



**Veterinary Medicines
Guidance Note**

Controlled Drugs

No 29

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**ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES**



TABLE OF CONTENTS

CONTENTS	PARAGRAPH	PAGE
INTRODUCTION	1	2
Controlled Drugs Schedules	3	2
PRESCRIPTIONS	5	3
SUPPLY OF A CONTROLLED DRUG	9	3
Errors on a Prescription	12	4
COLLECTION OF A CONTROLLED DRUG	13	4
Supply via the Internet	14	4
RECORD KEEPING REQUIREMENTS	16	5
REQUIREMENTS FOR PRODUCT LITERATURE AND SPCs	20	6
STORAGE REQUIREMENTS	21	6
Veterinarian's Bag	26	6
RETURNING/DESTRUCTION/DISPOSAL REQUIREMENTS	29	7
Returning of medicines that are used or part-used	29	7
Destruction	34	7
Controlled Drugs Liaison Officer (CDLO) or SINGLE POINT OF CONTACT (SPOCs)	37	8
IMPORT AND EXPORT	39	8
FURTHER INFORMATION	44	9

INTRODUCTION

1. The Home Office has overall responsibility for controlled drugs 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 guidance note is to provide guidance on requirements that specifically relate to veterinary medicines.
2. All veterinary medicines, regardless of whether they contain a controlled drug, must meet the requirements laid out in the Veterinary Medicines Regulations (VMR). The misuse of drugs legislation requirements are in addition to those in the VMR for medicines that contain a controlled drug.

CONTROLLED DRUGS SCHEDULES

3. All controlled drugs are listed in one of five Schedules in the Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations (Northern Ireland) 2002. A list of commonly encountered controlled drugs can also be found on the Home Office website (www.homeoffice.gov.uk/documents/cdlist.pdf) and requests to establish the control status of other drugs can be sent to licensing enquiries at licensing_enquiries.aadu@homeoffice.gsi.gov.uk. A list of all current veterinary medicines that are controlled drugs is also available on our website (www.vmd.gov.uk) under 'Vet/SQP', 'Controlled Drug Information'.
4. 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 controlled drugs 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

5. A prescription for any controlled drug 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 VMG Note 3 – Distribution Categories). A prescription for any controlled drug listed in Schedule 4 or 5 must meet all the requirements listed in the VMR only. This includes human drugs prescribed under the cascade.
6. 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 controlled drug is prescribed for an animal or herd under the veterinarian's care;
 - the name to whom the controlled drug 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
 - the prescribing veterinary surgeon's registration number with the RCVS.
7. A written prescription for a controlled drug 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.
8. For controlled drugs in Schedules 2-5 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 prescribing an extended prescription, the veterinary surgeon must be assured of the competence of the owner regarding the safe use of the product before issuing.

SUPPLY OF A CONTROLLED DRUG

9. A veterinary surgeon may supply a controlled drug that they have prescribed. Alternatively another veterinary surgeon, or a pharmacist, may also supply a controlled drug against a written prescription from a veterinarian.

10. A veterinary surgeon or pharmacist supplying a controlled drug specified in Schedule 2 or 3 must ascertain that the address specified in the prescription as the address of the person issuing it is an address within the United Kingdom. The person supplying the controlled drug must also be satisfied that the signature in the prescription is genuine, for example, by contacting the prescribing veterinary surgeon.
11. A veterinary surgeon or pharmacist supplying a controlled drug 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.

ERRORS ON A PRESCRIPTION

12. No person may alter a written prescription unless authorised to do so by the person who signed it. A pharmacist supplying a controlled drug may accept a prescription if it contains minor typographical errors or spelling mistakes provided that-
 - he is satisfied on reasonable grounds that he is supplying the drug in accordance with the intention of the person issuing the prescription;
 - he 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 (ie. they may add the words or the figures to the prescription if they have been omitted); and
 - he marks the prescription so that the amendment he has made is attributable to him.

COLLECTION OF A CONTROLLED DRUGS

13. A person collecting a controlled drug 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

14. Any person who wishes to supply a controlled drug 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 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.
15. The supply of CDs over the internet should be treated with great caution.

RECORD KEEPING REQUIREMENTS

16. Any person who purchases or supplies any product containing a controlled drug specified in Schedule 2 must maintain a Controlled Drug Register. This is in addition to the existing record keeping requirements detailed in VMG No. 16 – Record Keeping Requirements for Veterinary Medicinal Products.

The Register must:

- 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.
17. The Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations (Northern Ireland) 2002 do not specify the format in which the Register must be kept, however the Regulations 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 surgeons name and RCVS number, which are a matter of good practice to keep.
18. For each controlled drug 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.
19. For each controlled drug 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 controlled drug (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)

REQUIREMENTS FOR PRODUCT LITERATURE AND SPCs

20. Veterinary medicinal products containing controlled drugs in Schedule 2 or 3 must be clearly identified with “CD”, preferably in a black triangle, and the relevant Schedule detailed on their labels and leaflet if there is one.

STORAGE REQUIREMENTS

21. A veterinary surgeon, pharmacist or wholesale dealer must ensure that all controlled drugs 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 (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; <http://drugs.homeoffice.gov.uk/publication-search/drug-licences/security-guidance-0807?view=Binary>
22. This applies to all controlled drugs in Schedule 2 except Quinalbarbitone, and in Schedule 3, Buprenorphine, Diethylpropion, Flunitrazepam and Temazepam. It does not apply to any controlled drug specified in Schedule 4 or 5. 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).
23. A list of veterinary medicinal products containing controlled drugs that have additional storage requirements is available on our website, www.vmd.gov.uk.
24. It is good practice that controlled drugs are kept separate from other medicines. Nothing should be displayed outside to indicate that controlled drugs 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.
25. 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

26. 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 controlled drugs but a locked car alone is not.

27. 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.
28. Each veterinary surgeon is responsible for the receipt and supply of controlled drugs from their own bag and a separate Controlled Drugs Register must be maintained.

RETURNING/DESTRUCTION/DISPOSAL REQUIREMENTS

RETURN OF MEDICINES THAT ARE USED OR PART-USED

29. 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.
30. Any controlled drug may be returned to a veterinary surgery or pharmacy that has been prescribed for, and dispensed to an animal, and then returned unused or part-used. Any controlled drugs that have been returned should not be re-used and should be destroyed.
31. It is not a legislative requirement that the destruction of returned controlled drugs 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 controlled drugs that are returned and to have their destruction witnessed by another member of staff and signed against.
32. Returned controlled drugs should be destroyed as soon as possible. If this is not possible, the controlled drug must be clearly labelled as a return, and stored securely in compliance with safe custody regulations, but segregated from normal controlled drug stock to avoid potential dispensing errors or re-use.
33. Returned controlled drugs must not be entered into the controlled drug Register but should be recorded in a separate book or sheets designed for that purpose.

DESTRUCTION

34. Schedule 2 controlled drugs may not be destroyed except in the presence of an Animal Medicines Inspectorate (AMI) 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 controlled drugs under the Misuse of Drugs Regulations 2001 or the Misuse of Drugs Regulations (Northern Ireland) 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 controlled drug, form, strength and quantity, date it was destroyed and the signature of the witness and the professional destroying it.

35. There is no requirement to have the destruction of Schedule 3, 4 and 5 controlled drugs 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.
36. Controlled drugs 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 controlled drug 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 CONTROLLED DRUGS

37. Most Police Force 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 authorised under the MDRs if a Constable or authorised by the PCT Accountable Officer if employed by the Police service as a civilian..**
38. A list of CDLOs and SPOCs is available on the VMD website www.vmd.gov.uk under 'Vet/SQP info', 'Controlled Drug Information'.

IMPORT AND EXPORT

39. The import and export of controlled drug raw materials and finished preparations within Schedules 2, 3 and 4 Part I of The Misuse of Drugs Regulations 2001 are subject to a licensing regime which is operated by Home Office Drugs Licensing and Compliance Unit.
40. Those Schedule 4 Part II drugs in a medicinal form for personal use (i.e. already dispensed for a named animal or animals) are exempt from this requirement, as are all of the preparations within Schedule 5
41. For further guidance and information on licensing requirements use the link: <http://drugs.homeoffice.gov.uk/drugs-laws/licensing/>
42. For guidance on taking controlled drug medication prescribed to and accompanied by the nominated animal into or out of the UK, use the link: <http://drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/>

VETERINARY MEDICINES GUIDANCE NOTE 29

43. For guidance on importing or exporting a stock of controlled drugs into or out of the UK, use the link: <http://drugs.homeoffice.gov.uk/drugs-laws/licensing/import-export/>

FURTHER INFORMATION

44. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: (+44) (01932) 336911; Fax: (+44) (01932) 336618 or E-mail: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.gov.uk).

VETERINARY MEDICINES GUIDANCE NOTE

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