations;
- The name and certificate of registration of the supervising pharmacist must be conspicuously displayed at the premises;
- The certificate of registration of the retail pharmacy business must be conspicuously displayed at the premises (new) – certificates of registration relating to the pharmacy premises were not previously issued under the old legislation.

There is a further condition on a corporate body in that in order to conduct a retail pharmacy business, a corporate body must have submitted a statement to the Registrar specifying:

- the name of the superintendent pharmacist and
- declaring whether or not he or she is a Director in the corporate body.

This statement must be signed by the superintendent pharmacist and on behalf of the corporate body.

There are also further conditions on the pharmacists who may fill the roles of superintendent and supervising pharmacist in that they must have a minimum of 3 years' post registration experience practising whole-time as a registered pharmacist in a retail pharmacy business (or the equivalent under the old legislation or corresponding experience in another country).

When applying for registration of a retail pharmacy business, the pharmacy owner must:

- Nominate superintendent and supervising pharmacists, detailing their relevant three years' post-registration experience;
- Declare that the retail pharmacy business shall be conducted in accordance with 'Section 18' regulations;
- Declare that sale and supply of medicinal products shall be by or under the personal supervision of a registered pharmacist at all times. This latter requirement gives rise to the question where a pharmaceutical assistant (PA) is acting on behalf of a registered pharmacist in their temporary absence, and there is no change in the current provision for a PA to so act. However, it should be noted that the PA is acting on behalf of the registered pharmacist, and so therefore it will be the registered pharmacist and the supervising pharmacist who will be held accountable for the actions of the PA acting on behalf of a registered pharmacist. The supervising pharmacist is at all times responsible for the operation of the pharmacy.

### Superintendent pharmacist

The requirement for a superintendent pharmacist comes from Part 5, Sections 26 to 29 from Act. The term 'superintendent' is not used as such in the Act, but the requirement comes from these sections that a condition of registration of a retail pharmacy business is: "that the part of the business that consists of the **management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has three years' minimum post-registration experience**". There are further conditions in relation to retail pharmacy businesses owned by corporate bodies (as outlined above) and this is outlined in Section 28. The requirement for a superintendent pharmacist essentially hands the professional management of pharmacy practice back to the profession, back to the pharmacist.

### Supervising pharmacist

The requirement for a supervising pharmacist comes from the same Part of the Act, where the condition is "that, at the premises where the business is carried on or, if there are two or more of those premises, at each of them, there is a registered pharmacist who has three years' minimum post-registration experience, in **wholtime charge of the carrying on of the business** there."

The requirement for a supervising pharmacist is not a completely new concept; it is comparable to the principal authorised person under the old system – but the requirement is now firmly enshrined in legislation. There must be one supervising for each retail pharmacy business, and while the superintendent can act in respect of more than one retail pharmacy business, the supervising can not. In addition, both roles can rest in the one person.

### 'Section 18' regulations

The Regulation of Retail Pharmacy Businesses Regulations 2008 (SI No 488 of 2008) have been made under Section 18 of the Pharmacy Act 2007 by the Minister for Health and Children. These regulations, made for the 'purposes of the health, safety and convenience of the public', govern the operation of retail pharmacy businesses, and essentially are the framework within which the superintendent and supervising pharmacists carry out their roles. The rationale behind these regulations was to ensure that proper regulation and control of the 'supply chain' of medicinal products, from manufacturer to patient, is now in place. The manufacture and distribution of medicinal products is highly regulated, whereas prior to the Pharmacy Act 2007 and the registration and regulation of retail pharmacy businesses, it can be argued that the final, and indeed most important link in that supply chain, was not subject to robust, modern regulation.

The PSI has issued a Practice Notice outlining the implications and requirements of 'Section 18' regulations – this Practice Notice is re-printed in this issue and is also available to download from the PSI website, under the 'Publications' tab and selecting 'Practice Notices'.

Much of the content of these regulations is not new, and will be recognised by pharmacists as putting 'good pharmacy practice' or 'good dispensing practice' on a legislative basis, so that these are now the requirements that all retail pharmacy businesses must operate to. In addition, from the patient's point of view, these regulations also give a legislative basis to the pharmaceutical care that patients are entitled to receive, and in particular in the provisions of articles 9 and 10 which relate, respectively, to the review and counselling of prescribed medicinal therapy and non-prescription controlled medicines. These articles also recognise the role of the pharmacist, not only in the supply of medicinal products,

but also of the information and advice necessary for the correct and safe use of medicines.

Among the new requirements contained in these regulations are:

- that the pharmacy layout must enable the supervision by a pharmacist of the sale/supply of medicinal products (this is a reason why pharmacy owners must include a plan of the retail pharmacy business when applying for registration, to demonstrate that the physical layout of the pharmacy facilitates the pharmacist meeting their obligations in this regard);
- a retail pharmacy business must include a separate designated area to allow for review/discussion with patients in private (this provision pertains to all existing pharmacies from 01 November 2010);
- the requirement for supervising and superintendent pharmacists is reiterated;
- a 'duty register' (an ongoing, contemporaneous, retrievable record of the registered pharmacists at the premises) must be maintained. To facilitate compliance with this requirement the PSI has distributed a duty register in a day-diary format to all registered retail pharmacy businesses.
- the pharmacy owner and superintendent pharmacist must be satisfied as to the competency of pharmacists and other staff employed, and also to the identity and registration status of pharmacists;
- in relation to record-keeping, there is a provision which will allow for the validation and certification of pharmacy computer software in future.

The regulations also state that the PSI Council may publish guidelines to facilitate compliance with the regulations, and such guidelines will be issued over the coming months. In addition, the regulations designates a number of relevant provisions for the purpose of offences, but it should be borne in mind that if a requirement is not denoted as an offence in these regulations, it may well be covered elsewhere in the legislation or indeed have implications in terms of 'fitness to practise' or continued registration.

## Roles and Responsibilities of Superintendent and Supervising Pharmacists

### Superintendent pharmacist

The responsibilities of the superintendent pharmacist are broadly the same as that of the pharmacy owner. The superintendent pharmacist has overall control of the legal, professional and clinical policies pursued in the retail pharmacy business. They have overall control over the whole operation of either a single pharmacy or of all pharmacies within the entity/chain for which they act, and also for the monitoring and evaluation of the policies applied.

These policies should reflect good pharmacy practice, comply with legislation, standards and the Code of Conduct for pharmacists, and should also facilitate compliance with Code of Conduct for all pharmacists employed. These policies should ensure compliance with the requirements of 'Section 18' regulations and superintendent pharmacists are also encouraged to use the Pharmacy Practice Guidance Manual (PPGM) as a tool to audit practice and inform the development of policies. (The second session of this ICCPE module involved using the PPGM as a tool for self-audit processes.)

The superintendent pharmacist must be satisfied as to the competence of pharmacists employed, including the supervising pharmacist(s), and other staff; they must have an ongoing satisfaction that the supervisory role of pharmacist is facilitated in each retail pharmacy business; and they are responsible for the maintenance of the duty register.

### Supervising pharmacist

The supervising pharmacist is in 'whole-time charge' of the operation of the retail pharmacy business, and is responsible for operations even when absent. There is no specific definition in terms of minimum hours in the Act but requirement is that they must be practising in the pharmacy on a consistent and continuous basis, and for a significant proportion of the hours of business of the pharmacy in order to be able to fully exercise their responsibilities, and they must also be able to demonstrate how they exercise control when not there.

The supervising pharmacist is responsible for the management and control of the operation of the retail pharmacy business on a day-to-day basis; they are responsible for ensuring that appropriate procedures are in place to comply with legislation, standards, etc, and the policies of the pharmacy. In many instances, the supervising pharmacist may have a reporting relationship to the superintendent pharmacist.

The supervising pharmacist must ensure that staff are competent for the tasks assigned to them; they therefore have an important role in staff training, for example, training non-professional staff with regard to patient counselling and when patients should be referred to the pharmacist. The certificate of registration of the pharmacist acting as supervising pharmacist should be on conspicuous display in the retail pharmacy business.

## Notifications to the PSI

Changes in the name of the superintendent and/or supervising pharmacists in a retail pharmacy business must be notified to the PSI. Given that the nomination of these two positions are conditions of registration of a retail pharmacy business, the pharmacy owner and the pharmacist(s) holding these positions must be mindful of the need for an orderly transition. It follows therefore that the replacement of these pharmacists is quite a formal process and that there could be legal or fitness to practise consequences if not done properly.

A change of ownership of a retail pharmacy business cancels its registration – the pharmacy owner/superintendent pharmacist are obliged to inform the PSI, and the new owner must apply to register the retail pharmacy business.

Where a retail pharmacy business cancels its registration due to closing, the PSI must be informed in writing, and details given of the arrangements in place for the disposal of medicines held in the pharmacy and for patient access to records held.

The PSI/ICCPE taskforce intend to deliver further educational sessions later this year. During June it is planned to deliver a number of sessions on the Code of Conduct for pharmacists, including an outline of Part 6 of the Pharmacy Act 2007 which relates to complaints, inquiries and discipline.

Further details of this initiative will be posted on the PSI and ICCPE websites and pharmacists will be notified by email of the details of dates, locations, etc., when these are finalised.

*The PSI would like to thank the ICCPE for the opportunity to co-operate on this educational programme and the HSE pharmacists for their co-operation on this important educational activity. The PSI would also like to thank all the participants at the educational sessions for their engagement and feedback. A copy of this article and related legislation and Practice Notices are available to view and download from the PSI website [www.pharmaceuticalsociety.ie](http://www.pharmaceuticalsociety.ie) under the 'Publications' tab.*