Safe Prescribing and Dispensing of Controlled Drugs

Joint Guidance
Medical Council and Pharmaceutical Society of Ireland
Purpose of this Guidance

This resource aims to facilitate safer prescribing and dispensing of controlled drugs (CDs), with a particular focus on controlled drugs in schedule 2, 3 and schedule 4 part 1. It should be used by all prescribers and pharmacists in the collaborative, safe and effective care of patients. This guidance includes the recent changes made by the Misuse of Drugs Regulations 2017 which have replaced the now revoked Misuse of Drugs Regulations 1988, as amended.

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

PSI- The Pharmacy Regulator - www.psi.ie
Medical Council - www.medicalcouncil.ie
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1. Definitions

What is a Controlled Drug and what are Schedules?

Substances, products or preparations, including certain medicines, that are either known to be, or have the potential to be, dangerous or harmful to human health, including being liable to misuse or cause social harm, are subject to control under the Misuse of Drugs Acts 1977 to 2016. They are known as “controlled drugs”.

The Misuse of Drugs Regulations categorise controlled drug substances into five schedules (ranging from the most tightly controlled in schedule 1 to the least tightly controlled in schedule 5). Schedule 4 is divided into part 1 and part 2. The controlled drugs in each of these schedules, in practice and in this document, may be referred to as CD1s, CD2s, CD3s, CD4 part 1s, CD4 part 2s and CD5s, respectively.

Each schedule contains various drug substances and drug products based on their perceived medical benefit and their risk to public health. There are different restrictions to control the supply of each schedule of controlled drugs. CD1s have the most restrictions and CD5s have the least restrictions. Some CD5s are available to patients without a prescription.

In this guidance we focus primarily on the controlled drugs found in schedule 2, schedule 3 and schedule 4 part 1. The supply of these controlled drugs is subject to more specific requirements than those in schedule 4 part 2 and schedule 5.

We do not specifically refer to schedule 1 controlled drugs as they are not commonly prescribed or supplied as they are normally not regarded as having any therapeutic purposes. They may only be prescribed subject to Ministerial Licence.

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Examples of Controlled Drugs in Each Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule 1</td>
<td>Substances not ordinarily used as medicines for example, Raw Opium, Coca Leaf</td>
</tr>
<tr>
<td>Schedule 2</td>
<td>Opiate substances for example, Morphine, Fentanyl and Oxycodone</td>
</tr>
<tr>
<td></td>
<td>Some Stimulants for example, Lisdexamphetamine</td>
</tr>
<tr>
<td>Schedule 3</td>
<td>Certain Benzodiazepines and painkillers for example, Temazepam, Flunitrazepam, Pentazocine, Ketamine</td>
</tr>
<tr>
<td>Schedule 4 Part 1</td>
<td>Most Benzodiazepines and ‘Z-drugs’ for example, Diazepam, Alprazolam, Clonazepam, Midazolam and Zolpidem</td>
</tr>
<tr>
<td>Schedule 4 Part 2</td>
<td>Certain Anti-Epileptics for example, Phenobarbitone &lt;100mg</td>
</tr>
<tr>
<td></td>
<td>Certain MAOIs for example, Selegiline</td>
</tr>
<tr>
<td>Schedule 5</td>
<td>Lower strengths of painkillers for example, Codeine (below specified concentration)</td>
</tr>
</tbody>
</table>

Please note: The above table contains examples only and is not an exhaustive list.
All prescribers and pharmacists must familiarise themselves with, and refer to, the complete lists of controlled drugs contained in each schedule. The full listing can be found in the Misuse of Drugs Regulations 2017.

The Health Products Regulatory Authority (HPRA) website should be checked for accurate and up-to-date information regarding the classification of authorised medicines containing controlled drugs i.e. schedule 2, schedule 3, schedule 4 part 1, schedule 4 part 2 and schedule 5. Please see Appendix 6 for more information on how to carry out this search.

The HPRA has produced a list of authorised controlled drug products contained in each schedule. This list can be found on the HPRA website www.hpra.ie. Alternatively, the HPRA is contactable on +353 1 676 4971 or at info@hpra.ie.

2. Health Prescription

“Health prescription” and “health service requisition” are 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 Services) prescriptions.

3. Prescriber/Medical Practitioner

“Medical practitioner” refers specifically to doctors. “Prescribers” refers to healthcare professionals with prescriptive authority for controlled drugs i.e. doctors, nurse prescribers, dentists, veterinary practitioners and midwives.

4. Repeat Vs Instalment

- A “repeat prescription”, as defined in the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended, means a prescription which may be dispensed more than once.

  Schedule 2 and schedule 3 controlled drugs cannot be repeated.
  Schedule 4 (part 1 and part 2) and schedule 5 controlled drugs may be repeated.

- “Instalments” allow the total quantity of the medicine prescribed to be dispensed in smaller, specified amounts, at specified intervals.

  All controlled drugs can be legally dispensed in this manner, however, in accordance with the Misuse of Drugs Regulations 2017, ‘the number of instalments and the intervals at which the instalments may be dispensed’ must be specified on prescriptions for schedule 2, schedule 3 and schedule 4 part 1 prescriptions. Please see Appendix 1a for an example of correctly specified instalment directions.
5. Purpose of Controlled Drugs Legislation/Controls and Professional Responsibilities:

There is a strict system of control in place, both nationally and internationally, around the movement and supply of controlled drugs. These controls are intended to enable safe access to these medicines in light of the serious nature of the drugs concerned and substantial potential for abuse and misuse of these medicines.

In Ireland, these medicines are controlled by the Misuse of Drugs Acts and Regulations. These controls include restrictions on the people who can obtain or possess controlled drugs, and the strict legal obligations placed on pharmacists and prescribers charged with responsibility for the safe control of these substances.

The Misuse of Drugs Regulations 2017 are statutory instruments which came into force on 4th May 2017. They are vital in protecting patient health and safety. Failure to adhere to this legislation may result in patients receiving inadequate care and unnecessary and unacceptable burden and stress.

All prescribers (including doctors) and pharmacists must adhere to these regulations. It is an offence not to adhere to these regulations.

Additionally, medical practitioners and pharmacists, when registering with the Medical Council and the Pharmaceutical Society of Ireland (PSI) respectively, commit to adhering to professional standards and ethical guidelines set by their regulator.

Medical practitioners adhere to the Medical Council’s Guide to Professional Conduct and Ethics for Registered Medical Practitioners, which explicitly states that they must obey the Misuse of Drugs legislation.

Pharmacists must adhere to the PSI’s Code of Conduct. The Code of Conduct states that pharmacists must ‘comply with medicines legislation’.

Any patient requiring a controlled drug for their treatment is entitled to a correctly written prescription in order for them to lawfully access them. It is also an offence for medical practitioners to incorrectly write a controlled drug prescription, and it is an offence for a pharmacist to supply controlled drugs from an incorrectly written prescription. It is therefore incumbent upon both medical practitioners and pharmacists to ensure they are aware of their responsibilities and obligations under the Misuse of Drugs legislation to ensure the safe and appropriate supply of controlled drugs to their patients.
6. Prescriber Obligations

- Provide a valid prescription 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 theft and forgery
- Facilitate appropriate withdrawal of controlled drugs and follow-up and refer as necessary

7. Pharmacist Obligations

- Only dispense on the basis of a legally valid prescription
- Be satisfied that the signature of the prescriber is genuine
- Prior to supply, be satisfied as to the identity of the person or bona fide representative presenting the prescription or collecting controlled drugs
- Be vigilant for forgeries or unusual prescribing patterns
- Store controlled drugs in a safe manner, in accordance with the relevant legislation
- Record all supplies of schedule 2 controlled drugs (CD2) in the pharmacy’s controlled drugs register
- Communicate with the medical practitioner 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 refer as necessary
8. Prescriptions Required for CD2 and CD3 Drugs

Prescriptions Requirements for CD2 and CD3 Drugs

(Including handwriting requirements)

for example of compliant prescriptions see Appendix 1a and 1b

Date

Patient name (First name and surname)

Patient address

Name of medicine

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 and surname)

Address of prescriber

Profession (e.g. Medical Practitioner)

Registration number

Telephone number

Please note: Addressographs (sticker with patient name and address) are not acceptable as they are not considered indelible however it is acceptable to either print or handwrite these details.

Instalments

(Please see section 10 for further information)

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

Address not required for health prescription (i.e. GMS Prescription)

First instalment must be dispensed within 14 days

Last instalment must be dispensed within 2 months
9. Methadone Prescriptions and Prescriptions for Schedule 4 Part 1 CDs

Methadone prescriptions and prescriptions for schedule 4 part 1 CDs:

The following information must be included on the prescription, but does not need to be in the doctor's own handwriting i.e. can be computer generated or handwritten.

- Name of medicine
- Form (e.g. liquid/oral solution)
- Strength (e.g. 1mg/ml)
- Dose (e.g. 50 mls daily)
- Total quantity or total number of dosage units (words and figures) (e.g. 350 mls (three hundred and fifty mls))

Note:
An example of a schedule 4 part 1 private prescription, a schedule 4 part 1 GMS repeat prescription and a methadone prescription are included in Appendix 2, 4 and 5.
10. 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. The first instalment or supply on prescriptions for CD2 or CD3 drugs cannot be dispensed before the date of the prescription or later than 14 days after that date.
2. The address of the prescriber must be within the State for CD2, CD3 and CD4 part 1 drugs.
3. Repeat prescriptions are not permitted in the case of CD2 or CD3 drugs.
4. Prescriptions for CD2, CD3 and CD4 part 1 may be dispensed in instalments, provided that the intervals between instalments and the number of the instalments are specified.
5. For CD2 and CD3 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.
6. ‘Emergency supplies’ of CD2, CD3 or CD4 drugs, including those requested by prescribers, are not permitted under the legislation (with the exception of methylphenobarbitone, phenobarbitone and phenobarbitone sodium for the treatment of epilepsy).  

For ease of reference, Appendix 7 contains a table which clearly shows the prescription requirements for schedule 2, schedule 3 and schedule 4 part 1 controlled drugs.

**Requisitions**
Controlled drugs may also be obtained and supplied through the use of a requisition (or order), for administration by the medical practitioner in the course of their professional practice. Such a requisition must contain the following information:

- ✔ Name, address and profession
- ✔ Signature of the medical practitioner
- ✔ Date of requisition
- ✔ Name of the controlled drug
- ✔ Registration number
- ✔ Purpose of supply
- ✔ Total quantity of the medicine(s) to be supplied

The medical practitioner obtaining drugs through the use of a requisition should be asked by the pharmacist to produce identification.

An example of a requisition can be found in Appendix 3.
11. Overarching Principles

11.1 Communication

Good communication is essential to the effective functioning of healthcare teams. The existence of good, open communication channels between pharmacists and prescribers 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 well established. In prescribing and dispensing controlled drugs, where there is any doubt or confusion around the prescription, dosage, supply and administration, pharmacists and medical practitioners should 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.

11.2 Identifying Risk Factors/High Risk Patients

As part of this collaborative relationship, pharmacists and prescribers should, in particular, communicate and collaborate in the care of patients in high risk groups. Examples include:

- Patients with drug dependency issues
- Patients receiving addiction treatment services
- Patients under the management of multiple doctors
- Patient population who attend pain clinics
- Patients transitioning from one place of care to another
- Patients in residential care settings
- Patients at risk of developing sleep disordered breathing
- Prisoners
- Patients with mental health issues
- Homeless patients
- Patients with additional care requirements
  - Patients with poor health literacy or patients who don’t have English as their first language
  - Paediatric patients
  - Older people
  - Pregnant/breast feeding women
  - Patients with physical/intellectual disabilities
  - Patients suffering from chronic illnesses
  - Patients receiving palliative care

Engagement within and between the professions in the shared care of patients in these groups is particularly important to meet patients’ care needs. 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.
11.3 Relevant National Resources and Professional and Clinical Guidance

It is essential in the prescribing, dispensing and supply of controlled drugs that pharmacists and prescribers 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 scheduling of medicines containing controlled drugs (e.g. is a medicine a CD2 or CD3) (See Appendix 6)
- The online registration databases of both the Medical Council and the PSI: 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 PSI and the Health Information and Quality Authority (HIQA)
- National Clinical Guidelines from the National Clinical Effectiveness Committee and relevant faculties
- HSE Clinical Guidelines for Opioid Substitution Treatment (OST)
- HSE Medicines Management Programme Guidance on appropriate prescribing of Benzodiazepines and Z-drugs (BZRA) in the treatment of anxiety and insomnia
- Relevant international Guidelines from bodies such as the National Institute for Health and Care Excellence (NICE)
- All relevant legislation is available at www.irishstatutebook.ie

The above list is for ease of reference only and should not be considered exhaustive.

This guide is not a legal document. Its intention is to facilitate prescribers 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.
Appendix 1a
Example of Compliant Prescription for Schedule 2 and 3 CDs

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

Prescriber address not required for health prescriptions i.e. GMS prescription

4 May 2017

Joe Bloggs
Bloggstown
Co. Dublin

Please note: Addressographs (sticker with patient name and address) are not acceptable as they are not considered indelible, however, it is acceptable to either print or handwrite these details

Morphine Sulfate 10mg Tablet
Take One Tablet B.D.
56 Tablets (Fifty-Six)

Example of schedule 2 controlled drug

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

Installment instructions are not required to be handwritten

Dr John Doe

Note – Fine Blue font indicates handwritten details
Appendix 1b
Example of Compliant Prescription for Schedule 2 and 3 CDs

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

4 May 2017

Joe Bloggs
Bloggstown
Co. Dublin

Prescriber address not required for health prescriptions i.e. GMS prescription

Please note: Addressographs (sticker with patient name and address) are not acceptable as they are not considered indelible, however, it is acceptable to either print or handwrite these details

Oxycodone Hydrochloride 20mg Prolonged Release Tablets
Take One Tablet BID
5b Tablets (Fifty Six)

Example of schedule 2 controlled drug

Temazepam 10mg Tablets
Take one Tablet Noche Primera Mitte 21 Tablets (Twenty One)

Example of schedule 3 controlled drug

Dr John Doe

Note – Fine Blue font indicates handwritten details
Appendix 2
Example of Compliant Prescription Schedule 4 Part 1 CD

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

Prescriber address not required for health prescriptions i.e. GMS prescription

4 May 2017

Joe Bloggs
Boggstown
Co. Dublin

Please note: Addressographs (sticker with patient name and address) are not acceptable as they are not considered indelible, however, it is acceptable to either print or handwrite these details

Diazepam 5mg Tablets
Take One Tablet Nocte
7 Tablets (Seven)

These details do not need to be handwritten for a schedule 4 part 1 controlled drug prescription

Repeat x 2

Dr John Doe
Appendix 3
Example of a Compliant Requisition for Schedule 2, 3 and 4 Part 1 CDs

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

4 May 2017

Morphine Sulphate 10mg/ml Solution for Injection
Mitte 10 Ampoules

Midazolam 5mg/ml, 2ml Ampoules, Solution for Injection
Mitte 10 Ampoules

For use on-call: Patients receiving palliative care

Dr John Doe
### Appendix 4
Example of GMS Repeat Prescription for a Schedule 4 Part 1 CD

![Image of GMS Repeat Prescription](image)

**Prescriber address not legally required for health prescriptions**: GMS prescriptions. However, it is still best practice to include this.

**'Repeat' must always be stated on schedule 4 part 1 controlled drug repeat prescriptions, even on GMS repeat prescriptions**.
Appendix 5
Example of Methadone Prescription
Appendix 6

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

<table>
<thead>
<tr>
<th>Status</th>
<th>Authorised/Withdrawn</th>
<th>Authorised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence Issued</td>
<td>15/03/2013</td>
<td></td>
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<tr>
<td>Supply Status</td>
<td>Supply through pharmacies only</td>
<td></td>
</tr>
<tr>
<td>Dispensing Status</td>
<td>Product subject to prescription which may not be renewed (A)</td>
<td></td>
</tr>
<tr>
<td>Marketing Status</td>
<td>--Unknown--</td>
<td></td>
</tr>
<tr>
<td>Promotion Status</td>
<td>Promotion to Healthcare Professionals only</td>
<td></td>
</tr>
<tr>
<td>Conditions of Licence</td>
<td>This product contains a substance listed in Schedule 2 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988), as amended</td>
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</tr>
</tbody>
</table>
### Controlled Drug Prescription Requirements

<table>
<thead>
<tr>
<th>Legal Requirements</th>
<th>Schedule 2</th>
<th>Schedule 3</th>
<th>Schedule 4 Part 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written in Ink/Indelible</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Name (including the first name) of Practitioner</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practitioners' Registration Type and Number (e.g. medical, dentist, veterinary etc.)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date and Signature of Practitioner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address of Practitioner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Telephone Number of Practitioner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name (including the first name) and Address of Patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of Controlled Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose, Form and Strength of Controlled Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Quantity (in both words and figures)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeating Acceptable</td>
<td>×</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispense Within 14 days from Date of Issue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Must Not Be Dispensed Before Date of Issue on Prescription</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address of Practitioner is Within State</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency Supply Allowed ***</td>
<td>×</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*An addressograph is an adhesive label containing patient prescriber details such as name/address etc. They are not acceptable as they are not considered indelible however it is acceptable to either print or handwrite these details.

**A health prescription is, from a practical perspective, a GMS (General Medical Services) prescription

Note: Schedule 4 part 2 and schedule 5 medicines are to be written as per prescription requirements set out by Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. However emergency supplies of schedule 4 part 2 controlled drugs are also not permitted.

***Emergency supply exemption: methylphenobarbitone, phenobarbitone and phenobarbitone sodium may be given as an emergency supply for the treatment of epilepsy.
References

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. Regulation 16 (1)(f) of the Misuse of Drugs Regulations 2017
4. Misuse of Drugs (Safe Custody) Regulations 1982, as amended
5. Regulation 19 of the Misuse of Drugs Regulations 2017
6. Regulation 15 of the Misuse of Drugs Regulations 2017
7. Section 43 (8) Medical Practitioners Act 2007 and Regulation 15(2)(b) of the Misuse of Drugs Regulations 2017
8. Specific handwriting exemptions provided for Methadone and Schedule 4 Part 1 prescriptions, Regulation 15(4) of the Misuse of Drugs Regulations 2017
9. Regulation 8 (2)(c) and 8(3) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)
10. Regulation 14 of the Misuse of Drugs Regulations 2017
12. Regulation 15 (2)(d) of the Misuse of Drugs Regulations 2017