



AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Draft Guidelines on the Sale and Supply of Non- Prescription Medicinal Products from a Retail Pharmacy Business

To facilitate compliance with Regulations 5(1)(d), 5(1)(h) and 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

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1. Introduction

The purpose of these guidelines is to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), in relation to the sale and supply of non-prescription medicinal products from a retail pharmacy business and in particular with respect to Regulation 5 (1)(d), 5(1)(h) and Regulation 10.

The sale and supply of non-prescription medicinal products from a retail pharmacy business can occur in two ways: to an individual who attends the pharmacy in person, or at a distance through online purchases from the pharmacy website. These guidelines apply to the sale and supply of non-prescription medicinal products in both of these circumstances.

Pharmacists, by virtue of their medicines expertise, play a unique and important role in ensuring that medicinal products are used rationally, responsibly and safely in our society. As the most accessible primary healthcare providers, pharmacists are often the first, and in some cases the only, point of contact that a patient may have with a healthcare professional. Having medicinal products available from the pharmacist without the need for a prescription, increases patient access to healthcare, enabling and empowering patients to manage their own healthcare needs.

Pharmacists practice within a robust regulatory framework and have a legal and professional responsibility which requires that the practice by a pharmacist of his/her profession be directed towards maintaining or improving the health, wellbeing, care and safety of patients and the public. Pharmacists should use their professional skills, competence and specialised knowledge to establish the medical needs of the patient and to communicate the correct information and advice to patients. Pharmacists must be satisfied that the patient is aware of the appropriate use of the medicinal product, that it is being sought for that purpose and that it is not intended for abuse and/or misuse. Through their interactions with patients, pharmacists may facilitate the identification of wider health issues for the patient and provide opportunities for health promotion interventions, as well as referring patients to other healthcare professionals where necessary.

2. Legislative Basis

The operation of a retail pharmacy business is governed by the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). These PSI guidelines are intended to facilitate better compliance with Regulations 5(1)(d), 5(1)(h) and 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008, which confer obligations on pharmacy owners, superintendent pharmacists, supervising pharmacists and all other pharmacists, insofar as these regulations relate to the sale or supply of non-prescription medicinal products from retail pharmacy businesses. Furthermore, under the Pharmacy Act 2007, and the Regulation of Retail Pharmacy Businesses Regulations 2008, the supply of medicinal products from a retail pharmacy business must be made *'by or under the personal supervision of a pharmacist.'*

2.1 Regulation 5: Management and Supervision of a Retail Pharmacy Business

Regulation 5 sets out the obligations on the Pharmacy Owner and the Superintendent Pharmacist in terms of the management and supervision of a pharmacy.

5. (1) *The pharmacy owner and the superintendent pharmacist shall, inter alia, ensure that—*

(d) the sale or supply of medicinal products, including veterinary medicinal products, and the preparation, dispensing and compounding of prescriptions, including veterinary prescriptions, at the premises, are carried out by or under the personal supervision of a registered pharmacist,

(h) he or she is satisfied that all of the pharmacists and other staff, employed or engaged by him or her, or under his or her management, have the requisite knowledge, skills, including language skills, and fitness to perform the work for which they are, or are to be, responsible.

Thus the pharmacy owner and the superintendent pharmacist are obliged to ensure that the sale or supply of medicinal products must occur under the personal supervision of a pharmacist, and that the non-pharmacist staff employed by them have the skillset and knowledge necessary to effectively carry out their roles.

2.2 Regulation 10: Counselling in the Supply of Medicinal Products Other Than on Foot of a Prescription

Regulation 10 sets out the obligations on the pharmacy owner, the superintendent pharmacist the supervising pharmacist and all pharmacists to ensure that the medical needs of the patient are established and that appropriate counselling is provided to the patient in the course of the sale or supply of non-prescription medicinal products.

10. A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, in the course of the sale or supply of a medicinal product other than on foot of a prescription and prior to such sale or supply, a registered pharmacist is satisfied that the purchaser or other such person is aware of what the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.

2.3 Code of Conduct for Pharmacists

The statutory [Code of Conduct](#) for pharmacists requires that pharmacists exercise their profession in a manner that is directed to maintaining and improving the health, wellbeing, care and safety of patients and the public. In particular, pharmacists should use their professional skills, competence, and specialised knowledge about medicines for the benefit of patients and to encourage the rational and proper use of medicinal products. Pharmacists may be required to use their professional skills when decision-making, which at times is contrary to the wishes of the patient.

3. Guidance

3.1 Pharmacists' Involvement in the Sale and Supply of Non-Prescription Medicinal Products

- Under the Pharmacy Act 2007, the sale and supply of all medicinal products in a pharmacy must be carried out “by or under the personal supervision of a registered pharmacist”. This is a strict requirement that necessitates at all times, the active involvement of the pharmacist, whether directly with the patient, at a distance through an online purchase, or in circumstances where the sale or supply is being carried out by a non-pharmacist member of staff acting under the personal supervision of the pharmacist.
- Pharmacists have a legal and professional responsibility to ensure that all non-prescription medicinal products, both pharmacy-only medicinal products and those on the general sales list, are supplied safely and appropriately to patients.
- Policies and procedures should be in place in all pharmacies that detail the manner in which non-prescription medicinal products are sold or supplied.
- Non-pharmacist staff must be fully aware of the strict legal responsibilities of the pharmacist to personally supervise the sale and supply of all medicinal products and that they are aware of the essential professional input the pharmacist provides.
- The pharmacist should be readily identifiable to the public and accessible to them at all times.
- Certain prescription-only medicinal products have been reclassified for supply by pharmacists to patients without prescriptions. Due to the nature of these medicinal products and the associated counselling requirements and/or potential safety concerns, a private consultation between the pharmacist and the individual patient is required. It is not appropriate for non-pharmacist members of staff to carry out the sale or supply of these medications. Examples include Emergency Hormonal Contraception, Dovonex® Psoriasis Ointment, Curanail® and Domperidone containing products. Relevant guidance can be found in the PSI's Pharmacy Practice Guidance Folder and on the PSI website.
- The sale or supply of non-prescription medicinal products, which have a high potential for abuse and/or misuse, should be confined to the pharmacist. All staff members should be made aware of those products and refer all requests for these directly to the pharmacist.
- In order to comply with the statutory and professional obligations placed on pharmacists by the Act, the Regulations and the Code, following the request for a non-prescription medicinal product, pharmacists must be satisfied that they:
 - Are exercising control over the sale or supply as it is taking place.
 - Are aware of consultations taking place, including the nature of any advice or guidance that is being given by non-pharmacist staff members.
 - Are in a realistic position to intervene, as may be necessary.

3.2 Patient Consultation

A non-prescription medicinal product may be sought either in person in a pharmacy or for online purchase from a pharmacy's website. Request may be made for a specific product or symptoms may be described. The appropriate supply of non-prescription medicinal products is dependent on an effective consultation taking place.

Under Regulation 10, during the course of a consultation, pharmacists are required to ensure that the medical needs of the patient are established and that appropriate counselling is provided to the patient.

In all circumstances, consultations should have a structured approach and the following steps should be followed:

- 1. Obtain the necessary information**
- 2. Recommend the correct non-prescription medicinal product**
- 3. Provide relevant counselling**
- 4. Supply the non-prescription medicinal product**

3.2.1 Obtain the Necessary Information

- A consultation, undertaken personally by the pharmacist or under his or her personal supervision, must be carried out following the request of a non-prescription medicinal product in order to establish the medical needs of the patient as per requirements laid out in Regulation 10.
- An effective consultation is necessary to ensure that the medical needs of the patient are established and is dependent upon the quality, nature and extent of information exchanged between the pharmacist or non-pharmacist staff and the patient (for example through the use of open-ended questions, active listening and clear, user-friendly language).
- Such a consultation is necessary in order to establish whether the sale or supply of a non-prescription medicinal product best meets the needs of the patient.
- The necessary information that should be obtained from the patient should include, but is not limited to:
 - Who the medication is for
 - What the symptoms are
 - History of the complaint
 - Duration of the symptoms
 - Any relevant medical history
 - Any other medications/treatments taken

3.2.2 Recommend the Correct non-Prescription Medicinal Product

- In accordance with Regulation 10, prior to the sale or supply of non-prescription medicinal products, a registered pharmacist must be satisfied that:
 - The patient/purchaser is aware of the appropriate use of the medicinal product
 - The medicinal product is being sought for a legitimate purpose
 - The medicinal product is not intended for abuse and/or misuse
- Prior to recommending a product, it is necessary to ensure that the non-prescription medicinal product best meets the needs of the patient and that signs or symptoms that may be indicative of a serious or underlying condition, which may require referral to another healthcare professional, have been referred to the pharmacist.
- Screening for any potential drug interaction or ingredient allergies must be addressed, including but not limited to: interactions with other medicinal products, foods, drinks, herbal medicinal products or food supplements.

3.2.3 Provide Relevant Counselling

- Effective counselling facilitates the opportunity to improve a patient's health by increasing the patient's knowledge and understanding of their health condition and about the medicinal products used in the treatment of their condition. The intent should be to encourage the appropriate and rational use of medication and thus reducing medication related problems, including non-adherence and unnecessary use of medicinal products.
- When providing counselling to patients, necessary information on the safe and appropriate storage and disposal of the non-prescription medicinal product should also be provided to patients.
- The consultation area should be used when appropriate and patients encouraged to avail of this facility. More detailed guidance on the patient consultation area can be found in the [Guidelines on Patient Consultation Area in a Retail Pharmacy Business](#), in the Pharmacy Practice Guidance Folder and on the PSI website.
- When communicating information to patients, the pharmacist must adapt how they present information depending on the needs of the patient, taking into account such things as their language, and literacy and numeracy skills. They should be satisfied that the patient receives appropriate information both verbally and where appropriate in written format, and that the patient has a clear understanding of the information given to them. In some circumstances, it may be necessary for this information to be provided to a patient's representative/carer.
- Pharmacists should signpost the patient to other relevant information resources where appropriate e.g. approved websites, charities or support groups and they should outline to the patient circumstances in which they may need to return to the pharmacy for further advice or treatment
- Patients should be advised to return to the pharmacy or to contact their doctor as appropriate, should their symptoms persist or worsen.

3.2.4 Supply of Non-Prescription Medicinal Products

- Products can only be supplied in line with their relevant marketing authorisation. The pharmacist should be familiar with the Summary of Product Characteristics (SmPCs) of all products they supply, including their authorised indications, age limitations, contra-indications and any special warnings.
- Medicinal products should, where feasible, be supplied in their original pack, which will include the relevant Package Leaflet (PL) incorporating all the necessary information on its appropriate use. The presence of this information should be brought to the attention of the patient. Additional SmPCs and PLs of all products marketed in Ireland are available at either www.hpra.ie or www.ema.europa.eu/ema and should be referred to when necessary.
- Pharmacists should personally review all requests for the internet supply of medicinal products in order to satisfy compliance with these regulations and their professional obligations and responsibilities, in particular with respect to Regulation 10.

3.3 Additional Counselling Considerations

3.3.1 Supply to a Representative/Carer

- It is not always the case that the person requiring the non-prescription medicinal product can present at the pharmacy. In such circumstances, supply to a representative/carer may be necessary.

- As required under Regulation 10, the pharmacist should be satisfied that that it is reasonable to make the supply in the circumstances presented and that the representative/carer is aware of the appropriate use of the non-prescription medicinal product. The pharmacist should carefully consider the appropriateness of the supply of any medicinal product with a potential for dependency and/or abuse to a representative/carer of the patient.

3.3.2 Medicinal Products for Children

- Considering the high proportion of non-prescription medicinal products supplied for children, and that children are particularly vulnerable to overdose and side effects from medications, pharmacists should be particularly vigilant in the sale and supply of non-prescription medicinal products for the use in children. Supply by the pharmacist should be considered in such circumstances.
- When supplying non-prescription medicinal products to children, it is advisable to:
 - Check the child's age and weight where appropriate.
 - Provide accurate information regarding dosing instruction
 - Demonstrate how to use the dosing equipment
 - Provide detailed information on the safe and appropriate use of the medicinal product and ensure that the Package Leaflet is provided
 - Advise on the storage of the medicinal product and the necessity to keep it out of reach and sight of children.
- The pharmacist should be particularly mindful of the danger of treating signs and symptoms that may be masking an underlying condition in a child. The increased need for timely review and/or referral to an appropriate healthcare professional if symptoms do not improve, or worsen, should be emphasised to parents/carers.

3.3.3 Interactions

- When supplying non-prescription medicinal products to patients who are already on medication, pharmacists must be aware that certain medicinal product combinations can cause side effects that outweigh the benefits of their use. This may be particularly true in older patient groups, and in patients with chronic illnesses.
- Pharmacists should be satisfied that they have obtained all the necessary information from the patient with regard to their current conditions, medications and lifestyle in order to assess medication risk factors and to evaluate the risk-benefit relationship of making a supply of a non-prescription medicinal product.

3.3.4 Decision not to Supply

- Using their professional judgement, pharmacists make the final decision as to whether making a supply of a non-prescription medicinal product is in the best interest of the patient. If a product is deemed to be unsafe or inappropriate for a patient, the supply should not be given. In this instance the reasons for this decision should be communicated clearly and respectfully to the patient and they should be referred to another healthcare professional or service as appropriate.

3.3.5 Patient Follow-up and Aftercare

- The patient should be advised of the circumstances in which they should return to the pharmacy for further advice, or attend their GP or another healthcare professional. In this way pharmacists can help to ensure the ongoing care of the patient and empower them to take ownership of their own health and treatment.
- As with all medicinal products, any suspected adverse reaction, including those associated with medication errors, should be reported to the Health Products Regulatory Authority (HPRA) online via the HPRA website www.hpra.ie or by submitting the 'Yellow Card' available from the HPRA (01-6764971). Patients should be made aware of the importance of reporting any adverse reactions which they experience as a result of taking non-prescription medicinal products, to their pharmacist, another healthcare professional or directly to the HPRA.

3.4 Internet Supply

Regulations are in place governing the sale and supply of non-prescription medicinal products over the internet. Prior to the sale or supply of non-prescription medicinal products over the internet, the pharmacist should personally review all requests for such sales in order to satisfy compliance with their professional obligations and responsibilities. Pharmacists should carefully consider (in the course of their review), whether it would best meet the patients' needs if they engaged with the pharmacist in a verbal review (e.g. via telephone or skype conversation), attended the pharmacy personally or required referral to another healthcare professional. For further information on supply a distance see PSI [Guidance on Internet Supply of Non-Prescription Medicines](#).

4. Policies, Procedures and Training

Superintendent pharmacists must ensure that policies and procedures in the retail pharmacy business are in place to cover the appropriate supply of non-prescription medicinal products by the pharmacist or under their personal supervision. These should include policies and procedures outlining the steps to be followed during a consultation process and the circumstances within which referral to the pharmacist is required. Particular medicinal products or patient cohorts may require additional policies and procedures to ensure their safe and appropriate supply; these should be considered by the superintendent and supervising pharmacist in the context of all PSI guidance or guidance/information from other bodies. All policies and procedures should be reviewed on a regular basis and in response to errors, incidents or near misses. The superintendent pharmacist and supervising pharmacist must be satisfied that all pharmacists practising in the pharmacy, and relevant non-pharmacist staff members, are trained on, and are following, the relevant and up-to date policies and procedures pertaining to the sale and supply of non-prescription medicinal products.

4.1 Training of Pharmacy Staff

In line with Regulation 5(1)(h) of the regulations, the pharmacy owner and the superintendent pharmacist are obliged to ensure that all pharmacists and all non-pharmacist staff employed in the pharmacy, have all the required knowledge, skills, including language skills, training, and attributes for the work they are intending to carry out/are to be responsible for.

- All staff members involved in the sale of non-prescription medicinal products are appropriately trained in the pharmacy's Standard Operating Procedures (SOPs) and regularly re-trained as appropriate to ensure up to date knowledge of non-prescription medicinal products.
- Staff training should be documented.
- All staff members must operate within the limits of their authority and be clear of their roles and responsibilities.
- Sufficient pharmacy staffing levels are maintained to meet the requirements of all professional services provided in the pharmacy.

5. Other Useful Resources

- a) A specific range of reference materials relating to the sale and supply of medicinal products must be readily accessible on an on-going basis to all pharmacist and pharmacy staff. Detailed guidance on the required reference materials can be found in [Guidelines on the Equipment Requirements of a Retail Pharmacy Business](#) in the Pharmacy Practice Guidance Folder.
- b) The Pharmacy Practice Guidance Folder contains a suite of guidance and guidelines which can be of assistance in the sale and supply of non-prescription medicinal products.
- c) Suitable health information/promotion leaflets should also be available in the pharmacy, to serve as useful aids for patient counselling and provide patients with further information if needed.
- d) Contact information for some useful resources and organisations to help pharmacists meet the needs of their patients can be found under the '[Link](#)' Section on the PSI website.
- e) Pharmacists should make themselves aware of other digital resources that might assist patients.
- f) Section 2 of the Pharmacy Assessment System contains further information on the sale or supply of non-prescription medicinal products.

6. Self-Assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with these guidelines and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with these guidelines and all other relevant guidance and requirements.

Ask Yourself	Yes	No	Required Action
Are there documented policies and procedures relating to the sale/supply of non-prescription medicinal products available in the pharmacy?			
Are these policies and procedures reviewed and updated on a regular basis?			
Are all pharmacists and other relevant non-pharmacist staff aware of, and trained in, the pharmacy's policies and procedures in relation to non-prescription medicinal products, and are training records maintained?			
Are all pharmacists aware of the patient counselling requirements for the supply of non-prescription medicinal products?			
Is there a procedure for counselling in the sale/supply of non-prescription medicinal products, and a protocol outlining circumstances which require referral by a non-pharmacist staff member to the pharmacist?			
Is the pharmacist readily identifiable and available to the patient, and in a position to intervene in the sale/supply of all non-prescription medicinal products?			
Are all pharmacists and other relevant non-pharmacist staff aware of the necessity for all non-prescription medicinal product sale/supply to be carried out by or under the personal supervision of the pharmacist?			
Can the ability of the pharmacist to personally supervise all sales/supplies be demonstrated?			
Is the pharmacist satisfied that in the sale/supply of non-prescription medicinal products the patient is receiving the most appropriate medicinal product/advice and is aware of the appropriate use of the medicinal product?			
Is the pharmacist satisfied that the medicinal product sold/supplied is not intended for abuse/misuse?			
Are all pharmacists aware of the regulations in place governing the sale or supply of medicinal products over the internet?			
Are there adequate pharmacist and pharmacy staffing resources available to facilitate the sale/supply of non-prescription medicinal products by or under the personal supervision of the pharmacist?			

Ask Yourself	Yes	No	Required Action
Are all pharmacists aware of, and trained in, how to appropriately supply a non-prescription medicinal product to a representative/carer of the patient?			
Are all pharmacists and pharmacy staff aware of the potential necessity for the pharmacist to personally supply a medicinal product intended for use by a child?			
Is the patient consultation area made available to the patient for counselling in the sale/supply of non-prescription medicinal products?			
Are relevant records of the sale/supply of non-prescription medicinal products maintained, as deemed appropriate by the pharmacist and as required by PSI guidance for particular non-prescription medicinal products?			
Are there policies and procedures in place governing the supply of prescription-only medicinal products that are licenced for sale by pharmacists without prescriptions?			
Are all pharmacists aware of the guidance on the sale or supply of domperidone?			
Are relevant reference materials and a copy of the PSI guidance on the supply of non-prescription medicinal products readily available to all staff members in the pharmacy?			
Are all pharmacists familiar with the procedure for reporting a suspected adverse reaction to the HPRA, and are patients made aware of the need to report such reactions?			
Are all pharmacists in the pharmacy undertaking appropriate CPD to maintain their competence in the sale/supply of non-prescription medicinal products?			