Veterinary Council of Ireland

Controlled Drugs Guidance

Guidance and recommendations from the Veterinary Council of Ireland for veterinary professionals and veterinary practices in the management of controlled drugs

Contents

Controlled Drugs Guidance

Background

Registered veterinary practitioners and registered veterinary nurses have legal and professional responsibilities in relation to veterinary medicines. These are summarised in Chapter 5 of the Veterinary Council of Ireland's **Code of Professional Conduct for Veterinary Practitioners**. The use of controlled drugs ("**CDs**") in veterinary practice requires careful legal and professional consideration and must be strictly managed by veterinary professionals. Veterinary professionals involved in the storage, safekeeping, dispensing, record-keeping, destroying, and management of CDs must comply with national legislation on the misuse of drugs.

There are strict rules in place, both nationally and internationally, around the supply and administration of CDs. Regulation of CDs within veterinary practices in Ireland is governed by the Misuse of Drugs Acts and Regulations. Due to the serious nature of the drugs and their substantial potential for abuse and misuse, these rules are implemented to ensure safe access to CDs. These rules include restrictions on the people who can obtain or possess controlled drugs, and the strict legal obligations placed on prescribers charged with responsibility for the safe control of these substances. The relevant legislation describes in detail how CDs must be managed in veterinary practice, and veterinary professionals are expected to be familiar with the legislation and to be in strict compliance with it, for the safety and security of clinical teams, clients, and the public.

Purpose of this Guidance

This document is an informational guide for veterinary professionals in the State to assist the safe management of controlled drugs at registered veterinary premises in line with relevant legislation and best practice, and in the interest of safety for practice staff and the public.

Substances that are categorised as controlled drugs are listed in Schedules 1 to 5 of the Misuse of Drugs Regulations 2017, as amended.

The Veterinary Council of Ireland ("the Council") aims to facilitate safe management of controlled drugs at veterinary premises, with a particular focus on the management and safe custody requirements for controlled drugs listed in Schedules 2, and 3 of the Misuse of Drugs Regulations 2017, as amended. It is recommended that this guidance document is used by all veterinary professionals in their management of controlled drugs.

This document should not be viewed as standalone guidance on controlled drugs and should be read in conjunction with the relevant legislation available at **www.irishstatutebook.ie**:

- **Misuse of Drugs Act 1977 (as amended)**
- **Misuse of Drugs Act 1984**
- **Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017) (as amended)**
- **Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982)**
- **European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 (S.I. No. 36 of 2022)**

The Role of the Veterinary Council

The principal function of the Council is to regulate and manage the practice of veterinary medicine and veterinary nursing in the Republic of Ireland/the State in the public interest. The function of the Council also extends to the regulation and oversight of the practice of veterinary medicine at veterinary premises in the State, and to setting minimum standards for veterinary premises through the Premises Accreditation Scheme.

The Council, through the Premises Accreditation Scheme ("**PAS**"), sets down the minimum requirements for the safe management of veterinary medicines at registered veterinary premises. PAS Standard 4.2 requires that the storage, safekeeping, dispensing, record-keeping, and management of veterinary medicinal products, including controlled drugs, at a veterinary premises must be in conformance with the Veterinary Product Authorisation, Animal Remedies Regulations, the Misuse of Drugs Acts, and the Code of Conduct for Veterinary Practitioners.

Independently contracted Authorised Officers who inspect veterinary premises on behalf of the Council will investigate whether a premises is in compliance with requirements. If a premises is found to be not in compliance with the requirements as regards medicines, an Authorised Officer will report these findings to the Council. On receipt of such findings, the Council may take appropriate and proportionate action as it deems necessary, up to and including the revocation of the premises' registration and accreditation status, and the initiation of an investigation into the fitness to practise of registered persons practising at or from the premises.

The Council, through the introduction of this guidance in relation to controlled drugs, aims to support veterinary professionals in their compliance with legal requirements and to ensure robust and safe management of controlled drugs at veterinary premises in the interest of staff and patient safety, and public safety.

The Role of the Health Products Regulatory Authority

The Health Products Regulatory Authority ("**HPRA**") regulates medicines, clinical trials, and medical devices in the State in the interest of both public and animal health. The HPRA also performs inspections on behalf of the Department of Health for the purpose of granting controlled drug licences. It grants licences for medicines in line with national and EU legislation to companies who make, distribute and market them in Ireland, and as part of this process it audits manufacturers and wholesalers by carrying out inspections to ensure compliance with standards and legislation. The HPRA monitors the safety, quality, and effectiveness of medicines and veterinary medicines available in the State and is the point of contact for reporting adverse effects and quality problems regarding veterinary medicinal products. The HPRA informs veterinary practitioners and other healthcare professionals of any new product safety or quality information which emerges in relation to licensed medicines.

The Role of the Department of Agriculture, Food, and the Marine

The role of the Department of Agriculture, Food, and the Marine ("**DAFM**"), in the context of veterinary medicines, is to regulate the wholesale, retail and usage of veterinary medicinal products and to verify compliance with EU and National Legislation. The Department fulfills this role through a broad range of inspection activities including veterinary practice inspections. As part of these veterinary practice inspections, officers authorised by DAFM evaluate the controls in place for the safe usage and storage of controlled drugs.

Frequently Asked Questions (FAQs)

1. **What is the purpose of the Controlled Drugs Guidance document?**
   - This document provides guidance for veterinary professionals in Ireland on the safe management of controlled drugs at registered veterinary premises, in line with relevant legislation and best practices.

2. **What are controlled drugs (CDs)?**
   - Controlled drugs are substances, products, or preparations subject to control under the Misuse of Drugs Acts and Regulations. They are listed in Schedules 1 to 5 of the Misuse of Drugs Regulations 2017 (as amended).

3. **Which controlled drugs are commonly used in veterinary practice?**
   - Commonly used CDs include:
     - Schedule 2: Buprenorphine, Butorphanol, Codeine, Etorphine, Fentanyl, Methadone, Morphine, Pethidine, Quinalbarbitone
     - Schedule 3: Ketamine, Pentobarbitol, Phenobarbital
     - Schedule 4: Alprazolam, Diazepam, Midazolam
     - Schedule 5: Non-injectable preparations of Codeine, Dihydrocodeine, Morphine

4. **What are the requirements for maintaining a Controlled Drugs Register (CDR)?**
   - A CDR must be maintained for Schedule 2 CDs, recording all obtained and supplied CDs in chronological order with a running stock balance. It must be a bound book, not contain loose-leaf pages, and be preserved for two years from the last entry. There must be a separate register or separate part of a register for entries made in respect of each CD. Further information on what must be included in the CDR is found here.

5. **How should Schedule 2 and 3 controlled drugs be stored?**
   - They must be stored in a secure safe or cabinet that complies with the Misuse of Drugs (Safe Custody) Regulations 1982, secured to a wall or floor, locked when not in use, and kept out of public view. There must be no indication on the outside of the safe or cabinet that it contains controlled drugs. More information on the storage of CDs is available here.

6. **Who can access the keys to the controlled drugs safe or cabinet?**
   - Only authorised members of staff, such as a Registered Veterinary Practitioner or a nominated responsible person like a Registered Veterinary Nurse, can access the keys. Further information regarding CD safe keyholders is available here.

7. **What should be done if controlled drugs are carried in a vehicle?**
   - CDs should be transported in a locked glove compartment or lockable container, kept out of sight, and removed from the vehicle when not in use, especially overnight. More information regarding transporting CDs is available here.

8. **What are the procedures for the destruction and disposal of controlled drugs?**
   - CDs must be destroyed in a manner rendering them irretrievable, witnessed by an authorised person, such as a member of An Garda Síochána, and records of destruction must be kept for two years. Methods include using denaturing kits, mixing liquids with sawdust or cat litter, and crushing tablets with soapy water. More information regarding the destruction and disposal of CDs is available here.

9. **What should be done if there is a discrepancy in the Controlled Drugs Register?**
   - Discrepancies should be recorded, investigated, and corrected with a marginal note or footnote. Regular audits and reconciliations should be conducted to ensure accuracy. More information is available here.

10. Who can prescribe controlled drugs for animals?

- Only a Registered Veterinary Practitioner can prescribe CDs for animals, following a clinical examination or proper assessment of the animal's health status.

11. What should be done if there is a suspicion of prescription misuse?

- Any reasonable suspicion of prescription misuse should be reported to An Garda Síochána, as it is in the public interest to do so. More information is available here.

12. Can Registered Veterinary Nurses administer controlled drugs?

- Yes, provided a Registered Veterinary Practitioner has prescribed the drug, decided on the dose, and authorised the administration. The legal responsibility remains with the Registered Veterinary Practitioner.

13. What are the key points to remember for managing controlled drugs in veterinary practice?

- Maintain compliance with legislation, have SOPs in place, keep a CDR for Schedule 2 CDs, store CDs securely, have appropriate keyholder arrangements, ensure safe transport of CDs, have written policies for destruction and disposal, and report any prescription misuse.

Chapter 1
Guidance

Controlled Drugs - Definition

A controlled drug (**"CD"**) is any substance, product or preparation that is subject to control under the Misuse of Drugs Acts and Misuse of Drugs Regulations. Specifically, those drugs that are listed as a Schedule 1, 2, 3, 4, or 5 CD in the Misuse of Drugs Regulations 2017 (as amended).

CDs are closely regulated because they are susceptible to being misused or diverted and can cause harm. Registered Veterinary Practitioners are bestowed with the privilege of prescribing veterinary medicinal products and must remain vigilant of the responsibility that such privilege and access carries.

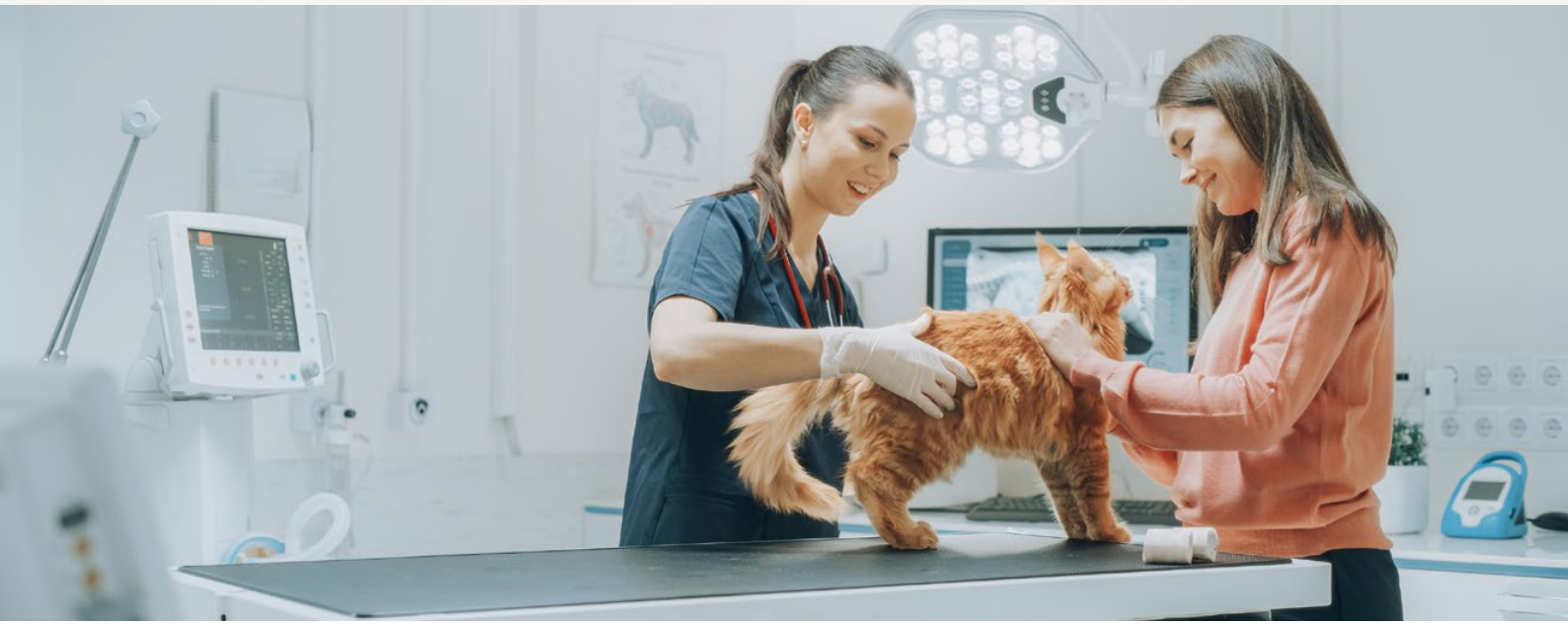
Misuse of Drugs Regulations 2017 (as amended):

Registered Veterinary Practitioners should be familiar with the provisions of the Misuse of Drugs Regulations 2017 (as amended) which include lists of controlled drugs in schedules and set out certain requirements that veterinary practitioners must comply with in relation to such drugs. Substances that are categorised as controlled drugs are provided within schedules in the regulations, however, schedules are subject to updates periodically.

The current revision of the regulations can be accessed in the **Irish Statute Book** online.

Updates to the regulations are also published online on the **Health Products Regulatory Authority** website.

If a veterinary practitioner or a veterinary nurse is in any doubt about the status of a particular drug, they can submit a query to the HPRA by email to **controlleddrugs@hpra.ie**.



Controlled Drugs Used in Veterinary Practice

There are five schedules of CDs in Irish legislation. Veterinary professionals should ensure sufficient familiarity with the CDs listed in Schedules 2, 3, 4, and 5 of the Misuse of Drugs Regulations 2017, as amended. *Schedule 1 CDs are not authorised for use in veterinary medicine under any circumstances.*

CDs that are more commonly used in veterinary practice:

CD Schedule	Controlled Drug Name
Schedule 2	Buprenorphine Butorphanol Codeine Etorphine Fentanyl Methadone Morphine Pethidine Quinalbarbitone
Schedule 3	Ketamine Pentobarbitol Phenobarbital
Schedule 4	Alprazolam Diazepam Midazolam
Schedule 5	Non-injectable preparations of: Codeine Dihydrocodeine Morphine

Table 1.1: *Controlled Drugs common to veterinary practice*

The Controlled Drugs Register in Respect of Schedule 2 and 3 Controlled Drugs

A Controlled Drugs Register (**"CDR"**) must be maintained at any veterinary premises where Schedule 2 CDs are kept in stock. Registered Veterinary Practitioners must record in their CDR, in chronological sequence and in a manner which will show a running stock balance, all Schedule 2 CDs that have been obtained and supplied by them. They must use a separate register or separate part of a register for entries made in respect of each class of drug and the entries in the register must be in the form specified in Schedule 6 of the Misuse of Drugs Regulations 2017, or as the case may require, in the form specified in Part 1 or Part 2 of Schedule 7 of the Misuse of Drugs Regulations 2017.

While it is not a requirement that a CDR is kept in respect of Schedule 3 CDs, it is good practice to keep a separate register for Schedule 3 CDs with a running stock balance, maintained in the same way as for Schedule 2 CDs.

In accordance with the Misuse of Drugs Regulations 2017 the CDR must be a bound book and must not contain any loose-leaf register pages or card index.

Audit and reconciliation can be achieved by recording supply and use, keeping a running total in the CDR, and having a system of reconciling the balance in the CDR with the stock in the CD safe. Audit and reconciliation should be carried out regularly at the veterinary practice, and discrepancies should be recorded and, where necessary, investigated.

The CDR can be maintained by a suitably trained person e.g. a Registered Veterinary Nurse, but ultimate responsibility lies with the Registered Veterinary Practitioner. Once tallied, the balance in the CDR should be marked as checked and signed. The balance check in the CDR should be counter-signed by the responsible Registered Veterinary Practitioner on a frequent basis. If this is carried out daily (or at least weekly depending on workload), discrepancies are much easier to trace. All entries in the CDR should be countersigned.

Veterinary practices must carry out audits of the CDR continuously. Authorised Officers when inspecting a veterinary premises will ask to see evidence that the CDR is being used and maintained appropriately.

Misuse of Drugs Regulations 2017 (as amended):

In accordance with Regulation 19 of the Misuse of Drugs Regulations 2017, Registered Veterinary Practitioners must comply with the following requirements in respect of the Controlled Drugs Register:

a) The class of controlled drug to which the entries on any page of the CDR relate, must be specified at the head of that page;

b) Each entry in the CDR must be made on the day when the controlled drug is obtained where it is reasonably practical to do so, or on the day when the transaction to supply the controlled drug is completed, or in any case on the following day;

c) No cancellation, obliteration, or alteration of an entry in the CDR must be made. The correction of an entry must be made only by entering a marginal note or footnote adjacent to the entry, which must specify the date on which the correction is made;

d) Every entry to the CDR and any correction of an entry must be made in ink so as to be indelible;

e) The CDR must not be used for any purpose other than recording entries in compliance with the requirements of the Misuse of Drugs Regulations 2017;

f) Where it is necessary to keep separate registers in respect of difference classes of controlled drugs, only one register must be kept at one time in respect of each class of controlled drug;

g) A separate CDR must be kept in respect of each premises at which the person required to keep the register carries on their business or occupation. Where the business is carried out in separate departments within a premises, a separate register may, with the approval of the Minister for Health, be kept in respect of each such department; and

h) Every CDR in use by a premises must be kept at the premises to which it relates and must be readily available for inspection.

In accordance with Regulation 22 of the Misuse of Drugs Regulations 2017, the CDR must be preserved for a period of two years from the date on which the last entry is made within it. In addition, every order, invoice, prescription or requisition on which a CD has been supplied to or by a registered veterinary practitioner must be preserved for a period of two years from the date of supply.

Safe Custody Requirements in Respect of Schedule 2 and 3 Controlled Drugs

To meet safe custody requirements, Schedule 2 and Schedule 3 controlled drugs must be stored in a secure safe or cabinet which complies with the requirements of the **Misuse of Drugs (Safe Custody) Regulations 1982**, and is used solely for the storage of medicinal products. This safe or cabinet must be secured to a wall or floor and must be locked when not in use and kept away from public view. There must be no indication on the outside of the safe or cabinet that it contains controlled drugs. The keys to the safe or cabinet must only be available to authorised members of staff who have appropriate training. It is recommended that the room housing the locked safe or cabinet should be lockable and tidy to avoid drugs being misplaced and should not be within view or accessible to the public.

While it is not a requirement in legislation, it is recommended that Schedule 4 and 5 CDs are also stored in a safe or cabinet that complies with the below requirements.

- The safe or cabinet must bear the inscription I.S. 267:1985 or at least comply with requirements set out in the Misuse of Drugs (Safe Custody) Regulations 1982.
- The safe or cabinet must be constructed of sheet steel not lighter than 16 gauge.
- The safe or cabinet must be secured by at least two bolts to the building's concrete wall or floor.
- The safe or cabinet must be double-locked with separate keys, or have a combination lock.
- The lock must be different to any other lock in the premises.
- Keys must only be made available to authorised staff members.
- The safe or cabinet must be kept out of public view.
- The safe or cabinet must not have anything on or around it which identifies it as CD storage.
- The safe or cabinet must be kept locked at all times when not in use.

Keys and Keyholders

Practices should have appropriate security arrangements for keys and keyholders. CD safes or cabinets must only be accessed by a Registered Veterinary Practitioner or a nominated responsible person at the practice such as a Registered Veterinary Nurse. For example, a locum veterinary practitioner may need to have access to the key, if they are in sole charge. A keyholder who is not a Registered Veterinary Practitioner should only remove CDs from the cabinet and/or return them to the cabinet on the specific authority of a Registered Veterinary Practitioner. While the task itself can be delegated, the legal and professional responsibility will remain with the Registered Veterinary Practitioner. Keys, and spare keys, to the locked safe or cabinet should also not be kept with keys to other parts of the building. Practices may consider auditing and recording individual access to keys, with a witnessed key signing-in and out procedure. However, all Registered Veterinary Practitioners may also have their own key, such that a signing-in and out protocol would not be required. In cases where a combination lock is used, it is recommended that the combination number is changed any time a staff member leaves the practice.

Vehicles

If a Registered Veterinary Practitioner carries CDs in their vehicle, they must take reasonable steps to prevent unauthorised access. CDs should be transported in a locked glove compartment or in a lockable container which should be kept locked when not in use. Any such container should be kept out of sight.

Registered Veterinary Practitioners should use their professional judgement when storing CDs in vehicles. This might require them to consider particular risk factors, such as whether practice vehicles are easily identifiable as such, whether the practice or practice vehicles have been targeted in the past and the locations at which practice vehicles are parked.

Registered Veterinary Practitioners should avoid, as much as possible, the storage of CDs in a vehicle overnight or when the vehicle is otherwise not in use. Registered Veterinary Practitioners considering leaving CDs in their vehicle overnight may have additional considerations. When a vehicle is unoccupied it is recommended that CDs are removed from the vehicle and returned to the practice CD safe. Practitioners should also liaise with their vehicle insurance provider to ensure they are appropriately covered to carry CDs in their vehicle.

Destruction & Disposal of Controlled Drugs

It is important for veterinary premises to have written policies and procedures in place setting out a clear process for the destruction and disposal of controlled drugs that is in accordance with applicable legislation.

Before disposing of wasted, expired, residual, or returned CDs, Registered Veterinary Practitioners must ensure that they are destroyed, rendering them irretrievable.

The destruction of Schedule 2, 3, and 4 CDs at a veterinary premises must be witnessed by a person authorised by the Minister for Health in accordance with the Misuse of Drugs Regulations 2017, such as a member of An Garda Síochána. Records of destruction must be retained for a period of two years. *See below section on Witnesses and Records for the Destruction of Controlled Drugs.*

Destruction of CDs should occur with sufficient frequency to ensure that excessive quantities are not stored at a premises awaiting destruction. The frequency should be determined by the practice following a risk assessment and determined based on the quantities used and the frequency of use of CDs at the premises.

There are various acceptable methods of destroying CDs:

- Out-of-date stock and CDs returned by clients can be denatured using commercially available denaturing kits, available for purchase from veterinary and pharmaceutical wholesalers, where the specific instructions for their use are followed carefully. Used kits can then be sent as pharmaceutical waste to be disposed of.
- As they are usually in smaller quantities, wasted or residual CDs in liquid form can be rendered irretrievable by collection into sawdust or cat litter which can then be sent as pharmaceutical waste to be disposed of.
- CDs in tablet form can be rendered irretrievable by crushing them and mixing them with soapy water, which can then be sent as pharmaceutical waste to be disposed of.
- In relation to adhesive transdermal patches, they can be cut up or the backing can be removed, and the patch folded over onto itself rendering it irretrievable, patches can then be transferred to pharmaceutical waste to be disposed of.

CDs that have been destroyed appropriately can be sent as pharmaceutical waste and disposed of by the practice pharmaceutical waste contractor.

Storage of Controlled Drugs for Destruction

Registered veterinary practitioners are not permitted to sell or supply any CDs which have been returned by a client, are damaged, or are out of date.

Returned, expired, or damaged Schedule 2 and Schedule 3 CDs must be stored in the controlled drugs safe or cabinet until they are destroyed. It is recommended that returned, expired, or damaged Schedule 4 CDs are also stored in the controlled drugs safe until they are destroyed.

To avoid the risk of inadvertently administering or supplying these drugs, veterinary practitioners must:

- Segregate these CDs from active stock within the safe or cabinet, and,
- Clearly label them as 'CDs for destruction'.

Returned CDs, expired CDs or damaged stock should not be allowed to accumulate in the controlled drugs safe or cabinet as this will increase the risk for errors to occur.

Witnesses and Records for the Destruction of Controlled Drugs

Destruction of CDs specified in Schedules 2, 3 and 4 of the Misuse of Drugs Regulations 2017, must be carried out and witnessed in accordance with the regulations. The destruction of CDs at a veterinary premises, when in relation to out-of-date, unused, damaged, or returned stock, must be carried out in the presence of a person authorised by the Minister for Health in accordance with the Misuse of Drugs Regulations 2017, such as a member of An Garda Síochána.

Clarification from the Department of Health on whether Registered Veterinary Practitioners may witness the destruction of CDs is currently pending. In the meantime, the Council recommends that the destruction of CDs at veterinary practice premises is witnessed by a member of An Garda Síochána.

Legislation requires practices to keep a record of the witnessed destruction of CDs at the premises. Such records must include the name, strength and form of the controlled drug, the quantity destroyed, the date of destruction, the destruction method used, and the signature of the person who witnessed the destruction of the controlled drugs. In accordance with the Misuse of Drugs Regulations 2017, records of destruction of CDs must be retained at the premises for a period of two years from the date the CDs were destroyed.

Audit & Discrepancies in the Controlled Drugs Register

Registered Veterinary Practitioners must regularly review the CDR to ensure they can satisfy themselves that the CDR has been completed correctly for all CDs. This review should include a balance check to ensure that the balance recorded in the CDR reflects the volume of all CDs present at the premises.

Liquid Controlled Drugs

Manufacturer's bottles of liquid CDs contain a small 'overage' in some cases. The extra liquid can cause a premises to have a slightly higher volume of CDs than expected in certain circumstances.

The frequency with which the CDR is reviewed should be determined by practice procedure. This may vary from practice to practice and will depend on the frequency of CD use, the volume of CDs dispensed, previous stock balance discrepancies etc.

To carry out a balance check, it is necessary for Registered Veterinary Practitioners to calculate the total volume of each CD product which is physically present at the premises, including:

1) The total volume of the full bottles of each product, and;

2) The total volume of open bottles of each product.

The total volume of liquid for each product (closed bottles plus open bottles) should then be compared against the balance recorded in the CD register for this product.

If the actual volume of the liquid in stock differs from the running balance recorded in the CDR for a CD product, it will be necessary to investigate the reason for the difference. A Registered Veterinary Practitioner should verify if:

- all receipts (invoices) have been correctly entered;
- all supplies (prescriptions, requisitions) have been correctly entered;
- any entries have been duplicated in error;
- any other errors have taken place.

If there is excess liquid stock compared to the expected balance and the Registered Veterinary Practitioner is satisfied that this is due to 'overage' from the manufacturer's bottles, the running balance may be adjusted to reflect the current stock level. This entry should be signed by the Registered Veterinary Practitioner and annotated to show that the adjustment is the result of 'overage'.

Amendments and Discrepancies

The details of any necessary correction or amendment to the CDR should be recorded in the footnote section at the bottom of the relevant page in the CDR. It may be necessary to demonstrate the workings of the reconciliation/investigation on a separate document. This should be retained with the CD register.

The Standard Operating Procedures ("**SOPs**") at the practice should clearly define the action that should be taken if a discrepancy between the CDR balance and the actual balance is identified, for example:

- What action the veterinary practitioner should take;
- When and how the premises Certificate of Suitability Holder and management should be notified;
- What records should be made, and;
- When the Gardaí should be notified.

In general, discrepancies of up to 10% should not cause undue concern.

Prescriptions & Prescribing

Only a Registered Veterinary Practitioner may prescribe a CD for an animal.

Registered Veterinary Practitioners who dispense CDs must obtain them in compliance with applicable legislation. Irrespective of the legal route of supply, the use and prescribing of CDs by Registered Veterinary Practitioners should demonstrate prudent practice, which is evidenced in the clinical records, in the interests of animal health, welfare and public health.

What constitutes prudent prescribing practice can vary depending on the medicinal product, the species, the number of animals and the environment in which they are treated. Registered Veterinary Practitioners should be mindful of the privilege extended to them where 'Prescription Only Medicines' are concerned. When providing a prescription for medicinal products for animals, Registered Veterinary Practitioners must only prescribe such products after a clinical examination, or any other proper assessment of the health status of the animal or group of animals has been carried out.

A prescription for a controlled drug must be in accordance with Section 15(2) of the of the Misuse of Drugs Regulations 2017:

Form of prescriptions for Schedule 2 and 3 drugs;

(a) the prescription shall be in ink or otherwise so as to be indelible;

(b) the prescription shall clearly indicate the full name (including the first name) of the registered veterinary practitioner and state their registration number;

(c) the prescription shall be signed by the practitioner issuing it with their usual signature and be dated by them;

(d) except in the case of a health prescription, the prescription shall specify the address of the practitioner issuing it;

(e) subject to paragraph (3), the prescription shall specify the telephone number at which the practitioner issuing it may be contacted;

(f) subject to paragraph (3), the prescription shall specify the name (including the first name) and address of the person to whom the controlled drug prescribed is to be delivered;

(g) subject to paragraph (4), the prescription shall specify in the practitioner's handwriting—

  (i) the name of the controlled drug to be prescribed,

  (ii) the dose of the controlled drug to be taken by the animal for whose treatment the prescription is issued,

  (iii) in the case of a prescription for a controlled drug which is a preparation—

(I) the form and, where appropriate, the strength of the controlled drug to be supplied, and

(II) either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied, and

(iv) in the case of a prescription for a controlled drug which is not a preparation, the total quantity (in both words and figures) of the controlled drug to be supplied.

Registered Veterinary Practitioners must advise clients on how CDs should be administered to their animals and demonstrate administration where appropriate. They should also advise on any likely side effects. Registered Veterinary Practitioners should also advise clients on the appropriate storage and disposal of prescribed CDs.

Reporting Prescription Misuse

Prescription misuse can involve (a) the alteration of an existing prescription, or (b) prescription fraud. Examples of prescription fraud include supplying the same prescription to multiple retailers for supply and/or forging the signature of a Registered Veterinary Practitioner. If a Registered Veterinary Practitioner has a reasonable suspicion of prescription misuse, they should report it to An Garda Síochána. It is in the public interest to report prescription misuse, and this overrides any obligations related to client confidentiality and data protection.

Further guidance in relation to prescribing is available to veterinary practitioners in Chapter 5 of the Council's **Code of Professional Conduct for Veterinary Practitioners**.

Registered Veterinary Nurses

A Registered Veterinary Nurse may draw up and administer a CD provided that a Registered Veterinary Practitioner has prescribed the drug to a specific animal, decided on the dose, has authorised that it be drawn up and is confident that the Registered Veterinary Nurse is competent to draw up and administer the prescribed dose. A Registered Veterinary Practitioner does not need to be present when the CDs are drawn up or administered, but the legal responsibility for the supply of the CDs remains with the Registered Veterinary Practitioner. For this reason, it is important that appropriate safeguards are in place. It is good practice, for example, for veterinary practices to have a standard operating procedure which sets out the procedures around access to CDs and the protocol for recording their use.

Standard Operating Procedures

Standards Operating Procedures ("**SOPs**") provide clarity and consistency for all practice staff handling CDs. SOPs should clearly outline a process and define who in the practice is responsible for the tasks outlined. SOPs are working documents and should be kept relevant and up to date, reflecting current legal and best practice requirements. Sufficient staff training should also be provided as necessary.

At a minimum, SOPs should be maintained at registered veterinary premises which cover the below points as regards the management of CDs:

- Sourcing/ordering of CDs
- Storage and record keeping of CDs
- Sale and supply of CDs to the public by Registered Veterinary Practitioners
- Dispensing and administration of CDs by Registered Veterinary Nurses under the direction of a Registered Veterinary Practitioner

- Prescribing of medications
- Audit and reconciliation of the Controlled Drugs Register
- Error and incident management
- Destruction and disposal of CDs
- Procedures for locum Registered Veterinary Practitioners
- Key Holder policy for the premises and CD safe
- Housekeeping and cleanliness of CD safe, dispensary, and safe location

Key Points to Remember

It is important for veterinary professionals to remember the privilege afforded to them where prescription only medicines and where CDs are concerned. Veterinary professionals have specific responsibilities to uphold the necessary standards of safety and security in relation to CDs, and this is in the best interests of fellow colleagues and members of the public.

Veterinary professionals should be familiar with this guidance and refer to it as often as necessary in the course of their daily practice. To ensure sufficient safety in relation to CDs at a veterinary premises, it is important to remember the following key points:

- Registered Veterinary Practitioners who dispense medicinal products must obtain them in compliance with legislation;
- Veterinary practices should have standard operating procedures (**"SOPs"**) which set out the procedures around access to controlled drugs (**"CDs"**) and the protocol for recording their use;
- A Controlled Drugs Register (**"CDR"**) must be maintained at any veterinary premises where Schedule 2 controlled drugs are kept in stock;
- Veterinary practices should carry out audits of the CDR continuously;
- To meet safe custody requirements, Schedule 2 and Schedule 3 controlled drugs must be stored in a secure safe or cabinet that complies with legislation;
- Practices must have appropriate security arrangements in place for keys and keyholders;
- If a Registered Veterinary Practitioner carries CDs in their vehicle, they must take reasonable steps to prevent unauthorised access;
- Veterinary practices must have written policies and procedures in place outlining suitable procedures for the destruction and disposal of CDs;
- Expired or damaged CDs must be segregated from active stock within the secure safe or cabinet, and labelled clearly as "CDs for destruction";
- Legislation requires practices to keep a record of the witnessed destruction of CDs at the premises;
- Registers, records, orders, invoices, and prescriptions in relation to CDs must be preserved for two years;
- SOPs must be in place at the practice which define the action that should be taken if a discrepancy between the CDR balance and the actual balance is identified;
- If a veterinary practitioner or any member of practice staff has a reasonable suspicion of prescription misuse, they must report it to An Garda Síochána.

Summary of Legal Requirements

CD Schedule	Controlled Drug Name	Storage in CD Safe/Cabinet required?	CD Register to be maintained & reconciled?	Destruction to be witnessed by an authorised person and recorded?
Schedule 2	Buprenorphine Butorphanol Codeine Etorphine Fentanyl Methadone Morphine Pethidine Quinalbarbitone	Yes	Yes	Yes
Schedule 3	Ketamine Pentobarbitol Phenobarbital	Yes	Recommended	Yes
Schedule 4	Alprazolam Diazepam Midazolam	No, but recommended	No	Yes
Schedule 5	Non-injectable preparations of: Codeine Dihydrocodeine Morphine	No, but recommended	No	No

Table 1.2: *Controlled Drugs common to veterinary practice; summary of requirements*

Chapter 2

Security Assessment at Veterinary Practice Premises

This Security Assessment Template has been adapted from an initiative introduced by the Pharmaceutical Society of Ireland to enhance security and safety around management of controlled drugs at pharmacies in Ireland. The assessment tool is designed to assist an audit of the veterinary premises to enhance security and facilitate the identification of risk to the safety of practice staff, practice clients and members of the public.

A security assessment at a veterinary practice premises can be carried out by the Certificate of Suitability Holder or another suitably trained member of staff.

Introduction to the Security Assessment Tool

Specific risks are associated with the operation of any veterinary practice premises. An objective security assessment of a premises will help increase the security of the practice and allow veterinary professionals to evaluate risk and take precautions to ensure maximum security standards. This will enhance the safety of practice employees and members of the public attending the practice.

The security assessment template is designed to help identify and assess this risk and provide a tool whereby a reduction of risk factors can be facilitated. The Council considers that all veterinary practices should comply with and perform such an assessment routinely, and particularly when:

- A premises is about to open for the first time;
- Any new practice staff have been employed;
- A practice relocates to a new premises;
- Significant refitting/refurbishment of an existing premises has taken place;
- A premises undergoes a routine inspection by the Council;
- A premises renews a Certificate of Suitability in respect of the premises.

Guide to Completing the Security Assessment

The security assessment template is divided into six sections which assess different aspects, namely the premises location, external grounds, building exterior, building internal (physical and security) and the security procedures and controls that should be in place. The template should be completed in full for a comprehensive assessment of security as regards to controlled drugs at the premises.

Section 1 - Location Details

This section is an introduction to location and staffing details of the veterinary practice premises. All relevant details should be completed. This security assessment may be performed by a suitably trained individual at the premises.

The location of a veterinary practice premises will often determine the risk associated with the property. Keyholder details should be readily available to the Gardaí and such individuals should be able to attend the practice without undue delay.

Section 2 - External Grounds

A review of the external environment of the veterinary practice premises is integral to the security assessment:

- The perimeter of the premises should be examined. There is a requirement to effectively delineate the boundaries of the premises, however the method used to achieve this requirement should be considered in relation to the possible protection that any physical perimeter (e.g. walls, fencing, hedging, etc.) can provide. Grounds with overgrown landscaping/shrubbery present may allow provision of unwanted cover and it may also block visibility both into and out of the premises. PAS Standard 10.3 requires that the premises grounds and exterior must be well maintained.
- External lighting could be effective, depending on the particular design and layout of the premises. The type of illumination used, and the mechanism for control (e.g. motion activated) will depend on the site. A veterinary practice premises located in an isolated rural area will have different security lighting requirements to one located on a high street. PAS Standard 10.5 requires that there must be adequate external lighting of the structure and environs.
- External C.C.T.V should be considered as a minimum-security measure and should monitor site entry points. Most modern C.C.T.V. systems now utilise computer-based digital technology and recording. The safe and secure storage of this equipment, as well as the recorded data, is essential in order to make it tamper-proof. Where V.C.R. tapes are still in use, they should be changed regularly to ensure optimum visual images.
- Stores and outhouses should be physically protected with suitable locks.
- Services to the veterinary practice, such as refuse areas, should be secured and the areas kept clear.
- Certain considerations may be particular to an individual practice premises, and these should be identified, and assessed, e.g. a practitioner residing or staying overnight at the practice premises will have specific risks to address.

Section 3 - Building Exterior

- Building design should be examined to identify potential blind spots/alcoves. If these exist, they should be covered by appropriate external lighting and/or C.C.T.V.
- Physical obstacles to entry reduce the risk of potential incidences. The type of roofing should be assessed. Flat roofs may provide access to a window or skylight. Any necessary corrective steps should be taken to address any issues noted. Particular attention should be paid to adjacent premises and the possibility of access through this route.
- PAS Standard 10.6 requires that all doors and windows be self-closing and secure.
- The nature of glazing in place at the premises should be assessed. Consideration should be given to the application of an anti-shatter film to glass or to the utilisation of laminated glass in windows and doors with appropriate strong frames and fittings. Window visibility should not be reduced by the use of posters and/or display material. Subject to planning, where necessary, grilles and/or shutters should be utilised to reduce unauthorised access.
- High quality doors and doorframes should be utilised, and if necessary and appropriate in the circumstances, steel re-enforcement should be considered.
- High quality locks are a necessity. Controlling access to the premises may need to be considered. The operation of "door buzzer" systems enable employees to control individual access to the practice.
- Telephone lines should ideally be underground to prevent tampering.
- Security signage which, for example, details a "prosecute all offenders" policy, or specifies time locks on safes, may deter. External evidence of an intruder alarm may also act as a deterrent to potential intruders.

Section 4 - Building Internal (Physical)

The internal layout of the veterinary practice premises can have a major impact on the security standing thereof.

- Use of mirrors to facilitate visibility in concealed areas, and the positioning of gondola shelving to allow clear lines of sight is recommended.
- High value goods and prescription-exempt pharmaceutical products should be protected.
- Service counters should be elevated above floor level, which allows for enhanced visibility for staff.
- Till guards, drop safes, and panic alarm buttons should be utilised where necessary.
- Display shelves should not be sited in such a manner as to impede visibility.
- Floor stand-alone units should not exceed 5 feet in height.
- Access to the dispensary should be restricted, with appropriate surveillance in place. Consideration should be given to the layout of the dispensary – products liable to abuse should be out of line of sight.
- Adequate staffing levels should be maintained to ensure no unauthorised access occurs.
- Controlled drug storage conditions should be as required by legislation, with the required standard of a safe anchored into a permanent wall or floor.
- Medicines, either stock held or returns for disposal, should not be stored in a manner which allows unauthorised access by staff or others.
- Entry to any and all staff rooms, including stock rooms, toilet facilities and administration offices, should be controlled and restricted.
- Good cash security procedures should be employed, with floor limits set as low as possible and observed by staff.
- The till should only be opened and supervised for a transaction. Cash safes can be fitted with time-delay locks, with prominent notices displayed to this effect. Cash should not be handled or counted in view of the public and more than one individual should be involved in the counting process.
- Access to behind counters should be minimised through the use of barriers or other measures.

Section 5 - Building Internal (Security)

- An adequate intruder alarm which conforms to relevant Irish and European standards should be utilised.
- Panic attack buttons, fixed and/or mobile should be utilised. A recognised monitoring service should be used. In the event of telephone lines being tampered with, mobile phones should be provided.
- Proprietors should familiarise themselves with An Garda Síochána Intruder Alarm Policy and staff should be aware of the steps to take in the event of a false alarm. C.C.T.V should be utilised to obtain maximum benefit with, as a minimum, all entrances to the practice premises under surveillance.
- Recording equipment should not be subject to access by unauthorised individuals. In the event of an incident occurring, a checklist form should be available to staff to record details of the event as soon as is practicable thereafter.
- Consideration should be given to the security and storage of recording equipment, e.g. back-up tapes/disks, etc.

Section 6 - Security Procedures & Controls (Checklist)

- A summary checklist detailing staff recruitment, selection and employment, cash security and control, medicines security and stock control, and general security procedures provides a quick reference to assess any security vulnerabilities in these areas.
- Introduce contingency plans to cater for security breaches and ensure that all employees are trained in appropriate action.
- Extra security measures may be required during particularly busy periods in the veterinary practice premises, which may necessitate heightened security.
- Provision is made to identify, assess and mitigate particular issues which may be particular to a specific veterinary practice premises.

The Veterinary Council of Ireland is committed to working co-operatively with veterinary practices in the interest of public and animal health. This is best achieved by a pro-active assessment of security risks in each veterinary practice premises in the State.

Veterinary Practice Premises Security Assessment Template

1. LOCATION DETAILS					
Address					
Location Details	Street - Urban/ Rural	Business/Retail Park	Residential Property	Isolated/High Visibility	Farm/ Equestrian Landscape
COS Holder					
Owner/Manager					
Risk Rating	High Medium Low				
Opening Hours			Evening Hours (If any)		
No. of Employees					
Keyholder(S) Contact Details	Tel:	Fax:	Email:		
Surveying Member(S)				Date:	
				Time:	
Accommodation Occupancy (Specify if Applicable)					
General Observations					

2. GROUNDS		
Details	**Observations**	**Recommendations**
Perimeter (Railings, Fencing, Boundary Delineation, etc.)		
Controlled Entry/Exit		
Grounds, Landscaping & Shrubbery		
Car Park		
External Lighting (Controlled Lighting Periods, etc.)		
C.C.T.V.		
Stores and Outhouses		
Signage/Security Notices		

Services (Fuel Tanks, Generators, Refuse Area)		
Other		

3. BUILDING EXTERIOR		
Details	**Observations**	**Recommendations**
Walls/Structure (Recesses, Rear Access, Etc.)		
Roofing (Flat/Pitched, Reinforced, etc.)		
Glazing (Protective Grilles, Coverings, Display Signage)		
Doors (Strength/ Construction/Locks)		
Controlled Entry/ Exit (Intercom/Push Button Release, etc.)		
Skylights		

Downpipes, IT/Telecom Cabling, Etc.		
Security Signage (Alarms, C.C.T.V., Time-Lock Safes, Etc.)		

4. BUILDING INTERNAL - PHYSICAL		
Details	**Observations**	**Recommendations**
Reception/Shop Floor Area (General Observations - Mirrors, Layout, High Value Goods, Anti- Theft Systems, Signage, etc.)		
Service Counters (Location/Elevated/Till Guards/Drop Safes/ Pabs/ Manned)		
Display Shelving (Height, Location of High Value Goods, Layout, Restricted Views)		
Medicines Dispensary (Restricted Access/ Counter Design/ Surveillance/Staffing)		

Medicines Dispensary (Controlled Drugs Cabinets/Securely Anchored/Adequate Data & Records Security)		
Entry to Private/ Staff - Only Areas (Access Controlled/ Reinforced, etc.)		
Cash Security (Floor Limits Observed/Cash Safes Fitted/Time Locks, etc.)		
Admin Offices		
Toilets		
Other		

5. BUILDING INTERNAL - SECURITY		
Details	**Observations**	**Recommendations**
Intruder Alarm (To Ire/EU -Recognised Standards, Panic Attack Buttons, Sensors, Contacts, etc.)		
Alarm Monitoring		
Mobile Phone Back-Up		
Panic Attack Facilities		
Keyholding Procedures		
C.C.T.V. (External Locations)		

C.C.T.V. Recording (Recording Quality, Security & Data Storage)		
Security Lighting		
Other (Is there an Incident Checklist Available in the Event of any Occurrence)		

6. SECURITY PROCEDURES AND CONTROLS - CHECKLIST		
A. Staff Recruitment, Selection and Employment		
(1)	Is there a Standard Employment Application form?	YES/NO
(2)	Are references/referees sought and verified?	YES/NO
(3)	Is a C.V. required or necessary and, if so, is it verified?	YES/NO
(4)	Is the applicant's background established/researched?	YES/NO
(5)	Is there a contract of employment?	YES/NO
(6)	Are terms of employment outlined to applicant?	YES/NO
(7)	Has the applicant signed terms of employment and accepted them?	YES/NO

B. Cash Security and Control		
(1)	Are tills properly secure and individually monitored?	YES/NO
(2)	Are staff trained and properly equipped for cash-handling duties?	YES/NO
(3)	Are floor cash limits in place and observed?	YES/NO
(4)	Are cash-counting procedures in place and verifiable?	YES/NO
(5)	Are there security procedures for electronic transactions?	YES/NO
(6)	Are there anti-counterfeit currency measures?	YES/NO
(7)	Are receipts tendered for all purchases?	YES/NO
(8)	Is cash collection/delivery to cash office and bank secure?	YES/NO
(9)	Is there an A.T.M. on site and is it secure?	YES/NO

C. Medicines Security And Stock Control		
(1)	Are "Just-in-Time" principles for stock purchase and delivery observed?	YES/NO
(2)	Is there designated staff for purchase and delivery duties?	YES/NO
(3)	Are all deliveries validated against delivery dockets?	YES/NO
(4)	Are there designated and secure delivery/storage areas?	YES/NO
(5)	Are there secure facilities for storage/display of high value goods?	YES/NO
(6)	Is there controlled access to stock by staff?	YES/NO
(7)	Are there regular stock audits?	YES/NO
(8)	Is security tagging necessary and available?	YES/NO
(9)	Is waste stock validated and controlled?	YES/NO
(10)	Is stock "store to floor" movement secure and validated?	YES/NO
(11)	Are 'controlled drugs' stored in accordance with legislation?	YES/NO
(12)	Are 'controlled drugs' registers maintained in accordance with legislation?	YES/NO
(13)	Is there sufficient security during delivery of 'controlled drugs'?	YES/NO
(14)	Are 'controlled drugs' speedily stored post delivery?	YES/NO
(15)	Is access to 'controlled drugs' limited to designated staff?	YES/NO

D. SECURITY PROCEDURES (GENERAL)		
(1)	Are secure opening/closing procedures in place for staff?	YES/NO
(2)	Is personal security adequate for all keyholders?	YES/NO
(3)	Are Crime Prevention Through Environmental Design principles (CPTED) in place for premises?	YES/NO
(4)	Are policies in place to defeat employee/customer theft?	YES/NO
(5)	Are policies in place to deal with aggressive customers?	YES/NO
(6)	Are staff trained in CO-OP principles for robbery?	YES/NO
(7)	Are staff adequately trained in security awareness?	YES/NO
(8)	Are admission policies in place under the Equal Status Act?	YES/NO
(9)	Are security procedures regularly reviewed?	YES/NO

ARE YOU SATISFIED WITH THE SECURITY ARRANGEMENTS IN PLACE AT THIS LOCATION? IF NOT, OUTLINE GENERAL SECURITY DEFICENCIES	YES/NO
SIGNED: *Please print*	DATE:

Appendix 1. – VCI Template Controlled Drugs Register

Product Name		**Form**	
Drug Schedule		**Strength**	
Active Ingredient		**Bottle/Pack Size**	

Date	**Balance**		**Usage**				**Reconciliation**				**Signed**	
Date of delivery / administration / destruction / reconciliation	*Amount Received or Balance Forward*	*Supplier (if entry is in respect of a delivery)*	*Patients Name*	*Amount Administered (including waste)*	*Amount Destroyed (Complete CD Destruction Register)*	*Running Balance*	*Total Actually in Stock*	*Discrepancy*	*Discrepancy Reported to Responsible Veterinary Practitioner (e.g. the COS Holder)*	*Explanation for Discrepancy*	*Registered Veterinary Practitioner/ Registered Veterinary Nurse Name & VCI Reg. No.*	*Signature (CDR must also be frequently countersigned by the responsible Registered Veterinary Practitioner)*

Appendix 2. – VCI Template Controlled Drugs Destruction Register

Date	Product Details			Destruction Details			Signatures			
Date	*Product Name*	*Product Strength & From*	*Page No. of CD Register*	*Quantity Destroyed*	*Reason for Destruction*	*Method of Destruction*	*Name of Registered Veterinary Practitioner / Registered Veterinary Nurse & VCI Reg. No.*	*Signature*	*Name & Position of Authorised Person Witnessing the Destruction*	*Authorised Person Signature*

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