FACTSHEET

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Safe custody and storage of Controlled Drugs (CDs)

All clinical staff working in GP practices who are involved in the supply, administration, storage, prescribing, and destruction of Controlled Drugs should ensure they have appropriate, timely, and up-to-date knowledge of the processes involved in managing such drugs.

GPs should be aware of their ethical obligations concerning Controlled Drugs as outlined in the Medical Councils Ethical Guide Paragraph 42.3 which states:

> *"When prescribing medications, you must comply with the Misuse of Drugs legislation and other relevant regulations and/or guidelines."*

The legislation governing the storage and supply of Controlled Drugs is covered under the Schedule of the Misuse of Drugs Act 1977, which was subsequently amended by legislation and further Misuse of Drugs Regulations.

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). An example of Controlled Drugs in each schedule can be found in the following joint guidance document from the Irish Medical Council and the Pharmaceutical Society of Ireland available here.

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)

Table 1 The above table contains examples only of Controlled Drugs and is not an exhaustive list. Extract from Safe Prescribing and Dispensing of Controlled Drugs[1]

This guidance is specifically aimed at providing General Practice staff with some practical tips to ensure compliance with the legislation in relation to the safe storage and custody of Schedule 2 Drugs.

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Controlled Drugs Register

All information regarding the supply, dispensing, destruction, and stock check of Controlled Drugs must be detailed in the Controlled Drugs register. The Controlled Drugs register should be:

- Kept on the premises at all times and available for inspection if required
- Written in chronological order and in ink or otherwise so indelible
- Have separate pages for each drug
- Illustrate the class of each drug at the head of each page
- Entries should be made on the date and time of dispensing of each drug
- Any corrections, obliterations, or alterations should be made in ink or otherwise so indelible in the margin or as a footnote and must be dated and signed

All Controlled Drugs Registers must be preserved for a period of two years from the date on which the last entry was made.

Ordering, dispensing, and stock check

All drugs ordered must show:

- The date the drug was received
- The name and address of the person or pharmacy from whom they were supplied
- The amount received i.e. amount of tablets, vials, or liquid
- The form and strength that were supplied

Stock levels should be checked regularly by two members of the practice team of which one should be a clinician, to ensure that no drugs are missing and to check the expiry dates of all drugs. Details of the stock check should be dated and timed and include the signatures of both staff members undertaking the task.

Drugs supplied/dispensed to patients

Once a controlled drug has been prescribed by a GP for dispensing within the practice, details of the drug dispensed to the patient must be entered into the controlled drug register as well as in the patient's clinical record. Before administration, the drug should be checked by two persons, ideally both clinicians. We understand this may not always be possible in a single-handed GP practice. Controlled drug entries must show:

- The date and time the drug was administered
- The strength and amount of the drug administered
- The name and registration number(s) (i.e. MCN and/or NMBI) of the staff involved in the checking/administration process
- Any waste if applicable
- The running balances of each drug

Secure custody storage of Controlled Drugs

Controlled Drugs should be stored within a locked cabinet, which is either fixed to the wall or floor. A designated person should be nominated within the practice as having overall responsibility for the Controlled Drugs cabinet. The keys to the cabinet should be kept in a designated area. The whereabouts and access to these keys should only be known by the clinically relevant members of staff. Alternatively, a digital combination lock may be a convenient solution. No unauthorised members of staff should have access to the keys or code of the combination lock.

January 2023

The stock of Controlled Drugs should be kept to a minimum and no signage/notice etc should be displayed outside to indicate that Controlled Drugs are kept within the locked cabinet.

Procedure for broken vials and disposal of out-of-date/unused Controlled Drugs

- If a liquid container or vial of a controlled drug is accidentally broken, details of the drug should be entered into the Controlled Drug Register, as with the procedure for giving the drug.
- The entry should be signed by the member of staff who broke the vial and witnessed by another staff member.
- Both staff must then witness the disposal of the broken vial into the sharps container.
- Any unused or expired Controlled Drugs should be returned to the pharmacy. The HSE Primary Care pharmacist will usually be able to advise in accordance with local best practice guidelines.

Procedure for a missing or unaccounted Controlled Drug

- All staff should be made aware that there is a controlled drug missing or unaccounted for.
- Two members of staff, ideally both clinicians should repeat the stock count.
- The time and date of the discovery of the missing drug should be noted in the control drug register.
- A Significant Event Analysis (SEA) should then be undertaken in line with the practice policy of managing such events.
- It may be necessary to inform An Garda Síochána or your local Primary Care Community Pharmacist of the missing controlled drug for further advice.

Controlled Drugs and the doctor's bag

- Where a GP requires a controlled drug for their doctor's bag, the new item should be entered on the appropriate page of the Controlled Drugs register. This entry should be made by two members of staff. This entry should indicate that the item is for the GP's bag.
- GPs should be mindful of the custody of Controlled Drugs when carrying out house calls. A doctor's bag once locked, is considered a suitable "locked receptacle".
- A doctor's bag containing Controlled Drugs should not be left in a vehicle overnight or for long periods and should be stored out of sight and locked in the boot of a car during transportation.

Controlled Drugs returned by a patient or their representatives

Patients should be advised to return all unused drugs for safe disposal to their local community pharmacist. In addition, when Controlled Drugs are dispensed, patients should also be advised of the caution they need to take when storing them in their own homes. They should also be advised to return any unused stock from their own home as soon as possible.

If you store Controlled Drugs in your practice, now might be an opportune time to undertake a risk assessment or practice audit to ensure you are compliant with the legislation.

Please do not hesitate to contact us at Medisec for specific advice and guidance.

References

January 2023

1. The Medical Council and Pharmaceutical Society of Ireland, *Safe Prescribing and Dispensing of Controlled Drugs,* (October 2017) PSI_and_Medical_Council_Joint_guidance.sflb.ashx (thepsi.ie)

The contents of this publication are indicative of current developments and contain guidance on general medico-legal queries. It does not constitute and should not be relied upon as definitive legal, clinical or other advice and if you have any specific queries, please contact Medisec for advice.

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