Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes

Pharmaceutical Society of Ireland

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Updates made following the enactment of the Misuse of Dugs Regulations 2017[1] (which replaced the Misuse of Drugs Regulations 1988 (as amended)[2] are highlighted in grey).

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1 Please note: where the Misuse of Drugs Regulations are sited in other legislation please refer to Schedule 9 "Provisions of revoked Misuse of Drugs Regulations 1988 and corresponding provisions in these Regulations' of the Misuse of Drugs Regulations 2017

2 Misuse of Drugs (Safe Custody) Regulations 1982, as amended, remain applicable

1. Introduction

The purpose of this notice is to remind all registered pharmacists, in retail pharmacy businesses, involved in the sale and supply of medicines (including controlled drugs and prescription-only medicines) to patients who are living in residential care settings/nursing homes, of certain requirements which must be fulfilled in meeting their professional obligations to those patients and to ensure compliance with legal and professional requirements.

In the provision of pharmacy services to these patients, pharmacists must ensure that they provide the same level of professional care and attention as they would to those patients who attend personally at their pharmacies.

2. Regulatory Environment

The sale and supply of medicinal products, including the sale and supply in respect of persons in residential homes, is regulated under the Pharmacy Act 2007 and may only be carried out by registered retail pharmacy businesses, by or under the personal supervision of registered pharmacists.

In the making of supplies of medicinal products to patients in these settings, the pharmacist must be satisfied that he or she complies fully with the requirements of:

- The Pharmacy Act 2007
- The Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
- The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) *(the prescription regulations)*
- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017)
- Any guidance issued by the PSI to facilitate compliance with any of these Acts and regulations or with any other legislation that may be relevant

Pharmacists should also ensure that their professional practice in relation to these patients, and their arrangements with the owners, managers and staff of the residential home, are in compliance with the statutory Code of Conduct for pharmacists, and that their independent professional judgement is not impaired, or perceived as being impaired, by any inducements, gifts, offers or benefits that may be offered or demanded.

3. Legal Basis for the Supply of Prescription-Only Medicines

Prescription-only medicines (including controlled drugs) must only be supplied on foot of and in accordance with the following:

(i) **An Original and Legally Valid Prescription for a Named Patient**

The original prescription must be physically present in the pharmacy and must have been reviewed by a pharmacist before the medicine is dispensed and/or supplied. In the case of a repeatable prescription, and therefore a prescription not in respect of a Schedule 2 or Schedule 3 controlled drug, the pharmacist must be satisfied that the prescription is within date, that it is appropriate in the particular circumstances that the supply be made and that the medicinal product supplied is labelled in accordance with the prescription regulations.

(ii) By Way of Emergency Supply (at the Request of a Doctor/ at the Request of a Patient)
The supply of any Schedule 1, 2, 3 or 4 controlled drug (other than methylphenobarbitone, phenobarbitone or phenobarbitone sodium for the treatment of epilepsy) or of a medicinal product containing a substance in the Fourth schedule of the prescription regulations, is not permitted by way of emergency supply. Furthermore, the use of the emergency arrangement in a routine or systematic manner is not appropriate.

NOTE: Supply of medicinal products that are controlled drugs

The supply of Schedule 2 and 3 controlled drugs under the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017) is subject to separate controls. Some of the issues arising with respect to the use of controlled drugs in residential care settings are addressed in the PSI's *Explanatory Note on the Documentation and Other Requirements to be met by Pharmacists in Retail Pharmacy Businesses in making supplies of Controlled Drugs to patients in nursing homes*.

4. Prescriptions: Their Importance and Functions

A prescription is a particular form of communication between the practitioner and a pharmacist which directs the supply of medicinal products to a patient named therein to be taken by the patient concerned in the manner specified. Prescriptions are given in writing and under the law are defined as legal documents.

A prescription authorises the pharmacist to supply the medicinal products concerned to the patient for use in accordance with the directions given. In the case of controlled drugs, the prescription also conveys the authority to the patient, and as necessary to his or her carer, to lawfully have the drugs concerned in his or her possession. The availability of these prescriptions to the authorities could become a matter of some importance should either the patient or his or her carer encounter difficulties with the law arising from some improper use of the medicines concerned or if the suggestion of unlawful possession were to be made.

Prescriptions frequently also discharge an accountancy function in the context of reimbursement arrangements as part of the health services. It must be noted that this is a secondary use and that it does not and cannot be considered as ever being the primary function of a prescription.

Note: The supply of prescription-only medicines (including Schedule 2 or Schedule 3 controlled drugs) on foot of any of the following is not permitted:

(i) A faxed or photocopy of a prescription (other than by way of supporting a request for the making of an emergency supply as provided for under regulation 8 of the prescription regulations)

(ii) A Kardex /medication chart/prescription list or copies thereof

5. Review of Medicine Therapy and Counselling of Patients

The requirements relating to the *'Review of medicine therapy and counselling of patients in the supply of medicinal products on foot of a prescription'* are set out in Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008.

5.1 Mandatory Review of Prescribed Medicine Therapy

Prior to the dispensing of a prescription, and prior to the supply of any medicinal product that has been prescribed, it is a statutory requirement[3] that a registered pharmacist must review the prescription having regard to the pharmaceutical and therapeutic appropriateness of the particular medicine therapy for the patient, including the use by the patient of any other medicines etc. that the pharmacist is, or ought reasonably be, aware of.

5.2 Patient Counselling

Following completion of the above mandatory review, the registered pharmacist must ensure that the patient has sufficient information and advice for the proper use and storage of their prescribed medicines. In doing so, the pharmacist must offer to provide individual counselling to each patient or to their carer on the occasion of each supply of the medicines concerned. The pharmacist must also offer to discuss with each individual patient, or with their carer, all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant.

In order to properly exercise his or her professional obligations with respect to patient counselling and overall patient care, following the conduct of the obligatory medication review, it is essential that the pharmacist would offer to personally attend on the patient in the home, and on a frequency appropriate to each individual patient's needs. Records of these offers by pharmacists to make themselves available to counsel patients in the nursing homes, and of counselling visits made, should be retained and kept available for review in the pharmacy.

While educational talks and health related lectures to care staff and patients within a home are welcome and instructive, they are not a substitute for the individual counselling of each patient and/or their carer in respect of their prescribed medicines following the required medication reviews. Furthermore, it is not sufficient to suggest that the patient or carer should read an enclosed package leaflet or instructions as a substitute for receiving the appropriate information and advice from a pharmacist following the mandatory medication review. Counselling should always be supported by the supply and/or availability to the patient of the relevant patient information leaflet(s).

3 Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

6. Delivery of Medicines

The pharmacist's responsibility towards patients, particularly those in residential settings, extends to the delivery of medicines. Medicines must be delivered safely and with appropriate directions for their use. When delivering medicines to a patient, the pharmacist must be satisfied that:

- The delivery method used is secure i.e. the medicines are in appropriately sealed containers that are tamper evident/ tamperproof.
- The delivery method safeguards confidential information about the patient and their medication.
- The medicines are delivered to the patient or to their carer promptly, safely and in a condition appropriate for use. They must be packed, transported and delivered in such a way that their integrity, quality, safety and efficacy are preserved. Particular care must be exercised with thermo-labile products.
- The delivery method used should incorporate an itemised verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is handed to the patient or carer. A signature should be obtained to indicate receipt of the medicines by the patient, his or her carer or other designated person. This documentation must be retained for review at the pharmacy premises.
- Delivery to a person other than the patient or carer should only be undertaken where the arrangements have been specifically designated by the patient or their carer.
- Delivery of medicines that are Schedule 2 or 3 controlled drugs must be appropriately receipted and accounted for. Such records should also be retained for review at the pharmacy premises.

Please also refer to the PSI's *Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business.*

7. Standard Operating Procedures

For each pharmacy making supplies to persons in residential care settings, it is essential that appropriate standard operating procedures (SOPs) are in place setting out the manner in which the sale and supply of medicines to those persons is carried out. These SOPs must include at a minimum:

- The essential prerequisites for the supply of the medicines, including the availability of a valid original prescription and the necessary checking that the dispensed medicine is in full compliance with the prescription requirements.
- The arrangements for the review of medicines therapy.
- The arrangements for individual patient counselling and record keeping around counselling.
- The arrangements for the transfer of medicines to patients and/or carers. This includes delivery and receipting of medicines.

All SOPs, together with training records, must be retained and available for review. As with any other process for which SOPs are used, the SOPs in place must be specific to the pharmacy practice concerned and must be subject to on-going review and be amended and updated as necessary to take account of experience gained in their ongoing use.

8. Medication Monitoring and Reviews as Recommended by HIQA

In line with the HIQA *National Quality Standards for Residential Care Settings for Older People in Ireland*[4], pharmacists should make themselves available to participate in the interdisciplinary review of each patient on long-term medication, at least on a three-monthly basis. These reviews should enable special consideration to be given to the specific medicines and issues highlighted in the HIQA standard, including antipsychotic medication, sleeping tablets and other sedating medication, anticonvulsant medication, medication for the management of depression, analgesic medications, medication for the management of constipation, anti-platelet and anticoagulant medication (prevention of stroke), NSAIDs and medications with potential interactions. Records of the pharmacist's participation in these reviews should be retained in the pharmacy.

The pharmacist should also make themselves available to actively participate in the development of medicines management policies in the residential homes concerned and to advise prescribers and other members of the care team on the safe and rational use of medicines. Participation in any of these reviews does not absolve the pharmacist from his or her obligation to conduct the mandatory reviews required under Regulation 9, as has been described above.

9. Disposal of Unwanted Medicinal Products

Pharmacists should also be satisfied that appropriate arrangements are in place in respect of the segregation and safe disposal of unused, out-of-date and other waste medicines which should be disposed of promptly and in line with the PSI guidelines on the disposal of medicinal products within a retail pharmacy business.

10. Responsibility

While this Notice is directed mainly at registered pharmacists, it remains the responsibility of all pharmacy owners, superintendent and supervising pharmacists, to ensure, on an on-going basis, that all the relevant legal, professional and other requirements are being appropriately and adequately met in the conduct of their retail pharmacy business(es).

Relevant legislation can be accessed through the PSI website www.thePSI.ie and is also available from www.irishstatutebook.ie. The statutory Code of Conduct for pharmacists and all guidelines and other guidance documents are also available on the PSI website.

Version Number	Date Issued
1	July 2010
2	February 2014
3	January 2015
4	March 2018

4 Standard 15 of the National Quality Standards for Residential Care Settings for Older People, HIQA, 2009.

11. 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
Is the same level of professional care and attention given to patients in residential care as is given to those patients who attend personally at the pharmacy?				
Are the pharmacy's/pharmacists' arrangements with the owners, managers and staff of the residential home in compliance with the Code of Conduct for pharmacists?				
In each supply of medicinal products to patients in residential care homes, do you have a legally valid prescription for a named patient?				
Are correct emergency supply procedures in place in the pharmacy i.e. this form of supply is only used in exceptional circumstances, and not as a routine arrangement?				
Are faxed/photocopied prescriptions and medication charts (or copies thereof) only used in the support of an emergency supply request, and not as a valid prescription?				
Is a full review of the pharmaceutical and therapeutic appropriateness carried out prior to the dispensing of a medicine to these patients, in light of the patients' medication history?				
Is individual counselling offered by the pharmacist, to every patient on the proper use and storage of their medicine, and on all other matters the pharmacist deems significant, on every occasion that medicines are dispensed?				
Is the patient counselling offered by the pharmacy, including offers of the pharmacist to attend the home, assessed on an individual patient basis, and a record of these offers and attendance kept in the pharmacy?				

Ask Yourself	Yes	No	N/A	Required Action
Is the manner in which medicines are delivered to the residential care home, secure, safe, and prompt and are they delivered in a condition suitable for use (e.g. appropriate storage of refrigerated items)?				
Does the delivery procedure include a signed, itemised and verifiable audit trail for all medicines delivered, from the pharmacy to the carer/patient?				
Is the delivery of Schedule 2 and Schedule 3 controlled drugs appropriately receipted and recorded and the records retained at the pharmacy?				
Is the pharmacist available to undertake an interdisciplinary review of each patient on at least a three monthly basis, in line with HIQA standards?				
Is the pharmacist available to actively participate in the review of medicines management policy in the residential home, and to provide advice to prescribers and other members of the care team on the safe and rational use of medicines?				
Are all waste medicines appropriately segregated, and promptly disposed of in line with PSI *Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business?*				
Are there written policies and procedures in place which detail all aspects of this service, including the dispensing, review, counselling and delivery of medicines to patients in residential care homes?				
Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				