

PRACTICE NOTICE

Implications of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

The Pharmacy Act 2007 provides under Section 18 that the Minister may, for the purposes of the health, safety and convenience of the public, make regulations regarding the operation of retail pharmacy businesses. These regulations (which came into force on 29 November 2008), taken in tandem with the provisions of Section 27, 28 and 29 of the Act, provide a framework to ensure that certain criteria are met in the operation of each and every retail pharmacy business. It is intended that during the course of 2009, the Council, with the prior approval of the Minister, will publish detailed Guidelines for the purpose of facilitating compliance. This preliminary notice is intended to assist in identifying issues that practitioners may already be aware of as being provided for in these regulations, and act as a quick self-check mechanism to ensure that the minimum requirements are being met. This notice is not intended to be a legal interpretation and does not purport to capture all the requirements of the regulations. It is recommended that reference be made to the regulations themselves where specific queries or issues arise.

The Regulation of Retail Pharmacy Businesses Regulations 2008 set out certain requirements to be complied with by persons carrying on retail pharmacy businesses. These also lay down requirements in respect of the sourcing, sale, supply and keeping of records in respect of medicinal products (including veterinary medicinal products). Requirements in respect of staff, premises, equipment and procedures are also laid down, including certain responsibilities that must be discharged by the superintendent and supervising pharmacists. The following points should, therefore, be considered as a check-list in their application:

- A pharmacist must supervise all the professional activity within the practice
- There is a requirement for a separate and designated area for patient counselling
- There must be a safe compliant with the Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended) for the storage of controlled drugs
- Obsolete medicinal products must be disposed of in a manner which will not present a danger to public health or to the environment
- There must be a named supervising pharmacist in whole-time control
- A contemporaneous 'duty register' must be maintained
- A written provision that the practice will not operate in the absence of a pharmacist should be present
- Public access should be prevented in the case of prescription-controlled medicinal products and CD5 controlled drugs
- Product withdrawal and recalls should be processed immediately on notification
- Performance assessments, adequate reference and competence evaluations should be carried out in respect of all personnel
- The identity and registration status of any pharmacist employed should be vouchsafed
- All medicinal products must be sourced from an authorised source and appropriate evidence of this retained
- All medicinal products supplied should be authorised appropriately for use
- Obsolete stock should be segregated and disposed of appropriately in a timely manner
- Storage provisions should be in place to manage returned controlled substances
- It should be ensured that a prescription review occurs as required by Article 9 of the regulations
- It should be ensured that the patient has sufficient information regarding storage of prescription-controlled medicinal products
- It should be ensured that the patient has sufficient information regarding proper use of the medicinal product
- It should be ensured that each patient presenting with a prescription is offered a counselling opportunity

- A written dispensing policy which encompasses the requirements of the Regulations should be in place
- A pharmacist must be aware of the supply of every prescription-exempt medicinal product
- All the required details must be recorded when a prescription, either for human or animal use, is dispensed
- Required records must be available for inspection as required

Staff, Premises, Equipment and Procedures

Articles 1 to 3 address the citation, commencement provision and interpretation provisions of these regulations. Of particular note are the definitions of the terms “superintendent pharmacist” and “supervising pharmacist” as they relate to the provisions of Sections 27, 28 and 29 of the Pharmacy Act 2007.

Article 4 of the regulations deals with staff, premises equipment and procedures, and the associated responsibilities as they apply to the pharmacy owner. This article addresses adequacy of the staff, premises, equipment and procedures and the requirement that pharmacy services be delivered from a registered premises. They refer to the layout of the practice and the requirement that it facilitate the supervision by a pharmacist of all the professional activity therein. They address the requirement for a separate and designated area for patient counselling (for existing practices this requirement comes into force on 1st November 2010) and refer to the provisions in place in respect of safe storage of controlled drugs. This Article also addresses the requirement to safely dispose of obsolete medicinal products.

Management and Supervision of Retail Pharmacy Businesses

Article 5 addresses the management and supervisory requirements pertaining to a retail pharmacy business, and delineates the particular responsibilities held by the pharmacy owner and the superintendent pharmacist. The article addresses the requirement that the part of the retail pharmacy business that consists of the management and administration of the sale and supply of medicinal products, is carried out in accordance with all legal requirements and under the personal control of the superintendent. Each retail pharmacy business must be in the whole-time charge of a supervising pharmacist having a specified degree of experience, and a record of the pharmacists on duty must be maintained in a contemporaneous, ongoing retrieval form. The operation of the pharmacy must at all times be under the supervision of a registered pharmacist with prescription-controlled medicinal products, both human and veterinary, and prescription-exempt medicinal products which would be classified as CD5 not publicly accessible. Co-operation with product withdrawal and/or recalls must be provided for. All staff must be fit and competent to discharge the duties assigned to them and the identity and registration status of any pharmacist employed must be satisfactorily established. It is required that the certificate of registration of the supervising pharmacist be conspicuously displayed.

Medicinal Products: Sourcing, Storage, Sale and Supply

Article 6 addresses the sourcing of authorised medicinal products and requires that any medicinal product sourced by the RPB is obtained from an authorised manufacturer or wholesaler in accordance with the legislative provisions in place which regulate this activity. The article makes provision for the acceptance of returned obsolete stock on the understanding that this would never be reused but disposed of appropriately. It also provides for the professional requirement when meeting the immediate need of an individual

patient or of the occasional transfer of stock between Retail Pharmacy Businesses. Article 7 addresses the requirement for the appropriate storage of medicinal products, and provides that the quality of medicinal products being handled by that pharmacy should be assured by adherence to storage conditions as specified in the marketing authorisation or other applicable standards. Article 8 relates to what medicinal products may be sold or supplied and requires that any such product is licensed in accordance with the legislative provisions in place which regulate that activity.

Patient Counselling: Prescription and Non-prescription

Article 9 of the regulations addresses the review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription. It provides that a pharmacist, prior to the dispensing of a prescription and supply of a medicinal product, shall review the prescription having regard to its pharmaceutical and therapeutic appropriateness for the patient. The nature of the review is indicated in broad professional and patient safety terms and requires that subsequent to the review the pharmacist shall ensure that the patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product. The pharmacist shall offer to discuss with the patient or his/her representative such professional matters as appropriate.

Counselling when supplying medicinal products other than on foot of a prescription is provided for in Article 10 of the Regulations, which require that in the course of such supply a pharmacist is satisfied of a number of criteria, encompassing that the purchaser is aware of the correct use of the product, that the product is being sought for the correct use and, insofar as the pharmacist is aware, the product is not intended for abuse or misuse.

Other Requirements

Article 11 addresses the provisions in place in respect of veterinary medicinal products which may be sold or supplied in accordance with the applicable legislative provisions in place which regulate this activity, i.e. animal remedies regulations.

Article 12 addresses the record-keeping requirements applicable in the case of the supply of medicinal products and refers to those provided for in the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended, and the Misuse of Drugs Regulations 1988, as amended. It also makes provision for the validation and certification of computer software that may be in use.

The keeping of records, marking of prescriptions and other related matters as applicable to veterinary medicines are addressed in Article 13.

The publication of Guidelines by the Council to facilitate compliance and designated offences are specified in Articles 14 and 15 respectively.

Useful links which facilitate access to relevant pieces of legislation are

http://www.dohc.ie/legislation/statutory_instruments/pdf/si20080488.pdf?direct=1

http://www.dohc.ie/legislation/statutory_instruments/pdf/si20030540.pdf?direct=1

<http://www.agriculture.gov.ie/legislation/SI2007/SI786-2007.pdf>