Draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business

1. Introduction

The purpose of the guidance is to outline the requirements that must be fulfilled when a retail pharmacy business provides a delivery service for prescription-only medicines to their patients. The delivery of medicines has always been permitted in certain circumstances. In light of the continuous development of practice it is necessary to clarify some of these circumstances in which delivery is appropriate.

The PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients, is through direct supply to the patient and/or carer following a face-to-face interaction between a pharmacist and the patient in the pharmacy. This direct communication with the patient and/or their carer during a face-to-face interaction allows the pharmacist to evaluate the patient's overall health and need, perform a full therapeutic review of the prescription and allow appropriate patient counselling to take place. It also allows the pharmacist to assess and verify the authenticity of the prescription.

It is recognised however that it may not always be practical for patients or carers to attend the pharmacy and in some circumstances it may be appropriate for medicines to be supplied by means of delivery to the patient at the patient's residence. The appropriateness of utilising a delivery service should be carefully considered in each circumstance.

In circumstances where delivery is considered to be appropriate for the patient, the pharmacist must comply with all legislative requirements for the supply of medicines and provision of pharmacy services and all requirements as per the Code of Conduct for Pharmacists and PSI guidance.

2. Legal and Professional Requirements in the Provision of a Delivery Service

Supply by mail order

Although a delivery service and 'supply by mail order' are separate concepts any proposed delivery service should be considered in light of the prohibition of 'supply by mail order' of prescription-only medicines in Ireland under Regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.

'*Supply by mail order*' has been defined in these Regulations as,

"*any supply made, after solicitation of custom by the supplier, or by another person in the chain of supply whether inside or outside of the State, without the supplier and the customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply.*"

In the regulation it is an offence to contravene regulation 19.

What is prohibited under 'supply by mail order'?

Any supply made (i.e. each and every supply) of a prescription-only medicine to a patient,

- after solicitation of the custom by the pharmacist and
- without the pharmacist and patient and/or carer or representative being simultaneously present and
- where the pharmacist and patient use a means of communication at a distance (e.g. telephone, email, text message, video conferencing etc.) to convey both the custom solicitation and the order for the supply

While many delivery services to a patient may not fall within the definition of 'supply by mail order' of prescription-only medicines, any delivery service provided for prescription-only medicines must not be in breach of this prohibition.

While a pharmacist is entitled to advertise and promote their general business, solicitation is a core aspect of the prohibition on 'supply by mail order'. Therefore pharmacists should be circumspect when offering a delivery service to patients. Any communication at a distance (e.g. phone call, email, texts etc.) by a pharmacy that is directed to a patient with a view to an order being placed for a prescription-only medicine and where the medicine will be delivered to the patient without face-to-face interaction between the pharmacist and patient is not permissible.

Why is 'supply by mail order' not considered suitable for prescription-only medicines?

It can be concluded that 'Supply by mail order' is prohibited in Irish law as it is considered that personal face-to-face interaction between pharmacists and their patients regarding prescription-only medicines is the most appropriate means by which these important medicines are supplied to patients. Pharmacists have a central role to play in ensuring, and advising patients on, the safe and appropriate use of medicines. Pharmacists must uphold the law and fulfil their professional obligations to patients.

Obligations on Owners and Managers of Pharmacies and Professional Obligations of Pharmacists

Regulation 9 of the Regulation of Retail Pharmacy Business Regulations 2008 (*S.I. No. 488 of 2008*) requires that a person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient. Accordingly, each registered pharmacist involved in the dispensing of a prescription has a professional obligation to effectively carry out such a review.

Following completion of the review, the registered pharmacist must be satisfied that the patient concerned has sufficient information and advice for the proper use and storage of the medicinal product concerned and that he or she has offered to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his or her professional

judgement, deems significant and which are also set out in greater detail in paragraph (3) of Regulation 9.

It must be noted that when a prescription is repeated, in the course of this dispensing process all legislative and professional requirements, including the provisions of Regulation 9 concerning the necessary therapeutic review and counselling, must be adhered to on each and every occasion the medicines are dispensed.

In addition to the legislative requirements, all pharmacists, in the course of their professional practice, are also obliged to comply with the Code of Conduct which requires that pharmacists provide a proper standard of practice and care to those to whom they provide professional services.

In providing a delivery service for prescription-only medicines :

- ✓ On each and every occasion that the supply of medicines (including repeat supplies) to a patient is considered, the pharmacist must use their professional judgement to determine whether the supply is appropriate and whether direct face-to-face contact with the patient or their carer is required.
- ✓ Pharmacists must carry out a full therapeutic review and ensure that the patient has sufficient information on the use, storage and disposal of the medicine involved. It is envisaged that for a comprehensive therapeutic review to be undertaken by the pharmacist, the pharmacist must have contact with the patient or their carer to ensure they have sufficient information to assess the patient's needs and must also satisfy themselves of the clinical appropriateness of supply.
- ✓ If the patient has a new prescription or change to their prescription, the pharmacists should have a face-to-face consultation with the patient or their carer.
- ✓ Pharmacists must also be in a position to verify the authenticity of the prescription and ensure the prescription complies with the relevant legal requirements.
- ✓ Superintendent pharmacists and supervising pharmacists are responsible for ensuring that robust policies and procedures are in place covering all aspects of the delivery service to ensure the service is safe and appropriate and that the medicine reaches the intended patient safely and with sufficient information and advice to enable the patient to take their medicine as prescribed.

In a delivery service, due to the increased number of steps involved in the dispensing process and the fact that the patient does not present in the pharmacy, there is increased potential for errors to occur and patients to receive the wrong medicine when supplied via a delivery service. Pharmacists should therefore be involved in all aspects of the preparation of the medicines for supply via a delivery system and a thorough double checking of all prepared packages, including name and address labelling and sealing should occur.

Delivery Mechanism

When the supply of a prescription-only medicine to a patient is made via a delivery service, the pharmacist is fully responsible for ensuring the safe delivery of the medicine to the patient and therefore must be satisfied that the route of delivery is suitable having regard to the nature of the medicine concerned and having regard to the integrity of the supply chain through which the medicines are to be delivered.

Factors to be taken into account include security, stability of the product, patient safety, ensuring that the medicines concerned will be received by the patient for which they are intended, the timeliness of the delivery and the avoidance of undue delays, and ensuring that the quality, safety and efficacy of the medicines concerned have not been altered from when they were dispatched from the pharmacy.

The pharmacist retains responsibility for the delivery of the medicine to the patient and must ensure that the delivery mechanism used:

- ✓ enables the medicine to be delivered securely and promptly to the intended recipient, in a condition appropriate for use;
- ✓ incorporates an itemised, verifiable audit trail for the medicine from the point at which it is requested by the patient from the pharmacy to the point at which it is received by and signed for by the patient or their carer/representative;
- ✓ safeguards any related confidential information about the medication or patient; and
- ✓ maintains any required specific storage and/or security requirements for specific medicines e.g. thermolabile medicines.

Please note the above guidance has been prepared by the PSI to assist pharmacists and pharmacy owners. They are advisory in nature and do not constitute legal advice.

Appendix A

Regulation of Retail Pharmacy Businesses Regulations 2008

Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription

Regulation 9

(1) A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned, a registered pharmacist reviews the prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient.

(2) The review provided for in paragraph (1) shall include screening for any potential therapy problems which may arise out of the use of any medicinal product that may have been prescribed and which the registered pharmacist is, or, in the course of his professional practice, ought reasonably to be, aware of. The potential problems to be screened for shall include those which may be due to therapeutic duplication, interactions with other medicinal products (including serious interactions with non-prescription medicinal products, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions, and clinical abuse and/or misuse.

(*3) Following completion of the review provided for in paragraph (1) the registered pharmacist shall ensure that each patient has sufficient information and advice for the proper use and storage of the prescribed medicinal product and shall offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant, and which may include one or more of the following as may be appropriate—*
(a) the identity of the medicinal product, its dosage form, the method and route of administration and the duration of therapy;
(b) the therapeutic benefit which may be expected from the use of the medicinal product;
(c) any special directions and precautions for the correct preparation, administration and use of the medicinal product;
(d) the importance of the need for compliance with the directions for use including techniques for self-monitoring during therapy;
(e) any common severe side-effects and adverse reactions or interactions and therapeutic contraindications which may be encountered, including their avoidance and the action to be taken should they occur;
(f) the action to be taken in the event of a missed dose;
(g) the methods for the safe disposal of the medicinal product in the event of the course of treatment not being completed, and
(h) any other matters which may be included or referred to in the summary of product characteristics for the medicinal product concerned.

Medicinal Products (Prescription and Control of supply) Regulations 2003, as amended.

Regulation 4 provides the following definition:

'supply by mail order' means any supply made, after solicitation of custom by the supplier, or by another person in the chain of supply whether inside or outside of the State, without the supplier and

the customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply;

Prohibition of mail order supply of medicinal products

Regulation 19
(1) A person shall not supply by mail order any medicinal product.
(2) A person who is the owner or occupier of any premises shall not use or permit the use of any such premises for the receipt, collection or transmission of orders or correspondence in connection with the supply by mail order of medicinal products.
(3) In the circumstances where the particular address of the premises referred to in paragraph (2) is not identifiable due to the use of a post office box, telephone number or an electronic mail address, any person making available facilities for such use shall be deemed to be the occupier of premises being used for or in connection with the supply by mail order of medicinal products.
(4) The provisions of this Regulation shall not apply to a medicinal product (not being a medicinal product specified in column 1 of the Eighth Schedule) which by virtue of these Regulations may be supplied otherwise than in accordance with a prescription. [Substituted by 2011 Amendment Regulations]