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

to Facilitate Compliance with Misuse of Drugs Acts 1977 to 2006 and Misuse of Drugs Regulations 2017 (as amended)

Pharmaceutical Society of Ireland

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Contents

1. Introduction

The purpose of this explanatory note is to set out the requirements under the Misuse of Drugs Acts for the supply by pharmacists in retail pharmacy businesses of Schedule 2 and Schedule 3 controlled drugs[1] to patients in nursing homes[2]. The need for this statement has arisen out of the number of queries being received by PSI seeking clarification in respect of the documentation requirements for the lawful supply of controlled drugs where patients in nursing homes are concerned.

The requirements for the making of supplies of controlled drugs, including the making of supplies to patients in nursing homes, are set out in the Misuse of Drugs Regulations 2017 (as amended) (S.I. No. 173 of 2017).

Under the Misuse of Drugs Acts, it is a fundamental principle that the person being supplied with a controlled drug is lawfully entitled to be in possession of that drug whether that authority be established by the holding of a valid prescription or by some other authority created under the Act. It is therefore extremely important that pharmacists, in making supplies of controlled drugs, are supported by the availability of the correct documentation and that the person being supplied has the appropriate authority to lawfully possess the drug.

Given the serious nature of the drugs concerned, their potential for misuse and/or abuse a strict regime of control of these substances is laid down in the Misuse of Drugs Acts and Regulations. This includes restrictions on those that can obtain or possess controlled drugs, and the strict obligations placed on pharmacists as the healthcare professionals charged with responsibility for the safe custody of these substances, and the lawful supply of those drugs to patients or other persons. It is important therefore that pharmacists fully comply with the particular legislative requirements laid down in this area and that they are fully aware of the identity of the person to whom the drug supply is being made, the authority of that person to possess the controlled drug and of the purposes for which the supply is intended.

This explanatory note therefore provides information on provisions of the legislation outlined below and also outlines the subsequent obligations on pharmacists in making supplies of controlled drugs to patients in nursing homes.

1 In this document, any reference to controlled drugs refers to the drugs in these two Schedules.

2 In this document, the term “nursing home” may also be considered as including “hospitals”.

2. Provisions of the Legislation

2.1 The Important Distinction Between Public Nursing Homes and Private Nursing Homes

Article 9(1)(a) of the Misuse of Drugs Regulations 2017 (as amended) (S.I. No. 173 of 2017) defines nursing homes as being those which are wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions. Nursing homes falling under this description are generally referred to as **public nursing homes**.

The effect of this definition is to establish a regime of control, as set out in the Regulations, for the sourcing, possession, supply, administration and use of controlled drugs in those public nursing homes where the organisational structures have identified individuals holding the positions of Director of Nursing or Director of Midwifery or Matron and Clinical Nurse Manager or Clinical Midwife Manager or Sister and including individuals identified as acting in either of those positions.

Nursing homes that are not covered by the above definition, such as **private nursing homes** and those public nursing homes that do not have the required identified personnel, may only obtain their supplies of controlled drugs from a registered retail pharmacy business on foot of prescriptions issued in the names of the individual patients that are resident in those homes. Therefore, the authority of nursing home staff to possess the controlled drugs is solely as a representative of the patient on the prescription.

2.2 Persons in a Public Nursing Home Authorised to Possess and Obtain Controlled Drugs

In the Misuse of Drugs legislation only the persons specified in the Regulations in public nursing homes are provided with the authority to lawfully possess (and thus to obtain and supply) controlled drugs.

At the outset, under the legislation the only person in a public nursing home holding the authority to lawfully possess and to obtain controlled drugs is the Director of Nursing or equivalent who, in the first instance, is the person responsible for the dispensing and supply of medicines at the nursing home. In this case, the authority only relates to controlled drugs that are in the form of medicinal products.

The necessary supplies of controlled drugs to the public nursing home may be made on foot of requisitions issued by the Director of Nursing or equivalent, which must also be signed by a practitioner[3] that is employed or engaged in the nursing home[4]. It should be noted that the Director of Nursing or equivalent's authority ceases once the nursing home has a pharmacist responsible for the dispensing and supply of medicines at the nursing home. In that case, this pharmacist is normally a member of staff of the nursing home and where controlled drugs are concerned, he or she replaces the Director of Nursing or equivalent and, under the Regulations, becomes the person responsible for the dispensing and supply of medicines at the public nursing home. Subsequently, in this explanatory note, reference will only be made to the Director of Nursing or equivalent as the person with the authority to possess and obtain controlled drugs in a public nursing home.

3 Article 14(5)(a) Misuse of Drugs Regulations 2017 (as amended).

4 Proviso (i) to Article 9(1), Misuse of Drugs Regulations 2017 (as amended).

2.3 Procedure for Supply of Controlled Drugs Within a Public Nursing Home

The Director of Nursing or equivalent, as the person responsible for the dispensing and supply of medicines at the public nursing home, is only authorised to supply controlled drugs to a Clinical Nurse Manager or equivalent in the home on foot of requisitions issued by that Clinical Nurse Manager or equivalent[5].

These requisitions must specify the total quantity of the drug to be supplied. The Director of Nursing or equivalent, having made the supply to the Clinical Nurse Manager or equivalent, is required to mark the requisition to show that the drug has been supplied and retain it together with the Register of controlled drugs that the Director of Nursing or equivalent is also required by law to keep. The Clinical Nurse Manager or equivalent is also required to retain a copy of the requisition but, unlike the Director of Nursing or equivalent, she is not required to keep a Register. It should be noted that all persons concerned are required to be in a position to fully account, personally, for any controlled drugs that they have requisitioned and taken into their possession in the course of their duties.

The Clinical Nurse Manager or equivalent is also authorised to be in possession of the controlled drugs that he or she has received on foot of requisitions from the Director of Nursing or equivalent (as the person responsible for the dispensing and supply of medicines at the nursing home). The Clinical Nurse Manager or equivalent is not entitled to supply any controlled drug otherwise than by way of administration in accordance with the directions of a practitioner[6] or to have in her possession any controlled drug that has not been obtained on requisition from the Director of Nursing or equivalent in the manner as described above[7].

2.4 The Role of Practitioners in Directing the Administration of Controlled Drugs

What has been described so far is the manner in which controlled drugs can be supplied into public nursing homes and subsequently provided to the wards for administration to patients in accordance with the directions of a practitioner.

In order for controlled drugs to be obtained in the nursing home in the first instance, it is necessary that the requisition issued by the Director of Nursing or equivalent be also signed by the practitioner employed or engaged in that nursing home[3]. Accordingly, there must be two signatures on the requisition and in that respect, the signing practitioner must be satisfied that the drugs listed on the requisition are necessary for the treatment of patients in that nursing home and that their use will be in accordance with the directions of a practitioner.

On the wards, the Clinical Nurse Manager or equivalent likewise must be satisfied that any administration of a controlled drug to a patient is in accordance with the directions of a practitioner. These directions are not prescriptions and are usually recorded in the individual patient's bed sheets, bed cards or Kardex systems, which are signed by the practitioner.

Where a pharmacist is responsible for the dispensing and supply of medicines at the nursing home, he or she too would be expected to occasionally carry out checks to ensure that the controlled drugs concerned are being administered in accordance with the directions of a practitioner. This becomes important as, unlike the Director of Nursing or Director of Midwifery or Matron, the pharmacist is entitled to obtain supplies in his or her own right without furnishing a requisition[8] and for that reason, he or she becomes responsible.

He or she must therefore be satisfied that the controlled drugs supplied are necessary for the treatment of patients in the nursing home and that, on supply to the Clinical Nurse Manager or equivalent, they are being appropriately used[6] and accounted for, as required by the Regulations.

5 Article 14(6), Misuse of Drugs Regulations 2017 (as amended).

6 Proviso (ii) to Article 9(1), Misuse of Drugs Regulations 2017 (as amended).

7 Article 9(1)(b), Misuse of Drugs Regulations 2017 (as amended).

8 Articles 14(2) and (4), Misuse of Drugs Regulations 2017 (as amended).

2.5 The Use of Prescriptions in Public Nursing Homes

Notwithstanding the above, it may be that a public nursing home may decide to rely on prescriptions issued in the names of individual patients, as the source of controlled drugs for use in the nursing home for those patients. That too is possible but it should be one system or the other. It would be considered bad practice to have two systems for the sourcing of controlled drugs running together. In that situation, it would be very difficult to assure the necessary accountability for the drugs concerned as required under the law. In other words, there should be only one source.

Where prescriptions are used as the manner in which controlled drugs are sourced for patients, it is important to remember that in that situation, the patient is in exactly the same situation as if the patient were in his or her own home. Furthermore, it would not be lawful or appropriate for one patient's medicines obtained on prescription to be availed of for administration to another patient in the home.

2.6 The Use of a Practitioner's Requisition for Supply to a Public Nursing Home

While supplies may be properly obtained by a practitioner for administration in the course of his or her professional practice it would not be lawful for such a practitioner to supply to, or for a Director of Nursing or equivalent to accept, supplies of controlled drugs obtained in this manner.

3. Obligations on Pharmacists in a Retail Pharmacy Business Supplying Controlled Drugs to Nursing Homes

From the above legislative provisions, it can be observed that a strict regime of control for controlled drugs is laid down in the Misuse of Drugs Legislations. Strict obligations are placed on pharmacists, as the healthcare professionals charged with responsibility for the safe custody of these drugs and for their lawful supply to patients and to other persons. Pharmacists must fully comply with the legislative requirements laid down in this area.

Pharmacists must therefore only supply controlled drugs into a private nursing home on foot of valid prescription or, in the case of a public nursing home, on foot of a valid prescription or a valid requisition signed by the Director of Nursing or equivalent of the nursing home and the practitioner employed or engaged in that home. Where emergency supplies of controlled drugs are provided to named patients, they must be in compliance with the legislation, including the specific additional conditions applicable to emergency supplies of controlled drugs.[9]

In addition, in making supplies of controlled drugs, pharmacists must ensure that they are fully aware of the identity of the person to whom the controlled drug supply is to be made and that the person being supplied has the authority to lawfully possess that drug.

Version Number	Date Issued
1	February 2014
2	October 2017
3	March 2024

9 Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)

4. Self-assessment Checklist

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

Ask Yourself	Yes	No	N/A	Required Action
Are you aware of the distinction between public and private nursing homes and the implications for making supplies of controlled drugs?				
In the supply of controlled drugs to patients in private nursing homes, do you always have a legally valid prescription for the named patients prior to supply?				
Where emergency supplies of controlled drugs are made to named patients, are they made in compliance with the requirements of the legislation, including the additional conditions applicable to controlled drugs?				
Are you satisfied that all prescriptions you dispense are genuine and legally valid?				
Are you satisfied that persons being supplied have the authority to receive and to lawfully possess the controlled drugs, either as the patients named on the prescriptions, or as bona fide representatives of the patients (i.e. acting as messengers)?				
Are you always satisfied as to the identity of the person for whose treatment the prescriptions have been issued?				
Are all staff aware that the emergency supply of controlled drugs is only permitted in exceptional circumstances, where the specific additional conditions are met, and that it is not appropriate as a routine method for supply?				