



AN RIALTÓIR CÓGAISÍOCHTA The pharmacy regulator

# Safe Prescribing and Dispensing of Controlled Drugs

Joint Guidance Medical Council and Pharmaceutical Society of Ireland



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.



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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.

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

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 <u>Misuse of Drugs Regulations 2017</u>.

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 <u>www.hpra.ie.</u> 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 <u>Medicinal Products (Prescription and</u> <u>Control of Supply) Regulations 2003, as amended</u>, 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 <u>Misuse of Drugs Regulations 2017</u>, '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<sup>1</sup>. 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<sup>1</sup>. 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 4<sup>th</sup> 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.

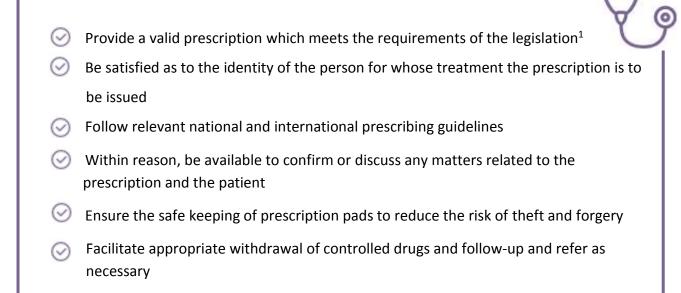
Additionally, medical practitioners and pharmacists, when registering with the Medical Council and the Pharmaceutical Society of Ireland (PSI) respectively, commit to adhering to professional standards and ethical guidelines set by their regulator.

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

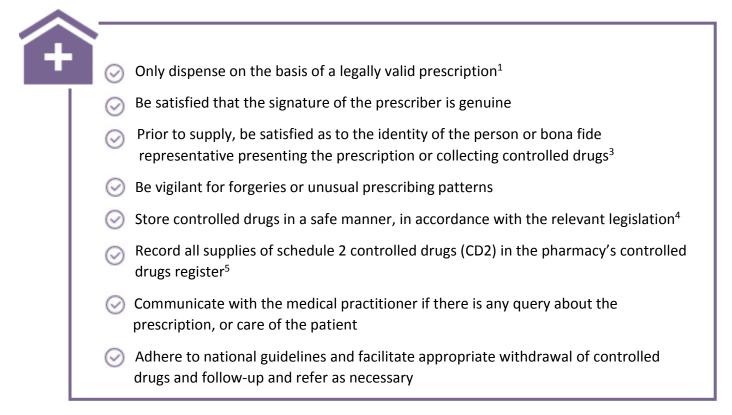
Pharmacists must adhere to the PSI's <u>Code of Conduct</u>. The Code of Conduct states that pharmacists must *'comply with medicines legislation'*.<sup>2</sup>

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



# 7. Pharmacist Obligations

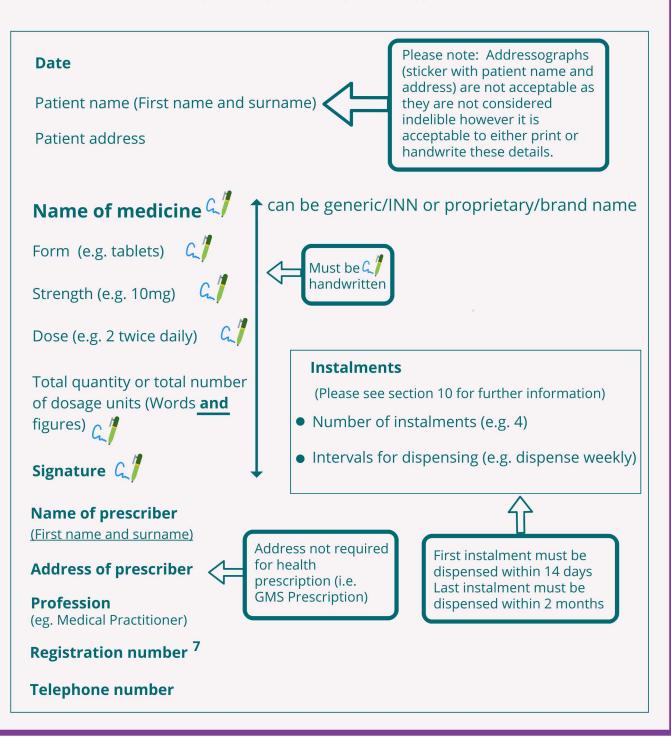


# 8. Prescriptions Required for CD2 and CD3 Drugs

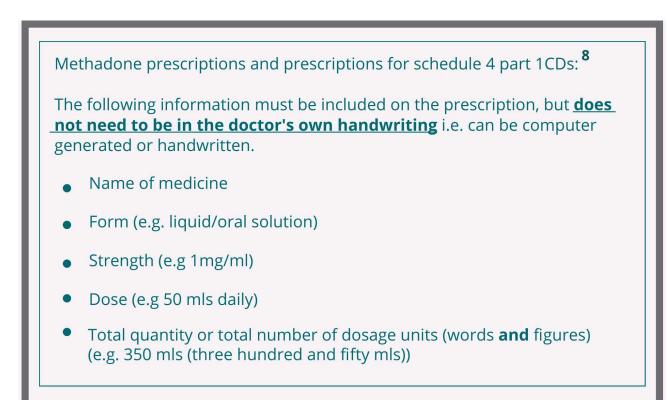
# Prescriptions Requirements for CD2 and CD3 Drugs<sup>6</sup>

(Including handwriting requirements) 年

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



# 9. Methadone Prescriptions and Prescriptions for Schedule 4 Part 1 CDs



### 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).<sup>9</sup>

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**<sup>10</sup>

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 <sup>7</sup>
- 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<sup>11</sup>. 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
- O 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**

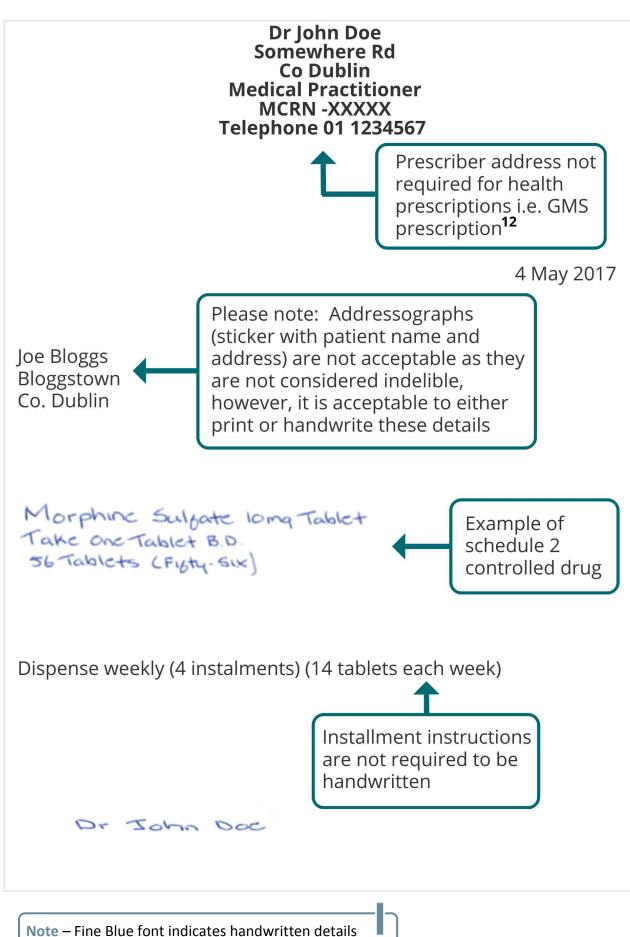
It is essential in the prescribing, dispensing and supply of controlled drugs that pharmacists and prescribers are aware of and have access to national resources, and adhere to current national and international guidelines. For example:

- Or 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 <u>Medical Council</u> and the <u>PSI</u>: 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 (<u>NICE</u>)
- O All relevant legislation is available at www.irishstatutebook.ie

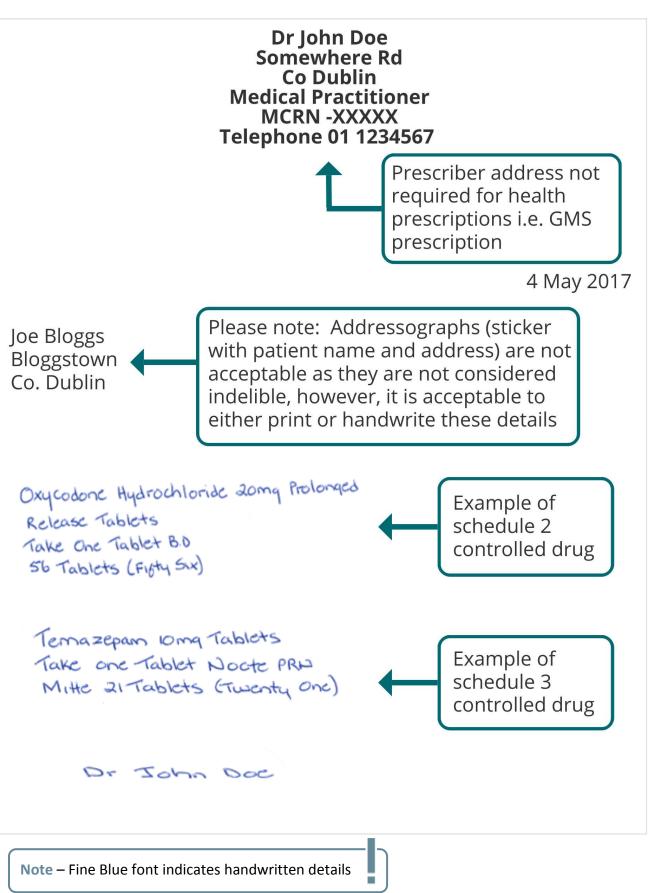
The above list is for ease of reference only and should not be considered exhaustive.

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.

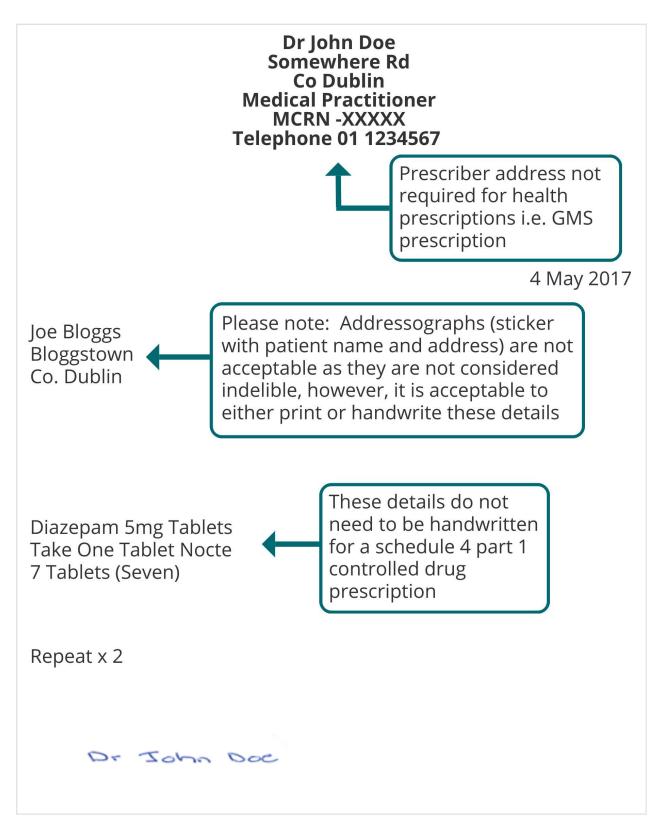
# Example of Compliant Prescription for Schedule 2 and 3 CDs



# Appendix 1b Example of Compliant Prescription for Schedule 2 and 3 CDs



# Appendix 2 Example of Compliant Prescription Schedule 4 Part 1 CD



# 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 -XXXXX 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 Doc

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

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# Appendix 5 Example of Methadone Prescription

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# Appendix 6

### HPRA Website – Information on Medicines Classification

### Step 1 – Access HPRA Home (<u>www.HPRA.ie</u>)

	Falow @TiteHPRA
HPRA An tÚdarás Rialála Táirgi Sláinte Health Products Regulatory Authority	Login Register Search aur website
ABOUT US MEDICINES VETERINARY MEDICAL DEVICES BLOOD, TISSUES, OR	IGANS COSMETICS CONTROLLED SUBSTANCES
Taking Medicines         Safely         We've launched a national information         campaign to highlight the importance of         taking medicines safely and effectively	And follow the directions that come with your medicine.
Find a medicine	l want to:
Medicines Veterinary Medicines Generics	Report an Issue Get foos
Enter a Traile Name, Active Substance or Ucence Number,      View all Medicines      Advanced Search	Q See guides & O Usit the Innovation Office

### Step 2 - Enter product name and select product

		ES BLOOD, TISSUES, ORGANS COSME	TICS CONTROLLED SUBSTANCES
medicines • medicines inform	ation × Find a medicine		
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Medicines Information			🖶 Print
Find a medicine	5 Microgram per hour	Transdermal Patch PPA1151/194/001	Summary of Product Characteristics
> Generic / Interchangeable List	Main Information		7 PARALLEL PRODUCT AUTHORISATION
Traditional Herbal Medicines	Trade Name	BUTRANS	HOLDER 8 PARALLEL PRODUCT AUTHORISATION
<ul> <li>Homeopathic</li> <li>Medicines</li> </ul>	Active Substances	BUPRENORPHINE	1 NAME OF THE MEDICINAL PRODUCT
> Vaccines	Strength	5 Microgram per hour	View More SPC Headings
> ATC codes	Dosage Form	Transdermal Patch	Latest Changes to Medicine Info & SPC
Safety Information			25 Aug 2018
> Safety Notices	Licence Holder	Imbat Limited	ATC Code(s) View all available
> Regulatory Information	Licence Number	PPA1151/194/001	Planas note changes to the medicine internetion and summary of perioduct
News & Events			characteristics are only evaluate from the 19/05/2015 prevents.
> Special Topics	Group Information		Changes made before this deta
Emergency Medicines	ATC Code	N02AE01 Orlpavine derivatives	annu avalance onne.

### 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 prescrip	ption 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					

# Appendix 7 Controlled Drug Prescription Requirements

Legal Requirements	Schedule 2	Schedule 3	Schedule 4 Part 1
Written in Ink/Indelible	Addressograph* not acceptable 🗸	Addressograph* not acceptable 🗸	Addressograph* not acceptable 🗸
Full Name (including the first name) of Practitioner	✓	✓	✓
Practitioners' Registration Type and Number (e.g. medical, dentist, veterinary etc.)	✓	✓	~
Date and Signature of Practitioner	✓	✓	✓
Address of Practitioner	Not required for a Health Prescription $\checkmark$	Not required for a Health Prescription	Not required for a Health Prescription $\checkmark$
Telephone Number of Practitioner	Sufficient if written on hospital value and the set of	Sufficient if written on hospital v patients bed card or medication record	Sufficient if written on hospital patients bed card or medication record
Name (including the first name) and Address of Patient	✓	✓	✓
Name of Controlled Drug	Must be handwritten	Must be handwritten	Not required to be handwritten 🛛 🗸
Dose, Form and Strength of Controlled Drug	Must be handwritten	Must be handwritten	Not required to be handwritten 🗸
Total Quantity (in both words and figures)	Must be handwritten	Must be handwritten	Not required to be handwritten 🗸
Repeating Acceptable	×	×	~
Dispense Within 14 days from Date of Issue	✓	✓	×
Must Not Be Dispensed Before Date of Issue on Prescription	✓	✓	✓
Address of Practitioner is Within State	✓	✓	✓
Emergency Supply Allowed ***	×	×	×

\*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

- 1. Misuse of Drugs Acts 1977 to 2016 and the Misuse of Drugs Regulations 2017
- 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
- 11. A Guide to Professional Conduct and Ethics for Registered Medical Practitioners (8th Edition, 2016) page 10, paragraph 4.4
- 12. Regulation 15 (2)(d) of the Misuse of Drugs Regulations 2017