
Safe Prescribing and Dispensing of Controlled Drugs

Medical Council/Pharmaceutical Society of Ireland Joint Guidance

Purpose of this guidance



This resource should be used by all medical doctors and pharmacists in the collaborative, safe and effective care of patients, to facilitate safer prescribing and dispensing of controlled drugs (CDs), and with a particular focus on Controlled drugs in Schedule 2, 3 and Schedule 4 Part 1.¹ This guidance includes the recent changes made by the Misuse of Drugs Regulations 2017.

While this guidance provides some information on legal requirements applicable to hospital or residential, settings it is primarily aimed professionals working in a primary care setting.

Purpose of controlled drugs legislation/controls

There is a strict system of control in place, both nationally and internationally, around the movement and supply of controlled drugs.² These controls are intended to enable safe access to these medicines in light of the serious nature of the drugs concerned and the substantial potential for abuse and misuse of these medicines. In Ireland, these medicines are controlled by the Misuse of Drugs Acts and Regulations.³ These controls include restrictions on the people who can obtain or possess controlled drugs, and the strict obligations placed on pharmacists and medical doctors charged with responsibility for the safe control of these substances.

Professional Responsibilities

Medical Practitioners are obliged to:



- Provide a valid prescription⁴ which meets the requirements of the legislation
- Be satisfied as to the identity of the person for whose treatment the prescription is to be issued
- Follow relevant national and international prescribing guidelines
- Within reason, be available to confirm or discuss any matters related to the prescription and the patient
- Ensure the safe keeping of prescription pads to reduce the risk of forgery
- Adhere to national guidelines and facilitate appropriate withdrawal of controlled drugs and follow up and referral as necessary

Pharmacists are obliged to:



- Only dispense on the basis of a legally valid prescription⁴
- Be reasonably satisfied that the signature of the prescriber is genuine
- Be satisfied as to the identity of the person or bona fide representative presenting the prescription or collecting medicines, prior to supply⁵
- Be vigilant for forgeries or unusual prescribing patterns
- Store controlled drugs in a safe, in accordance with the relevant legislation⁶
- Record all supplies of Schedule 2 controlled drugs (CD2) in the pharmacy's controlled drugs register⁷
- Communicate with the doctor if there is any query about the prescription, or care of the patient
- Adhere to national guidelines and facilitate appropriate withdrawal of controlled drugs and, follow up and referral as necessary

Prescriptions Requirements for CD2 and CD3 Drugs⁸

(Including handwriting requirements) 

for example of compliant prescription see appendix 1

Date

Patient name

Patient address

Name of medicine  (can be generic/INN or proprietary/brand name)

Form (e.g. tablets) 

Strength (e.g. 10mg) 

Dose (e.g. 2 twice daily) 

Total quantity or total number of dosage units (Words and figures) 

Signature 

Name of prescriber (First Name & Surname)

Address of prescriber

Profession (eg. Medical Practitioner)

Registration number⁹

Telephone number

Instalments

(See section below on prescription validity and instalments)

- Amount of instalments (e.g. 4)
- Intervals for dispensing (e.g. dispense weekly)

Health prescriptions e.g. (GMS) are exempt from specifying the following details:¹⁰

- Address of prescriber

Methadone prescriptions and prescriptions for Schedule 4 Part 1 CDs:¹¹

The following information must be included on the prescriptions, but **does not need to be in the doctors own handwriting** i.e. can be computer generated or handwritten.

- Name of medicine
- Form
- Strength (e.g 10mg/ml)
- Dose (e.g 50 mls daily)
- Total quantity or total number of dosage units (words **and** figures)

Note:

An example of a Schedule 4 Part 1 and a methadone prescription are included in Appendix 2 and 3.

Other Relevant Legal Requirements

Prescription Validity and Instalments

Prescriptions are usually valid for a period of six months from the date of issue; however, there are additional restrictions in the context of controlled drug prescriptions:

1. Prescriptions for CD2 or CD3 drugs cannot be dispensed before the date of the prescription or later than **14 days** after that date (except in the case of instalments)
2. The address of the prescriber must be within the state
3. Repeat prescriptions are not permitted in the case of CD2 or CD3 drugs
4. Prescriptions for CD2 or CD3 drugs may be dispensed in instalments, provided that
 - the intervals between instalments and the amount of the instalments is specified, and
 - The first instalment must be dispensed within 14 days and the last instalment must be dispensed no later than two months from the date on the prescription
5. 'Emergency supplies' of CD2, CD3 or CD4 drugs are not permitted under the legislation (with the exception of methylphenobarbitone, phenobarbitone and phenobarbitone sodium for the treatment of epilepsy).¹²

Requisitions¹³

Controlled drugs may also be obtained and supplied through the use of a requisition (or order), for administration by the medical doctor in the course of their professional practice.

Such a requisition must contain the following information:

- Name, address and profession
- Signature of the doctor
- Date of Requisition
- Name of the controlled drug
- Registration number ⁹
- Purpose of supply
- Total quantity of the medicine(s) to be supplied

In the interest of patient safety, the doctor obtaining drugs through the use of a requisition may be asked by the pharmacist to produce identification.

Overarching Principles

Communication

Good communication is essential to the effective functioning of healthcare teams.¹⁴ The existence of good, open communication channels between pharmacists and medical doctors is of particular importance in assuring the safe and efficient supply of controlled drugs to patients. By having in place a strong system of partnership, firmly based in the shared care of patients, efficiencies can be achieved in assuring that patients receive the best possible care in a more integrated system. These links are of course well established. In prescribing and dispensing controlled drugs, where there is any doubt/confusion around the prescription, dosage, supply and administration, pharmacists and doctors are encouraged to engage with the relevant health care professional without delay. This is particularly important at transitions of care and the initial prescriber should have clear communication with the patient's GP and the pharmacist, as necessary.



Identifying risk factors / high risk patients



As part of this collaborative relationship, pharmacists and doctors should, in particular, communicate and collaborate in the care of patients in high risk groups or with additional care requirements, for example patients:

- In Palliative care
- With drug dependence issues
- In addiction treatment services
- Under the management of a number of doctors
- Transitioning from one place of care to another
- In residential care settings

Engagement within and between the professions in the shared care of patients in these groups is particularly important, in order that patients' care needs are met. This includes shared responsibility for follow up and after care for all patients, and collaborative working in the implementation of appropriate withdrawal procedures for controlled drugs.

Relevant National Resources Professional and Clinical Guidance



It is essential in the prescribing, dispensing and supply of controlled drugs that pharmacists and doctors are aware of and have access to national resources, and adhere to current national and international guidelines. For example:

- The Health Products Regulatory Authority (HPRA) website for the confirmation of the classification of medicines (e.g. classification of a medicine as a CD2 or CD3) (See Appendix 3)
- The online registration databases of both the Medical Council and the Pharmaceutical Society of Ireland: to confirm registration, find contact details and be aware of any conditions attached to the registration of healthcare professionals
- Resources or advice from relevant healthcare regulators, including the Medical Council, the Pharmaceutical Society of Ireland and the Health Information and Quality Authority (HIQA)
- National Clinical Guidelines from the National Clinical Effectiveness Committee and relevant faculties
- Relevant international Guidelines from bodies such as the National Institute for Health and Care Excellence (NICE)
- The full legislation, available at www.irishstatutebook.ie

This guide is not a legal document. Its intention is to facilitate medical practitioners and pharmacists in interpreting several pieces of legislation and provide a practical tool in the collaborative care of patients. Links to relevant legislation have been provided for direct consultation

Definitions

Controlled Drug

Some prescription medicines are controlled under the Misuse of Drugs legislation. These medicines are called controlled medicines or controlled drugs

These medicines are listed in schedule 1,2, 3, 4 or 5 of the Misuse of Drugs Regulations 2017

Examples

Schedule	Examples of Medicine in that schedule
Schedule 1	Substances not ordinarily used as medicines e.g. Raw Opium
Schedule 2	Opiate substances e.g. Morphine
Schedule 3	Certain benzodiazepines and painkillers e.g. Temazepam
Schedule 4 Part 1	Benzodiazepines and 'Z drugs' e.g. Diazepam
Schedule 4 Part 2	Anti- epileptics e.g. Phenobarbitone <100mg
Schedule 5	Lower strengths of painkillers e.g. Codeine (below specified concentration)

Health Prescription

“health prescription” and “health service requisition” means a prescription or a requisition issued in connection with arrangements made under section 59 of the Health Act, 1970 upon a form supplied by or on behalf of a health board;

From a practical perspective, this relates to GMS (General Medical Scheme) prescription

References

1. List of Controlled Drugs as provided by Health Products Regulatory Authority
2. Including requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended)
3. The national controlled drugs legislation forms an essential part of the Government's actions against drug abuse and drug related crimes and are in compliance with Ireland's obligations under the United Nations Convention on Narcotic Drugs 1961 (as amended), in particular Articles 30 and 33 of that Convention, to which Ireland is a Party
4. Misuse of Drugs Acts 1977 to 2016 and the Misuse of Drugs Regulations 2017
5. Regulation 16 (1(f)) of the Misuse of Drugs Regulations 2017
6. Misuse of Drugs (Safe Custody) Regulations 1982, as amended.
7. Regulation 19 of the Misuse of Drugs Regulations 2017
8. Regulation 15 of the Misuse of Drugs Regulations 2017
9. Section 43 (8) Medical Practitioners Act 2007 and Regulation 15(2)(b) of the Misuse of Drugs Regulations 2017
10. Regulation 15 (2)(d) of the Misuse of Drugs Regulations 2017
11. Specific handwriting exemptions provided for Methadone and Schedule 4 Part 1 prescriptions, Regulation 15 (4) of the Misuse of Drugs Regulations 2017
12. Regulation 8 (2) (c) and 8 (3) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)
13. Regulation 14 of the Misuse of Drugs Regulations 2017
14. A Guide to Professional Conduct and Ethics for Registered Medical Practitioners (8th Edition, 2016) page 10, paragraph 4.4
15. Note exemptions for methadone and schedule 4 part 1 controlled drugs detailed on page 4 and appendices 2 and 3

Appendix 1

Example of Compliant Prescription for Schedule 2 and 3 CDs¹⁵

Dr John Doe
Somewhere Rd
Co Dublin
Medical Practitioner
MCRN -XXXXX
Telephone 01 1234567

04 May 2017

Joe Bloggs
Bloggstown
Co. Dublin

Sevredol 10mg Tablets

Take one tablet B.D.

56 tablets (fifty-six)

Dispense weekly (4 instalments) (14 tablets each week)

Dr John Doe

Note – Fine Blue font indicates handwritten details

Appendix 2

Example of Compliant Prescription Schedule 4 Part 1 CDs

Dr John Doe
Somewhere Rd
Co Dublin
Medical Practitioner
MCRN -XXXXX
Telephone 01 1234567

04 May 2017

Joe Bloggs
Bloggstown
Co. Dublin

Valium 5mg tablets

Take one tablet nocte

7 tablets (seven)

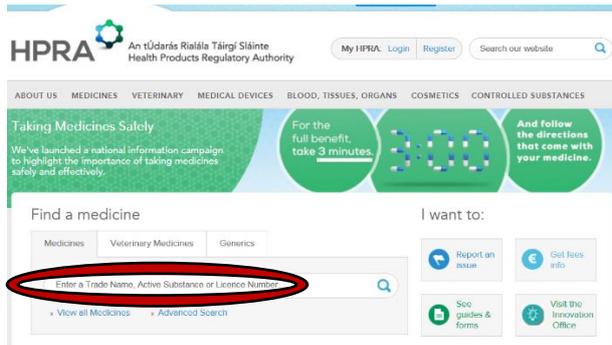
Repeat x 2

Dr. John Doe

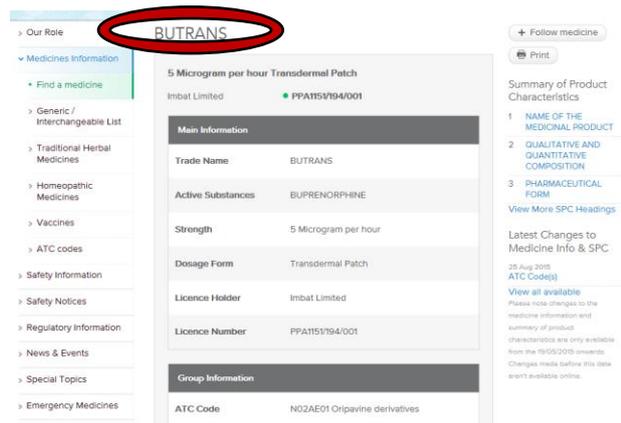
Appendix 4

HPRA website – Information on Medicines Classification

Step 1 – Access HPRA Home (www.HPRA.ie)



Step 2 - Enter Product name and select product



Step 3 - Scroll down to 'Status' and 'Conditions of License' for details on CD Classification

Status

Authorised/Withdrawn Authorised

Licence Issued 15/03/2013

Supply Status Supply through pharmacies only

Dispensing Status

Product subject to prescription which may not be renewed (A)

Marketing Status --Unknown--

Promotion Status Promotion to Healthcare Professionals only

Conditions of Licence

This product contains a substance listed in Schedule 2 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988), as amended