



ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

**VETERINARY MEDICINES
GUIDANCE NOTE
No 20**

**CONTROLLED
DRUGS**

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at veterinary surgeons and pharmacists and is intended to provide guidance on the prescribing and supply of controlled drugs (CDs) and the additional requirements which must be met under misuse of drugs legislation.

The quick start guide is a summary of the provisions of the misuse of drugs legislation, detailed information is found in the body of the VMGN.

The Home Office has overall responsibility for CDs and associated legislation which relates to both veterinary and human medicines. In Northern Ireland this responsibility (excluding imports and exports) falls to the Department of Health, Social Services and Public Safety (DHSSPS).

All CDs are listed in one of five Schedules contained in the *Misuse of Drugs Regulations (MDR) 2001 and the Misuse of Drugs Regulations (Northern Ireland) (MDR(NI)) 2002*. The substances are scheduled according to their therapeutic usefulness and need for legitimate access, as well as potential for misuse and the harms caused by that misuse, to both the individual and society. Schedule 1 CDs are subject to the greatest restrictions and Schedule 5 the least.

All veterinary medicines, regardless of whether they contain a CD, must meet the requirements laid out in the Veterinary Medicines Regulations (VMR). The requirements contained in the misuse of drugs legislation are in addition to those in the VMR for medicines that contain a CD. The following is a summary of the main additional legislative requirements:

Prescriptions – There are special requirements for prescriptions for any CDs listed in Schedule 2 or 3 (excluding temazepam). It is also an offence to supply any Schedule 2 or 3 drug against a faxed or e-mailed prescription.

Validity of a prescription – A written prescription for a CD in Schedule 2, 3 and 4 is valid for 28 days only.

Supply of a CD – If you are supplying a Schedule 2 or 3 CD against the prescription from another veterinary surgeon you must first ascertain that the address specified in the prescription as the prescriber's address is an address within the UK. You must also be satisfied that the signature in the prescription is genuine.

Record keeping – a Controlled Drugs Register (CDR) should be kept for Schedule 2 CDs. There are very specific legislative requirements for the format of a CDR which are detailed in the body of the VMGN.

Storage requirements – Schedule 2 and certain Schedule 3 CDs (those containing Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam) must be securely stored in a locked receptacle to which only authorised persons may have access.

Destruction and disposal of CDs – Schedule 2 CDs may only be destroyed in the presence of authorised persons. These drugs must be rendered irretrievable before

disposal, for example, by placing an injectable solution into sawdust, or cat litter. Tablets may be crushed and mixed with soapy water. Please see body of the VMGN for further information.

There are also a number of good practice requirements which are detailed in the body of the VMGN.

FURTHER INFORMATION

- For more information on the requirements of CDs please contact the VMD's Legislation team on 01932 338317 or alternatively contact VMD reception on 01932 336911 and quote "controlled drugs".

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Introduction and Summary

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not shown in this VMGN. The VMGN will be updated as necessary and the date of the most recent update is shown on the front cover.
2. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMGN 1 Controls of Veterinary Medicines, which is published on the Veterinary Medicines Directorate's (VMD) website: http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx gives basic information about the scope of the VMR and the requirements for Marketing Authorisations (MAs). This note details the requirements for veterinary surgeons regarding the storage, supply and administration of controlled drugs (CDs).
3. The Home Office has overall responsibility for CDs and associated legislation which relates to both veterinary and human medicines. In Northern Ireland this responsibility (excluding imports and exports) falls to the Department of Health, Social Services and Public Safety (DHSSPS). The purpose of this VMGN is to provide guidance on requirements that specifically relate to veterinary medicines.
4. All veterinary medicines, regardless of whether they contain a CD, must meet the requirements laid out in the VMR. The misuse of drugs legislation requirements are in addition to those in the VMR for medicines that contain a CD.

Controlled drugs schedules

5. All CDs are listed in one of five Schedules in the *Misuse of Drugs Regulations 2001(MDR) and the Misuse of Drugs Regulations (Northern Ireland) (MDR(NI)) 2002*. A list of commonly encountered CDs can be found on the Home Office website (www.homeoffice.gov.uk/publications/drugs/drug-licences/controlled-drugs-list) and requests to establish the control status of other drugs can be sent to Home Office licensing enquiries at licensing_enquiries.aadu@homeoffice.gsi.gov.uk. A list of all current veterinary medicines that are CDs is also available on our website (www.vmd.defra.gov.uk).
6. The substances are scheduled according to their therapeutic usefulness and need for legitimate access, as well as potential for misuse and the harms caused by that misuse, to both the individual and society. Schedule 1 CDs are subject to the greatest restrictions and Schedule 5 the least. Drugs within:

Schedule 1 have little or no therapeutic value and have a high potential for misuse; they are the most strictly controlled and can only be lawfully dealt with under a Home Office licence or a DHSSPS licence if in Northern Ireland. They are not used in veterinary medicines.

Schedule 2 have therapeutic value but are highly addictive. Their use is strictly controlled, including special prescription, storage, destruction and record keeping requirements.

Schedule 3 includes barbiturates and some benzodiazepines and whilst 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 in 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.

Prescriptions

7. A prescription for any CD that is listed in Schedule 2 or 3 (excluding temazepam) must meet all the requirements below, in addition to those already listed in the VMR (detailed in VMGN 3 Guidance for Retailers - under Distribution Categories, which is published on the VMD's website
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

A prescription for any CD listed in Schedule 4 or 5 must meet all the requirements listed in the VMR only. This includes human drugs prescribed under the cascade. For further information please refer to VMGN 13 Guidance on the Use of the Cascade, which is published on the VMD website
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

8. If a written prescription is issued, it may be hand-written, typed in a computerised form or computer generated, but must be signed by the person issuing it. **It is an offence to supply against a faxed or emailed prescription.** It must also contain:
- a declaration that the CD is prescribed for an animal or herd under the veterinarian's care;
 - the full name and address of the owner plus the name of the animal to whom the CD prescribed is to be delivered;
 - the name and form of the drug;
 - the amount of the product prescribed in both words and figures;
 - the strength of the preparation (if more than one strength is available);
 - the dose to be administered ("Take as directed" or "Take as required" is not acceptable); and

It is also good practice to add the prescribing veterinary surgeon's Royal College of Veterinary Surgeons (RCVS) registration number.

9. A written prescription for a CD in Schedules 2, 3 and 4 is valid for 28 days only. As with all other veterinary medicines, prescriptions for Schedule 5 drugs are valid for six months.

10. For all CDs it is considered good practice for only 28 days worth of treatment to be prescribed unless in situations of long term ongoing medication, for example, when treating epilepsy in dogs. If more than 28 days worth of treatment is prescribed the veterinary surgeon must be assured of the competence of the owner regarding the safe use of the product.
11. 'Repeat dispense' prescriptions (multiple prescriptions issued at the same time, setting out doses to be supplied over a period of time, usually up to a year) are not allowed for CDs in Schedules 2 and 3. This is due to the fact that a prescription for these drugs is only valid for 28 days. However, 'repeat prescriptions' (single prescriptions, with multiple repeats (within 28 days of issue) are allowed for drugs in all Schedules as a prescription can legally be issued without a consultation. It is considered good practice, however, that a patient should be reviewed before prescribing a Schedule 2 or 3 drug but this is a clinical decision not a legal requirement.

Supply of a Controlled Drug

12. A veterinary surgeon may supply a CD that he/she has have prescribed. Alternatively another veterinary surgeon, or a pharmacist, may also supply a CD against a written prescription from a veterinarian.
13. A veterinary surgeon or pharmacist supplying a CD specified in Schedule 2 or 3 must ascertain that the address specified in the prescription is the address of the person issuing it and is an address within the UK. The person supplying the CD must also be satisfied that the signature in the prescription is genuine, for example, by contacting the prescribing veterinary surgeon.
14. A veterinary surgeon or pharmacist supplying a CD specified in Schedule 2 or 3, must, at the time of the supply, mark on the prescription the date on which the drug is supplied and retain the prescription on the premises from which the drug was supplied for at least 5 years.
15. Veterinary nurses are not permitted to possess or supply Schedule 2 CDs under the misuse of drugs legislation unless under the supervision of a veterinary surgeon.

Wholesale supply

16. The signature on CD requisitions must be hand-written in ink, and a faxed requisition is only an instruction to the wholesaler to prepare the CD for delivery. A veterinary surgeon who faxes a requisition for CDs to a wholesaler should only do so on the condition that the original of the requisition will be provided to the wholesaler prior to physical delivery at the practice. This is necessary so that the supplier can satisfy themselves, as required under the misuse of drugs legislation, of the genuineness of the signature and the profession/occupation of the person requisitioning the CD.

The requisition form must contain the following information:

- Name, address and profession/occupation of the recipient;
- Purpose for which the drug is supplied;
- Name, form, strength of the drug and the total quantity supplied;
- Signature of the prescriber (handwritten);

- Date of order;
 - Name and address of the supplier. This **must** be recorded indelibly on the requisition form at the time the supply is made.
17. There is no requirement for a veterinary surgeon to keep a copy of a CD requisition under the MDR. However, this can be done as best practice to improve the audit trail of CDs received.
18. For advice on the licensing requirements for wholesale supply of CDs you should contact the Home Office on drugs_licensing.aadu@homeoffice.gsi.gov.uk. More information on applications for a licence is also available at <http://www.homeoffice.gov.uk/drugs/licensing/>

Errors on a prescription

19. No person may alter a written prescription unless authorised to do so by the person who signed it. A pharmacist supplying a CD may accept a prescription if it contains minor typographical errors or spelling mistakes provided that:
- he/she is satisfied on reasonable grounds that he/she is supplying the drug in accordance with the intention of the person issuing the prescription;
 - he/she amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes or so that the prescription complies with the requirements to contain the total quantity of the preparation or the number of dosage units in either words or figures but not both (i.e. they may add the words or the figures to the prescription if they have been omitted); and
 - he/she marks the prescription so that the amendment he/she has made is attributable to him/her.

Collection of a Controlled Drug

20. A person collecting a CD specified in Schedule 2 may be asked to provide proof of their identity before the drug is supplied. If the person supplying the drug is not satisfied with that person's identity then they should refuse to supply the drug.

Supply against a prescription via the internet

21. Any person who wishes to supply a CD via the internet must still meet all legislative requirements, both in the VMR and the misuse of drugs legislation. Schedule 2 and 3 drugs must not be supplied unless the original prescription has been received first. It is good practice that the receipt of the drug be confirmed by requiring a signature at the time of delivery. If a Schedule 2 drug is being delivered via a courier it should be received and signed for by the person specified on the prescription.
22. The supply of CDs over the internet should be treated with great caution.

Record Keeping Requirements

23. Any person who purchases or supplies any product containing a CD specified in Schedule 2 must maintain a Controlled Drugs Register (CDR). This is in addition to the existing record keeping requirements detailed in VMGN 14 Record Keeping Requirements for Veterinary Medicinal Products, which is published on the VMD's website
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

The Register must:

- be either: 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 that 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 is capable of being 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;
 - be kept at the premises to which it relates 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.
24. The misuse of drugs legislation allows for the physical task of completing the CDR to be delegated by the prescribing veterinary surgeon. However the responsibility for the supply remains the responsibility of the prescribing veterinary surgeon.
25. The MDR 2001 and the MDR(NI) 2002 do not specify the format in which the Register must be kept, however the VMR do specify that the following headings must appear for all CDs purchased and supplied. Additional, but relevant, information may also be included in the Register such as running balances and the veterinary surgeon's name and RCVS number, which are a matter of good practice to keep.
26. For each CD purchased the following details must be recorded in the Register:
- Date supply received
 - Name and address from whom received (e.g. wholesaler, pharmacy)
 - Quantity received
27. For each CD supplied the following details must be recorded in the Register:
- Date supplied
 - Name/address of person or firm supplied
 - Details of the authority to possess - prescriber or licence holder's details
 - Quantity supplied

- Person collecting a Schedule 2 CD (patient/patient's rep/healthcare professional) and if a healthcare professional, their name and address
- Was proof of identity requested of patient/patient's rep (yes/no)
- Was proof of identity of person collecting provided (yes/no)

28. 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. It is recommended that the veterinary surgeon records the total use of the product even if the reconciliation of the quantity used exceeds the nominal volume on the product stated on the label.

Requirements for Product Literature and SPC

29. Veterinary medicinal products (VMP)s containing CDs in Schedule 2 or 3 must be clearly identified with "CD", preferably in a black triangle, and the relevant Schedule detailed on the product label and package insert if there is one.

Storage Requirements

30. A veterinary surgeon, pharmacist or wholesale dealer must ensure that all CDs under their control are kept in a locked container, which is constructed and maintained to prevent unauthorised access to the drugs and can only be opened by a veterinary surgeon, pharmacist, wholesaler or other persons authorised by her/him. This applies to all CDs in Schedule 2 (with the exception of Quinalbarbitone) and Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam in Schedule 3. It does not apply to any CD specified in Schedule 4 or 5.

31. For any questions relating to this legislation, contact the Home Office on: 020 7035 4848 or DHSSPS(NI) on: 028 9052 3348 or your local Controlled Drug Liaison Officer (CDLO) or Single Point of Contact (SPOC) on CDs(see paragraph 34 below).

32. For further information on storage requirements see *Misuse of Drugs (Safe Custody) Regulations 1973* or the *Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973*. A list of suppliers of prefabricated strong rooms is also available on the Home Office website following this link:
www.homeoffice.gov.uk/publications/drugs/drug-licences/security-guidance-0807?view=Binary

33. A list of authorised VMPs containing a CD is available on our website via this link:
<http://www.vmd.defra.gov.uk/mswd/controlled-drug.aspx> . The list indicates which of these VMPs have special storage requirements, as referred to above.

34. It is good practice that CDs are kept in a separate container from other medicines. Nothing should be displayed outside to indicate that CDs are kept within the container. The room housing this container should be lockable and tidy, to avoid drugs being misplaced. This room should not normally be accessible to clients, nor should the keys required for access be kept with those to other parts of the building.

However, if clients do have to enter the area it is good practice that they should be continuously supervised until such time as they leave the area.

35. It is recommended that other drugs that are liable for misuse, such as ketamine, are locked in the container and their use recorded in an informal register.

Veterinarian's bag

36. 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 then these should be transported 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 but a locked car alone is not.
37. It is good practice for the locked bag not to be left unattended in a vehicle for any length of time. This does not apply to locked containers that are fixed within the boot of the car.
38. Each veterinary surgeon is responsible for the receipt and supply of CDs from their own bag and a separate CDR must be maintained.

Returning/Destruction/Disposal Requirements

Return of medicines that are used or part-used

39. It is considered good practice for the prescribing veterinary surgeon to make every effort to recover and destroy any remaining product if the animal dies before completing a treatment.
40. Any CD prescribed for and dispensed for an animal may be returned to a veterinary surgery or pharmacy unused or part-used for the purpose of destruction. Any CD that has been returned should not be re-used and should be destroyed.
41. The destruction of returned CDs does not have to be carried out in the presence of an authorised witness, nor does it have to be recorded. However, it is good practice to make a record of any CDs that are returned and to have their destruction witnessed by another member of staff and signed against.
42. Returned CDs should be destroyed as soon as possible. If this is not possible, the CD must be clearly labelled as a return, and stored securely in compliance with the storage requirements set out above, but segregated from normal CD stock to avoid potential dispensing errors or re-use.
43. Returned CDs must not be entered into the CDR but should be recorded in a separate book or sheets designed for that purpose.

Disposal of waste product

44. The requirements relating to witnessing of destruction of Schedule 2 CDs under the MDR apply to "stock". The term "stock" refers to CDs that have not been issued or dispensed to a "patient". Left over medicines are generally considered waste if they are unusable. This means any leftover medicines, for example liquids, which are still

required for use is considered as “stock”. A witness is required if these are to be destroyed on expiry or for other reasons.

45. Any medicine left over in an ampoule or vial which is considered unusable is considered ‘waste product’. There is no legal requirement to have the disposal of waste product witnessed by an Authorised Person. However, it is good practice that the destruction of waste medicines is recorded in the CDR to avoid any anomalies with the running balance. It is also considered good practice to have the disposal witnessed by another member of staff and the witness to initial the CDR entry to confirm the medicine has been destroyed at the time the medicine is destroyed or denatured.

Destruction

46. Schedule 2 CDs must be destroyed in the presence of a VMD or RCVS Practice Standards Scheme Inspector, a witnessing veterinary surgeon who is independent of the practice concerned (this excludes locums who have or are acting in the practice, family members or any relationship that may pose a risk of collusion), or another person authorised to witness the destruction of CDs under the MDR 2001 or the MDR(NI) 2002 such as a Police contact. A record must be made of the date of destruction and the quantity destroyed, which the witness must sign. It is good practice to also record the name of the CD, form, strength and quantity, date it was destroyed and the signature of the witness and the professional destroying it. This does not apply to patient-returned medicines – please refer to paragraph 38 and 39 above.
47. There is no requirement to have the destruction of Schedule 3, 4 and 5 CDs witnessed except where a veterinary surgeon or pharmacist has produced the Schedule 3 preparation, for example, for use under the cascade. Due to the well known abuse of ketamine, it is considered good practice to have the destruction witnessed.
48. CDs should be rendered irretrievable before disposal. This can be achieved, for example, by placing an injectable solution into sawdust or cat litter, or by using a CD denaturing kit. These are plastic boxes containing absorbent material which can be passed on to a waste contractor. Solid formulations can be crushed and mixed with soapy water. Further advice on the disposal of veterinary medicines is available from the Health and Safety Executive (www.hse.gov.uk or tel: 0845 345 0055).

Controlled Drug Liaison Officer (CDLO) or a Single Point of Contact (SPOC) for CDs

49. Most Police forces throughout the UK have a dedicated CDLO or SPOC who is available to liaise with any veterinary practice within their area. A CDLO or SPOC is able to offer advice on safe storage; auditing; destruction; suspicious activity; internal thefts; forged or stolen prescriptions; as well as ‘current crime trends’ and ‘demands on the streets’; etc. A CDLO is also authorised under the MDR (if a Constable), or authorised by the Primary Care Trust (PCT) Accountable Officer (if employed by the Police service as a civilian) to witness the disposal of CDs.
50. A list of CDLOs and SPOCs is available on the VMD website <http://www.vmd.defra.gov.uk/mswd/controlled-drug.aspx>

Import and Export

51. The import and export of CD raw materials and finished preparations within Schedules 2, 3 and 4 Part I of The MDR 2001 are subject to an import/export licensing regime which is operated by the Home Office Drugs Licensing and Compliance Unit.
52. Those Schedule 4 Part II drugs in a medicinal form for personal use (i.e. already dispensed for a named animal or animals) will not need a personal import or export licence to enter or leave the United Kingdom, as are all of the preparations within Schedule 5.
53. For further guidance and information on licensing requirements use the link: <http://www.homeoffice.gov.uk/drugs/licensing/>
54. For guidance on taking a veterinary medicinal product containing a CD prescribed to and accompanied by the nominated animal into or out of the UK use the link: www.homeoffice.gov.uk/drugs/licensing/personal/
55. For guidance on importing or exporting a stock of CDs into or out of the UK, use the link: www.homeoffice.gov.uk/drugs/licensing/import-export/

Further Information

56. For more information on the requirements for veterinary medicines containing CDs please contact the VMD's Legislation team on 01932 338317 or alternatively contact VMD reception on 01932 336911 and ask for information on "controlled drugs".

List of Abbreviations

CD	Controlled Drug
CDLO	Controlled Drugs Liaison Officer
CDR	Controlled Drugs Register
DHSSPS	Department of Health, Social Services and Public Safety
MA	Marketing Authorisation
MDR	Misuse of Drugs Regulations 2001
MDR (NI)	Misuse of Drugs Regulations 2002
RCVS	Royal College of Veterinary Surgeons
SPOC	Single Point of Contact for Controlled Drugs
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations



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OF VETERINARY MEDICINES

VETERINARY MEDICINES GUIDANCE NOTE

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