

Section 1



Guidelines for Retail Pharmacy Businesses

Introduction

This section contains a copy of the Regulations of Retail Pharmacy Businesses Regulations 2008, along with guidelines made under Regulation 14, to facilitate compliance with the requirements of these regulations.

Two articles from the Irish Pharmacy Journal have also been included in this section to provide guidance on the role and responsibilities of the superintendent and supervising pharmacist, along with a letter from the then Registrar of the PSI, Ambrose McLoughlin, which was sent to all superintendent pharmacists in July 2009.

The Regulation of Retail Pharmacy Businesses Regulations 2008 set out certain requirements to be complied with by persons carrying on a retail pharmacy business for the sourcing, storage, sale, supply and keeping of records, in respect of medicinal products. Requirements relating to staff, premises, equipment and procedures are also stipulated. In addition, the Regulations specify responsibilities that must be discharged by the pharmacy owner, superintendent and supervising pharmacists.

Both the superintendent pharmacist and the supervising pharmacist must undertake to conduct the retail pharmacy business for which they are responsible in compliance with the provisions of the Pharmacy Act 2007, the Regulations of Retail Pharmacy Businesses Regulations 2008 and professional guidelines. The pharmacy owner, in completing their annual continued registration application form, must also provide an undertaking that they too will ensure full compliance with the Act and all Regulations and professional guidelines as are in force.

There is a specific requirement in the Regulations for the pharmacy owner and superintendent pharmacist to ensure that all staff members have the requisite knowledge, skills and fitness to perform the work for which they are responsible. This would include ensuring that all staff members are aware of legislation, and guidelines from PSI, as well as guidance from other bodies which is relevant to their role. This folder will be of assistance in this regard.

There should also be clear Standard Operating Procedures (SOPs) for all tasks in the pharmacy, which are unique to each pharmacy and tailored to the pharmacy/dispensary design and staff. All pharmacy staff members must be trained on the pharmacy's SOPs and follow these when carrying out their roles. SOPs should be reviewed in light of new guidance and on an ongoing basis to ensure that they are fit for purpose.