

BVZS GUIDELINES FOR THE PRESCRIPTION, SUPPLY AND CONTROL OF PRESCRIPTION-ONLY VETERINARY MEDICINES (POMs) IN ZOOLOGICAL COLLECTIONS AND WILDLIFE RESCUE CENTRES

BVZS receive regular requests for advice from its members who provide veterinary services to zoological collections (whether or not they are licensed under the Zoo Licensing Act 1981) and wildlife facilities (including rescue centres). The very nature of these organisations, and the animals kept there, present unique challenges for the veterinary surgeon charged with their care, both from a clinical and a regulatory perspective. This advice note is intended to assist members interpret the regulation associated with the use of POMs medications in these facilities. Further advice can be obtained from the Royal College of Veterinary Surgeons, Veterinary Medicines Directorate or the Veterinary Defence Society (if you are a member).

The most frequently asked questions include:

1. What is the legal position when prescribing and/or supplying POMs, including Controlled Drugs?
2. What advice or guidance is available?
3. Do zoo premises or wildlife facilities have to be registered with the RCVS as Veterinary Practice Premises?
4. Can a stock of drugs be kept at the zoo collection or wildlife facilities for a veterinary surgeon to use at a later date?
5. Are there circumstances in which POMs can be left at a zoo collection or wildlife facilities for use by staff in the absence of the veterinary surgeon?
6. Does this also apply to Controlled Drugs?
7. What about drugs for euthanasia?
8. Are there any circumstances in which a veterinary surgeon can prescribe or supply POMs (including Controlled Drugs) to a lay person for use in animals that are not under his/her care and there has been no clinical assessment?
9. Does the Cascade apply to zoo animals and wildlife and what are the implications of this?
10. What is the position with respect to the supply of Etorphine?
11. What is the position with the supply of Narcan/Naloxone for emergency use in humans?

1. What is the legal position when prescribing and/or supplying POMs, including Controlled Drugs?

The Veterinary Medicine Regulations 2013 were produced in ostensibly the current form in 2005 (for the purpose of implementing EU regulation EU 82/2001) and have been updated regularly since.

They require that a veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V must first carry out a ‘**clinical assessment of the animal**’, and ‘**the animal must be under that veterinary surgeon’s care**’. Neither phrase is defined in the legislation.

For the avoidance of any doubt, exactly the same requirement applies to Controlled Drugs (POM-V [CD] or the human equivalent). However, Controlled Drugs have additional prescription, storage and recording requirements which are dealt with below.

The Misuse of Drugs Act 1971 deals principally with the illegal possession/supply/use of controlled drugs and places drugs in 3 classes of ‘seriousness’.

Class A includes Heroin, Cocaine, but also Etorphine, Fentanyl, Methadone, Pethidine and Barbiturates (in an injectable form) all of which appear in licensed veterinary or human products.

Class B includes Barbiturate tablets and recently Ketamine.

Class C includes Diazepam, certain anabolic steroids and now Tramadol. The Class in which a drug appears determines the penalties for illegal use, or misuse of these drugs.

The Misuse of Drugs Regulations 2001 (made under the 1971 Act) give legal authority to certain people, including veterinary surgeons, to possess, use, prescribe and supply products containing Controlled Drugs. They place the products in five Schedules which dictate conditions of prescription, secure storage and recording of use.

Schedule 1

e.g. LSD, Ecstasy, Cannabis.

There is no legal authority for a veterinary surgeon to possess drugs in this schedule. Possession requires a Home Office licence.

Schedule 2

e.g. Etorphine (Immobilon), Quinalbarbitone (Somulose), Methadone (Comfortan), Fentanyl (Recuvyra), Pethidine.

There are enhanced requirements for prescription, requisition, record keeping, disposal and safe custody. All, except Quinalbarbitone, must be stored in a suitable locked cabinet secured to the fabric of the building at all times.

Schedule 3

e.g. Phenobarbitone (Epiphen), Pentobarbitone Sodium (Euthatal, Dolethal), Buprenorphine (Vetergesic).

The safe custody requirements of Schedule 2 apply to Buprenorphine, although Barbiturates are exempt. Nevertheless, the RCVS PSS advise all Schedule 3 drugs are locked away. There is no requirement to keep a register of their use.

Schedule 4

e.g. Ketamine, Clenbuterol (Ventipulmin), Nandrolone Laurate (Nandrolin).

There is no legal safe custody or record keeping requirements, although due to the potential for the drug's abuse, it is not only considered good practice, but it is also a requirement of the RCVS Code to Professional Conduct (and VMD guidance) that products containing Ketamine are kept secure in the CD cabinet and an 'informal' register of their use is maintained. Ketamine has recently been reclassified as a Class B drug (from Class C) and therefore the sanctions for illegal use are more severe. There is currently a consultation running to re-classify Ketamine as Schedule 2 under the Veterinary Medicine Regulations 2013.

Schedule 5

e.g. products containing Codeine (Pardale-V). These are largely exempt from full control.

A full list of authorised veterinary Controlled Drugs can be found at:

<http://www.vmd.defra.gov.uk/vet/controlled-drug.aspx#authorised>

A full list of all Controlled Drugs can be found at:

http://webarchive.nationalarchives.gov.uk/+/http://www.homeoffice.gov.uk/publications/drug_s/drug-licences/controlled-drugs-list

2. What advice or guidance is available?

RCVS supporting Guidance Note 4.9 of the Code to Professional Conduct interprets ‘**under his or her care**’ as:

- the veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner’s agent.
- that responsibility must be real and not nominal.
- the animal or herd must have been seen immediately before prescription or recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe.
- the veterinary surgeon must maintain clinical records of that herd/flock/individual.
- What amounts to 'recent enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case.
- A veterinary surgeon cannot **usually** have an animal under his or her care if there has been no physical examination.

Guidance Note 4.12 interprets ‘**Clinical Assessment**’ as an assessment of **relevant clinical information** which **may** include an examination of the animal’ (our emphasis).

The BVA Good Practice Guide On Veterinary Medicines and BSAVA Medicines Guide, supported by the VMD, recognise that in particular cases, it will be reasonable to allow selected clients to hold a small reserve of some preparations provided the veterinarian has identified a recurring need for the use and is satisfied that the client has demonstrated their reliability in all aspects of using medicines. In many ways, zoological collections are not unlike the commercial farm situation where veterinary surgeons attend regularly enough to consider they have sufficient personal knowledge of stock for the animals to be ‘under their care’.

3. Do zoo premises or wildlife facilities have to be registered with the RCVS as Veterinary Practice Premises (VPP)?

Since April 2009, veterinary surgeons may only supply veterinary medicinal products from ‘Veterinary Practice Premises’ or VPP registered with the RCVS and must maintain a record of all premises and places where they store or keep medicines. Details of what premises the RCVS and VMD are likely to consider to a VPP can be found on the RCVS website at <http://www.rcvs.org.uk/registration/register-of-veterinary-practice-premises/frequently-asked-questions/>

Where a vet has supplied veterinary medicines to a zoological collection or wildlife facilities from Veterinary Practice Premises already registered as such with the RCVS, it is unlikely that further registration of the receiving premises would be required.

Alternatively, if an organisation employs their own veterinary surgeon(s) and drugs are delivered direct from a wholesaler to the premises they may well need to be registered. However, the VMD acknowledge that each case is treated on its merits and advice should be sought from the RCVS in the first instance.

4. Can a stock of medications be kept at the zoo collection or wildlife facility for a veterinary surgeon to use at a later date?

Yes.

The RCVS guidance allows for a veterinary surgeon to keep a small stock of medications at a business or client premises for him/her to prescribe at a later date. He/she need not be permanently based at the premises which do not have to be registered, but the veterinary surgeon should maintain a record of the premises at which any such stocks are kept.

To store Controlled Drugs at a business or client premises that have not yet been legally prescribed may require a Home Office licence whereas if they have already been legally prescribed for animals under care following a clinical assessment they may not require a Home Office licence. The medications (whether Controlled Drugs or not) should be kept securely to prevent access by unauthorised personnel and the safe custody requirements of Controlled Drugs still strictly apply.

5. Are there circumstances in which prescription only medicines can be left at a collection for use by staff in the absence of the veterinary surgeon?

Yes. If, following a clinical assessment, a veterinary surgeon recognises a recurring need for a POM in an animal (or animals) under his/her care he/she may supply a small quantity of drugs appropriate to this need.

However, it must be remembered that it is illegal for any lay person to diagnose disease in animals or to treat them with Prescription Only Medicines unless directed to do so by a veterinary surgeon.

Part 1 paragraph 1 of Schedule 3 of The Veterinary Surgeons Act 1966 allows a minor medical treatment to be given to an animal by its owner or by a person in the employment of the owner. For clarification, this dispensation does not apply to animals that either belong to someone else or are not 'owned' at all, such as wildlife.

It is acknowledged that there may be occasions where prior knowledge of an animal (or group of animals) under his/her care allows a veterinary surgeon to authorise, in clearly defined circumstances, the use of POMs from the small stock of medicines that have been left at the premises.

Alternatively it may be possible to make a clinical assessment by way of a telephone consultation which he/she can offer advice and prescribe treatment.

In wildlife facilities, however, it will be more difficult for a veterinary surgeon to satisfy themselves that animals they have never seen, but may be presented in the future, are truly 'under his/her care' and that they can make a reasonable clinical assessment. In addition the question of whether the animals are 'owned' by the wildlife rescue centre may also present a difficulty (see question 7).

At all times the veterinary surgeon must retain absolute control and responsibility for the storage and use of the Prescription Only Medicines that he/she has supplied irrespective of who now owns them. In order to do so, it is advisable that only a very limited number of staff are authorised to have access to the medicines left at the zoo collection and the prescribing veterinary surgeon must satisfy themselves they are adequately trained and understand the limits of their authority. Written Standard Operating Procedures are invaluable in this respect.

6. Does this also apply to Controlled Drugs?

For the avoidance of doubt, Controlled Drugs are no different to other Prescription Only Medicines inasmuch as they can be prescribed and supplied by veterinary surgeons to animals under their care following a clinical assessment, in just the same circumstances as other Prescription Only Medicines. This situation occurs in other types of veterinary practice, for example the supply of Phenobarbitone tablets (Schedule 3, Class B controlled drug) to an owner for the treatment of an epileptic dog.

The RCVS Code of Professional Conduct states:

Veterinary surgeons should take extra care when prescribing controlled drugs, to ensure that the medicines are used only for the animals under treatment.

Zoological collections present unique challenges and a veterinary surgeon may legally identify situations where, he or she authorises a nominated, trained, experienced keeper to administer Controlled Drugs, for example to sedate or tranquilise an animal, under their express direction, but when the veterinary surgeon is not present.

Any POM-V (CD) left at a zoological collection in such circumstances will still need to meet any safe custody and record keeping requirements set out in the Misuse of Drugs Regulations 2001 and the veterinary surgeon will retain ultimate (and legal) responsibility for their security and safe use. It bears repeating that the illegal use and supply of Controlled Drugs attracts severe penalties.

7. What about Controlled Drugs for euthanasia?

Injectable Pentobarbitone and Quinalbarbitone (both Class A drugs) are incorporated in certain authorised veterinary medicines classified as POM-V (CD3) and POM-V (CD2) respectively. As such they can legally be prescribed and supplied by veterinary surgeons, following a clinical assessment, for use in animals ‘under their care’ as defined above.

Euthanasia is not an act of veterinary surgery (within the meaning of The Veterinary Surgeons Act) although giving an intravenous injection or otherwise administering a licensed veterinary medicine is. There is an exemption for owners (or their employees) at Part 1 para 1 of Schedule 3 of The Veterinary Surgeons Act which allows them to perform a ‘minor medical procedure’ (a term that is not strictly defined) on their own animal or that of their employer.

There may be circumstances where a veterinary surgeon with animals under his/her care within a zoological collection might be able to set out clearly defined parameters, which may involve a telephone consultation, which allow him/her to authorise a named individual to perform euthanasia with a POM-V that has been supplied in advance.

In the case of wildlife facilities it is imperative that animals are signed over to the facility by the finder so they become ‘owned’ by the organisation. However, in most cases wildlife cannot reasonably be said to be under the veterinary surgeons care or to have received a clinical assessment unless there is significant veterinary input at the premises.

8. Are there any circumstances in which a veterinary surgeon can prescribe or supply POMs (including Controlled Drugs) to a lay person for use in animals that are not under his/her care and there has been no clinical assessment?

The only exception occurs where the Secretary of State has authorised the administration of such a product to a wild animal pursuant to Schedule 3 para 4(2) of The Veterinary Medicines Regulations.

9. Does the Cascade apply to zoo animals and wildlife and what are the implications of this?

Yes.

It is acknowledged that there are no, or very few, authorised veterinary medicines for many species treated at zoos and wildlife rescue centres and so, to safeguard animal welfare, veterinary surgeons may use the provisions set out in the Cascade. Guidance on the Cascade is available in the VMD’s guidance note 13 (<http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNote13.pdf>). However, when treating an animal of species ‘*traditionally farmed for its meat or other produce*’, veterinary surgeons must only prescribe a medicinal product whose active ingredient appears in Table 1 of EU 37/2010 irrespective of whether the animal is in a zoo. The only exceptions are for equidae, provided they have a passport with the declaration at section IX signed by the owner to say that it can never go for human consumption, and for deer where a ‘no eat’ tag can be applied (VMD guidance note 16 <http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNote16.pdf>).

10. What is the position with respect to the supply of Etorphine?

Products containing Etorphine (Immobilon and M99) are, in some cases, still the drug of choice for chemically capturing some zoo animals (e.g. equidae, elephants and rhinoceros). They are powerful opiates that are rapidly fatal to humans following accidental injection or absorption of even small

quantities and cannot be used safely without having an appropriate reversing agent immediately available.

The law allows veterinary surgeons to prescribe Etorphine for use by others in dart guns assuming they can fulfil the requirement that the animals are under their care.

However, it would not be considered appropriate to leave Etorphine in a syringe in consideration of both health and safety issues and the potential for drug degradation. The product should only be supplied in the original bottle encased in the thick polystyrene in which it is packaged. It should only be drawn up immediately before use.

11. What is the position with respect to the supply of Narcan/Naloxone for emergency use in humans?

Naloxone is a safe, efficacious drug for reversing the effects of opioid overdoses. There are no veterinary products containing Naloxone and those available for humans are POM. As such Naloxone can only be supplied to named individuals at risk of opioid overdose, via a medical prescription. A veterinary surgeon cannot legally prescribe for another person.

However, a veterinary surgeon can legally order/purchase/possess a human POM although, in ordinary circumstances, cannot use it to treat another person. The Human Medicines Regulations 2012 provides that only individual patients with a legitimate prescription and appropriate medical practitioners are allowed to administer parenteral (injectable) POMs including Naloxone.

However, there is an important exception.

In June 2005 Naloxone was added to the list of medicines that can legally be administered **by anyone** for the purpose of saving a life in an emergency. (Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order).

In practice, if a veterinary surgeon is using Immobilon/M99 he can legally possess Naloxone and anyone can then use that drug in an emergency in order to save life.

If Immobilon/M99 is to be used in the absence of a veterinary surgeon then probably the only legal route for a non-vet to possess the drug would be for an individual to get a prescription from their doctor. Nevertheless, in an emergency this drug could then be administered by **anyone** to **anyone** else in order to save life.