# Controlled Drugs Guidance

Common topics: consolidation of legislation and advice





# Controlled Drugs Guidance

# Introduction

Veterinary surgeons and veterinary nurses have legal and professional responsibilities in relation to veterinary medicines. These are summarised in Chapter 4 of the Supporting Guidance to the Codes of Professional Conduct, see <a href="https://www.rcvs.org.uk/vetmeds">www.rcvs.org.uk/vetmeds</a>

The use of controlled drugs (CDs) in veterinary practice raises additional legal and professional considerations and must be strictly managed. Veterinary professionals involved in prescribing, supplying, recording, storing, disposing or destroying CDs must comply with the law on misuse of drugs and veterinary medicines. Regulation of CDs within veterinary practice is governed and inspected by the Home Office, the Veterinary Medicines Directorate (VMD) and the Royal College of Veterinary Surgeons (RCVS).

The legislation describes in detail how CDs must be managed in practice and veterinary professionals are expected to be familiar with this. But, the legislation is complex and organisations with responsibility for enforcing various aspects of the legislation have published additional advice and guidance to provide clarity on the legal requirements. Added to this, there are other useful sources of advice from organisations such as the British Small Animal Veterinary Association (BSAVA). A list of relevant legislation and advice is contained in Annex A to this document.

Nevertheless, the RCVS continues to receive regular enquiries relating to CDs. This document looks at the most common areas on which advice is sought and draws together the key parts of existing legislation and guidance in response. This document should not be viewed as standalone guidance on CDs and should be read in

conjunction with the current legislation and guidance. The VMD and Home Office have assisted with this document.

# Legal requirements

All CDs are listed in Schedules 1 to 5 of the Misuse of Drugs Regulations 2001. These are numbered in decreasing order of severity of control. The Schedules relate to the drugs' therapeutic usefulness, the need for legitimate access and the potential harm caused by their misuse. In short, Schedule 1 CDs are subject to the most restrictions; Schedule 5 the least.

Veterinary medicines only contain CDs in Schedules 2, 3, 4 and 5. This means that veterinary surgeons have the authority to supply all but Schedule 1 CDs. Legal possession and supply of Schedule 1 CDs requires Home Office authority.

- Schedule 2 CDs have therapeutic value but are highly addictive and may be subject to abuse. Their use is strictly controlled, including special prescription, storage, destruction and record keeping requirements.
- Schedule 3 includes barbiturates and some benzodiazepines. While less rigorously controlled than drugs in Schedule 2, they are also subject to special prescription writing requirements. Some are also subject to special storage requirements.
- Schedule 4 is divided into 2 parts; Part 1 contains most of the benzodiazepines and Part 2 contains the anabolic and androgenic steroids. There are no additional special controls on Schedule 4 drugs.
- Schedule 5 includes preparations containing substances such as codeine or morphine, which are used in such low strength that they present little or no risk of misuse. There are no additional special controls on Schedule 5 drugs.

Key advice areas (in alphabetical order)	Page
Audit	4
Buprenorphine	4
Cabinets	4
Cars	5
CDLOs (Controlled Drugs Liaison Officers)	5
Denaturing	6
Destruction and disposal	7
Discrepancies	7
Electronic (or faxed) prescriptions	7
Emergency wholesale supply	7
Fentanyl	8
Import and export	8
Ketamine	8
Keys and keyholders	9
Out of date stock	9
Posting CDs within the UK	9
Prescriptions and prescribing	10
Prescription misuse	10
Registers and record keeping	11
Requisitions	11
Returned CDs	11
Standard Operating Procedures (SOPs)	11
Tramadol	11
Under-age clients	11
Veterinary nurses administering CDs	12
Wastage	12

#### **Audit**

Ideally, all CDs should be audited continuously. For practices in the RCVS Practice Standards Scheme, Assessors will particularly want to see a full audit and reconciliation of all Schedule 2 CDs (i.e. the Controlled Drugs Register (CDR) and the balance of drugs in stock).

Audit and reconciliation can be achieved by recording supply and use, and keeping a running total in the CDR, and having a system of reconciling the balance in the CDR with the stock in the CD cupboard. This should be done regularly (at least weekly) and discrepancies should be recorded and, where necessary, investigated.

The CDR can be maintained by a suitably-trained person e.g. a veterinary nurse, but ultimate responsibility lies with the veterinary surgeon. The BSAVA advise that once tallied, the balance should be marked as checked and signed – this can be done by someone responsible for the CDR and does not necessarily have to be a veterinary surgeon. If this is carried out daily (or at least weekly depending on workload), discrepancies are much easier to trace. Wherever possible, this should be countersigned.

See also: Registers and record keeping

# **Buprenorphine**

Buprenorphine is a Schedule 3 CD. Its use does not need to be recorded in a CDR, but unlike most other Schedule 3 CDs, it must be stored in a CD cabinet. Schedule 3 drugs are also subject to extra prescription-writing requirements (see Prescriptions and prescribing).

If dispensing transmucosal buprenorphine to clients, as this is off-licence use, the RCVS requires that written consent should be obtained from the client (see RCVS supporting guidance Chapter 4 on the Cascade).

The BSAVA provides additional guidance on dispensing transmucosal buprenorphine to clients as follows:

This short-term analgesic treatment is sometimes used for cats via the prescribing cascade and clients may in some circumstances be supplied with buprenorphine to administer to their cat at home. There is no specific guidance for this, but the veterinary surgeon should:

- ✓ Have a genuine clinical reason for prescribing the medicine under the Cascade.
- ✓ Obtain informed consent for unauthorised use from the client
- ✓ Ensure that they have personally discussed this treatment with the client and be satisfied that the client is responsible and able to administer the medication.

- ✓ Emphasise that this drug is a CD and that it should be treated with extreme caution (e.g. keep out of reach and sight of children; skin splashes should be washed off immediately).
- ✓ Demonstrate correct handling of the medication during administration.
- Only supply a limited amount of buprenorphine, preloaded into appropriate syringes that are capped with a syringe bung and dispensed in appropriate packaging.
- ✓ Request that the client return all used and any unused syringes to the practice for disposal.
- Provide all this information in written format for the client and record all pertinent information within the client record.

#### **Cabinets**

It is important for veterinary surgeons to store CDs securely and appropriately in a suitable cabinet to prevent unauthorised access. The following CDs are legally required to be stored in a locked container which is compliant with the Misuse of Drugs (Safe Custody) Regulations 1973:

- All CDs in Schedule 2 (with the exception of quinalbarbitone)
- CDs in Schedule 3 containing buprenorphine, diethylpropion, flunitrazepam and temazepam

The RCVS considers it advisable for all CDs in Schedule 3 to be stored in the CD cabinet.

The Safe Custody Regulations describe the requirements for CD cabinets, safes and rooms and the standards to which they must be manufactured or built.

# Location of the cabinet

The VMD advise that the room housing the locked container should be lockable and tidy to avoid drugs being misplaced. The room should not normally be accessible to clients. However, if clients do have to enter the area, you should consider continuously supervising them until they leave the area. You should consider keeping CDs in a separate container from other medicines.

The BSAVA say the cabinet should be situated in a secure place away from public view.

# Design and construction of the cabinet

Cabinets must adhere to the Safe Custody Regulations in terms of design and construction.

The VMD advise that the locked container is constructed and maintained to prevent unauthorised access to the

drugs. There should be no indication on the outside of the container that CDs are kept in the container.

The BSAVA advise that it is important that the CD cabinet meets the requirements set out by the Regulations, as deviation from the standards increases the risk of theft. The British Standard coding for medicine cabinets is BS 2881:1989 and has three levels of security. An assessment of the risk should be made and a cabinet commensurate with that risk purchased. The most appropriate cabinet should be carefully selected for individual premises.

Schedule 2 of the Misuse of Drugs (Safe Custody)
Regulations 1973 stipulate structural requirements in
relation to safes, cabinets and rooms used for keeping
CDs. Home Office guidance note "Security Guidance
for all existing or prospective Home Office Controlled
Drug Licensees and/or Precursor Chemical Licensees
or Registrants" (January 2014) summarises cabinet
construction requirements.

In addition, the BSAVA advise that:

- The cabinet must be bolted to the wall or floor.
- Preferably it is double-locked with separate keys.
- The lock must be different to any other lock on the ward.
- Keys must only be available to authorised members of staff
- The cabinet must not have anything attached to it which identifies it as a CD cabinet.
- The cabinet must be kept locked when not in use.

## Further advice on cabinets

Retailers of CDs cabinets can confirm they meet the legal requirements and practices may wish to request formal confirmation when purchasing such cabinets. In addition, many police forces in the UK have Controlled Drugs Liaison Officers (CDLOs) who offer advice on various matters, including safe storage. Contact details for officers by area can be obtained from the <u>Association of Police Controlled Drugs Liaison Officers</u>.

See also: Keys and keyholders; CDLOs

#### Cars

The VMD advise that if a veterinary surgeon requires a supply of Schedule 2 or 3 drugs (excluding drugs listed in Schedule 1 of the Misuse of Drugs (Safe Custody) Regulations) for call out visits, the CDs should be transported in a locked glove compartment or in a lockable bag, box or case which should be kept locked when not in use. If such a bag, box or case is locked, it is considered a suitable receptacle for storing CDs. Simply being placed in a locked car is not suitable. The RCVS also recommends that the container (which could also be a safe e.g. laptop safe, sat nav safe, strong cash box) is kept out of sight.

The VMD advise that veterinary surgeons should consider making sure the locked bag is not left unattended in a vehicle for any length of time. The VMD advise in particular that this does not apply to locked containers that are fixed within the boot of the car. The RCVS considers that leaving controlled drugs in a vehicle overnight would generally be considered 'long term'.

The RCVS recognises that not all vets will use vehicles with boots or vehicles that they can modify (lease cars for example.) In those situations, the RCVS considers that it is reasonable to secure the lockable container to a structure in the vehicle, for example using a laptop or sat nav safe with a metal cable tethered to an anchor point in the car, such as the seat runners or seatbelt post, or bolting the lockable container to the floor of the vehicle. It is also important to keep this out of sight, for example, well hidden under the seat.

Above all, veterinary surgeons should use their professional judgement when storing controlled drugs in vehicles and they must take reasonable steps to minimise unauthorised access. This might require them to consider particular risk factors, such as whether practice vehicles are easily identifiable as such, whether practice vehicles have been targeted in the past and where practice vehicles are parked. Veterinary surgeons considering leaving controlled drugs in their car overnight may have additional considerations. In some cases, it may be safer for the controlled drugs to be removed from the vehicle or returned to the practice. Veterinary surgeons may also wish to seek specific advice on vehicle security from their local CDLO.

The VMD advise that veterinary surgeons are responsible for the receipt and supply of CDs from their own bag and must maintain a separate CDR. The RCVS considers that this is required for veterinary surgeons who keep controlled drugs in their car for any length of time, but that those taking controlled drugs from the practice for short-term use are not required to maintain a separate CDR but they must record their use in the main CDR.

## **CDLOs**

Most police forces in the UK have Controlled Drugs Liaison Officers (CDLOs) who offer advice on all aspects of CD use within veterinary practice, including safe storage, auditing, destruction, suspicious activity, internal theft, forged or stolen prescriptions as well as 'current crime trends'. Contact details for officers in your area can be obtained from the Association of Police Controlled Drugs Liaison Officers.

# **Denaturing**

Veterinary surgeons must ensure that CDs are rendered

irretrievable before disposal. There are several methods of doing this.

The BSAVA advise to denature drugs as follows:

#### Out-of-date stock and returned drugs

There are commercially available denaturing kits, and these can be used to destroy out-of-date stock CDs and returned CDs. Veterinary surgeons should follow the instructions for use and disposal specific to the kit, as these may differ depending on the kit used.

# Residual or waste drugs

Residual CDs are not usually denatured using kits because, as their destruction is required daily, this would prove too costly. Instead, residual drugs can be rendered irretrievable by collection into cat litter. Periodically, this cat litter is then sent as pharmaceutical waste through the waste contractor.

The VMD advise that CDs should be rendered irretrievable before disposal, e.g. by using a denaturing kit. Alternatively, an injectable solution may be placed into sawdust or cat litter and tablets may be crushed and mixed with soapy water.

See also: Destruction and disposal

# **Destruction and disposal**

Destruction of controlled drugs is subject to a number of important considerations as set out below.

The VMD advise that the legal requirements to witness the destruction of Schedule 2 CDs apply to stock. This refers to CDs that have not been issued or dispensed to a patient. However, any leftover medicines, for example liquids, which are still required for use, are considered as stock. A witness is required if these are to be destroyed on expiry or for other reasons.

There is no legal requirement to have the disposal of waste product witnessed. Leftover medicines are generally considered waste and not stock if they are unusable. Any medicine leftover in an ampoule or vial which is considered unusable is considered waste product.

# Frequency of destruction

Destruction of CDs should occur with sufficient frequency (for example, monthly) to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

#### Witnessing

The VMD advise that Schedule 2 CDs (and Schedule 3 and 4 CDs that have been prepared extemporaneously for use

under the prescribing Cascade) must be destroyed in the presence of, and instructed by, any of the following:

- An Inspector appointed under the VMRs (this includes a VMD inspector or RCVS Practice Standards Assessor)
- A veterinary surgeon independent of a practice where the destruction takes place (including those who have no personal, professional or financial interest in the veterinary practice where the drug is being destroyed but excluding temporary staff and family members)
- A person legally authorised to witness the destruction of CDs such as a CDLO

In addition, the VMD advise that a veterinary surgeon acting as an independent witness should not accept or demand any form of payment beyond that reasonable to cover transportation costs for witnessing the destruction of a CD.

The BSAVA acknowledge that although there is no legal requirement to do so, it is good practice that CDs of all Schedules be destroyed in the same way.

#### Recording destruction and disposal

The VMD advise that a record must be made of the date of destruction and the quantity destroyed, which the witness must sign. The witness, if an independent veterinary surgeon, should record their RCVS number and confirm their independence in writing in the CD register. The VMD also say that the following information should be recorded: name of the CD, form, strength and quantity, and the signature of the professional destroying the drug.

The BSAVA have some specific guidance on destruction in the following three circumstances:

Residual or 'waste' CDs left in ampoules

Any medicine left over in an ampoule or vial which is considered unusable is considered waste product (as opposed to practice stock). Both the amount administered and the amount denatured should be recorded on the same line of the CDR to ensure that the running balance tallies – e.g. if 10mg morphine is dispensed to a patient but only 5mg is administered the record should show that 5mg was given and 5mg was wasted. Doing so ensures that the whole vial or ampoule is accounted for in the CDR. It is

good practice for the entry in the CDR to be double signed.

Out of date drug stock

Expired stock should not be marked out of the running balance in the CDR until it is destroyed.

#### **Returned drugs**

As the drug has been dispensed to a patient, there is no requirement to have its destruction witnessed or recorded.

However, it is good practice to have it witnessed by another member of staff. It is also good practice to record CDs that are returned and destroyed and to have a second staff member countersign. This record should not be in the CDR and an alternative register can be kept specifically for this purpose. Returned CDs should be stored in the CD cupboard, but clearly separated from the rest of the stock, until destroyed.

# **Special requirements**

Any special handling or disposal requirements (e.g. for cytotoxic medicines) must be observed.

See also: Returned CDs

# **Discrepancies**

The balances in the CDR should always tally with the amounts of CDs in the cabinet. If they do not, the discrepancy must be reported to the senior veterinary surgeon, and steps taken to investigate and resolve the matter.

The BSAVA advise that discrepancies are inevitable when using multidose CDs due to needle-hub and syringe deadspace. Multidose vials of CDs increase the potential for abuse, and running balances are difficult to keep due to deadspace volumes. An SOP should be in place detailing what to do in the event of a discrepancy.

The BSAVA say that one way of accounting for deadspace volume is to add this to each dose dispensed, but the volume is likely to vary, depending on the manufacturer of the needle and syringe, and the size of the syringe used.

The RCVS advise that there should be a procedure in place for dealing with discrepancies and this should detail the arrangements for investigating and reporting. Such arrangements could include:

- ✓ Inform the senior veterinary surgeon immediately.
- ✓ Ensure the following information is carefully checked:
- All CD orders received from the wholesaler have been entered into the correct page of the CDR.
- All CDs administered have been entered into the CDR.
- Items have not been accidentally put in the wrong place in the CD cabinet or left out.
- Arithmetic to ensure that balances have been calculated correctly (perhaps two members of staff to check the balance to confirm calculations.)
- Check running totals and discrepancies at the end of each bottle; a weekly stock check against the CDR will minimise this.
- ✓ If the error or omission is traced, the veterinary surgeon in charge should make an entry in the CDR clearly

- stating the reason for the discrepancy and the corrected balance. This entry should be witnessed by another veterinary surgeon or a veterinary nurse and both should sign the CDR.
- ✓ If no errors or omissions are detected, steps should be taken to investigate and report the discrepancy.
- ✓ Practice clinical records for the CD use should be checked to ensure that all use has been recorded.
- ✓ Interviews with relevant staff members may be required and, if so, the details recorded.
- ✓ The practice may wish to consider reporting the discrepancy to the local police or CDLO in line with the practice's policy for reporting incidents (CDLOs may be able to offer advice on this.)
- ✓ Security arrangements and procedures should be reviewed as soon as possible and, where applicable, codes to the CD cabinet or key safe changed.
- ✓ If there are concerns that a veterinary surgeon or veterinary nurse is involved in suspected theft, the RCVS should be notified in addition to the police.

See also: Wastage

# **Electronic (or faxed) prescriptions**

It is an offence to supply a Schedule 2 or 3 CD against an electronic or faxed prescription; the original prescription must be obtained before the medicine is dispensed and retained for at least five years.

The dispensing veterinary surgeon should undertake checks to ensure the prescription is genuine.

See also VMD guidance on <u>retail of veterinary medicines</u>, which includes advice for online retailers.

#### **Emergency wholesale supply**

It is an offence for one veterinary practice to supply another with CDs unless a wholesaler licence is in place. The exception to this is where there is a temporary supply shortage. The BSAVA advise that it may be possible to justify a one-off emergency supply if the welfare of a patient is at risk (e.g. if a practice runs out of methadone and needs to treat an animal in pain). The transaction should be clearly recorded in both the supplier's and the recipient's CDR.

#### **Fentanyl**

Fentanyl is a Schedule 2 CD. It is therefore subject to safe custody requirements and its use must be recorded in a CDR.

There are now two veterinary authorised fentanyl products, both of which are POM-V Schedule 2 CDs:

- One is a transdermal solution authorised for use in dogs for control of significant post-operative pain. You must use personal protective equipment when applying this and you cannot order the product without first watching a short training video.
- The other is an injectable solution authorised for use in dogs, again for the control of significant postoperative pain and also intra-operative analgesia.

The licensed products may not be suitable for a particular case and recourse may be had to fentanyl patches. Fentanyl patches can provide highly effective pain relief after orthopaedic operations, their use also carries significant risks, including respiratory depression (particularly in small children) and risks to the patient and other household pets should they lick or ingest the patch.

Good practice guidance as agreed by the RCVS and BSAVA:

- ✓ Ideally, neither the transdermal solution nor fentanyl patches should be used if there are small children in the household.
- ✓ Veterinary surgeons should be mindful of the risks of ingestion by other animals.
- ✓ It is vital to get the client's informed consent, which must include an explanation of the risks.
- ✓ The client must be told what to do if a fentanyl patch
  comes off and how to safely dispose of the patch.
- ✓ This information should be provided in writing and recorded on the client record.

Further information about the risks and best practice can be found in the <u>BSAVA Client Information Leaflets</u>.

#### Import and export

The import and export of CD raw materials and medicines (packaged for use) under Schedules 2, 3 and 4 Part I is licensed by the Home Office.

Schedule 4 Part II drugs must be carried on the patient (or pet owner), or in their luggage, through UK ports. Importation or exportation using postal or courier services is not permitted.

When in a medicinal form for personal use (i.e. already dispensed for a named animal or animals) these and Schedule 5 CDs do not need a personal import or export licence to enter or leave the UK.

# Ketamine

On 30 November 2015 ketamine was rescheduled to Schedule 2 and is subject to the strict storage, prescription, dispensing, destruction and record keeping requirements that apply to all CDs in this schedule. For further details on these requirements please see the VMD veterinary medicines guidance on CDs: <a href="https://www.gov.uk/controlled-drugs-veterinary-medicines">www.gov.uk/controlled-drugs-veterinary-medicines</a>

# Keys and keyholders

# Keyholders

Practices should have appropriate security arrangements for keys and keyholders.

RCVS advice is that CD cabinets must only be accessed by a veterinary surgeon or a nominated responsible person at the practice. For example, the RCVS recognises that sometimes a locum may need to have access to the key, if they are in sole charge. A keyholder who is not a veterinary surgeon should only remove CDs from the cabinet and/or return them to the cabinet on the specific authority of a veterinary surgeon. While the task itself can be delegated, the legal and professional responsibility will remain with the veterinary surgeon.

The VMD advise that the locked container should only be opened by a veterinary surgeon or other persons authorised by the veterinary surgeon.

The BSAVA advise that keyholders of the cabinet can be any nominated persons within the practice. Those persons holding keys should have appropriate training and, ideally, should be a qualified veterinary surgeon or veterinary nurse. In addition, the BSAVA advise that locums and students should not be given access to the key (but see RCVS exception above).

# Security arrangements for the key

The VMD advise that keys to the locked container should not be kept with keys to other parts of the building.

The BSAVA advise that the key should not be left in a 'secret' place whereby there is free access to the key. The BSAVA recommend the use of combination key boxes (see below).

The Home Office suggests that the same level of security controls are applied to all cabinet keys (including spares), as would be to the CDs contained within, since failure to ensure that will lead to security arrangements being compromised. The Home Office also recommend that access to individual keys should be audited and recorded, with a witnessed key signing-in and out procedure. However, the RCVS Practice Standards Scheme accepts that all vets may have their own key, such that signing-in and out is not required.

Detailed information on key security is set out in the Home Office guidance document referenced above. Veterinary surgeons and veterinary nurses are strongly encouraged to read this document in full.

#### Key boxes

Practices may use key boxes with combination locks, but there are additional considerations when taking this approach.

The BSAVA advise that a combination key box which is wall-mounted is acceptable practice provided that the combination is changed regularly (monthly).

The Home Office advises that key boxes may be considered for holding the key for a cabinet or small safe. It does not consider it good key management practice to lock a key in a desk drawer or other office furniture, irrespective of whether the key is locked in an additional box. It also recommends that spare keys should be kept in a separate safe to which only very few employees have access.

The RCVS Practice Standards Scheme requires that the combination to key boxes is changed regularly, at least monthly.

## **Combination locks on CD cabinets**

The Home Office encourages the use of a CD cabinet that has been fitted with a combination lock, as this avoids the need to make separate arrangements for the safe storage of a key. The Home Office guidance above provides detailed information on the use of combination locks. In short, the Home Office advises that if businesses decide to use combination locks, the combination should only be known to those persons authorised to operate the lock. The following rules are regarded as good practice by the Home Office regarding the use of combination locks:

- Combinations should not be written down;
- Combinations that are issued to individual members of staff should not be shared with anyone else, including colleagues;
- All combinations should be changed regularly, or at least every six months as a minimum, to prevent the locks from being compromised (the RCVS recommends that combinations for CD cabinets are changed monthly);
- Combinations should also be changed whenever there are grounds to suspect that they may have become known to an unauthorised person;
- Regardless of whether a combination is shared by a group of people or issued to individuals, it should be changed whenever a member of that group or the individual to whom it was issued leaves the business or otherwise no longer requires access to the lock.

#### Out of date stock

It is illegal to use or supply out of date medicines, and so they must be disposed of. This includes part-used medicines that have been open for more than the designated number of days after being broached.

The BSAVA advise that expired CDs should be clearly labelled as such and stored in the CD cabinet until destruction – but separated from in-date practice stock to avoid potential dispensing errors or re-use.

See also: Destruction and disposal

# Posting CDs within the UK

The BSAVA state that in ordinary circumstances, CDs should never be sent through the post.

In exceptional circumstances (e.g. for a client unable to travel to the practice and unable to send a representative), then recorded delivery or 'signed for' courier delivery are most appropriate. Prescription medicines may be sent via Royal Mail, but it is advisable to check current details on prohibited goods and packaging guidelines with the Royal Mail first.

# **Prescriptions and prescribing**

Only a veterinary surgeon may prescribe a CD for an animal. The prescription can be written or verbal. A written prescription is only required if the drug is to be supplied elsewhere.

# Writing prescriptions

General prescription requirements detailed in the VMRs must be met.

The following additional requirements apply to written prescriptions for any CD listed in Schedule 2 or 3:

- ✓ A declaration that the CD is prescribed for an animal or herd under the veterinary surgeon's care.
- ✓ Full name and address of the owner plus the name of the animal to whom the CD prescribed is to be administered.
- ✓ Name and form of the drug, even if only one form exists.
- ✓ Amount of the product prescribed, in both words and figures.
- ✓ Strength of the preparation (if more than one strength is available).
- ✓ Dose to be administered ('take as directed' or 'take as required' are not acceptable).
- ✓ RCVS registration number of the prescribing veterinary surgeon\*.
- \* This is a requirement of The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland)

Regulations 2015. The Northern Ireland Department for Health, Social Service and Public Safety is working to implement similar changes as soon as possible. Until those legislative changes are implemented in Northern Ireland, vets in Northern Ireland will not be required to include their RCVS number on prescriptions for Schedule 2 and 3 CDs.

The prescription must be signed in ink by the person issuing it and may be hand-written, typed in a computerised form or computer generated.

The VMD advise that you should only post date prescriptions for Schedules 2 and 3 CDs in specific and exceptional circumstances (e.g. if there is to be a delay in the start of the 28 day period due to a bank holiday). However, the decision whether to prescribe in this manner is a clinical decision for the veterinary surgeon who must consider the risk of diversion of the CD. The veterinary surgeon has full responsibility for the decision.

# Validity and repeat prescriptions

CDs in Schedules 1 to 4 have a prescription validity of 28 days. Prescriptions for Schedule 5 CDs (and all other prescription medicines) have a validity of 6 months.

You can only dispense a prescription for a CD in Schedule 2 or 3 once and only within the 28 days of the validity of the prescription.

Single prescriptions with multiple dispenses (i.e. repeatable prescriptions) are not allowed for CDs in Schedules 2 and 3. Repeat prescriptions for Schedule 4 and 5 CDs are permitted. The repeats must be dispensed within the period of validity of the prescription (28 days or six months). If the prescription is not repeatable you should consider stating this on the prescription to avoid any misuse of the prescription. If the prescription has a section that states number of repeats you should consider crossing this out if the prescription is not to be repeated to avoid any misuse of the prescription.

# Quantity

The VMD advise that for all CDs, you should consider prescribing only 28 days' worth of treatment unless in situations of long term ongoing medication (e.g. when treating epilepsy in dogs). If you prescribe more than 28 days' worth of treatment you must be sure the owner is competent to use the medicine safely.

# Instalment prescriptions

The first instalment must be dispensed within the 28 day validity period. Further instalments do not need to be dispensed during the 28 day validity for Schedule 2, 3 and 4 CDs.

#### **Retention of prescriptions**

Veterinary surgeons supplying Schedule 2 and 3 CDs against another veterinary surgeon's prescription should:

- Retain the prescription on the premises from which the drug was supplied for at least 5 years
- Mark on the retained prescription the date on which the supply was made
- Record the name of the person who collected the CDs in the CDR (for CDs of Schedule 2 only)

# **Prescription misuse**

Suspected prescription misuse (which could include an alteration to an existing prescription or prescription fraud) can be reported to the Veterinary Medicines Directorate (VMD) via its dedicated <u>prescriptions misuse page</u>. Making such a report will, in most cases, require a veterinary surgeon to release confidential information about their client to the VMD.

The RCVS considers that reporting cases of prescription misuse is in the public interest and in most cases a report to the VMD will be a justified breach of client confidentiality. For general advice on client confidentiality please see the relevant Supporting Guidance (<a href="www.rcvs.org.uk/confidentiality">www.rcvs.org.uk/confidentiality</a>) and for advice on a case by case basis please contact the RCVS Professional Conduct Department on 020 7202 0789.

# Registers and record keeping

Any person who purchases or supplies any product containing a Schedule 2 CD must maintain a CDR. The BSAVA Medicines Guide sets out the CDR requirements as per the Misuse of Drugs Regulations 2001 and advise that registers must:

- Be a computerised system or a bound book (which does not include any form of loose leaf register or card index).
- Be separated into each class of drug
- Have a separate page for each strength and form of drug at the head of each page.
- Have the entries in chronological order and made on the day of the transaction or, if not reasonably practical, the next day.
- Have the entries made in ink or in a computerised form in which every entry can be audited.
- Not have cancellations, obliterations or alterations.
- Corrections must be made by a signed and dated entry in the margin or at the bottom of the page. This author brackets the mistake and then makes a footnote at the bottom of the page detailing the mistake. The running balance is then corrected as necessary.
- Be kept at the premises to which they relate and be available for inspection at any time. A separate register

must be kept for each set of premises.

- Not be used for any other purpose.
- Be kept for a minimum of two years after the date of the last entry.

The BSAVA advise that for ambulatory vets carrying CDs in their vehicle, ideally there should be a separate register. If the CDs are moved back to the practice after each visit then it may be acceptable to have just one register in which the CD is signed out on departure and signed back in again on return.

The BSAVA advise that a computerised register must not be alterable at a later date after an entry has been made: it must be auditable, printable and appropriate back-up must be kept.

The RCVS understands that there are currently no suitable electronic registers for veterinary practices, however, CDLOs may be able to advise further on possible options.

CDs in Schedules 3, 4 and 5 do not need to be recorded in the CDR but invoices must be retained for 5 years.

The VMD advise that the CDR must record for all CDs purchased and supplied:

- date supply received
- name and address of supplier (e.g wholesaler, pharmacy)
- · quantity received

The VMD also advise that the CDR must record for all CDs supplied (including by way of administration):

- date supplied
- name and address of person or firm supplied
- details of the authority to possess (prescriber or licence holder's details)
- · quantity supplied
- the person collecting a Schedule 2 CD (animal owner or animal owner's representative, or healthcare professional) and if a healthcare professional, their name and address
- whether proof of identity was requested of the animal owner or animal owner's representative (yes or no)
- whether proof of identity of the person collecting was provided (yes or no)

The Veterinary Medicines Directorate has produced an <u>Example CD Register</u> to show how the use of CDs may be recorded.

The Register can be 'maintained' by a suitably trained person (e.g. a veterinary nurse), but ultimate responsibility lies with the veterinary surgeon.

#### Requisitions

A requisition is a supply of a CD for stock purposes rather than for a named patient. As of 30 November 2015, a specified form must be used for the requisition of Schedule 2 and 3 CDs. The form is available here.

#### **Returned CDs**

Any CDs returned to the practice by clients should not be re-used and should be destroyed as soon as possible. The Veterinary Medicines Directorate (VMD) advises that the CD must be clearly labelled as a return and stored in the CD cabinet – but separated from practice stock CDs to avoid potential dispensing errors or re-use.

The VMD advise that the requirements to witness and record the destruction of CDs do not apply to returned CDs. However, they advise that veterinary surgeons should consider making a record of any CD that is returned and having the destruction witness by another member of staff and signed against. This can be recorded in a separate book or sheets designed for that purpose.

Where an animal has died part way through treatment, the VMD recommends that the prescribing veterinary surgeon should consider making every effort to recover and destroy any remaining product.

See also: Destruction and disposal

# **Standard Operating Procedures (SOPs)**

Standards Operating Procedures (SOPs) should provide clarity and consistency for all staff handling CDs. SOPs should define who in the practice is responsible. SOPs are working documents and should be kept up to date, reflecting current legal and good practice requirements. The BSAVA Medicines Guide includes guidance for writing SOPs. CDLOs may also be able to provide advice to practices on their SOPs for CDs.

# **Tramadol**

As a Schedule 3 CD tramadol is exempt from safe custody requirements but the RCVS advises that all Schedule 3 CDs should be stored in a CD cabinet.

Tramadol is a human medicine and so its use must be in accordance with the Cascade. The RCVS advises that in such cases the client's consent in writing should be obtained for their animal to be treated under the Cascade.

# **Under-age clients**

The Home Office advice is that the authority granted to veterinary surgeons to supply CDs is not restricted to the age of the recipient of the drug. However, the RCVS advises that particular care should be taken in

these circumstances and veterinary surgeons should not supply CDs to anyone under the age of 18, unless in their professional judgement it is appropriate to do so.

# **Veterinary nurses administering CDs**

The RCVS considers that a veterinary nurse may draw up and administer a CD provided the veterinary surgeon has prescribed the drug to a specific animal, decided on the dose, has authorised that it be drawn up and is confident that the veterinary nurse is competent to draw up and administer the prescribed dose. Whether or not to authorise the drawing up should be considered on a case by case basis.

A veterinary surgeon does not need to be present when the drugs are drawn up or administered, but the legal responsibility for the supply of the CDs remains with the veterinary surgeon. For this reason, it is important that appropriate safeguards are in place. It is good practice, for example, to have a standard operating procedure which sets out the procedure for accessing CDs and the protocol for recording their use. As well as access to the CD cabinet being limited to authorised individuals within the practice (see above), for added safeguarding, practices could consider having two responsible persons (i.e. two veterinary surgeons / one veterinary surgeon and one veterinary nurse / two veterinary nurses under veterinary direction) jointly accessing the cabinet, drawing up the medication and completing the CDR. The medication should then be administered to the patient immediately, witnessed by the second colleague.

Veterinary nurses may be asked to administer CDs out of hours when there is no vet on the premises. The RCVS advise is that the veterinary surgeon must prescribe the drug and decide on the dose and may also want to consider, before going off duty, drawing up the correct dose, labelling it and leaving it with instructions as to what time it is to be given to a particular patient. A veterinary nurse is not able to decide to give a CD or change the dose (i.e. make prescribing decisions) without the instructions of a veterinary surgeon.

See also the RCVS supporting guidance on <u>delegation to</u> <u>veterinary nurses</u>.

# **Wastage**

Discrepancies between the amounts recorded as used, the volume of the product left in the vial and the total stated volume must be avoided.

The VMD advise that pharmaceutical companies try to ensure that every bottle of medicine is precisely filled but some small variability may occur. This may result in discrepancies regarding the amount of CD used when taking into consideration the volume remaining in the container.

There may also be some wastage within the needle and hub of the syringe each time the product is withdrawn, so called 'deadspace'.

The Home Office has advised the VMD that discrepancies of up to 10% should not cause undue concern. Reconciliation at the end of each bottle is recommended to avoid consolidation of errors. Obviously, a balance of LESS than expected should be treated with greater concern. While efforts should always be made to minimise wastage, the Home Office, the VMD and RCVS Practice Standards Inspectors are all aware that some wastage due to deadspace will be unavoidable and these small discrepancies should always be recorded.

See also: Discrepancies

# **Annex A: List of Controlled Drugs Legislation and Guidance**

# Legislation all available at www.legislation.gov.uk

Misuse of Drugs Act 1971

Misuse of Drugs Regulations 2001

Misuse of Drugs Regulations (Northern Ireland) 2002

Misuse of Drugs (Safe Custody) Regulations 1973

Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973

The Controlled Drugs (Supervision of Management and Use) Regulations 2013

Veterinary Medicines Regulations 2013

# Other guidance

RCVS Codes of Professional Conduct for Veterinary Surgeons and Veterinary Nurses

Supporting Guidance, Chapter 4, Veterinary Medicines

Supporting Guidance, Chapter 11, Communication and Consent, paragraph 11.19

Supporting Guidance, Chapter 17, Veterinary Team and Business, paragraph 17.5

Practice Standards Scheme, Section 8.3

VMD <u>Controlled drugs: veterinary medicines</u>

Retail of veterinary medicine

The Cascade: Prescribing unauthorised medicines

Record keeping requirements for veterinary medicines

Home Office General security guidance for controlled drugs suppliers

BSAVA Guide to the use of Veterinary Medicines

BVA Good Practice Guide on Veterinary Medicines (members only resource)