

Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business

Pharmaceutical Society of Ireland

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1. Introduction

The purpose of these guidelines is to outline the requirements that must be fulfilled when a retail pharmacy business provides a delivery system for dispensed medicines to their patients.

Many pharmacies have traditionally provided a delivery service for dispensed medicines whenever this was necessary in the interest of the health, safety and convenience of the patient. This guidance document therefore sets out the obligations of pharmacy owners and pharmacists including superintendent, supervising and registered pharmacists, in assuring the security and safety of delivery systems and ensuring compliance with legal and professional requirements.

The PSI considers that the optimal and safest way for dispensed medicines to be supplied is through direct supply to the patient or carer following a face to face interaction between a pharmacist and the patient or carer in the pharmacy. This direct communication with the patient or their carer during a face to face interaction allows the pharmacist to evaluate the patient's overall health and need, perform the required therapeutic review of the prescription and for the required patient counselling to take place. It also allows the pharmacist to verify the authenticity of the prescription and to evaluate the safety and appropriateness of supplying the medicine in the particular circumstances presented.

It is recognised, however, that it may not always be practical for patients or their carers to attend the pharmacy in person and in some circumstances it may be necessary and appropriate for the dispensed medicines to be supplied by means of arranged delivery to the patient. The appropriateness of the particular delivery system to be used should always be carefully considered and assured in each circumstance.

In the supply of medicines via a delivery system pharmacists should apply all the usual safe dispensing and patient counselling practices for patients served in a retail pharmacy setting. In circumstances where arranged delivery is considered to be appropriate, the pharmacist must comply with all legislative and professional requirements for the supply and delivery of medicines including the Code of Conduct for Pharmacists and any other relevant PSI guidance that may have been published.

2. Guidance

In considering a system to deliver dispensed medicines to patients, pharmacists and pharmacy owners must consider a number of steps and actions from the request by the patient for a delivery to the provision of the medicine to the patient. Each of these steps is governed by legal and professional obligations to the patient to assure safe and secure supply of the medicines to the patient via an appropriate method of delivery.

These requirements are outlined:

2.1 Obligations on pharmacy owners and pharmacists, including superintendent and supervising pharmacists

2.2 Therapeutic review of prescriptions and patient counselling by pharmacists

2.3 Methods of delivery

2.4 Pharmacy policies and procedures

2.5 Prohibition on 'supply by mail order'

2.1. Obligations on Pharmacy Owners and Pharmacists, including Superintendent and Supervising Pharmacists

Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) requires that a person carrying on a retail pharmacy business¹ ensures 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 responsible for the dispensing of a prescription has a statutory and 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 their carer all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant².

It must be noted that in the case of a repeatable prescription, when the patient is seeking a repeat supply of the prescribed medicine, all legislative and professional requirements must be adhered to on each and every occasion that the medicine is dispensed. This includes compliance with the Code of Conduct for Pharmacists and compliance with Regulation 9 as described above.

1 Includes pharmacy owners, superintendent pharmacists and supervising pharmacists.

2 These are also set out in greater detail in paragraph (3) of Regulation 9.

2.2. Therapeutic Review of Prescriptions and Patient Counselling by Pharmacists

In the supply of medicines via a delivery system, pharmacists should apply all the usual professional activities employed in the dispensing of prescriptions including therapeutic review and patient counselling in order that patient care be provided to the usual expected standard. In addition particular attention should be paid to the additional assessment and delivery steps in a delivery system as outlined below.

In line with a pharmacist's legal and professional obligations, when dispensing a prescription and supplying medicines to a patient, including supply via a delivery system, it is required that:

- When a new prescription is presented or a significant change is made to an existing prescription, the pharmacists should have a face to face consultation with the patient or their carer. In *exceptional* circumstances where such face to face consultation is not practical the pharmacist should establish the appropriateness of supply by other means including a delivery system³.

- The pharmacist is satisfied as to the authenticity of the prescription and as to the safety and appropriateness of supplying the medicine in the particular circumstances presented.

- The pharmacist has carried out a full therapeutic review of the prescription and has had contact with the patient or their carer for that purpose.

- The pharmacist is satisfied that the patient or their carer has sufficient information on the use, storage and disposal of the medicine involved.

- In the case of a repeatable prescription, if a patient were to seek the supply of multiples of the quantity specified by the prescriber, the pharmacists should only agree to such supply with caution and then only in exceptional circumstances. In this context the pharmacist should also be mindful of their obligations to have regard to the rate of dosage specified on the prescription⁴ and the fact that such supplies may not be appropriate for certain patients or medicines. Furthermore the necessity that the medicines concerned be appropriately stored in the patient's home and the need to avoid wastage must also be taken into account.

Prior to the supply and delivery of a dispensed medicine using a delivery system it is required that:

- On each and every occasion that a supply is made via a delivery system (including repeat supplies), the pharmacist must consider whether or not the supply and delivery is appropriate and whether or not the necessary review including patient contact and counselling can be achieved without face to face contact with the patient or their carer.

In the supply and delivery of a dispensed medicine using a delivery system, pharmacists should have appropriate procedures and records in place in the pharmacy regarding this service.

³ This could include contact with another healthcare professional that has contact with the patient.

⁴ Regulation 7(2) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.

2.3. Methods of Delivery

Whatever method of arranged delivery is used, the pharmacist is fully responsible for ensuring that the system used is suitable having regard to the nature of the medicine concerned and the integrity of the supply chain through which the medicines are to be delivered. Factors to be taken into account in a delivery system include security, timeliness, the capacity to meet the necessary storage requirements during transit to prevent deterioration and the confidence that the medicine concerned will be received by the patient for whom they are intended.

In a delivery system, because of the increased number of steps involved in the dispensing process and particularly because the patient does not present in the pharmacy, there is increased risk of errors occurring (e.g. patients receiving the wrong medicine). The pharmacist is responsible for all steps in the process including dispensing, labelling, packaging and ultimate delivery to the patient. A thorough double check involving the pharmacist should occur throughout the process and in particular of all prepared packages for delivery to the patient.

The pharmacist retains responsibility throughout for securing the safe delivery of the medicine to the patient and therefore must be satisfied that the delivery system used:

- enables the medicine to be delivered securely (i.e. the medicines are in appropriately sealed containers that are tamper evident) and promptly to the intended recipient and in a condition appropriate for use

- incorporates an itemised, verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is received by and signed for by the patient or their carer or other person authorised by the patient

- safeguards confidential information about the medicine or patient

- complies with any specific storage, security and carriage requirements, restrictions and prohibitions as may be applicable for certain medicines e.g. thermolabiles, cytotoxics

- incorporates the actions to be taken in the event of a failed delivery

2.4. Policies and Procedures

Superintendent pharmacists and supervising pharmacists are responsible for ensuring that policies and procedures are in place and adhered to 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 use their medicine as prescribed. The policies and procedures in place should consider and address any additional issues which may not arise in the pharmacy setting but may arise in a delivery service e.g. regarding access to a patients' home or responding to knowledge of, or raising concerns, on abuse.

2.5. Prohibition on Supply by Mail Order

By virtue of regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) the supply by mail order of prescription-only medicinal products is prohibited and accordingly is an offence.

In those regulations, 'supply' includes 'sell' and 'Supply by mail order' is 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 arranging their delivery systems, pharmacy owners and pharmacists should, therefore, ensure that they do not contravene this prohibition.

Relevant legislation can be accessed through the PSI website www.thePSI.ie, and is also available from www.irishstatutebook.ie.

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3. Self-assessment Checklist

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

Ask Yourself	Yes	No	N/A	Required Action
On each occasion that a delivery is requested, has the pharmacist considered the suitability of a delivery service for the individual patient?				
Are the obligations relating to a full therapeutic review, as required under Regulation 9, fully complied with on each and every occasion that a prescription is delivered?				
Has the pharmacist had contact with the patient/ their carer for the purpose of this review?				
Is the pharmacist satisfied that the patient /their carer has sufficient information on the use, storage and disposal of the medicine involved?				
Does face to face contact take place when a new prescription is presented or a significant change to an existing prescription takes place?				
Are multiple supplies of a repeatable prescription only supplied, at the request of the patient, with caution and in exceptional circumstances?				
Is an appropriate record maintained of the procedures in the pharmacy?				
Is the pharmacist in a position to demonstrate their control and supervision over all aspects of the delivery service provided?				
Is an itemised, verifiable audit trail in place, which assures the security of the medicine from when it leaves the pharmacy until it is signed for by the patient/carer?				
Is there a system in place that ensures the patient or carer or authorised representative is the recipient of the medicine?				
Is confidential information regarding the medicine and the patient safeguarded throughout the delivery process?				
Are all storage, security or carriage requirements which may apply to a specific medicine complied with in the course of the delivery service?				
Does the delivery system incorporate actions to be taken in the case of a failed delivery?				
Are policies and procedures in place in the pharmacy covering all aspects of the delivery service?				

