BSAVA Guide to the Use of Veterinary Medicines

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Veterinary Medicines Directorate

The Veterinary Medicines Directorate supports this *Guide to the Use of Veterinary Medicines* written and published by the BSAVA.

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BRITISH SMALL ANIMAL VETERINARY ASSOCIATION

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Introduction from the editors

Welcome to the ***BSAVA Guide to the Use of Veterinary Medicines***. We hope that these pages will provide a comprehensive and authoritative guide to the safe and legal use of veterinary medicines in companion animals in the UK, for all members of the veterinary team.

The editors are very grateful to the various experts in their respective fields who have contributed to the Guide. NOAH, RCVS, BVA and the VMD all maintain websites and publish literature relevant to veterinary medicines. The editors would encourage you to make use of these and other sources of information, just as we have done.

In this edition all sections have been updated and expanded. There is also a new section on responsible prescribing and dispensing for exotic pets, zoo and wildlife species. We have added multiple choice questions at the end of each section to enable the Guide to be used for individual or practice team training. Everyone who uses veterinary medicines has a legal, ethical and moral responsibility to use them appropriately. Many infringements of the law relating to the possession, use and disposal of veterinary medicines are criminal offences and we hope that this guide will help practitioners stay on the correct side of the law in an area where this can sometimes be problematic.

The law in the UK relating to the use of veterinary medicines – the Veterinary Medicines Regulations – are in turn based on EU laws. These EU laws are under review as the update of the Guide is being published and with the uncertainty of Brexit we can expect changes in both EU and UK law in the years ahead. The editors would encourage you to stay up to date with the progress of this review and the changes that will surely follow.

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Useful links

AMTRA	Animal Medicines Training Regulatory Authority
ABPI	Association of the British Pharmaceutical Industry
BP	British Pharmacopoeia
BVA	British Veterinary Association
EMA	European Medicines Agency
NOAH	National Office of Animal Health
PSS	Practice Standards Scheme
RCVS	Royal College of Veterinary Surgeons
RPS	Royal Pharmaceutical Society
SPC	Summary of Product Characteristics
VMD	Veterinary Medicines Directorate
VMR	Veterinary Medicines Regulations
VPIS	Veterinary Poisons Information Services

Authorization and classification

KEY POINTS

- Veterinary Medicinal Products (VMP) are authorized by the Veterinary Medicines Directorate (VMD) or the European Medicines Agency (EMA)
- They are assessed for safety, efficacy and quality
- All must have a Marketing Authorization (MA)
- Authorized VMP must display a VM or EU code
- There are four main categories of authorized veterinary medicines:
  - POM-V medicines that can only be prescribed by a veterinary surgeon (veterinarian)
  - POM-VPS medicines that can be prescribed by a veterinary surgeon, pharmacist or suitably qualified person (SQP)
  - NFA-VPS medicines that can be supplied by a veterinary surgeon, pharmacist or SQP
  - AVM-GSL medicines that can be sold by anyone

The Veterinary Medicines Directorate (VMD), an executive agency of the Department for Environment, Food and Rural Affairs (Defra), is the UK regulatory authority for veterinary medicines and has responsibility for the development of the Veterinary Medicines Regulations (VMR). The VMR regulate the authorization, manufacture, distribution and use of veterinary medicines in the UK.

The VMR transpose EU legislation relating to veterinary medicinal products (VMP) and are explained in the Veterinary Medicines Guidance pages of the VMD website ( ) (replacing the previous Veterinary Medicines Guidance Notes). They are a very useful reference text for veterinary practices.

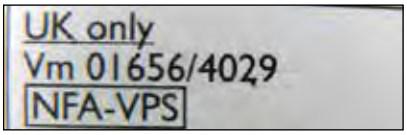
Authorization of Veterinary Medicinal Products

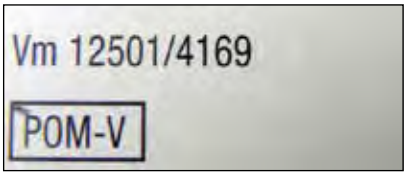
VMP are defined by the EU as:

1. Products that are medicinal by presentation – 'any substance or combination of substances presented as having properties for treating or preventing disease in animals'.
   - A product is likely to be considered medicinal by presentation if its label or product literature indicates that it will treat or prevent a disease, or if it is advertised as having such properties. The use of words such as *cures*, *treats*, *prevents*, *relieves*, *heals*, *anthelmintic and antibiotic* are considered to be medicinal claims.
2. Products considered medicinal by function – 'any substance or combination of substances which may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.
   - Medicinal by function means that the product contains a substance or ingredient whose properties exert a medicinal effect or restore, correct or modify a physiological function.

In order to be marketed in the UK, the VMP must have a marketing authorization (MA) granted by the VMD or by the EMA. The VMD or the EMA will only grant an MA if satisfied that the product meets safety, quality and efficacy criteria, and complies with EU law.

The VMR specify the criteria that products have to comply with in order to be granted an MA, including the information that must be displayed on an authorized product's label. The product's authorization number must be included on its label. UK authorization numbers include the letters 'Vm' or 'Vh' followed by five digits, an oblique, then four digits (e.g. Vm 01234/5678). An EU authorization granted by the EMA is formatted with the letters EU followed by four sets of numbers (e.g. EU/1/23/456/789). If the MA or EU authorization number on a VMP is not present, veterinary surgeons should be wary because, with certain exceptions, unless a VMP has a valid UK or EU MA, it is illegal for it to be advertised, sold or supplied in the UK.





Classification of VMP

In the UK there are four main categories of authorized VMP:

- Prescription-only medicine – veterinarian (**POM-V**)
- Prescription-only medicine – veterinarian, pharmacist, suitably qualified person (**POM-VPS**)
- Non-food animal – veterinarian, pharmacist, suitably qualified person (**NFA-VPS**)
- Authorized veterinary medicine – general sales list (**AVM-GSL**).

POM-V

POM-V medicines may only be prescribed by a veterinary surgeon following a clinical assessment of an animal under their care.

The prescribing veterinary surgeon may then administer the medicine or supply it to the client or give the client a written prescription to obtain the product from another veterinary surgeon or a registered pharmacist.

POM-VPS

POM-VPS medicines may only be prescribed by a veterinary surgeon, pharmacist or a suitably qualified person (SQP). There is no requirement for the prescriber to carry out a clinical assessment of the animal before prescribing a POM-VPS and the animal does not have to be under the prescriber's care.

These products are mainly authorized for administration to food producing animals, but a small number is authorized for non-food producing animals.

NFA-VPS

Products categorized as NFA-VPS are those indicated for non-food producing animals to routinely prevent or reduce endemic disease. They do not have to be prescribed, but they can only be supplied by a veterinary surgeon, pharmacist or an SQP.

AVM-GSL

AVM-GSL medicines are authorized VMP that are considered to have a wide margin of safety and which may be supplied without any special advice. There is no requirement for anyone retailing AVM-GSL medicines to be qualified and they do not have to be supplied from a registered, authorized or approved premises, but a wholesale dealer's authorization is required to wholesale such products.

Additional categories of veterinary medicines regulated by the VMR

Exemptions for Small Pet Animals (ESPA) products

These products, formerly known as SAES (Small Animal Exemption Scheme) products, are VMP for administration to minor species of small animals kept as pets (e.g. caged birds, fish, companion rabbits and small rodents). They do not have an MA and they may be retailed by anyone, but a wholesale dealer's authorization (WDA) is required to wholesale them.

Homeopathic remedies

Homeopathic remedies are considered to be VMP in the VMR if they are prepared from homeopathic stock in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia, or in a pharmacopoeia published by the British Pharmacopoeial Commission, or the competent authority of any EU Member State. Generally, veterinary homeopathic remedies can be placed on the market in the UK with a registration from the Secretary of State, rather than an MA. They may be retailed by anyone, but a wholesale dealer's authorization is required to wholesale them.

'Unauthorized' (cascade) products

Under the prescribing cascade, if there is no UK authorized VMP to treat a certain species or condition, a veterinary surgeon may prescribe one of the following, in this order:

- UK authorized VMP for use in another animal species or for another condition in the same species
- UK authorized human medicinal product
- VMP authorized in another EU Member State (a Special Import Certificate (SIC) is required)
- VMP prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorization permitting the manufacture of that type of product.

If there is no suitable VMP available in the UK or EU, the VMD will consider allowing a veterinary surgeon to import a VMP authorized in a third country, or a human medicine from an EU Member State or a third country, under a SIC.

These unauthorized products, usually human medicines, should be prescribed and supplied as if they were POM-V medicines.

See also **Prescribing cascade**.

See also **Importing medicines**.

Controlled Drugs

Some VMP are authorized as Controlled Drugs (CDs) under the Misuse of Drugs Regulations 2001 in Great Britain and under the Misuse of Drugs Regulations (Northern Ireland) 2002 in Northern Ireland.

Generally, CDs are categorized as POM-V and subject to the controls of the VMR. However, CDs containing substances falling under Schedule 2 of the Misuse of Drugs Regulations (and some Schedule 3 CDs) are subject to additional storage, prescribing, disposal and recording requirements.

See also **Controlled Drugs**.

QUESTIONS

1. Which organization is responsible for controlling the responsible, safe and effective use of veterinary medicines in the UK?
    a. AMTRA
    b. VMD
    c. NOAH
    d. Home Office
2. What testing does a veterinary medicine go through in order to get an MA?
    a. Safety, cost, appearance
    b. Cost, quality, safety
    c. Batch numbers, safety, cost
    d. Safety, efficacy, quality
3. What categories of medicines can SQPs prescribe and supply?
    a. POM-V; POM-VPS
    b. POM-VPS; NFA-VPS; AVM-GSL
    c. POM-V; NFA-VPS
    d. POM-V; POM-VPS; NFA-VPS; AVM-GSL
4. AVM-GSL is the acronym for:
    a. Any Veterinary Medicine – General Sales List
    b. Approved Veterinary Medicine – General Sale Log
    c. Authorized Veterinary Medicine – General Sales List
    d. Advanced Veterinary Medicine – General Sales List
5. Who can supply Exemption for Small Pet Animals products?
    a. Vets only
    b. Vets and all SQPs
    c. Vets and companion animal SQPs only
    d. Anyone

ANSWERS 1 – b; 2 – d; 3 – b; 4 – c; 5 – d

Prescribing, supplying, dispensing and labelling procedures

KEY POINTS

- A prescription can be oral (if the prescriber also supplies or administers the medicine), or it can be in writing
- Written prescriptions are valid for 6 months unless the prescriber specifies a shorter period

'Prescribing' refers to the action of assessing the animal's disease or condition and deciding on the most appropriate medicine to supply or administer. A prescription, which can be either oral or written, is the means by which the action of prescribing is relayed to the customer.

Products classified as 'prescription-only medicine – veterinarian' (POM-V) and 'prescription-only medicine – veterinarian, pharmacist, suitably qualified person' (POM-VPS) may be prescribed orally if the prescriber also supplies or administers the product.

Where a veterinary medicine is not supplied by the person who prescribed it, the prescription must be written.

The classification of a veterinary medicine determines who can prescribe it (see also **Authorization and classification**).

POM-V

Only a veterinary surgeon (veterinarian) may prescribe a POM-V medicine (or a product for administration under the cascade). A POM-V medicine may only be prescribed following a clinical assessment of the animal, and the animal must be under that veterinary surgeon's care.

The Veterinary Medicines Regulations (VMR) do not define what a clinical assessment is nor 'under the vet's care' but the RCVS's Code of Professional Conduct for Veterinary Surgeons provides guidance (see sections 4.9–4.12).

POM-VPS

A veterinary surgeon, pharmacist or suitably qualified person (SQP) may prescribe a POM-VPS medicine. The animal does not have to be under their care and they do not have to carry out a clinical assessment of the animal. However, when prescribing a POM-VPS medicine, the prescriber must consider all available information about the animal(s), its condition and the required treatment, before deciding on the most appropriate veterinary medicinal product (VMP) to supply.

Products classified as 'non-food animal – veterinarian, pharmacist, SQP' (NFA-VPS) or 'authorized veterinary medicine – general sales list' (AVM-GSL) do not have to be prescribed unless they are supplied for use outside of their marketing authorization (i.e. under the cascade).

Written prescriptions

Any person who is permitted to supply a POM-V or POM-VPS medicine may also supply such a product in accordance with a written prescription from another prescriber. They must satisfy themselves that the prescription has been written and signed by a person entitled to prescribe the product, and that the person being supplied is the person named on the prescription.

It is an offence for any person to alter a written prescription unless authorized to do so by the prescriber.

Alexei Logvinovich/Shutterstock.com

A written prescription for a veterinary medicine must include the following information:

- Name, address and telephone number of the person prescribing the product
- Qualifications of the person prescribing the product (it is good practice to include their RCVS or SQP number)
- Name and address of the owner or keeper of the animal
- Identification (including the species) of the animal or group of animals to be treated
- Premises at which the animal(s) are kept, if this is different from the address of the owner or keeper
- Date
- Signature (or other authentication) of the person prescribing the product
- Name and amount of the product prescribed
- Dose and administration instructions
- Necessary warnings
- Withdrawal period, if relevant
- If it is prescribed under the cascade, a statement to that effect.

Written prescriptions for POM-V or POM-VPS medicines:

- Are valid for 6 months unless the prescriber states a shorter period
- May only be used once unless the prescriber specifies that it is repeatable
- If repeatable, the number of repeat supplies that may be made must be specified (if the prescription is not repeatable, it is considered good practice for it to state that).

Written prescriptions for Controlled Drugs

If a written prescription is issued for a Controlled Drug (CD) it can be typed, computer generated or handwritten, but it must be personally signed by the person issuing it.

It is an offence to supply a Schedule 2 or 3 CD against a faxed or emailed prescription.

In addition to the general prescription requirements above, a written prescription for a Schedule 2 or 3 CD should state an exact dose in words as well as in figures (e.g. not 'as directed'), and it must include the RCVS number of the veterinary surgeon prescribing the drug.

A written prescription for Schedule 2 or 3 CDs can only be dispensed once and only within 28 days. Single prescriptions with multiple dispenses (repeatable prescriptions) are not allowed for Schedule 2 and 3 CDs. It is good practice to mark the prescription 'no repeats'.

It is a best practice recommendation to dispense only 28 days of CDs at a time. If it is considered necessary to dispense a CD for a longer period (e.g. in the case of an epileptic dog on long-term medication), the veterinary surgeon must make sure that the owner is competent to use and store it safely.

See also **Controlled Drugs**.

Supplying procedures

KEY POINTS

- When veterinary medicines are supplied, the owner must be advised on how to use the medicine and on any warnings or contraindications
- If a veterinary surgeon delegates the handing over of a medicine to a team member, they must be satisfied that the person handing it over is competent to do so
- A veterinary surgeon must authorize each transaction for POM-V, POM-VPS and NFA-VPS medicines

A veterinary surgeon may only supply POM-V, POM-VPS and NFA-VPS medicines from premises registered with the RCVS as veterinary practice premises (VPP).

A pharmacist may also supply POM-V, POM-VPS and NFA-VPS products from a registered VPP, as well as from premises registered as a pharmacy with the General Pharmaceutical Council (GPhC) in Great Britain or the Pharmaceutical Society of Northern Ireland (PSNI) in Northern Ireland. They may also supply POM-VPS and NFA-VPS products from an approved SQP retailer premises.

An SQP may supply POM-VPS and NFA-VPS medicines from premises approved as SQP retailer premises. SQPs may also supply those products from a registered VPP or a registered pharmacy.

When a veterinary surgeon, pharmacist or SQP prescribes a POM-V or POM-VPS medicine, or supplies a product classified as NFA-VPS, they must:

- Satisfy themselves that the person who will use the product is competent to do so safely and intends to use that product in accordance with its authorization
- Advise the customer on how to administer it safely and on any warnings or contraindications
- Only prescribe or supply the minimum amount required for the treatment of the animal.

A veterinary surgeon must **authorize** each transaction individually before the product is supplied. The transaction may be authorized by the veterinary surgeon at the time of supply (e. g. during a consultation).

For supply in the absence of the veterinary surgeon (e. g. clients requesting repeat prescribing of long-term medicines), the veterinary surgeon could meet the requirement to authorize each transaction in a number of ways:

- By the veterinary surgeon making a note on a client's record that repeat prescriptions can be supplied to that client within a certain time limit
- By a member of staff taking a call from a client and putting a medicine aside for the veterinary surgeon to authorize before it is supplied
- In the case of a client unexpectedly coming into the practice, by means of a phone call to the veterinary surgeon to authorize the supply.

If the veterinary surgeon does not personally hand the product over, they must be satisfied that the person who is handing it over is competent to do so. This could entail having a written procedure (a standard operating procedure (SOP)) in place and staff training to achieve and maintain an appropriate level of competence.

Pharmacists must also authorize each transaction individually before the product is supplied and, if not personally handing the product over, must be satisfied that the person who is handing it over is competent to do so.

See also **Prescribing cascade**.

See also **Correct storage, dispensary management and standard operating procedures**.

Wholesale dealing

Wholesale dealing means the procurement, holding, storage or distribution of a VMP to a person who intends to further wholesale it or to supply it by retail. It does not include the retail supply of a VMP to the end-user (owner of the animal).

A wholesale dealer's authorization (WDA) is required to wholesale any veterinary medicine, including those categorized AVM-GSL, Schedule 6 products, homeopathic remedies and products imported under a Special Import Certificate. A human wholesale dealer licence issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) is required to wholesale UK authorized human medicines, even if they are supplied for veterinary use.

Emergency supply

An authorized retailer of veterinary medicines may supply products which fall within the scope of the qualification they hold to another authorized retailer, in order to relieve a temporary supply shortage that could be detrimental to animal welfare.

Labelling procedures

KEY POINTS

- There is no legal requirement to label veterinary medicinal products (VMP) supplied in their authorized packaging
- The Royal College of Veterinary Surgeons (RCVS) requires labelling on all dispensed products
- All cascade products must be labelled

While there is no legal requirement to label authorized veterinary medicines that are dispensed in their original packaging for an authorized use, the RCVS Code of Professional Conduct states that VMP must be supplied in appropriate containers and with appropriate labelling; the Veterinary Medicines Directorate (VMD) also considers it good practice for all POM-V medicines to have a dispensing label attached. However, care should be taken so that labels do not obscure any information (e.g. batch numbers or expiry dates) on the packaging. It is an offence to cover this information.

Whilst there are no specific labelling requirements in the VMR or in the RCVS Code of Professional Conduct, the Practice Standards Scheme (PSS) requirements for labelling POM-Vs (see below) may prove helpful.

For a **VMP supplied in a container other than that specified in the marketing authorization** (e.g. tablets dispensed into smaller containers), the person supplying the product must ensure that the container is 'suitably labelled' and must supply sufficient written information for the medicine to be used safely.

This legal requirement may be met by:

- Labelling the product in accordance with the PSS requirements (see below)
- Providing a copy of the package insert or the summary of product characteristics (SPC) to the client.

Only when using a medicine prescribed under the cascade, is it legally necessary to attach a dispensing label.

RCVS PSS requirements for labelling VMP

Medicines other than POM-Vs

- In accordance with their MA and the VMR.
- Name and address of the practice supplying the product.

POM-V medicines

All POM-V medicines supplied by the practice must be legibly and indelibly labelled with:

- Name and address of the animal owner
- Name and address of the veterinary practice supplying the medicine
- Date of supply
- Name, strength and quantity of product
- Dosage and directions for use
- 'For animal treatment only'
- For topical preparations: 'For external use only'.

VMP supplied under the cascade

A person who supplies a product under the cascade must label the product with:

- Name and address of the pharmacy or veterinary practice supplying the product
- Name (or initials) of the veterinary surgeon who prescribed it
- Name and address of the animal owner
- Identification (including the species) of the animal or group of animals to be treated
- Date of supply
- Expiry date of the product, if applicable
- Name or description of the product (at least the name and quantity of active ingredients)
- Dosage and administration instructions
- Any special storage precautions
- Any necessary warnings for the user, target species, administration or disposal of the product
- Withdrawal period, if relevant
- 'Keep out of reach of children' and 'For animal treatment only'.

These are a legal requirement of the Veterinary Medicines Regulations.

QUESTIONS

1. Which of the following facts about prescribing is correct?
    a. It is the same as selling
    b. Only veterinary surgeons are allowed to prescribe
    c. It is assessing requirements and choosing the most appropriate medicine
    d. It always consists of writing a written prescription
2. When a POM-V medicine is prescribed the veterinary surgeon must:
    a. Be sure that the person who will use the product is competent to do so safely
    b. Advise the customer on how to administer the medicine safely and on any warnings or contraindications
    c. Make sure, if another staff member hands it over, they are competent to do so
    d. All of the above
3. A written prescription for a POM-V medicine does not need to include:
    a. The identification of the animal or group of animals to be treated
    b. The expiry date of the product
    c. The premises at which the animals are kept if this is different from the address of the owner or keeper
    d. The dose and administration instructions and any necessary warnings
4. Medicines prescribed under the cascade:
    a. Must always be labelled
    b. Never need to be labelled
    c. Must be labelled if they are not in their original packaging
    d. No legal requirement to label, but RCVS recommends it as best practice

ANSWERS 1 – c; 2 – d; 3 – b; 4 – a

Record keeping and audits

KEY POINTS

- Medicines records should to be kept for 5 years
- Practices must be able to carry out a stock audit
- Controlled Drugs (CDs) should be audited continuously

Record keeping

Veterinary practices should have an efficient stock control system to monitor the use of veterinary medicines and to allow for the recall of an individual medicine or particular batch.

The **record keeping requirements** for Veterinary Medicinal Products (VMP) are set out in the Veterinary Medicines Regulations (VMR). Records of the retail supply (which includes administration by a veterinary surgeon (veterinarian) of 'prescription-only medicine – veterinarian' (POM-V) and 'prescription-only medicine – veterinarian, pharmacist, suitably qualified person' (POM-VPS) medicines, must be kept for 5 years.

For the receipt and retail supply of POM-V and POM-VPS medicines the following records must be kept:

- Date of receipt and supply (which includes administration by the veterinary surgeon)
- Name and quantity of the VMP
- Name and address of the supplier or recipient
- If there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription
- Batch number (for products used for non-food producing animals, the batch number only needs to be recorded either on the date of receipt of the batch or the date the batch is first supplied or used).

The requirement for keeping records of medicines purchased may be met by retaining the invoices or delivery notes from suppliers. Records may be electronic or hard copy, but must be durable, permanent and available for inspection upon request.

There are extra requirements for **food producing animals**. Small animal veterinary surgeons called upon to treat farm animals, including food producing animals kept as 'pets' (e.g. 'backyard' chickens), need to be aware that any veterinary surgeon who administers a VMP to a food producing animal must either personally enter the following information into the livestock keeper's record book or provide the details to the livestock keeper to enter them:

- Veterinary surgeon's name
- Name, amount and batch number of the product
- Date of administration
- Withdrawal period
- Identification of the animals.

In addition, if a veterinary surgeon prescribes or administers an unauthorized VMP to a food producing animal (e.g. a 'backyard' chicken or farm animal pet) under the cascade, the veterinary surgeon must also keep in their own records a record of the:

- Date of examination of the animals
- Name and address of the owner
- Identification and number of animals treated
- Result of the veterinary surgeon's clinical assessment
- Trade name of the product if there is one
- Manufacturer's batch number shown on the product if there is one
- Name and quantity of the active substances
- Doses administered or supplied
- Duration of treatment
- Withdrawal period.

See also **Prescribing cascade**.

Audits

A veterinary practice should have the ability to carry out a detailed audit of POM-V and POM-VPS medicines at least annually. Incoming and outgoing medicines should be able to be reconciled with the stock held and any discrepancies noted. This is in order to ensure that medicines can be recalled effectively if there is a problem with a particular batch.

Every practice should be able to follow an audit trail to identify who has been supplied with a particular batch and which animals have been treated. To achieve this each practice needs to:

- Perform a full stock take of all prescription medicines (an annual stocktake for accounting or tax purposes will suffice)
- Keep records of all medicines received (e.g. by retaining invoices/delivery notes from wholesalers/suppliers)
- Keep records of all medicines supplied to clients (e.g. on the practice management system or separate sales log)
- Record all out of date or damaged medicines discarded or medicines transferred to other premises or vehicles.

If computerized records are used, there must be an adequate back-up system in place.

It is up to the practice to account for discrepancies. If discrepancies occur, the practice must decide what level is acceptable and whether any further action may be required. There will obviously be discrepancies in the case of medicines used during procedures and not priced individually (e.g. premedicants, anaesthetics and euthanasia medicines) and from spillages and breakages.

The VMR do not specify a system or set procedure for conducting the audit. It is up to the individual practice to decide how best to carry out the audit.

One category of medicine that should be audited continuously is Controlled Drugs (CDs). This can be achieved by recording supply and use, and keeping a running total in the Controlled Drug Register, and having a system of reconciling the balance in the Register with the stock in the CD cupboard. This should be done regularly (at least weekly). See also **Controlled Drugs**.

Records and the ability to carry out a medicine audit will be checked by inspectors from the Veterinary Medicines Directorate (VMD) or Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (PSS) assessors when they inspect the practice. The inspectors and assessors will particularly want to see a full audit and reconciliation of all Schedule 2 CDs (i.e. the Register and the balance of drugs in stock).

QUESTIONS

1. How long should records of prescription-only medicines be kept?
   a. 1 year
   b. 7 years
   c. 5 years
   d. 10 years
2. When do batch numbers of POM-V and POM-VPS medicines have to be recorded for non-food producing animals?
   a. Every time a medicine is used
   b. Never
   c. Only for CDs
   d. Either on the date the batch was received or the date the batch was first used
3. Which categories of medicines must be audited annually?
   a. POM-V only
   b. POM-V and POM-VPS only
   c. POM-V, POM-VPS and NFA-VPS only
   d. All categories of medicines
4. How is a continuous audit of CDs carried out?
   a. By recording all CDs coming in and out of the practice
   b. By regularly checking the balance of the CD Register against the stock in the CD cupboard
   c. By checking that vets have signed the Register
   d. By using a computerized record

ANSWERS 1 – c; 2 – d; 3 – b; 4 – b

Controlled Drugs

KEY POINTS

- The Home Office has responsibility for the Misuse of Drugs Act 1971 and associated Regulations and the police enforce the law for Controlled Drugs.
- Advice and guidance are provided by the Veterinary Medicines Directorate (VMD) and the Royal College of Veterinary Surgeons (RCVS)
- CDs are in very common use in veterinary practice and they must be strictly managed
- It is essential that veterinary surgeons (veterinarians) and veterinary nurses are familiar with the regulations
- Writing easy to follow standard operating procedures (SOPs) will demonstrate governance of CDs within the practice and can be used as a training tool

Many of the CDs that are abused (e.g. opioids, ketamine, benzodiazepines) are very commonly used in modern veterinary practice and are necessary to ensure the welfare of patients (e.g. analgesia). Legislation has been put into place, firstly in an attempt to control drug abuse by reducing availability, and secondly, to facilitate a practical way to safely manage CDs within a healthcare setting.

The legislation

Changes introduced in April 2019

Gabapentin and pregabalin have been reclassified as Class C, Schedule 3 Controlled Drugs. They are exempt from safe custody requirements but must follow CD prescription writing requirements. Although not a legal requirement, the RCVS recommends that all Schedule 3 CDs are kept under safe custody

In the UK there are a number of legislative documents that describe how CDs must be regulated. However, interpretation of information contained within these documents can be difficult and time-consuming and much of the recent legislation does not apply to veterinary practitioners.

The Home Office is the parliamentary body responsible for writing, updating and enforcing CD legislation (i.e. the law). Much of the responsibility for overseeing the use of these drugs in veterinary medicine has been delegated from the Home Office to the veterinary medicines regulatory body – the Veterinary Medicines Directorate (VMD). The VMD Guidance for veterinary surgeons can be found on their website ( ).

The VMD also delegates some of this responsibility to the Royal College of Veterinary Surgeons (RCVS), and either of these regulatory bodies may inspect a veterinary practice to ensure that CDs are being stored and used responsibly.

Misuse of Drugs Act 1971 ( )

This legislation controls the availability of drugs that are considered 'dangerous or otherwise harmful'. The Misuse of Drugs Act (MDA) renders all activities associated with drugs contained within it as unlawful, but provision is made for the use of CDs within medicine. The MDA classifies CDs by letter (Class A, Class B and Class C) and describes the penalty associated with possession, intent to supply and use. Increasing evidence of physical (bladder dysfunction) and psychological damage associated with the recreational use of ketamine led to this drug being reclassified under the MDA in 2014 to a Class B drug. Offences under the MDA include 'allowing premises you occupy or manage to be used unlawfully for the purpose of producing or supplying controlled drugs'. The MDA states that veterinary surgeons may prescribe, administer or supply CDs and may have CDs in their possession when acting as a veterinary surgeon.

Misuse of Drugs (Safe Custody) Regulations 1973 ( )

This legislation describes the requirements for CD cabinets, safes and rooms, and the standard to which they must be manufactured or built. It is important that the CD cabinet meets the requirements set out by these regulations, as deviation from the standards increases the risk of theft. These regulations are currently being revised by the Home Office.

An assessment of the risk should be made and purchase of a cabinet commensurate with that risk. It is advisable to ensure that any CD cabinet purchased complies with the Misuse of Drugs (Safe Custody) Regulations.

Misuse of Drugs Regulations 2001 (🌐)

This is the most relevant piece of legislation to the veterinary surgeon and classifies CDs into five Schedules. Drugs are scheduled according to a risk–benefit analysis of therapeutic value *versus* harm if abused.

Controlled Drug Schedules

There are five Schedules, as described by the Misuse of Drugs Regulations 2001.

Schedule 1

These drugs have little or no therapeutic value and are under the strictest control. Possession of these drugs requires a Home Office licence. They have no use within veterinary medicine (e.g. cannabis and lysergic acid diethylamide (LSD)).

Schedule 2

These drugs have much therapeutic value but are highly addictive and, therefore, subject to abuse. These drugs are subject to strict prescription, dispensing, destruction and record keeping requirements (e.g. morphine, methadone, pethidine, fentanyl, quinalbarbitone and ketamine). All are subject to strict safe custody requirements, except quinalbarbitone.

Schedule 3

These drugs (e.g. barbiturates, buprenorphine and midazolam) also have therapeutic value, but the potential for abuse is less. They are, therefore, subject to less strict requirements compared with Schedule 2 drugs. Their use does not have to be recorded in a CD Register and they are not subject to safe custody requirements, apart from buprenorphine, diethylpropion, flunitrazepam and temazepam. However, the RCVS recommends that all Schedule 3 Controlled Drugs are locked away.

Tramadol, gabapentin and pregabalin, which were previously uncontrolled, have now been classified as Schedule 3 (and Class C) CDs. They are exempt from safe custody requirements (see RCVS advice above), but must follow CD prescription writing requirements.

Schedule 4

These drugs are not subject to safe custody or recording requirements and include diazepam and anabolic steroids.

Schedule 5

These very low strength preparations (e.g. Pardale – codeine/paracetamol) are exempt from all CD requirements, except that invoices must be kept for a minimum of 2 years.

Specific requirements

There is a list of all veterinary authorized medicines containing CDs available on the UK Government website (🌐).

Requirement	Schedule			
	2	3 *	4	5
Safe custody	✓ except quinalbarbitone	✗ exceptions apply	✗	✗
Extra prescription requirements	✓	✓	✗	✗
Prescription validity	28 days	28 days	28 days	6 months
CD Register	✓	✗	✗	✗
Independent witness for destruction	✓	✗	✗	✗
Invoice kept for 2 years	✓	✓	✓	✓

* The RCVS recommend that all Schedule 3 CDs are kept in safe custody

Special cases

Quinalbarbitone

This drug is currently classified as a Schedule 2 CD, but it does not require safe custody (i.e. it does not need to be kept in the CD cabinet). However, it is good practice to keep it secure. It does need to be recorded in a CD Register.

Buprenorphine

This drug is classified as a Schedule 3 CD and its use does not need to be recorded in the CD Register, but safe custody does apply.

Midazolam

Midazolam has been moved from Schedule 4 to Schedule 3 and therefore prescription requirements apply. It does not need to be kept in the CD cabinet (although the RCVS recommends that all Schedule 3 Controlled Drugs are kept in the CD cabinet) and recording in a CD Register is not required.

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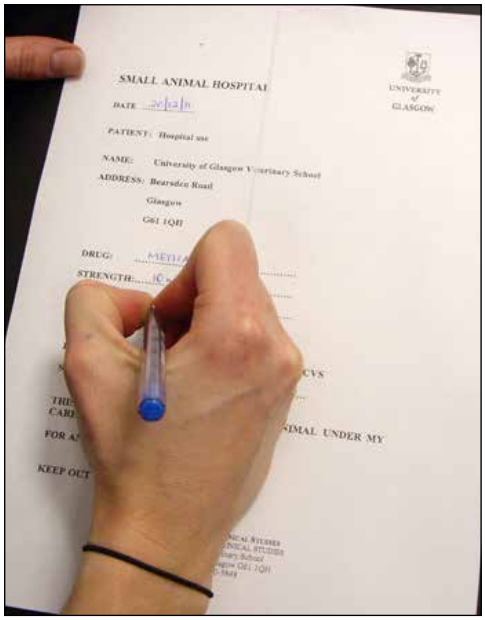
Ordering Controlled Drugs requisitions and stock

A requisition, for the purpose of this guide, is supply of a CD for stock purposes rather than for a named patient. A written requisition is required, which can be computer generated or hand written. Requisitions must be **signed in ink by the practitioner** and it is good practice to include the Member of the RCVS registration number. It is an offence to supply a Schedule 2 or 3 CD from a faxed or electronic requisition. The medicine can be prepared so that it is ready for dispatch, but the original prescription must be received prior to dispatch. Copies of requisitions should be kept to assist with auditing.

As of 30 November 2015, a mandatory form for the requisition of Schedule 2 and 3 CDs is required. There are separate forms for England, Wales and Scotland.

- **England** form FP34PCD – CD requisition form (Schedules 2 and 3) is available on the NHS Business Service Authority (NHSBSA) website (🌐) or from veterinary wholesalers.
- **Wales** form WP10CDF – available from NHS Wales (🌐) or from veterinary wholesalers.
- **Scotland** – all private prescribers must apply to join the Prescriber List for Controlled Drugs by completing an Annex D Form. This is then signed by an Authorized Signatory for your Local Health Board and passed to eVadis to receive a Unique Prescriber Code. This enables you to purchase CDRF forms and order CDs from veterinary wholesalers.



On receipt, the requisitioned drugs must be stored safely as soon as possible and an entry must be made in the CD Register. This can be delegated, but responsibility lies with the veterinary practitioner. Stock levels of CDs should be kept to a minimum based upon clinical requirements.

If, on receipt of CDs, there are vials or ampoules broken, or if what is supplied does not match what was ordered, then the wholesaler or pharmacist must be informed immediately, and discrepancies clearly accounted for in the CD Register.

WARNING

It is an offence for one veterinary practice to supply another with CDs unless a wholesaler licence is in place. 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 Registers

Prescription requirements for Controlled Drugs

A prescription is the act of deciding and instructing on the use of a veterinary medicine. **Only a veterinary surgeon may prescribe a CD to an animal.** The prescription can be written or verbal. A written prescription is only required if the drug is to be supplied elsewhere. General prescription requirements detailed in the Veterinary Medicine Regulations (VMR) must be met. See also **Prescribing, supplying, dispensing and labelling procedures**.

In addition to the normal prescription writing requirements, when writing a prescription for a Schedule 2 or 3 CD the following must also be included:

- 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' is not acceptable)
- The RCVS number of the prescribing veterinary surgeon.

The prescription must be written indelibly (or computer generated) and the signature must be in ink. It is an offence to supply a Schedule 2 or 3 CD from a faxed or electronic prescription.

Prescription validity and repeats

- CDs in Schedules 2, 3 and 4 have a prescription validity of 28 days. Schedule 5 CDs (and all other prescription medicines) have a validity of 6 months.
- A prescription for a Schedule 2 or 3 CD can only be dispensed once and within 28 days.
- Repeat prescriptions (those that can be used more than once) cannot be issued for Schedule 2 and 3 CDs. If this is a pre-printed statement on a prescription, it must be crossed out in ink. It is good practice to mark the prescription 'no repeats'.
- Repeat prescriptions are allowed for Schedule 4 and 5 CDs.

It is best practice to only prescribe and/or dispense 28 days' worth of CDs at a time. More can be given (e.g. in the case of an epileptic dog on long-term medication) if the veterinary surgeon is sure that the owner is competent to use and store it safely.

Prescription errors

If an error is made, it is best practice to rewrite the prescription. Only the person who issued the prescription is allowed to alter it.

The Controlled Drug Register

Registers must:

- Be either a computerized 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 computerized 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. The 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 2 years after the date of the last entry.

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

The Register must be used to record details of:

- Purchase – date, name and address of supplier; amount supplied; signature of the person entering the purchase and countersigned if possible. An RCVS registration number should also be included as good practice
- Dispensing – date, name and address of owner (or animal name/case number if this can be used to identify the client in an electronic record); quantity dispensed; quantity disposed of; name or signature of the prescriber with their RCVS number (good practice); and running balance.

For ambulatory veterinary surgeons 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 upon return.

Electronic Registers

A computerized CD Register may be kept provided that entries cannot be altered once they have been made: it must be auditable, printable and appropriate back-up must be kept. There are currently no suitable electronic CD Registers available for veterinary practice.

Register discrepancies

Discrepancies are inevitable when using multidose CDs (e.g. pethidine, methadone and ketamine), due to needle-hub and syringe dead space. Multidose vials of CDs increase the potential for abuse (a quantity could be withdrawn and replaced with saline), and running balances are difficult to keep due to dead space volumes. It is the opinion of the VMD that these discrepancies are 'acceptable'. A standard operating procedure (SOP) should be in place detailing what to do in the event of a Register discrepancy. One way of accounting for dead space 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 syringe used. An example CD Register can be viewed on the VMD website ( ).

Stock reconciliation

The running balances in the Registers should be checked regularly. The stock of each drug should be counted and checked against the running balance in the Register. Once tallied, the balance should be marked as checked and signed – this can be done by someone responsible for the Register, and this does not necessarily have to be a veterinary surgeon. This should be carried out at least weekly (more frequently in a busy practice). This continuous audit is a Practice Standards Scheme (PSS) requirement and also makes it easier to trace and account for discrepancies.

Recording of returned Controlled Drugs

Any CD returned by a client should not be reused. Destruction of returned CDs does not have to be witnessed by an authorized person; however, it is 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 CD Register 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.

The Controlled Drugs cabinet

Cabinets must adhere to the Safe Custody Regulations 1973 in terms of design and construction. They should be constructed and maintained to prevent unauthorized access. They must only be able to be opened by a veterinary surgeon or person authorized by the veterinary surgeon. Other requirements include:

- The cabinet must be attached by substantial bolts to the fabric of the building (e.g. bolted to the wall or floor)
- It should have a robust multi-point lock
- Preferably it should be double locked (with separate keys)
- Cabinets must be kept locked when not in use
- The lock must be different to any other lock in the practice
- Keys must only be available to authorized members of staff
- The cabinet should be for the sole use of storing CDs
- The cabinet must not have anything attached to it which identifies it as a CD cabinet
- It must meet or exceed the requirements of the Misuse of Drugs Act.

CD cabinets should, ideally, be double locked (with separate keys).

A cabinet should not have anything attached to it that identifies it as a CD cabinet.

Keyholders

Access to the cabinet should be restricted to the veterinary surgeon or any persons authorized by him or her – ideally, they should be a qualified veterinary surgeon or veterinary nurse, but any team member may have access as long as they have been authorized by the veterinary surgeon and are named in the SOP. Keyholders of the cabinet can be any nominated persons within the practice. Those persons holding keys should have appropriate training.

The key should not be left in a 'secret' place whereby there is free access to the key. However, a combination key box which is wall-mounted is acceptable practice provided that the combination is changed regularly (monthly) and that the key safe is not immediately adjacent to the CD cabinet. SOPs should be in place to control access to the CD cabinet and should name those people authorized to access the cabinet.

Controlled Drugs in vehicles

If Schedule 2 or 3 CDs are taken out on visits, they should be transported in a lockable bag, box, case or glove compartment. They must be kept locked away when not in use. Ideally, CDs should never be left unattended in a vehicle. However, if this is necessary, there should be a locked container fixed to the body or within the boot of the car, which must meet the requirements of the Safe Custody Regulations. A locked vehicle alone is not enough. If a stock of a CD is to be kept in a vehicle, then a separate Register must also be maintained.

Destruction of Controlled Drugs

All CDs must be destroyed by denaturing to render them irretrievable, but only the destruction of Schedule 2 CDs requires independent witnessing. CDs may be presented for destruction in three different circumstances:

- **Residual or waste drug** – a whole ampoule of a CD (e.g. 10 mg morphine) is dispensed to a patient but only 5 mg is administered to the patient and the remainder is denatured. Both the amounts administered and denatured are recorded on the same line of the Register to ensure that the running balance tallies (the whole vial is accounted for in the Register). Double signing is good practice (this does not have to be witnessed by an independent witness)
- **Out of date drug stock** – destruction of this falls under the Misuse of Drugs Regulations 2001, and as such it must be witnessed. This includes expired 'in-use shelf-life' (e.g. a part-used bottle of methadone which has been open for more than 28 days). Expired stock should be kept in the cabinet, labelled appropriately and separated from in date drugs. It should not be marked out of the running balance in the Register until it is destroyed
  - For Schedule 2 CDs, the destruction must be witnessed by an RCVS Assessor or VMD inspector, a Controlled Drug Liaison Officer (CDLO) from the police force (a list of CDLOs can be found on the Association's website ( )), or an independent veterinary surgeon. In order to be considered independent of the practice, another veterinary surgeon must have no personal, professional or financial interest in the practice where the drug is destroyed (i.e. locum team members or family members cannot do this). The independent veterinary surgeon must not be paid to witness the denaturing, apart from reasonable travel expenses. Their RCVS number should be recorded in the CD Register
  - For Schedule 3, 4 and 5 CDs, destruction does not need to be witnessed by an independent witness, but it is good practice to have it witnessed by another team member
- **Returned drug** – as the drug has been dispensed to a patient, there is no requirement to have the destruction of this drug witnessed or recorded. However, it is good practice to have it witnessed by another member of staff. This would include part-used infusions.

All CDs destroyed must be **denatured such that they are rendered irretrievable**. There are commercially available denaturing kits, and these can be used to destroy out of date stock CDs and returned CDs. These kits are granules that react with liquids to form a solid gel. Liquid forms of drugs should be removed from ampoules and vials and poured into the denaturing kit; fentanyl patches can be folded upon themselves and placed in the gel with everything else; and tablets should be crushed, mixed with water and added to the gel. The container should be stored in the cabinet for 24 hours to allow the gel to solidify. The container is then sent as pharmaceutical waste through the waste contractor.

Residual CDs are not usually denatured in this way 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.

- In **England and Wales**, the destruction and disposal of CDs are subject to the Waste Management Licensing Regulations 1994 and the Hazardous Waste (England and Wales) Regulations 2005. The Environmental Agency (EA) is responsible for these Regulations in England and Wales and, having considered the risks, has decided that it does not believe it is in the public interest to expect pharmacies and veterinary surgeons to obtain a waste management licence for denaturing CDs, as this is seen by the EA as a 'low risk' activity. Instead, the EA has advised that pharmacies and veterinary surgeries should apply for a **T28 Exemption Certificate**, which enables them to comply with the

requirements of the Misuse of Drugs Regulations 2001 by denaturing CDs prior to their disposal. Further guidance on the T28 form is available from the EA website ( ).

- In **Scotland**, information is available from the Scottish Environment Protection Agency website ( ).
- In **Northern Ireland**, information is available from the Northern Ireland Department of Health and Socail Care website ( ).

Advertising and internet sales

Advertising of CDs to clients is prohibited (e.g. a practice cannot advertise to clients that it is now using methadone to provide analgesia during and after surgical procedures). However, a veterinary surgeon is allowed to discuss this with the client during a consultation.

Although it is perfectly legal for CDs to be supplied by internet pharmacies, the same legislation applies. The original prescription must be received before the CDs are supplied and they must be delivered by courier and signed for by the person specified on the prescription. The advice from the VMD is to treat the internet supply of CDs with great caution.

Mailing of Controlled Drugs

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), recorded delivery or 'signed for' courier delivery is 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.

Standard operating procedures for Controlled Drugs

SOPs are unambiguous documents (i.e. they cannot be misinterpreted) that describe a procedure or task that must be followed. They are working documents and subject to review on a regular basis.

CD SOPs within staff training protocols are very useful as they provide clarity and consistency for all staff handling CDs and define who in the practice is responsible and accountable. These SOPs will ensure that the Regulations are being followed and form the basis of an audit to demonstrate clinical governance within a practice.

SOPs should cover:

- Ordering and receipt of CDs
- Who has access to CDs
- Where the CDs are stored
- Dispensing CDs
- Transportation of CDs for visits
- Disposal and destruction of CDs
- Who to alert if complications arise
- Record keeping, including maintaining CD Registers and the continuous auditing of CDs
- What to do if a discrepancy occurs.

SOPs must, however, be appropriate to the setting (there is no one size that fits all). Below is an example SOP for what to do in the event of a large discrepancy in the CD Register:

- Check the mathematics
- Check the deliveries
- Check the records for drug use
- Check the pharmaceutical waste bin and the rest of the practice
- Alert all team members that there is a discrepancy
- Ask all team members if they can help explain the discrepancy
- Alert the senior veterinary surgeons in the practice/management of the group of the discrepancy
- If the missing drugs are not located, the police CDLO can be alerted.

It should be remembered that veterinary surgeons are ultimately responsible for all CDs in the practice.

See also **Correct storage, dispensary management and standard operating procedures**.

Special Precautions for dispensing Controlled Drugs to clients

Dispensing transmucosal buprenorphine to clients

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 unauthorized 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

- Emphasize 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.

Fentanyl patches

The RCVS have issued the following advice about fentanyl use:

- Fentanyl patches, a Schedule 2 CD, have been used in some practices for pain relief, particularly following orthopaedic procedures. These are not authorized for veterinary use, so informed consent must be obtained for their use under the cascade. There are significant risks, particularly to small children; fentanyl can cause significant respiratory depression. (The RCVS published advice for practices on Controlled Drug use can be found on their website ( )).

Practices should be particularly mindful of the risks of this powerful analgesic:

- Ideally, fentanyl patches should not 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 and inform the client what to do if the patch comes off as well as how to safely dispose of the patch
- Provide all this information in writing and record all information on the client record.

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Further information about the risks of fentanyl and best practice can be found in the BSAVA Client Information leaflets ( ).

QUESTIONS

1. 28 days after it was opened there is stock of 2.4 ml of ketamine left in a bottle. What should happen to it?
   a. It can be used until the bottle is finished
   b. It can be disposed of in the pharmaceutical waste bin without witnessing
   c. It must be denatured, recorded in the Register and witnessed by another practice team member
   d. It must be denatured, recorded in the Register and witnessed by an independent veterinary surgeon
2. Rover has been receiving a methadone infusion to control postoperative pain. He is now comfortable and the methadone is no longer necessary. What happens to the remaining methadone in the syringe?
   a. It is waste and is denatured, ideally witnessed by another team member and not recorded in the Register
   b. It can be squirted down the sink
   c. It is denatured and needs to be witnessed by an independent witness and recorded in the Register
   d. The whole syringe and contents are placed in the pharmaceutical waste bin
3. Which of the following is true regarding the drug tramadol?
   a. It is not classified as a Controlled Drug
   b. It is a Schedule 2 Controlled Drug and must be locked in a Controlled Drug cabinet
   c. It is a Schedule 3 Controlled Drug and legally can be kept on a dispensary shelf, but the RCVS recommends that all Schedule 3 drugs are locked in a CD cabinet
   d. It is a Schedule 4 Controlled Drug, but should be treated as a Schedule 2 Controlled Drug
4. A discrepancy of 20 ml of methadone is noted at the end of the month stock reconciliation. What is the first thing that should be done?
   a. Find the likeliest culprit and blame them
   b. Call the police
   c. Consult the discrepancy policy SOP
   d. Mark the discrepancy in the Register and adjust the running balance accordingly

ANSWERS 1 – d; 2 – a; 3 – c; 4 – c

Cytotoxic drugs

KEY POINTS

- Cytotoxic drug treatments (including veterinary small molecule inhibitors) are now commonplace in clinical veterinary practice
- The standards of practice expected in the handling of cytotoxic drugs are changing and evolving
- All employers are expected to undertake a risk assessment and implement appropriate control measures before the handling of any hazardous substances, including cytotoxic drugs
- Clinical competency is not necessarily indicative of competency in health and safety matters

Treatment of cancer in animals with cytotoxic and other potentially hazardous drugs (including veterinary small molecule inhibitors), is now commonplace in clinical practice, and there is an increasing and appropriate expectation for their safe handling and use. The **Health and Safety at Work Act (1974)** states that *'it is the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees,... including, so far as is reasonably practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances.'*

Competence

An employer must appoint a 'competent person' to help meet their health and safety duties. In general terms, the definition of a competent person is someone who has the necessary skills, experience and knowledge to manage health and safety. It is important to recognize, therefore, that veterinary clinical training is not necessarily an indication of competence in health and safety management. External consultancy may be necessary to ensure that competent advice is available.

Risk assessment 'Health and Safety'

Risk assessment is a simple process with practical outcomes that reduce risk to employees as far as is reasonably possible.

Via risk assessment, a competent person should identify what might cause harm and prioritize appropriate and sensible control measures. For the use of cytotoxic drugs in veterinary small animal practice, a '5 step' risk assessment might include:

1. **Identify the hazards.**
   - Cytotoxic drugs have acute effects (e.g. irritation of skin), which are typically drug-specific and can be found in the Summary of Product Characteristics (SPC) (available from the VMD product information ( )), which should be consulted as part of general Control of Substances Hazardous to Health (COSHH) management.
   - Cytotoxic drugs can be carcinogenic, mutagenic, teratogenic and abortifacient, and increase the risk of stillbirths.
   - Chronic health effects from exposure to cytotoxic drugs include known increased risks of secondary cancers in treated patients and increased risks of spontaneous abortion in healthcare workers (Dranitsaris *et al.*, 2005).
2. **Who might be harmed?**
   - Those who might be harmed by exposure include those handling, preparing and administering the drugs, those caring for hospitalized patients, other workers in the vicinity and members of the public (owners). In human healthcare workers, systemic exposure to cytotoxic drugs is documented despite the use of control measures (NIOSH, 2016).
   - Pay attention to groups of workers who may be at particular risk (e.g. young workers, trainees and new and expectant mothers, or men and women trying to conceive). Pregnant workers are especially at risk, as some drugs may be harmful to their unborn children.
3. **Evaluate the risk and decide on precautions.**
   - Potential sources of exposure for healthcare workers.
   - Other considerations are the physical layout of the clinic and the nature of the patient(s) including their size (and therefore relative dose) and ease of handling/treating.
   - See 'Control measures' below.
4. **Record your significant findings.**
5. **Review your assessment and update if necessary.**
   - The frequency of review will be determined by issues, such as the size of the practice, changes to facilities, staff and procedures and other factors as deemed pertinent by the competent person.

Control measures

The Health and Safety Executive (HSE) outlines that good practice in the control of substances hazardous to health is encapsulated in the eight generic principles set out below (with specific reference to controls for cytotoxic drugs). See also the HSE website ( ).

1. **Minimize emission, release and spread.**
   - Of clinically equivalent alternatives, choose drugs with the lowest risk profile.
   - Dispense minimum quantities necessary.
   - Minimize hospitalization to reduce staff exposure to treated patients.
   - Limit the number of people handling and treating cases.
   - Prepare and administer drugs in chosen designated areas.
   - Maintain effective hygiene of patients and facilities.
   - Provide washing facilities for staff and patients.
2. **Consider routes of exposure.**
   - Inhalation.
   - Ingestion.
   - Absorption.
   - Injection.

3. **Choose control measures proportionate to the risk.**
   - Those preparing and administering are most frequently exposed to undiluted drug.
   - Those caring for treated patients can be exposed to native and metabolized drug in lower concentrations through body fluids and excreta, as can owners (although with less frequency) and others in the vicinity.
4. **Choose effective control options.**
   - Store drugs securely and ensure they are appropriately labelled.
   - Preparation/administration.
     - Consider closed handling systems; designated preparation facilities, e.g. a negative pressure isolator hood; out-sourcing formulation and preparation.
     - Oral medication should be in sealed capsules which should not be broken and may need to be re-encapsulated for more accurate dosing.

   - Excreta.
     - Consider segregated nursing, splash barriers, absorbent bedding and floor level kennels.
     - Use appropriate sites for urination/defecation.
     - Consider needs of patients with urinary catheters.
   - Waste disposal.
     - Ensure cytotoxic waste (including excreta) is stored, handled and transported to minimize risk of exposure and according to regulations.
   - Spillages.
     - Consider obtaining a spill kit and developing a spill protocol.
   - Equipment should be monitored, maintained and serviced in a timely fashion and in accordance with prevailing regulations.

5. **Personal protective equipment.**
   - Skin protection to prevent splash.
     - Gowns – long sleeve, water resistant.
     - Gloves – cytotoxic resistant.
   - Airway (powders or aerosol).
     - Respiratory protective equipment (FFP3, fitted to the user).
   - Eyes.
     - Splash guards or goggles.
   - Face.
     - Splash guards.

6. **Review the effectiveness of controls.**
   - Accident/incident reporting.
   - Monitoring of equipment use.
   - Environmental monitoring by wipe testing (available for some drugs; workplace exposure limits do not exist).
   - Health surveillance/reporting is not in routine use, but organizations are expected to record those exposed to cytotoxic drugs in the workplace.

7. **Provide information and training.**
   - Staff trained to standard operating procedures (SOPs)
     - Derived from risk assessments.
     - Cover all aspects of use as above.
     - Accessible, practicable and meaningful.
   - Identification of treated patients.
   - Owner advice and information sheets.
   - Documentation and record keeping.
8. **New measures, new risks.**
   - Systems to identify and respond to new procedures and risks.

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QUESTIONS

1. Which of the following is not a typical risk to health from exposure to cytotoxic drugs?
   a. Spontaneous abortion and birth defects
   b. Photosensitization
   c. Cancer
   d. DNA mutations
2. Which of the following is the least likely route of exposure as a result of a spillage of liquid cytotoxic drug?
   a. Inhalation
   b. Absorption
   c. Ingestion
   d. Injection
3. Which of the following controls is least beneficial for the prevention of exposure of clinical personnel to cytotoxic drugs?
   a. Negative pressure isolators for drug preparation
   b. Closed system transfer devices
   c. Chemotherapy gowns and nitrile gloves
   d. Outsourcing of preparation
4. Which of the following are not advised for the management of health and safety related to cytotoxic drugs in veterinary practice?
   a. Risk assessment
   b. Limiting handling to veterinary staff only
   c. Competent advice
   d. Documented staff training

ANSWERS 1 – b; 2 – d; 3 – c; 4 – b

Registration of premises and inspections

KEY POINTS

- Veterinary surgeons (veterinarians) can only supply veterinary medicines from registered veterinary practice premises (VPP)
- Inspectors will check Controlled Drugs (CDs) records, storage of medicines, medicines' records, supply procedures and disposal of medicines
- All VPP will have a medicines inspection either from the Royal College of Veterinary Surgeons (RCVS) or the Veterinary Medicines Directorate (VMD)
- There will be a report after the inspection setting out any action points or deficiencies found, which will have to be corrected
- The VMD is responsible for enforcement of the Veterinary Medicines Regulations (VMR) and can issue improvement and seizure notices

Registration of veterinary practice premises

A veterinary surgeon may only supply veterinary medicinal products (VMP) classified as 'prescription-only medicine – veterinarian' (POM-V), 'prescription-only medicine – veterinarian, pharmacist, suitably qualified person (SQP)' (POM-VPS), 'non-food animal – veterinarian, pharmacist, SQP' (NFA-VPS) or cascade products from premises registered with the RCVS as a VPP. Application forms for the registration of a VPP are available to download from the RCVS website ( ).

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Completed forms and the registration fee (currently £34) must be sent to the RCVS registration department. On receipt of a completed application, the RCVS will process the form and add the premises to the Register of VPP (RVPP). The RCVS holds the RVPP on behalf of the VMD.

Practices that are accredited members of the RCVS Practice Standards Scheme (PSS) do not have to register separately, as the RCVS already holds sufficient information on them to fulfil the registration requirements. On a regular basis, the RCVS provides the VMD with details of non-PSS VPP.

The requirement to register a VPP relates to vets supplying from registered practice premises, and does not mean that every veterinary surgeon must have a registered VPP of their own. The provisions create a register of VPP, not a register of veterinary surgeons.

Inspection of VPP

Inspections of registered VPP are regularly carried out to assess compliance with the VMR, and the Misuse of Drugs Regulations 2001.

Inspections generally focus on:

- How medicines are prescribed and supplied
- Storage of veterinary medicines, particularly temperature-sensitive products such as vaccines
- Storage and recording of Controlled Drugs (CDs)
- Record keeping for POM-V, POM-VPS and cascade products.

Veterinary practices that are members of the PSS are inspected by the RCVS PSS assessors and a medicines inspection forms part of the whole practice inspection.

PSS practices have a full assessment every 4 years. When a PSS practice is due for an assessment, the PSS team will contact the practice via Stanley (the RCVS PSS administration tool) with details of the proposed assessor. If the practice

perceives a conflict of interest with the assessor, they can request a different assessor. The assessor will then contact the practice to arrange a mutually agreeable date for the visit, which must take place within 3 months. Practices can also be notified of a spot check at any point with 24–48 hours' notice. These are short 1–2 hour assessments and focus on limited areas, which may include medicines.

Practices pay an application fee to join the PSS and then an annual fee based on the number of individual premises. An assessment fee is only charged if an assessment is requested by the practice because of moving premises or changing accreditation. An additional fee is also charged if the practice decides to be assessed for the optional awards.

The VMD aims to inspect non-PSS practice premises at least once every 4 years, and charges a fee for each inspection. The frequency depends on the level of compliance found at the previous inspection (see below). The VMD will generally give a VPP at least 10 days' written notice of an intended inspection. The notification letter explains what the VMD will check and points the practice to the inspection criteria in the retail of veterinary medicines guidance (formerly Veterinary Medicines Guidance Note Number 3 Annex B) ( ).

If a VPP has applied to the PSS and provides the VMD with written confirmation from the RCVS, the VMD will cancel its inspection. In all other cases, the VMD will only agree to cancel an inspection if there is a genuine and justified request from a VPP, and the VPP proposes an alternative date. If the VPP does not confirm a date for another inspection, the VMD will make an unannounced inspection within 4 months.

If a VMD inspector arrives to conduct an inspection but is unable to because no-one is available, the VMD will charge an appropriate amount of the fee for the visit.

The VMD also inspects SQP retailer premises, and they must be inspected before they can be approved. Applicants should allow 10 days for the application to be processed and then a further 30 working days for an inspection. They will then be notified if their premises are suitable to be approved and receive written confirmation. SQP retailers are notified a few days in advance of an inspection. SQPs should be aware of the inspection criteria as they are repeated in their Code of Practice.

The on-site inspection

The inspection criteria are set out on the 'retail of veterinary medicines' page of the VMD website. A summary of the general inspection findings is also published on the VMD website on the 'registration and inspection of veterinary practice premises' page ( ).

The RCVS PSS criteria and standards are set out in the Practice Standards Scheme Small Animal Modules and Awards document ( ). Section 8 (Medicinal Products) covers Medicines and the Dispensary area.

Both the VMD and the PSS inspections include checks on the RCVS registration of veterinary surgeons and premises, as well as the registration and qualifications of any SQPs. See also **Suitably Qualified Persons**.

On arrival, the VMD inspector will explain the purpose of the inspection, and ask about the practice. They will want to know, for example:

- The main contact people (and email addresses)
- What species the practice treats (e. g. companion animal only, equine, mixed)
- The number of veterinary surgeons and veterinary nurses
- What practice management system is in place
- Who the wholesale supplier is.

RCVS PSS assessors will expect to speak to a cross-section of staff involved in the normal activities of an operational day. The purpose of such discussions is so that the assessor can be satisfied that practice policies are not only in place but are understood by relevant staff and are applied in the day-to-day operation of the practice, and to encourage better practice. The assessor will record the number of veterinary surgeons, veterinary nurses and other members of staff spoken to in the course of an inspection.

Both RCVS assessors and VMD inspectors will cover the inspection criteria. In relation to the supply of VMP, they will particularly check the following aspects:

Premises

- The premises are a permanent and secure building or a mobile unit based at a fixed address, which does not allow the entrance and harbouring of wild birds or vermin.
- There are appropriate staff amenities, toilets and hand washing facilities, and these are separate from the VMP storage areas.

Controlled Drugs

- CDs are appropriately stored and recorded, and in the case of Schedule 2 CDs, they are being continuously audited. See also **Controlled Drugs**.

Storage of medicines

- The storage arrangements allow VMP to be stored in accordance with the manufacturers' recommendations in the summary of product characteristics (SPC). Storage areas need to be monitored by the use of maximum and minimum thermometers to check that temperatures do not fluctuate from the manufacturers' recommended range, and the maximum/minimum temperatures are regularly recorded.
- VMP are stored in areas away from excessive light/moisture.
- VMP are stored in areas that are not accessible to the public or domestic pets.

- There are no VMP on self-service, except authorized veterinary medicines – general sales list (AVM-GSLs) or those marketed under the Schedule 6 exemption.
- There is an effective stock control system in operation and out of date, damaged or returned medicines are segregated from usable products and ultimately disposed of correctly.

See also **Medicine waste disposal**.

See also **Correct storage, dispensary management and standard operating procedures**.

Records

Appropriate records are kept of all VMP, and in particular those supplied under the cascade and for food producing animals.

See also **Record keeping and audits**.

Supply procedures

- Out of date VMP, including those past their 'broached or use-by' date, are not used or supplied to clients (it is illegal to use or supply a product after its expiry date).
- For POM-V medicines supplied, there is evidence that they have been prescribed by a veterinary surgeon, and that each transaction has been authorized by a veterinary surgeon or pharmacist. In practice, this may be achieved by:
  - The veterinary surgeon handing over the medicine
  - The veterinary surgeon making a note on the client's record that repeat prescriptions can be supplied for a set time
  - A member of staff taking a telephone request from a client and getting the veterinary surgeon to authorize the medicine before it is supplied.
- For POM-VPS medicines supplied, there is evidence that they have been prescribed by a veterinary surgeon, pharmacist or SQP, and that each transaction has been authorized by one of those professionals.
- For POM-V, POM-VPS and NFA-VPS medicines, there is evidence that before the medicine is supplied, the prescriber:
  - Checked that the person who will be administering the medicine is competent to do so safely
  - Checked that the client intends to use it for a purpose for which it is authorized
  - Advised the client on safe administration of the medicine and on any warnings/contraindications stated on the label or package leaflet.
- Staff 'handing over' medicines to clients have been trained to do so (e. g. have knowledge of practice protocols and have a standard operating procedure (SOP) in place). Both VMD inspectors and PSS assessors will expect to talk to staff to ascertain how training takes place.
- All veterinary medicines, including medicines prescribed in accordance with the cascade, are appropriately labelled.
  See also **Prescribing, supplying, dispensary and labelling procedures**.
- Written prescriptions include all the information required under the VMR.

See also **Correct storage, dispensary management and standard operating procedures**.

Disposal

- Unusable VMP are appropriately disposed of and recorded (e.g. by logging disposed products against a 'dummy' client on the practice management system called 'Disposal').

See also **Medicine waste disposal**.

Reporting the results of the inspection

The VMD inspector will summarize the inspection findings at the end of the inspection. They will then send a written report within 4 weeks, which details the findings and corrective actions required (if any). The VPP will also be invoiced for the inspection.

PSS assessors will submit a report to the RCVS within 14 days. This will recommend one of the following:

- Outright pass or fail
- Pass subject to compliance with stated conditions within a stipulated timeframe
- Pass at a category other than that applied for.

The action points will be shown on the report. If there are large numbers of action points, a re-assessment may be necessary. Normally, the practice will be able to upload evidence on to Stanley to show that they have complied with the action points. There is a timeframe for evidence upload. For Controlled Drugs, or other serious issues, the timeframe is usually 1 month; for other medicines it is usually 3 months.

In the case of VMD inspections, the deficiencies are classified as minor (other), major or critical.

Minor (other) deficiencies

- A deficiency that is minor and poses no potential risk to human or animal health, or the environment.
- A deficiency that does not indicate a significant deviation from the requirements of the VMR, Codes of Practice or Guidance.
- A deficiency that cannot be classified as either critical or major, because there is insufficient information to classify it as such.

Major deficiencies

- A non-critical deficiency that has produced, or has the potential to produce, a possible risk to human or animal health, or the environment.
- A deficiency that indicates a major deviation from the requirements of the VMR.
- A deficiency that indicates a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements.
- A combination of more than six minor (other) deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.
- Minor (other) deficiencies that have been brought to the attention of the business on previous occasions but have not been resolved.

Critical deficiencies

- Deficiencies that have produced, or have the potential to produce, a significant risk to human or animal health, or the environment.
- A deficiency that indicates a significant deviation from the requirements of the VMR through serious negligence or intent.

The VMD then applies an inspection interval based on the number and type of deficiencies noted, as follows:

VMD Veterinary Practice Premises risk-based inspection plan

Inspection findings	Compliance category	Inspection points*	Max. inspection interval in months by category
0 deficiencies; recommendations only	5	0	48
1–6 minor (other)	4	1–6	48
More than 6 minors and/or 1–3 majors	3	7–21	36
3 majors plus 1 or more minors up to and including 5 majors	2	22–35	24
More than 5 majors and/or any critical	1	36 and over	24

*A minor deficiency = 1 point; a major deficiency = 7 points; a critical deficiency = 36 points

Enforcement

The VMD remains responsible for enforcement of the VMR in all VPP. The VMD inspectors follow an Enforcement Strategy ( ) that aims to deal with deficiencies (non-compliance) by taking an 'inform, insist, enforce' approach.

Improvement notices

The VMD inspectors have the power to serve improvement notices on any person they believe is not complying with the VMR. The notice will clearly set out:

- How that practice/person is failing to comply with the VMR
- The exact nature of the failure
- Measures that need to be taken to comply
- How quickly these measures should be taken.

All improvement notices will give the person at least 14 days to take the measures necessary to comply with the VMR.

Seizure notices

The VMD inspectors also have the power to seize products, records and equipment (including computers) when they believe those items are related to a serious breach of the VMR (critical deficiencies). The seizure notice will set out the inspector's grounds for seizing the item(s) and inform the practice/person how they can make a claim against the seizure. If no claim is made within 28 days then, unless the products are being retained for criminal proceedings, they will be destroyed.

- In the most serious of breaches, the VMD may instruct the RCVS to remove a premises from the register of VPP.
- In the formal actions outlined above, there are appeal procedures set out in the VMR.
- An individual or company may also be prosecuted.
- All improvement notices, seizure notices and prosecutions are published on the VMD website and in its quarterly online journal, *Marketing Authorisation Veterinary Information Service (MAVIS)*.

QUESTIONS

1. A veterinary surgeon can supply POM-V, POM-VPS, NFA-VPS and cascade medicines:
    a. Only from a veterinary practice premises registered with the RCVS
    b. From any veterinary practice, pharmacy or SQP retailer premises
    c. Only from a premises that the VMD have inspected
    d. Only from their own registered premises
2. The standard interval between inspections is:
    a. 5 years
    b. 5 years for PSS and 4 years for the VMD
    c. 4 years
    d. 4 years for PSS and 2 years for VMD
3. Inspectors/Assessors will check that for POM-V and POM-VPS medicines there is evidence that the prescribing veterinary surgeon has:
    a. Checked that the person who will be administering the medicine is competent to do so safely
    b. Checked that the client intends to use the medicine for a purpose for which it is authorized
    c. Advised the client on the safe administration of the medicine and on any warnings/contraindications stated on the label or package leaflet
    d. All of the above
4. How can a VPP prepare for an inspection by the VMD?
    a. Contact the RCVS to discuss what is required
    b. Phone a friend
    c. Read the VMD retail of veterinary medicine guidance webpage
    d. All of the above

ANSWERS 1 – a; 2 – c; 3 – d; 4 – c

Correct storage of medicines, dispensary management and standard operating procedures

KEY POINTS

- Medicines must only be stored in secure locations
- Medicines should be stored in accordance with their datasheet or summary of product characteristics (SPC)
- Environmental conditions where medicines are stored must be monitored

Storage of medicines

Premises

To enable the Veterinary Medicines Directorate (VMD) to fulfil its obligations under European law to maintain and improve traceability of, and accountability for, veterinary medicines, all premises from which medicines are to be prescribed and supplied must be registered as Veterinary Practice Premises (VPP) with the Royal College of Veterinary Surgeons (RCVS). All registered premises are inspected by the VMD, except those practices who are members of the RCVS Practice Standards Scheme which are inspected by the RCVS as part of this scheme. See also **Registration of premises and inspections**.

A VPP must be a permanent building or part of a permanent building, be clean, well maintained and vermin proof. Premises where medicines are held should be capable of being secured to deter intruders. Controlled Drugs and injection equipment are attractive not only to drug misusers but also to professional criminals. Professional advice should be obtained on the suitability of the premises, locks, shutters, security alarms and so forth.

Areas of the practice used for the storage or supply of medicines must not be residential, and public access should be denied or controlled to areas where 'prescription-only medicine – veterinarian' (POM-V), 'prescription-only medicine – veterinarian, pharmacist, suitably qualified persons (SQP)' (POM-VPS) and 'non-food animal – veterinarian, pharmacist, SQP' (NFA-VPS) medicines are held (they should be 'staff only areas'). There should be no smoking, food consumption or storage of food in areas where medicines are stored or supplied, with notices in place informing staff and clients accordingly. Particular attention should be taken with fridges; the storage of medicines alongside food or laboratory samples must be avoided.

A record must be kept at the practice's main premises of all other locations where medicines may be stored (e.g. practice cars or homes where medicines are kept for on call purposes).

Consulting rooms

Medicines stored in consulting rooms should be kept to a minimum and should be placed out of sight in drawers or cupboards. There is no requirement for these cupboards to be locked, but it is considered good practice to do so if clients are left in consulting rooms unsupervised. Medicines subject to abuse should not be held in consulting rooms.

Practice cars

Medicines held in vehicles should be kept to a minimum. Only those used frequently and only sufficient quantities for immediate use should be carried routinely because the temperature within the car may fluctuate greatly causing reduced efficacy of the products. Any medicines that are kept in vehicles should be clean and well organized.

Cars should be fitted with refrigerated units for temperature sensitive medicines and the temperature of these monitored to ensure they are maintained between 2°C and 8°C. Temperatures should be monitored in vehicles to ensure that medicines requiring storage at a controlled ambient room temperature are not left in vehicles when temperatures exceed 25°C or go below 8°C.

Precautions against theft such as not storing medicines in the car for long periods of time or overnight, not leaving medicines on display, and parking vehicles in secure areas should be considered. Controlled drugs (CDs) should be stored in either a locked glove box or in a separate locked bag, box or case that is removed from the vehicle if it is left unattended for any significant period of time.

See also **Controlled Drugs**.

The dispensary

Care should be taken to ensure safe storage of all medicinal products. Medicines must be stored in accordance with the manufacturer's SPC or datasheet. SPCs for all UK authorized veterinary medicines can be found in the VMD product information database ( ).

Medicines should be protected from environmental conditions that may damage or degrade them such as light, temperature and humidity. Storing products in their original packaging will give the best protection against environmental damage. The dispensary should also be fitted with blinds on any windows to protect against bright light, and light sensitive products should be kept in their outer packaging. Ventilation must be adequate, and hot water sterilizers and autoclaves should not be used in the dispensary because they may adversely affect the humidity of the room.

To avoid contamination, medicines should not be stored in toilet or washing areas, or laboratories. Medicines to be supplied to clients should not be stored in areas where animals are kept such as kennels, except those medicines already dispensed.

Flammable products must be stored in an appropriate flammables cabinet specifically designed for this purpose, preferably on the floor to prevent breakages.

Shelving should be of sturdy construction and well designed to reduce the possibility of breakage and spillage. It should be designed in such a way to ensure medicines are easy to locate with areas suitable for small and bulk storage.

Medicines should be protected from dust and dirt and a regular cleaning schedule should be developed to maintain a high standard of cleanliness.

Temperature monitoring

Particular attention should be paid to ensure medicines are stored at the correct temperature in accordance with the SPC. Products to be stored at a controlled ambient room temperature do not require refrigeration and should be kept between 8°C and 25°C. Storage of products at a controlled ambient temperature should be monitored if the temperature is outside this range or remains unusually high or low for any significant period of time.

Products that require refrigeration such as vaccines, insulin, antisera and some reconstituted antibiotics must be stored in a fridge between 2°C and 8°C. These products should be removed from the delivery cool chain as soon as possible and stored in a fridge. They should only be removed from the refrigerator for **immediate** use.

Care should be taken to ensure the refrigerator maintains a temperature between 2°C and 8°C. Thermometers must be appropriately situated within the fridge (i.e. not touching the chiller plate and not placed in a compartment away from the veterinary medicines). Temperatures should be monitored at least daily, and this should ideally be the responsibility of a named person(s). Maximum/minimum thermometers and a log book can be used for this purpose. The thermometers should be reset after the readings have been recorded.

A written plan should be in place detailing the actions to be taken should temperatures in the dispensary or refrigerator fluctuate outside the recommended temperatures. For example, this may include the direction to dispose of insulin if the temperature drops below 2°C or that further information should be sought from the medicine manufacturer if the temperature of the fridge was maintained above 8°C for longer than a few minutes.

Regular cleaning, servicing and stock control in refrigerators should be performed as for other storage areas. It is good practice to have a separate shelf or area available for medicines that have been prepared for collection by an owner or for use by an in-patient.

The use of continuous data loggers to monitor the temperature can be convenient, but these should only be used if an audible alarm or flashing light alarm alerts the user to temperatures deviating from the required range. Weekly downloading of the temperatures into graph format is useful to determine trends in temperature fluctuations, but notice of temperatures outside the required range comes too late to prevent the product being used if an audible alarm is not present. Data loggers should be downloaded at least weekly.

Practice cars should be fitted with refrigeration units and monitored in the same way as the practice fridge.

Stock control

Efficient stock control allows you to have the right product at the right place at the right time. It ensures that capital is not tied up unnecessarily and protects against problems arising in the supply chain.

KEY POINTS

- Stock control processes must be in place to ensure medicines are used or disposed of within their shelf-life (including their in-use shelf-life)
- Good stock control will reduce waste and save money
- It is an offence to supply or administer an out of date medicine, including veterinary medicines which have exceeded their in-use shelf-life opening

It is good practice to:

- Set stock levels to allow accurate stock holding
- Have a named person(s) responsible for stock control
- Store products in original packaging, in a logical order
- Supply a product leaflet or SPC with all products dispensed
- Dispense products with the shortest expiry date first
- Store products with different batch numbers together.

Dates of deliveries and items delivered from manufacturers or wholesalers should be recorded unless this information is on the retained invoice or delivery note. Packs with damaged or defaced packaging and out of date stock should be stored separately while awaiting disposal. Once stock has been dispensed and taken from the practice premises it should not be accepted back into the dispensary unless correct storage during this time can be guaranteed. The batch number of products dispensed for administration to food producing animals must be recorded on the case file for batch tracking purposes. For small animals it is enough to record the date of first usage of each box or bottle.

Stocking levels

In order to perform stock control effectively, stock order levels (maximum and minimum) must be set for every product. This could be done using a small card placed on the products at the correct place, a sticker on the shelf or a fully automated system. Any system will require information such as product description, order up to level (OUTL), reorder point (ROP), supplier, item code, etc.

The amount of stock to be kept can be calculated using this basic equation: OUTL = D x L (D = daily demand; L = lead time).

In practice, however, average daily demand is very difficult to calculate accurately and does not take weekends, public holidays or periods of exceptional use into account. It may be better to work on a principle of 2 or even 4 weeks cover so the average daily demand becomes the average demand for 2 or 4 weeks. This will allow sufficient stock to cover for any emergencies. It may be wise to keep 4 weeks cover of any medicines used in emergency situations but only 2 weeks of routine products where the consequences of not having a bottle in stock are not so high. If the item is seasonal, extra consideration will be needed to set an OUTL which may be different for specific seasons.

Repeat orders can be a cost effective way of ordering stock for frequently used products. It must be recognized, however, that the product will have been bought and paid for within a month. Until enough stock is sold to cover what has been paid, the practice will be out of pocket. If just 2–4 weeks supply is ordered, you should always have sold the stock on by the time you come to pay the wholesaler for it, which helps with cash flow.

Products subject to intermittent use will not fit into the calculation of OUTL. For example, some emergency medicines are used infrequently but when required, large volumes may be used. This needs to be factored in when OUTLs are set.

Stock control is an ongoing process. Stock levels should be altered as new products are brought to the market or preferences change.

Stock rotation

Products with the shortest expiry should be dispensed first to reduce the number of products going out of date. This can generally be achieved by ensuring that all new stock from deliveries is placed at the bottom or back of current stock, but it is useful to double check the expiry dates of the newly delivered stock are longer than current stock, particularly if orders are placed with different companies.

Stock loss and annual stocktake

There are a number of reasons for stock loss within a veterinary practice. These include:

- Products going out of date
- Broken or damaged stock
- Items mistakenly not charged for
- Theft
- Items charged for by wholesalers but not received
- Wholesaler credit for goods returned or missing not received
- Consumable wastage.

Products going out of date means money lost to the practice. Setting appropriate ROPs and OUTLs will reduce stockholding and lead to fewer products going out of date. Monthly date checking should be performed to ensure products are used before they expire (where clinically appropriate).

The VMD requires all practices to perform an annual stocktake where incoming and outgoing medicinal products are reconciled. Any missing items must be accounted for. Out of date products are considered 'stock' until they are removed from the stockfile. In the annual stocktake, all products that have gone out of date must be accounted for or they will be assumed to be missing. Broken or damaged stock should also be recorded for stocktaking purposes. A system should be put in place to ensure all items used are charged for appropriately. This will ensure not only that the practice maximizes their income, but that purchases and sales of each product can be reconciled for the annual stocktake. See also **Record keeping and audits**.

To prevent the theft of medicines, food and pet products, ensure clients do not have access to medicine cupboards when left alone in the consulting room and ensure any waiting room displays are within sight of reception staff. Regular stocktakes of vulnerable items should be performed to check for discrepancies.

Medicines received from wholesalers should always be checked against delivery notes and any missing or damaged goods claimed for at the time of receipt. Once a claim has been made, ensure the credit is received by reconciling credit notes against returns books.

It is advised that practices set up a dummy client called 'Disposal' on their practice management system and record all medicines that are unusable. This can help the practice identify where medicines are being wasted and also help with reconciling stock during audits.

Medicine returns

As correct storage conditions (and therefore safety and effectiveness) of medicines returned by owners cannot be guaranteed, such products should be disposed of and not accepted back into stock unless the practice can guarantee that the product has been stored according to its SPC. Products dispensed for animals on the premises that have not left the practice can be accepted back into stock, providing the storage conditions are known to be acceptable and they are not contaminated in any way (e.g. by using the same syringe to withdraw multiple oral doses from a bottle of liquid medicine).

Unwanted or mistakenly ordered medicines should be returned to wholesalers as soon as possible. There may be restrictions on such returns as returned medicinal products may be destroyed.

Expiry dates and in-use shelf-life

It is illegal to supply or administer a medicine after the expiry date detailed on the pack or to obscure the expiry date on the packaging of any medicine. Requirements in EU and national legislation to ensure the stability and safety of the produce mean that some products such as injectables have an in-use shelf-life.

Any medicine which is stipulated to be used within a given timeframe should be marked with the date of opening and use by date. This is the length of time after which the product must be disposed of upon opening. For most multidose injectables, the in-use shelf-life is usually, but not always, 28 days, thus making it an offence to administer the product after 28 days of opening (unless the expiry date of the product itself is shorter; check the bottle for details).

Multidose vials should be marked with the date of first opening and the use by date. Bright stickers can be useful to draw attention, but all multidose vials with an in-use shelf-life now have a space to write this information. Any medicine left in the vial after the specified time must be discarded. For single-use ampoules, the required dose should be withdrawn immediately and the remainder disposed of. Oral liquids should generally be disposed of 6 months after opening. Care should also be taken with some medicines that are sensitive to humidity as these may have an in-use shelf-life stated on the SPC.

A named person(s) should be in charge of date checking the medicine store once a month and a log should be kept of this check. When date checking, short dated stock should be marked as such and brought to the front of the shelf to be used first. Any stock that has gone out of date should be separated and recorded before destruction.

Broken or damaged medicines

Any medicine with a broken or damaged container should be segregated immediately for safe disposal. Care should be taken with spilled or leaked medicines. Check the SPC and COSHH assessments to identify if the medicinal product is hazardous before cleaning takes place, and use appropriate personal protective equipment if advised. A spill kit should contain gloves, absorbent material and a laminated copy of the SOP for dealing with spillages. Spill kits for cytotoxic spills should contain overshoes, gloves, a gown, 'chemosorb pads', disposable bags and a step-by-step users guide.

Dispensary management

KEY POINTS

- A single person should be responsible for dispensary management
- A dispensary manual should be written detailing standard operating procedures (SOPs) and risk assessments
- All staff involved in medicines handling should be suitably trained

One person should be responsible for ensuring the legal requirements, safety assessments and best practice procedures are carried out. This person should be responsible for ensuring:

- The layout of the dispensary is efficient and appropriate shelving is used
- The dispensary is always clean and tidy
- Date checking is performed and recorded regularly

- Staff are suitably trained
- SOPs are written and implemented
- Stock control is efficient to reduce stock loss
- Storage conditions (particularly temperature) are monitored in the dispensary and practice cars.

The dispensary manual

A dispensary manual should be prepared containing standard operating procedures (SOPs), risk and Control of Substances Hazardous to Health (COSHH) assessments, blank forms and other useful information (e.g. on special suppliers and unusual products). This should be available to and read by all those involved in dispensing medicines.

Staff training

All those involved in medicine supply should be suitably trained. To prevent both contamination of the medicinal products and to protect the staff member, training should include the requirement for a high standard of personal cleanliness, with regular hand washing seen as essential and open wounds covered at all times. Staff should also be trained on how to avoid direct contact with medicines, such as wearing gloves or using a tablet counting triangle and spatula.

Although there is no legal requirement for staff members working in the dispensary to have formal training, all staff members should have read the dispensary manual and be aware of practice SOPs and risk assessments.

The RCVS Practice Standards Scheme (PSS) requires at least one member of staff in veterinary hospitals to have completed a dispensing course such as the BSAVA dispensing course, the University of Glasgow dispensing course or similar in the last 5 years. The National Proficiency Test Council (NPTC) provides competency testing in the safe use of veterinary medicines. It should be considered best practice for the person responsible for dispensary management to have completed one of these courses.

Standard operating procedures

KEY POINTS

- SOPs ensure staff and patient safety
- SOPs should be written in an appropriate format depending on the task described
- SOPs should be written by someone performing the task regularly and reviewed by someone who does not know the task
- SOPs should be reviewed regularly

A standard operating procedure (SOP) is a written document describing routine procedures carried out in veterinary practice. Well written SOPs provide direction, improve communication, reduce training time and improve work consistency. SOPs should be:

- Provided for all staff members
- Regularly reviewed
- Designed according to practice policy.

Use of SOPs may be taken, along with relevant training and continuing professional development (CPD), as sufficient evidence that staff are regarded as 'competent' under the requirements of the Veterinary Medicines Regulations (VMR).

Benefits of implementing SOPs include:

- Providing assurance of the quality of the service
- Ensuring the achievement of good practice
- Enabling veterinary surgeons to delegate and so free time up for other duties
- Avoiding confusion over who does what
- Providing advice and guidance to locums and part-time staff
- Providing a useful tool for training new staff members
- Contributing to the audit process
- Providing financial benefits
- Most importantly, protecting staff and clients.

SOPs can be written in four different formats: simple steps; hierarchical steps; graphic procedures; or a flowchart. The most appropriate format to use will depend on the number of steps involved in the process and how many decisions the user has to make during the procedure.

Simple steps

Many tasks in a veterinary practice, such as cleaning kennels, are repetitive and require few decisions to be taken. For these tasks, a simple set of steps to be carried out is sufficient detail to enable a member of staff to complete the procedure. The SOPs entitled 'Using ampoules' and 'Date checking the dispensary' (see later) are examples of this type of format. Unfortunately, due to the low level of detail, there is room for staff to misinterpret the procedure. For more detailed procedures, a hierarchical step SOP may be more appropriate.

Hierarchical steps

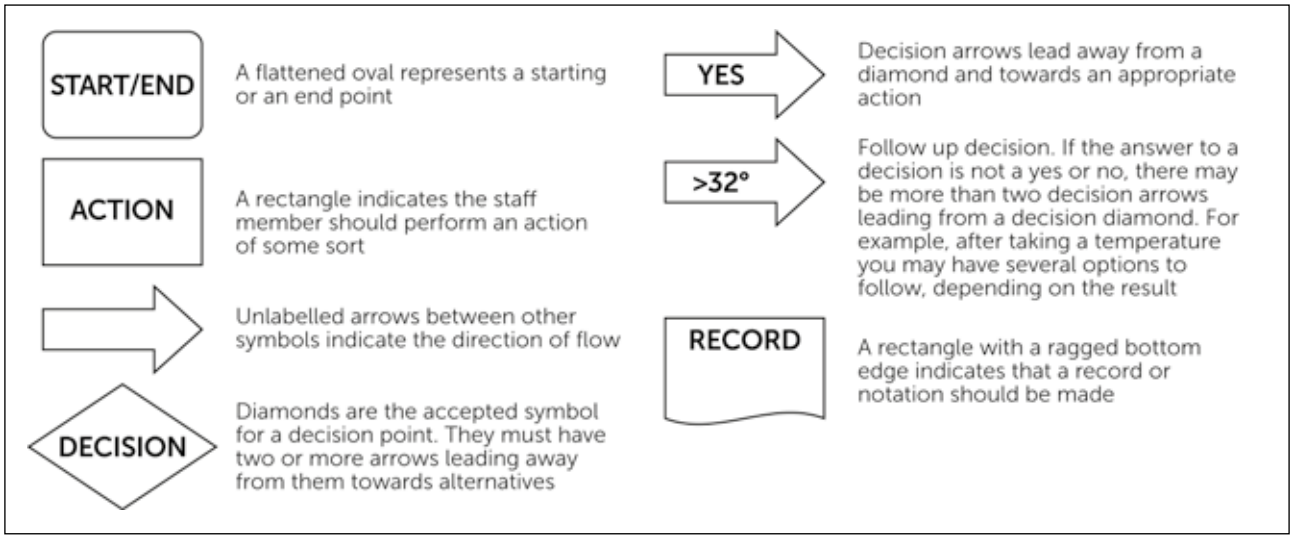
This format produces very detailed and precise SOPs, which in turn produce consistent work patterns. Simple steps are broken down into more detailed subsections, detailing exactly what the operator is required to do. Experienced staff members may only need to look at the subsections occasionally, whilst new staff can use the subsections to help learn the procedure. The SOP entitled 'Receiving a Schedule 2 or 3 Controlled Drug' (see later) is an example of this type of procedure.

Graphic procedures

If the procedure is a long process, a graphic SOP should be considered. These break down longer tasks into shorter sub-processes that consist of only a few steps. Photographs and diagrams can also be used to illustrate the procedure. These can be supplemented with explanatory text and are useful when a process would require a lengthy description if written in words. The SOP entitled 'Recapping needles' (see later) is an example of this type of procedure.

Flowcharts

Procedures that require many decisions should be written as flowcharts. These are simply a graphical way of presenting the logical steps in a decision making process. This style of SOP is useful when a staff member has to make decisions on how to progress with a procedure. A simple example of this is shown in the SOP entitled 'Medicines returned by customers or not used by in-patients' (see later). There are generally accepted symbols for flowcharts, which should be used. These are:



How to write a standard operating procedure:

1. Decide on the purpose (e.g. how to receive a medicine from a wholesaler).
2. Decide on the author. This should be someone who performs the task regularly.
3. Draft the content. An SOP should include:
   - The method of carrying out the procedure in sufficient detail and in logical steps
   - A list of personnel by job description who can carry out the procedure
   - Where in the practice the procedure may be undertaken
   - The identity of the person in overall control of the procedure in the practice
   - The date of implementation
   - The date of review.
4. Consult others. Ideally, input from someone new to the task should be sought to ensure the information is clear and detailed enough, as well as from someone who knows the task well to point out anything that may have been missed.
5. Once the final draft is complete, the SOP should be put into circulation. It may be useful to ask staff to sign to say that they have read and understood the document.
6. Once accepted, the SOP should be named and possibly numbered if the practice has many SOPs.
7. SOPs should be reviewed regularly.

If something goes wrong when a novice member of staff performs an activity after reading an SOP, the SOP is not detailed enough or written logically and should be reviewed.

Some examples of SOPs are shown below. These examples are illustrative and should be adapted according to practice policy.

USING AMPOULES

1. Injectables should be treated as intended for single use only unless the label specifically indicates that they are authorized and intended for use on more than one occasion. When a dose is decided upon, the closest volume ampoule should be chosen for dispensing.

The correct volume should be drawn up and the remainder of the ampoule drawn into a second syringe for disposal. If it is a Controlled Drug, the remainder should be added to a denaturing container; this does not need to be witnessed by an independent witness, but it is good practice for it to be witnessed in-house.

See also **Controlled Drugs**.

3. The disposed remnant should be recorded as a whole medicine for disposal and placed in the Medicines Waste Bin or 'Pharmy Bin'
4. The empty ampoule should be placed in the sharps bin.
5. If the drug is a Schedule 2 Controlled Drug, a record must be made in the Controlled Drugs Register. You should note the amount used and the amount discarded; for example, if you used 0.5 ml from a 1 ml ampoule, the Register should read *"0.5 ml given and 0.5 ml wasted"*.

Develop date checking matrix	Perform date checking	Deal with out-of-date drugs	Complete matrix
Ensure all areas of the pharmacy are included. All areas should be date checked every 3 months following the date checking matrix, ideally by the same staff member.	As each area is checked, move stock with the shortest expiry date to the front and stock with the longest expiry date to the back. Identify stock with less than 4 months shelf life and record short dated items in a book used for this purpose. Highlight short dated stock with short dated stickers. Remove out-of-date stock. Place this stock in a location, differentiated from normal stock – clearly marked 'Out of Date' stock, whilst you complete the rest of the date checking.	Record quantities and values of out of date medicines for accounts purposes and annual audit and dispose of this stock appropriately in a pharmaceutical waste bin.	Record completion of date checking of each area on the matrices by initialing and writing the date of completion in the relevant box. Every 4 weeks, check the short dated stock book and remove any out-of-date stock. Retain matrices for 6 months. The matrices must be available for inspection by authorized persons.

RECEIVING A SCHEDULE 2 OR 3 CONTROLLED DRUG

1. Check that any packages received are intact and not damaged.
    a. If the stock that has been received is damaged or incorrect, contact the supplier and notify them immediately.
    b. Complete a returns form according to the SOP 'How to return medicines to the wholesaler', but continue with steps 2–6.
2. Immediately open the package(s) containing the CD(s) and check the stock received against the invoice and delivery note or the request made to another pharmacy.
    a. Check the product name, strength, dosage form, pack size, expiry date and that the manufacturer's tamper-evident seal is intact.
3. If the CD that has been received is a Schedule 2 CD, make a record in the relevant section of the CD Register.
    a. Information to record: Date of receipt of drug, amount received, name and address of company you received the drug from, running balance.
    b. Make a manual count of the stock received and any stock already held to ensure that the resulting balance is correct. If there is any discrepancy, notify the person in charge.
    c. If the CD is damaged or irretrievable, a veterinary surgeon should make a footnote to indicate this and ask a second person to sign the record to confirm that the stock was received in this condition.
4. Store all Schedule 2 and 3 CDs requiring safe custody in the CD cupboard.
    a. Damaged stock should be stored in the CD cupboard, in a sealed bag, clearly marked as "Damaged Stock".
5. When any damaged/incorrect stock is returned to the supplier, ensure records of the return are made in the CD Register.
    a. Information to record: date of return, amount returned, name and address of person or firm returned to, running balance.
6. It is good practice to keep invoices for all CDs for 2 years.

RECAPPING: THE 'ONE-HAND' TECHNIQUE

Many accidental needlestick injuries occur when staff are recapping needles. Recapping is a dangerous practice: if at all possible, dispose of needles immediately without recapping them.

If it does become necessary for you to recap a needle (e.g. to avoid carrying an unprotected sharp when immediate disposal is not possible), do not bend or break the needle and do not remove a hypodermic needle from the syringe by hand.

To safely recap needles, use the 'one-hand' technique:

Step 1
Place the cap on a flat surface, then remove your hand from the cap.

Step 2
With one hand, hold the syringe and use the needle to 'scoop up' the cap.

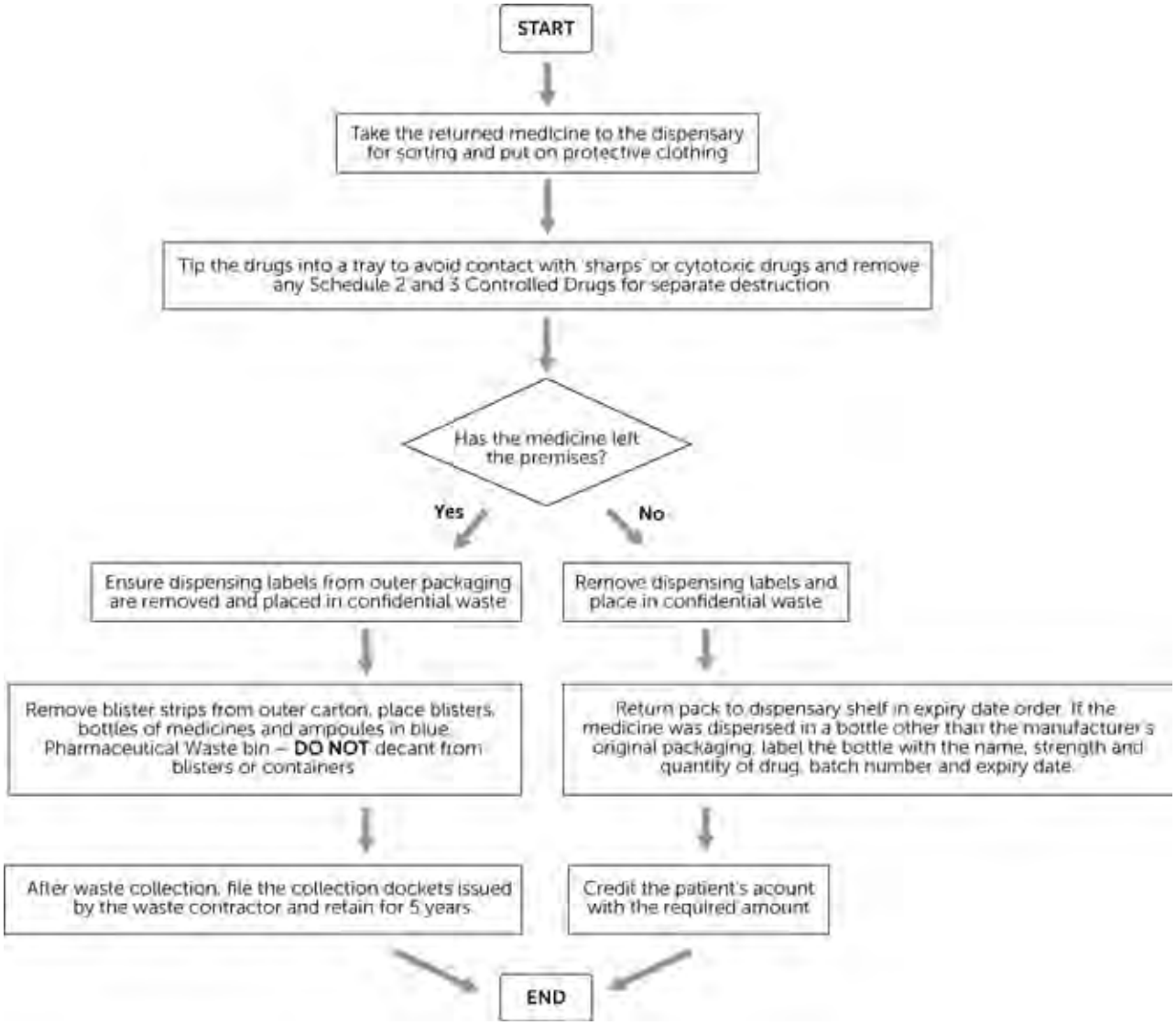
Step 3
When the cap covers the needle completely, use the other hand to secure the cap on the needle hub.
Be careful to handle the cap at the bottom only (near the hub).


Step 1


Step 2


Step 3

Medicines returned by customers or not used by in-patients



QUESTIONS

1. Temperature-sensitive vaccines should normally be stored between:
    a. 10–12°C
    b. 2–8°C
    c. -1–3°C
    d. 10–14°C
2. Once opened, most multidose injection bottles must be discarded after:
    a. 14 days
    b. 24 hours
    c. 1 month
    d. 28 days
3. Medicines returned by customers:
    a. May be returned to stock and resold
    b. Must be disposed of unless the practice can guarantee they have been stored according to their SPCs
    c. May be used in-house
    d. Should be returned to the wholesaler
4. Dispensary SOPs can be used in practice to:
    a. Show evidence that staff are competent to hand over medicines
    b. Ensure consistency
    c. Reduce errors
    d. All of the above
5. Standard operating procedures should be written by:
    a. Someone familiar with the task
    b. Someone unfamiliar with the task
    c. The practice manager
    d. The head nurse
6. The estimated amount of stock that should be held can be calculated using the equation:
    a. OUTL = D x L
    b. D = OUTL/L
    c. D = L x OUTL
    d. OUTL = D/L

ANSWERS 1 – b; 2 – d; 3 – b; 4 – d; 5 – a; 6 – a

Suitably qualified persons

KEY POINTS

- Suitability qualified persons (SQPs) can prescribe and supply 'prescription-only medicines – veterinarian, pharmacist, SQP' (POM-VPS) and 'non-food animal medicines – veterinarian, pharmacist, SQP' (NFA-VPS) medicines
- SQPs must operate from an approved premises
- SQPs cannot diagnose disease
- SQPs must assess owners' competence and advise on warnings and safe administration
- SQPs cannot prescribe 'prescription-only medicine – veterinarian' (POM-V) medicines or initiate use of the cascade

Definitions

'Suitably qualified person (SQP)' is a phrase used in the Veterinary Medicines Regulations (VMR) to describe a person who is permitted to prescribe and supply veterinary medicines classified as POM-VPS or NFA-VPS in the UK. Most of the medicines in the 'veterinarian, pharmacist, SQP' (VPS) categories have preventive uses (e.g. external and internal antiparasitic medicines, farm animal vaccines and nutritional supplements). SQPs may, like anyone else, supply medicines classified AVM-GSL and those sold under the exemption scheme for small pet animals. SQPs must register with the Animal Medicines Training Regulatory Authority (AMTRA), Vetpol or VetSkill. It should be noted that holding an RVN (registered veterinary nurse) qualification does not allow the person to supply NFA-VPS products unless they also hold an SQP qualification.

Over 7000 SQPs are registered with AMTRA. Such SQPs have to renew their registration with AMTRA each year and pay an annual fee. AMTRA monitors continuing professional development (CPD) and deals with complaints about breaches of professional standards.

SQPs must comply with a Code of Practice issued by the Department for Environment, Food and Rural Affairs (Defra) Secretary of State through the Veterinary Medicines Directorate (VMD) and distributed by AMTRA. SQPs must supply only from authorized premises and only from within the animal group categories for which they are trained and registered.

SQP should not be confused with the broader term Registered Qualified Person (RQP) which encompasses:

- Veterinary surgeons registered with the Royal College of Veterinary Surgeons (RCVS)
- Pharmacists registered with the General Pharmaceutical Council (in Great Britain) or the Pharmaceutical Society of Northern Ireland
- SQPs registered with AMTRA or VetSkill.

The regulations also define other types of 'qualified person', including Manufacturing Qualified Persons and Pharmacovigilance Qualified Persons.

The category of an SQP is indicated by a character or characters within their SQP number. The most common are:

- R-SQP – qualified to supply for all species groups
- E-SQP – equine and companion animal only
- C-SQP – companion animal only.

There are other potential species combinations with their own prefixes. More information can be found on the AMTRA website ( ).

Premises

SQPs must operate from approved premises, which may be a registered veterinary practice or a registered pharmacy, where no further registration is needed, or an SQP retailer's premises registered with the VMD. The VMD will inspect premises and register them annually. For more information, see the VMD's guidance on retail of veterinary medicines ( ).

See also **Registration of premises and inspections**.

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Legal duties

When prescribing a POM-VPS product, the SQP must always take account of:

- The disease/condition of the animals requiring treatment
- The type of holding and the animals being treated
- The authorized veterinary medicines on the market, and their warnings and contraindications
- The responsible use of medicines (see below)
- The requirement to prescribe the minimum amount of product necessary for the treatment and condition presented
- The requirement for the person receiving the product to use it for an authorized use
- The abilities and competence of the person who will administer the product
- Any available farm or animal health plan.

That prescription may be in writing but usually will be verbal. SQPs need not see the animal and in any case may not diagnose disease.

For horses and other equidae, the SQP must check whether the animal has been declared as non-food-producing in their horse passport.

For anthelmintic products for sheep and cattle, SQPs should follow the recommendations of the Sustainable Control of Parasites in Sheep (SCOPS) and the Control of Worms Sustainably (COWS) groups.

In supplying a POM-VPS or NFA-VPS product, the SQP must always:

- Be satisfied that the person who will use the product is competent to use it safely and for its authorized use
- Advise on warnings or contraindications
- Provide advice on safe administration.

SQPs may not break the immediate packaging of a medicine, so cannot supply a small number of tablets from a tub, but may for instance supply individually-wrapped boluses or parts of a blister strip of tablets, provided that all the required written information is supplied to each client, such as by providing a copy of the package insert or summary of product characteristics (SPC).

Cascade use

On their own authority, an SQP may only supply medicines and advise on use consistent with the SPC. If a client wishes to use a medicine for a species for which it is not authorized, or by an administration route not authorized, or under a different dosage regime, then an SQP may only supply the medicine in accordance with a prescription from a veterinary surgeon under the prescribing cascade. The prescription should be retained for inspection.

See also **Prescribing cascade**.

Examinations and categories

The Code of Practice for SQPs requires that all SQP qualifications be at Higher Education Level 4 (equivalent to first-year degree level) or above, unless integrated within a broader veterinary nursing qualification (when they may be at level 3) and outlines the required syllabus.

Candidates seeking to become AMTRA SQPs are assessed by examinations set and marked by Harper Adams University taking place at locations throughout the UK. All AMTRA SQPs have to pass an AMTRA viva and relevant written examinations. Additional species modules may be added at future dates, extending the range of medicine groups available to the SQP.

The most common route to AMTRA SQP qualification is to pass a base examination, which covers legislation, anatomy, physiology and disease challenges. In addition to the base module, there are species modules: farm animal, equine, avian and companion animal. SQPs have to pass relevant species group module(s), as well as the base and oral examinations. Thus, SQPs can combine species modules to create the qualification relevant to them and their business.

Alternatively, qualified registered veterinary nurses may become SQPs via a shorter written examination, which concentrates on legislation and application of the knowledge and understanding they are already likely to have, in order to become a C-SQP. They can build on this by adding the farm animal, avian or equine modules.

Some veterinary pharmacy qualifications are also recognized by AMTRA as the academic basis for SQP registration.

Continuing professional development

Once qualified, an AMTRA SQP must show they are keeping up to date. There is a two-yearly requirement for CPD points. These can be gained from accredited meetings and webinars, accredited distance learning and private study. CPD is compulsory: those not gaining enough CPD points cannot continue as SQPs without passing fresh examinations. More information can be found on the AMTRA CPD webpage ( ).

SQPs in veterinary practice

An SQP working in a veterinary practice has the legal right to prescribe and supply POM-VPS and NFA-VPS medicines without recourse to the veterinary surgeon, and to anyone, not just clients of the practice. Without an SQP, every decision to supply any medicine (other than those on free sale) must be made by a veterinary surgeon on a case-by-case basis, which may pose logistical challenges as well as potentially inhibiting clients and thus compromising animal care.

Being an SQP gives no extra rights in relation to POM-V medicines. The veterinary surgeon must prescribe the product and authorize each transaction individually, but may authorize another person to hand over the product provided the veterinary surgeon is satisfied that the person handing it over is competent to do so. It is not necessary to be an SQP to be regarded as competent.

QUESTIONS

1. Which organization is responsible for registering SQPs?
    a. AMTRA or VetSkill
    b. VMD
    c. NOAH
    d. The Home Office
2. Which categories of medicines can SQPs supply or prescribe?
    a. POM-V; POM-VPS
    b. POM-VPS; NFA-VPS; AVM-GSL
    c. POM-V; NFA-VPS
    d. POM-V; POM-VPS; NFA-VPS; AVM-GSL
3. When supplying a POM-VPS or NFA-VPS medicine, an SQP must:
    a. Be satisfied that the person who will use the product is competent to use it safely
    b. Advise on warnings or contraindications
    c. Provide advice on safe administration
    d. All of the above
4. SQPs working in veterinary practice can:
    a. Prescribe POM-V medicines
    b. Use the prescribing cascade
    c. Prescribe and supply POM-VPS and NFA-VPS medicines without recourse to the veterinary surgeon
    d. Supply all wormers and flea treatments to non-clients

ANSWERS 1 – a; 2 – b; 3 – d; 4 – c

Health and safety

KEY POINTS

- The Control of Substances Hazardous to Health (COSHH) Regulations require employers to control substances that are hazardous to health
- Assessments and subsequent actions reduce the risks associated with working with hazardous substances
- If five or more staff are employed, risk assessments must be written down
- Medicines can be classified as low, medium or high risk (high risk require individual, detailed assessments)
- Use the information in summary of product characteristics (SPC) or safety datasheets to perform risk assessments

The Health and Safety Executive (HSE) is the enforcing authority for workers in England, Scotland and Wales. The equivalent in Northern Ireland is the Health and Safety Executive Northern Ireland (HSENI). Their mission is to prevent work-related death, injury and ill health. To achieve this aim, they provide free advice and guidance to employers on minimizing risk in the workplace, and inspect workplaces to ensure that serious risks are managed appropriately. It is the responsibility of all staff members to ensure risks to health are minimized, and that any health and safety guidelines are followed appropriately. Employers should ensure that guidelines are followed for the writing and implementation of both risk and COSHH assessments. Health and safety in the dispensary requires identification of **hazards** and **risks**.

- A **hazard** is anything that may cause harm, such as chemicals, electricity, working from ladders, an open drawer, etc.
- The **risk** is the chance, high or low, that somebody could be harmed by these and other hazards, together with an indication of how serious the harm could be.

Control of substances hazardous to health

The 2002 COSHH Regulations require employers to control substances that are hazardous to health. You can prevent or reduce workers' exposure to hazardous substances by:

- Finding out what the health hazards are
- Deciding how to prevent harm to health (risk assessment)
- Providing control measures to reduce harm to health
- Making sure control measures are used
- Keeping all control measures in good working order
- Providing information, instruction and training for employees and others
- Providing monitoring and health surveillance in appropriate cases
- Planning for emergencies.

Every employer or self-employed person is legally required to make an assessment of the health and safety risks arising out of their work. The purpose of the assessment is to identify what needs to be done to control health and safety risks. If a practice employs five or more people, the assessment(s) must be recorded in writing. Failure to adequately control hazards can lead to prosecution under the COSHH Regulations and civil action from injured or ill employees. A hazardous substance may be defined as any substance which can cause adverse health effects or disease.

Hazardous substances include:

- Substances used directly in work activities and classified as dangerous to health under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation 2007 (recognizable by their warning symbols) (e.g. cleaning agents)
- Substances generated during work activities (e.g. waste fumes from anaesthesia equipment)
- Naturally occurring substances (e.g. dust from litter trays, if concentrations in the air exceed levels specified in the COSHH Regulations)
- Biological agents, such as bacteria and other microorganisms
- Other substances that may pose a risk to health, but not covered by the Classification Labelling and Packaging (CLP) Regulations for technical reasons (e.g. medicines).

To comply with COSHH Regulations, the following eight steps must be followed:

1. Assess the risks.
2. Decide what precautions are needed.
3. Prevent or adequately control exposure.
4. Ensure that control measures are used and maintained.
5. Monitor the exposure.
6. Carry out appropriate health surveillance.
7. Prepare plans and procedures to deal with accidents, incidents and emergencies.
8. Ensure employees are properly informed, trained and supervised.

Safety datasheets provide information regarding the substance. They do not constitute the COSHH assessment. The assessment must be task-based, considering the quantity used, the way in which the substances are used, who will be affected and how.

Risk assessment

A risk assessment involves five steps:

1. Identify the hazards.
2. Decide who might be harmed and how.
3. Evaluate the risks and decide on precautions.
4. Record your significant findings.
5. Review your assessment and update if necessary.

Areas of work in the dispensary requiring risk assessment include:

- General medicines handling
- Handling cytotoxic drugs
- Spillage of medicines
- Manual handling: accessing high shelves, moving drug order, etc.
- Trip hazards
- Waste disposal.

The HSE has produced a blank sample risk assessment that may be used either as a template or as a guide to creating a practice-specific risk assessment document. It is available for download from the HSE website ( ).

Risk assessments should be carried out for all these tasks and reviewed annually. Standard operating procedures (SOPs) should be written detailing the required control methods, and all staff should be required to sign to acknowledge that the SOPs have been read and understood.

When working with veterinary medicines, there is a wide variation in risk. Many medicines can be classified as low or medium risk but others pose a very serious risk to health.

See also **Correct storage, dispensary management and standard operating procedures**.
See also **Cytotoxic drugs**.

Low and medium risk substances

Risks associated with handling low and medium risk medicines can be adequately controlled by performing assessments by therapeutic group/type/route of administration. For example, the practice can produce standard methods for the control of exposure to:

- Injectable anaesthetics
- Inhalation anaesthetics
- Pour on anthelmintics
- Steroidal compounds
- Vaccines
- Antibiotics
- Disinfectants.

Within these groups, practices must identify specific risks such as penicillin allergy.

High risk substances

Specific and detailed assessments along with the resulting control methods should be made for high risk substances such as:

- Cytotoxic drugs
- Tilmicosin (e.g. Micotil)
- Hormones
- Oil-based vaccines
- Glutaraldehyde disinfectants
- Large animal etorphine.

In general, when handling medicines members of staff must:

- Treat all medicinal products as potentially harmful
- Be aware of the hazards associated with medicines and know the results of the COSHH and risk assessments
- Wear disposable gloves when handling any open or loose products
- Be familiar with the practice SOPs for handling medicines and use additional protective clothing and equipment as and when specified
- Inform the health and safety officer if they (or their partner) are or are trying to become pregnant. In the case of pregnancy, be aware of and avoid handling teratogenic drugs (see the *BSAVA Small Animal Formulary* for a listing) likely to harm the unborn child, or drugs likely to cause miscarriage. In the case of trying to become pregnant, be aware of and avoid mutagenic drugs, which can affect eggs and sperm
- Inform the health and safety officer if they experience any allergies or adverse effects thought to be caused or made worse by the handling of, or exposure to, veterinary medicinal products (VMP)
- Wash their hands after handling medicines, even if disposable gloves have been worn.

Summaries of product characteristics

To perform risk assessments, employers require information on the safe use of medicines, chemicals and disinfectants.

Manufacturers are no longer required to produce safety datasheets for medicines. Information of the safe use of each medicine can be found in the SPC. The Veterinary Medicines Directorate product information database ( ) has a full list of veterinary SPCs for:

- Currently authorized products
- Expired products
- Suspended products
- Registered homeopathic products
- Refused products
- Specified feed additives.

For non-veterinary authorized drugs (e.g. human prescription-only medicines) used under the prescribing cascade, SPCs can be found online ( ).

Chemicals and disinfectants are required under REACH regulations 2007 ( ) to have a safety datasheet and appropriate warning symbols on the product packaging.

RIDDOR and reporting incidents

Under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), the accidental release of any substance that may cause a major injury or damage to health, is classed as a dangerous occurrence and should be reported to the HSE. However, a small spillage of a cytotoxic drug, which is well contained and easily dealt with, is not reportable. Spillage of a large amount, to which people could have been exposed, is reportable.

In addition, there are a number of specific injuries that must be reported:

- Fractures, other than to fingers, thumbs and toes
- Amputations
- Any injury likely to lead to permanent loss of sight or reduction in sight
- Any crush injury to the head or torso causing damage to the brain or internal organs
- Serious burns (including scalding) which
  - Covers more than 10% of the body
  - Causes significant damage to the eyes, respiratory system or other vital organs
- Any scalping requiring hospital treatment
- Any loss of consciousness caused by head injury or asphyxia
- Any other injury arising from working in an enclosed space which
  - Leads to hypothermia or heat-induced illness
  - Requires resuscitation or admittance to hospital for more than 24 hours.

Accidents must be reported, where they result in an employee or self-employed person being away from work, or unable to perform their normal work duties for more than seven consecutive days as the result of their injury. Any accident or injury that prevents an employee or self-employed person from performing work duties for more than three consecutive days must be recorded in an accident book, but is not notifiable.

How to report

Online: go to the website (🌐) and complete the appropriate online report form. The form will then be submitted directly to the RIDDOR database. You will receive a copy for your records.

Telephone: all incidents can be reported online but a telephone service remains for reporting fatal and specified injuries only. Call the Incident Contact Centre on 0845 300 9923 (opening hours Monday to Friday 8.30 am to 5 pm).

Further information

- For further information on COSHH regulations 2002, see the HSE website (🌐)
- For further information on risk assessments, see the HSE website (🌐)
- For further information on REACH, see the HSE website (🌐)
- For further information on CLP, see the HSE website (🌐)

QUESTIONS

1. Risk assessments that should be carried out for the dispensary include:
    a. Spillage of medicines
    b. Manual handling
    c. Handling of cytotoxic medicines
    d. All of the above
2. Specific and detailed COSHH assessments must be performed for which one of the following?
    a. Steroids
    b. Inhalation anaesthetics
    c. Hormones
    d. Antibiotics
3. The VMD website does not hold SPCs for which one of the following?
    a. Currently authorized veterinary medicines
    b. Human medicines
    c. Suspended products
    d. Registered homeopathic products
4. Accidents or injuries that result in an employee being off work for what length of time must be reported under RIDDOR?
    a. 1 day
    b. 3 consecutive days
    c. 7 consecutive days
    d. 10 consecutive days

ANSWERS 1 – d; 2 – c; 3 – b; 4 – c

Medicine waste disposal

KEY POINTS

- Waste must be segregated correctly
- Learn the key colours for hazardous (yellow, orange and purple) and non-hazardous (blue and black) waste
- Ensure all segregated waste is correctly labelled with the legally required European Waste Catalogue (EWC) and Hazardous Property (HP) codes where applicable
- Use the appropriate terminology – healthcare waste: medicinal, non-hazardous or hazardous.
- Ensure all staff are properly trained for correct waste segregation

Medicinal waste disposal is an important part of healthcare waste management within a veterinary practice. It should be incorporated into the scheme of work (known as the Pre-Acceptance Audit*) for healthcare waste management; the rules and requirements are relevant across the waste management requirements within the practice.

Additional sources of information that will help shape the management of medicinal waste include:

- British Veterinary Association (BVA) Waste Guidelines
- Department of Health and Social Care guidance booklet *Safe Management of Healthcare Waste*
- The practice's waste contractor's systems and processes.

Veterinary surgeons (veterinarians) are advised to start with the veterinary guidelines. If these, or the other sources of information mentioned above, do not answer any queries the practice may have regarding medicine waste disposal, advice from the Department of Health and Social Care or BVA or waste contractor should be sought.

* Pre-Acceptance Audit is also known as the Pre-Collection Audit and is now the commonly used terminology.

Waste segregation

The key component of veterinary healthcare waste management is **segregation**. Waste must be designated to special bins and disposed of according to strict guidelines.

Types of Disposal

Waste type	Colour	Disposal type	Notes	Code
Hazardous waste	**Yellow**	For highly regulated, high temperature specialist incineration	Individual bin consignment paperwork and additional tax payment	180202 plus relevant HP code
Hazardous waste	**Orange**	For highly regulated, specialist processing but slightly less costly because of avoidance of specialist incineration	Individual bin consignment paperwork and additional tax payment	180202 plus relevant HP code
Hazardous medicinal waste	**Purple**	For highly regulated, high temperature specialist incineration	Individual bin consignment paperwork and additional tax payment	180207 plus relevant HP code
Non-hazardous medicinal waste	**Blue**	For regulated specialist incineration	Annual paperwork recording	180208
Offensive waste	**Yellow/ Black Striped**	For deep land-fill or incineration for energy	Not applicable to medicinal waste Annual paperwork recording	180203
Domestic waste	**Black or recycling**	For recycling, land-fill or incineration for energy	Annual paperwork recording	Dependent on waste type (e.g. cardboard 150101)

Colour coding

Although not a strict legal requirement, the UK has devised a colour coding system to help ensure the correct waste is disposed via the correct waste stream.

UK healthcare waste colour coding

Colour	Hazardous/non-hazardous	Contents	Notes
Yellow	Hazardous waste for incineration	Any waste that is deemed to fall into definition laid out in the hazardous property codes (HP)	Medicinal hazardous waste is mainly purple waste. HP9 (infectious) waste is the most relevant code. No medicines in this stream. All hazardous wastes cannot be moved between branches
Orange	Hazardous waste for treatment prior to disposal	Any waste that is deemed to fall into definition laid out in the hazardous property codes (HP)	Treatments include autoclaving or disinfection. No medicines in this stream. All hazardous wastes cannot be moved between branches
Purple	Hazardous medicinal waste	Cytotoxic or cytostatic medicines or items contaminated with these	All hazardous wastes cannot be moved between branches
Blue (the 'pharmy bin')	Non-hazardous medicinal waste	Medicines	Denatured Controlled Drugs in this stream
Black and yellow stripes	Non-hazardous offensive waste	Veterinary blood, body fluid or excrement contaminated waste	No medicines in this stream
Black	Domestic waste	Packaging	Packaging must not be contaminated. Recycle where possible

Bins

Pharmaceutical waste bin – non-hazardous

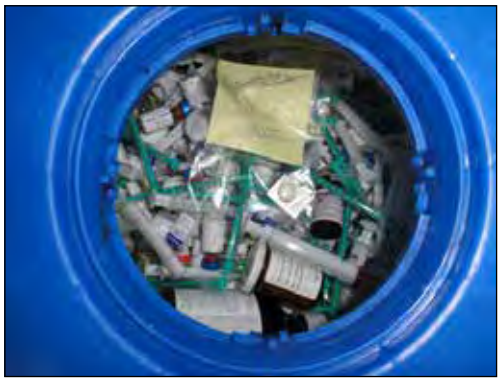
The pharmaceutical waste disposal bin, also known as the 'pharmy bin', is the main disposal bin for pharmaceutical waste. The contents of the bin should be recorded and the record made available to the disposal contractor. Exemption exists for low volume disposals, but it is good practice to keep a record. A dummy client file on the practice management system, either computerized or manual, could be created for this purpose. The date, type and amount of medicine is logged. Computerized practices will automatically 'destock'. A printout or photocopy of the record is the basis of the contents list of the pharmaceutical waste bin, along with a list of any medicines returned by the clients. This information is an important component of the medicine audit.

The pharmaceutical waste bin should be blue leak-proof plastic*, EWC code 18 02 08. The contents of this bin should be non-hazardous and include:

- Vaccine bottles
- Empty injection bottles (not cytotoxic/cytostatic medicines)
- Syringes (not cytotoxic/cytostatic medicines)
- Whole medicines (not cytotoxic/cytostatic medicines)
- Denatured Controlled Drugs.

All syringes placed in the bin should have been fully discharged of content. Snap-top glass vials should not be placed in these bins; they should be placed in the sharps bin.

* Availability of blue containers is unpredictable so they might be supplied as yellow or yellow with a blue lid but that does not mean they are hazardous wastes!



Sharps

The sharps bin should be yellow, orange or purple, which indicates 'hazardous waste'. Bins must comply with the British Standard 7320:1990; EWC codes are 18 02 02 (yellow/ orange) and 18 02 07 (purple). Cytotoxic/ cytostatic waste should be segregated to purple sharps bins. Other waste should be disposed of in yellow or orange bins depending on the method of disposal. Content of sharps bins includes:

- Used needles
- Glass vials
- The purple bin may also be used for other cytotoxic/cytostatic waste
  - Empty injection bottles
  - Syringes
  - Whole medicine
  - Other items contaminated with cytotoxic/cytostatic medicines (e.g. giving sets)
  - Any materials used for mopping up spills, contaminated gloves and contaminated dressings.

Domestic waste

Domestic waste should be placed in a black bag and put out for regular collections. Where possible, waste should be recycled. Medicine packaging must not contain any traces of medicine or have been in direct contact with the medicine.

Medicinal 'domestic' waste includes:

- Non-contaminated paper
- Non-contaminated card
- Non-contaminated plastic packaging.

Waste codes

Known as European Waste Catalogue (EWC) codes or List of Waste (LOW) codes, these are a legal requirement and should be recorded on all disposed waste containers. They instruct on the content of the bin and how it will be disposed of.

European Waste Catalogue (EWC) waste codes

	Non-hazardous	Hazardous
18 02 01	Sharps (except 18 02 02)	
18 02 02		Wastes subject to special requirements in order to prevent infection
18 02 03	Wastes not subject to special requirements in order to prevent infection	
18 02 05		Chemicals consisting of or containing dangerous substances
18 02 06	Chemicals other than those mentioned in 18 02 05	
18 02 07		Cytotoxic and cytostatic medicines
18 02 08	Medicines other than those mentioned in 18 02 07	

In addition to the EWC code, hazardous waste must be defined under one of the Hazardous Property (HP) codes. For veterinary medicines these include:

- HP6 – toxic teratogenic
- HP7 – carcinogenic
- HP9 – infectious
- HP10 – toxic for reproduction
- HP11 – mutagenic.

Whole pharmaceuticals

These are made up of the following:

- Returned stock
- Out of date stock
- Damaged stock.

Returned stock

The decision to accept returned medicines will vary on an individual basis and should include consideration of refunds, social responsibility for taking the medicine out of circulation and the practice relationship with the client. It is permissible to reuse returned medicines provided the practice is sure that they have been stored according to the summary of product characteristics (SPC). Damaged or incorrectly stored medicines will need disposal and this will incur a cost if done at the practice; disposal by the client at home falls outside the Waste Regulations.

Out of date stock

Out of date medicines should always be disposed of and never used. It is illegal to supply or use out of date medicines. For multidose injectable medicines, the broach date of the vial must be recorded and disposal after the designated number of days. This is usually (but not always) 28 days after the broaching.

Damaged stock

Damaged stock includes any in-transit damages or spillages and breakages. For spilled medicines, the medicine should be contained with the practice 'spill kit' (sand, sawdust or cat litter), swept into a container, and the content and amount estimated and recorded. The container can then be disposed of into the pharmaceutical waste bin.

Disposal of whole pharmaceuticals

The medicines should be collected into the 'pharmy bin'. **It is important to ensure that solid and liquid medicines are kept separate**. There have been several recorded incidences of fires started by chemical reactions within pharmaceutical waste bins. Tablets should be kept within blister packs or the original packaging. If these are not available, tablets of the same medicine should be collected into tablet envelopes or tablet pots before disposal.

Residue pharmaceuticals

These are waste items that have been contaminated with medicines.

Empty medicinal containers

This type of waste includes all empty multidose bottles, vaccine vials, medicinal contaminated packaging and contaminated tablet pots. These should be collected into the pharmaceutical waste bin and can be mixed with whole medicines. Only the containers of cytotoxic/cytostatic medicines need to be segregated as hazardous waste. The majority are non-hazardous. A detailed list is not required.

Medicine delivery wastes

This includes discharged syringes, giving sets, cannulae and catheters that have been medicinally contaminated. All sharps must be detached before disposal.

Sharps/needles

Advice from the BVA via the Environment Agency states that all sharps should be disposed of as hazardous waste. It is also Environmental Agency advice that the needle is not removed from the syringe body after use and the whole lot is disposed of as 'sharps'. Larger sharps containers are available. However, disposal of sharps and syringes together will prove expensive because charges are usually calculated by volume and/or weight.

Provided the practice has carried out training and a risk assessment, the separation of needle and syringe after use can be considered. The syringe can be segregated into the empty vials pharmaceutical waste bin. The needle needs to be disposed of into the hazardous sharps container.

It should be noted that cytotoxic/cytostatic contaminated sharps and syringes must be further segregated into purple sharps bins. Such waste items should not be moved between branch surgeries.

Controlled Drugs

Controlled Drugs (CDs) require additional recording and action before disposal. All CDs must be effectively denatured before disposal. This applies to out of date whole medicines; it is not necessary to apply denaturing to residual amounts left in used vials, syringes or needles. It is permitted to open packaging and de-blister to aid denaturing. Denaturing kits are available from veterinary wholesalers. When denaturing Schedule 2 medicines, a witness must be present and sign that the procedure has been carried out. The record of disposal should be entered into the CD Register so that purchase, use and disposal appear in one single record.

Destruction of out of date Schedule 2 CDs, as well as some Schedule 3 CDs, under the prescribing cascade must be witnessed by a Veterinary Medicines Directorate (VMD) inspector, an Assessor of the Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (PSS), a veterinary surgeon who is independent of the practice, or a police officer (such as a Controlled Drugs Liaison Officer (CDLO)) in England, Wales and Scotland. In Northern Ireland, destruction of CDs must be witnessed by a person authorized by the Department of Health.

Once mixed with the denaturing agent, the waste can be deposited into the standard pharmaceutical waste bin. It needs to be recorded on the pharmaceutical waste bin list as a denatured CD. Schedule 3, 4 and 5 CDs are not subject to such rigour, but they still need to be denatured prior to disposal. This does not need external witnessing by an authorized person, but it is best practice to record the event witnessed by a member of the practice staff.

Registration for T28 exemption

Because the denaturing of CDs is, in effect, processing waste, the practice must apply for an exemption from a waste processing licence. This is a free service and available via their website ( ). This EA (English) register also has links to the Scottish, Welsh and Northern Irish exemption sites.

See also **Controlled Drugs**.

Cytotoxic and cytostatic medicines

These medicines are deemed to be hazardous waste and will carry variable hazard codes. They all fall under EWC code: 18 02 07. This means that they must be segregated from all other pharmaceuticals and be disposed of by specialist contractors. The items for disposal include unused medicine, used vials, contaminated syringes, needles, cannulae and contaminated protective clothing. It is important that the disposed medicines are defined by their particular hazardous property (HP) code (see earlier).

The following classes of medicines should be included in this classification:

- Cancer chemotherapeutics (e.g. vincristine, epirubicin/pharmorubicin, methotrexate and all similar classes of tumour toxic medicines)
- Antiviral medicines, including interferon
- Ciclosporin medicines in any form
- Certain hormonal preparations (which are teratogenic or toxic to reproduction) including prostaglandins and androgens (e.g. Alizin aglepristone).

These wastes must be segregated into purple containers (the separate sharps bin should have a purple top, the separate pharmaceutical waste bin should have a purple lid or label and the soft waste bag should be purple). The EWC and HP codes must be clearly visible. The waste needs to be consigned to a specialist contractor and a fee is payable to the Environment Agency on disposal. Such waste items should not be moved between branch surgeries. Carriage of cytotoxic and cytostatic waste in unlicensed vehicles is illegal.

In practical terms, it is unlikely that the volume of this type of waste will be high. It is probably sufficient for the practice to have one cytotoxic sharps bin that is used for all such needles, syringes and used vials. Out of date cytotoxic medicines can also be added, provided they are listed and mixing precautions (see earlier) are observed. Where other contaminated items are produced (e.g. giving sets, cannulae and gloves), these too can be disposed of via the cytotoxic sharps bin. For practices producing large volumes of such waste (e.g. oncological specialists), larger volume sharps bins could be considered.

Terminology

The waste regulations have made some traditional definitions obsolete. Waste from the practice should now be referred to as **healthcare waste**. Use of the words 'clinical waste' should be avoided as this now carries a legal definition and refers specifically to hazardous waste. Traditionally, pharmaceutical disposal was covered by the DOOP (Destruction of Old Pharmaceutical) Regulations and such waste was called DOOP waste. It is more accurate now to refer to the waste as pharmaceutical waste as a category of healthcare waste. DOOP bins are now **pharmaceutical waste bins**. It is therefore preferable to stop referring to medicinal waste as DOOP.

Variations in legislation for Scotland

The above regulations are specific to England and Wales. By and large, the above information is relevant to Scotland. The key difference is the substitution of the word 'special' for 'hazardous', i.e. Scottish 'special waste' is equivalent to English 'hazardous waste'.

Where Scottish waste contractors are giving different advice, it is advised to seek a further opinion from the Scottish Environment Protection Agency (SEPA).

Variations in legislation for Wales

Natural Resources Wales (NRW) now has responsibility for waste regulation, and may develop variations from the English Environment Agency. So far, the only variant is for registration of T28 exemption.

Variations in legislation for Northern Ireland

The Northern Ireland Environment Agency (NIEA) are developing their own variation of the waste regulations. Practices are advised to be aware of any regional requirements.

QUESTIONS

1. A needle used to deliver a water-based vaccination is disposed of via:
    a. A white-topped sharps bin
    b. A yellow-topped sharps bin
    c. A purple-topped sharps bin
    d. A pharmaceutical waste bin
2. What EWC code is used to define the disposal of a half-empty bottle of oxytocin, past its 28th day broach date?
    a. 18 02 03
    b. 18 02 05
    c. 18 02 06
    d. 18 02 07
3. The colour orange defines:
    a. Non-hazardous waste that must be incinerated
    b. Hazardous waste that must be incinerated
    c. Non-hazardous waste that can go to land-fill
    d. Hazardous waste that needs special treatment before disposal
4. Controlled Drug wastes, once denatured, are disposed of as:
    a. Hazardous waste that must be incinerated
    b. Non-hazardous waste via the pharmaceutical waste bin
    c. Non-hazardous via the offensive waste bin
    d. Hazardous in the purple-coloured waste bin
5. Cytotoxic and cytostatic medicines include:
    a. Alizin (Aglepristone)
    b. Ciclosporins
    c. Aciclovir
    d. All of these three medicines

ANSWERS 1 – b; 2 – d; 3 – d; 4 – b; 5 – d

Prescribing cascade

KEY POINTS

- The legal provisions for 'cascade use' exist to allow prescribing veterinary surgeons (veterinarians) to ensure animal health and welfare where authorized veterinary medicines are not available
- Where authorized veterinary medicinal products (VMP) exist for the treatment of a condition, prescribing veterinary surgeons should use these products first
- The veterinary medicines industry is far smaller than the human medicines sector (circa 2.5% the size of the human medicines industry in the EU). For this reason, it is not possible for the animal medicines industry to develop products for the treatment of all conditions affecting all species that veterinary surgeons are required to treat
- Suspected adverse reactions involving both authorized and 'cascade use' of products should be reported to the regulatory agency, the Veterinary Medicines Directorate (VMD)
- Where VMP are being used under the cascade, written consent should be received from the animal owner(s)

Legislative background

The cascade is a long-standing legal flexibility providing a rational balance between the legislative requirement for veterinary surgeons to prescribe and use authorized VMP where they are available, and the need to prescribe other medicines where they are not. It is intended to increase the range of medicines available for veterinary use, in order to avoid unacceptable suffering.

The current European Union Veterinary Medicines Directive (2001/82) is the basis of veterinary medicines regulation throughout all EU Member States. National laws, such as the UK Veterinary Medicines Regulations (VMR), are heavily based on the EU law. The EU Veterinary Medicines Directive is currently going through the final steps in its review process. It is expected that a new European VMR will come into effect across the EU in late 2021 or early 2022. At the time of writing (November 2018), the precise relevance of these new European VMR to the UK remain unclear, as a result of the current ongoing deliberations about the UK's exit from the EU and the future relationship that will exist between the UK and the EU.

The current law starts from the principle that all VMP must be authorized, and that use of an unauthorized medicine, or use of an authorized medicine in an unauthorized way, is an offence. This protects animals, users, consumers and the environment from the potentially serious effects of untested or poor quality VMP.

However, the law recognizes that there are circumstances where the benefits of treatment of animals with unauthorized medicines outweigh the risks, particularly where there are no veterinary authorized medicines for a condition or for a species. As a result, the legislators have given veterinary surgeons a unique privilege by way of an exemption from the legal requirement to use an authorized VMP for the species and condition that they are treating. This privileged exemption is known as the 'prescribing cascade', or simply 'the cascade', and it exists to ensure animal health and welfare needs are met.

The veterinary medicines industry in the EU is worth approximately 2.5% of the human medicines industry. As a result, it is not possible for veterinary medicines companies to develop authorized medicines for each and every condition of a wide variety of species. This is particularly the case for so-called 'minor use, minor species' medicines. Companies simply may not obtain a return on investment and the financial incentives to develop products for all conditions in all species are not there.

Cascade use and authorized use

Authorized use is when a product is used in accordance with the clinical advice given on the summary of product characteristics (SPC). The SPCs for all authorized veterinary medicines are available on the VMD Product Information Database ( ).

Cascade use refers to any use of a veterinary medicine that is not specified in the SPC, including use in another species or to treat another disease, or use at a different dose rate or duration.

The importance of using authorized medicines

Individual animal species have physiological differences from humans and from each other, which may affect the way the animal responds when it is treated. The authorization system for VMP requires each to have proven quality and effectiveness and most importantly safety for the animal, the user (veterinary surgeon, farmer, pet owner), the environment and, for

food producing animals, the consumer of food from animals. This assurance has to be provided for each species and each indication on the SPC of the veterinary product, a legal document which is approved by the regulatory agency. The authorization process requires independent regulators to carry out an assessment of VMP licence applications against criteria of safety, quality and efficacy when used in accordance with the manufacturer's recommendations.

In addition, animal medicines containing the same active ingredient as human medicines may be formulated differently. For example, for orally administered products, the formulation needs to ensure that the medicine is properly absorbed through the gut, a process which can differ between animal species and between animals and people. Human medicine formulations may contain different excipients or have different bioavailability from VMP. Therefore, using a medicine which is not authorized for animals increases the risk of treatment failure or harm to the treated animal.

Veterinary surgeons remain entirely responsible for the treatment of animals under their care; use of a medicine prescribed in accordance with the cascade should be supported by clear auditable clinical evidence to justify the veterinary surgeon's decision.

Generic medicines

It is important to address the potential confusion with the use of the words 'generic medicine'. Authorized veterinary generic medicines exist legitimately and can be used by veterinary surgeons in the same way as other authorized VMP. A generic medicine is essentially a 'copy' of the pioneer or originally developed product. After the original data protection period of the product has expired, other companies may produce generic medicines of the product. Generic veterinary medicines undergo the usual assessment for safety, quality and efficacy. A generic VMP is, of course, a fully authorized VMP, in the same way as the 'pioneer' product.

However, human medicines, including human generic medicines that contain a similar active ingredient to the authorized veterinary medicines, may not be used unless there is no suitable veterinary medicine available.

Compliance with the cascade–how does it work in practice?

Prescription and use by veterinary surgeons of human medicines or extemporaneous preparations (often called 'veterinary specials'), where a suitable UK authorized veterinary medicine is available, is an offence under the VMR and is also contrary to the Royal College of Veterinary Surgeons (RCVS) Code of Professional Conduct.

However, as outlined above, to avoid unacceptable suffering, there are occasions when the prescribing veterinary surgeon can justifiably prescribe under the cascade. Responsibility for the prescription and use of the medicine remains with the prescribing veterinary surgeon.

The legal basis for the cascade is as follows (see the Veterinary Medicines Regulations 2013 Schedule 4 ( )):

a. The first option the veterinary surgeon should use is a product authorized for that condition in that species
b. If there is no authorized VMP available in the UK for the condition, the veterinary surgeon responsible may treat the animal species with the following, in this 'cascaded' order:
   - A VMP authorized in the UK for use with another animal species for that condition, or another condition for that species
c. If there is no such medicine:
   - A UK authorized human medicine
   - A VMP not authorized in the UK, but authorized in another EU member state for use with any animal species (if the animal in question is a food producing animal, this must be a food producing species)
d. If there is no such medicine:
   - A VMP prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorization for that type of product (often referred to as 'veterinary specials').

Import certificates

Where there is no suitable authorized medicine in the UK to treat a particular condition and when the situation so requires, a veterinary surgeon may wish to seek an import certificate.

A product authorized in another EU Member State, which sits at point (b) in the cascade as described above, requires a Special Import Certificate (SIC), which must be obtained from the VMD.

An authorized veterinary medicine from outside the EU or human medicines from outside the UK all require a Special Treatment Certificate (STC), which must also be obtained from the VMD.

More information on how to import products can be accessed via the VMD website ( ).

As part of the application process for import certificates, veterinary surgeons are required to demonstrate that there is no suitable authorized product available, to justify the intended use of the cascade. Factors such as the cost of the products and the withdrawal period are not acceptable reasons to import alternatives.

Supply under the cascade

Only veterinary surgeons are permitted to prescribe under the cascade. However, a suitably qualified person (SQP), a veterinary nurse, or indeed any member of the practice staff can supply any medicine when acting under the direction of a veterinary surgeon. The responsibility for ensuring that such a person carries out the task correctly remains with the veterinary surgeon giving that direction.

Medicines prescribed by a veterinary surgeon in accordance with the cascade may also be supplied against a written prescription by other legal retailers of veterinary medicines (another veterinary surgeon, a pharmacist or an SQP), provided the medicine is of a classification and for a species for which the supplier would normally be legally permitted to supply it.

Exemption for small pet animals

A veterinary surgeon may choose to use an exemption for small pet animals (ESPA) medicine at any time in accordance with the recommended use of the medicine. Thus, the cascade neither compels nor prevents the use of an ESPA medicine.

However, should the veterinary surgeon wish to use the ESPA medicine in a different way than that specified on the label because of a professional judgement that such a medicine could provide a safer or better option for treatment, then this would be considered to fall under the last of the cascade options (i.e. extemporaneous preparation).

Scope of the cascade

The cascade provisions apply 'in particular to avoid unacceptable suffering'. The legislation on the cascade does not allow the cost of the medicine to be taken into account when deciding which medicine to use. For example, it is not permissible to use a human medicine or extemporaneous preparation product because it is cheaper. Any use of a human medicine, imported medicine or extemporaneous preparation instead of the authorized veterinary medicine has to be justified by the veterinary surgeon on clinical grounds alone.

Some examples are given by the UK regulatory agency, the VMD, to provide guidance on how the cascade should work in practice and can be found on the VMD website ( ).

Suspected adverse events

If a veterinary surgeon concludes that an authorized VMP does not exist in a particular case because of a lack of efficacy using the authorized product or the likelihood of unacceptable side effects based on past experience when treating that animal, all experiences of this kind involving veterinary medicines, whether authorized use or unauthorized use, should be reported as suspected adverse events to the VMD or the marketing authorization holder, where they are recorded and monitored as part of the VMD's Suspected Adverse Event Surveillance Scheme.

Labelling of medicines prescribed under the cascade

The following information must be included on labels for products administered under the cascade. Where the product is supplied in its original packaging and already includes some of this information which remains legible following the application of the dispensing label, it is not necessary to repeat this information on the dispensing label. If it is not feasible to include all of the information on the label due to the size of the packaging, it must be included on a separate sheet.

Supply of veterinary medicinal products for use under the cascade

1. A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.
2. Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

    a. The name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product
    b. The name of the veterinary surgeon who has prescribed the product
    c. The name and address of the animal owner
    d. The identification (including the species) of the animal or group of animals
    e. The date of supply
    f. The expiry date of the product, if applicable
    g. The name or description of the product, which should include at least the name and quantity of active ingredients
    h. Dosage and administration instructions

i. Any special storage precautions
j. Any necessary warnings for the user, target species, administration or disposal of the product
k. The withdrawal period, if relevant
l. The words 'Keep out of reach of children' and 'For animal treatment only'.

Record keeping requirements

For all prescription products, vets are required to keep the following records of receipt and supply:

1. Any person permitted under these Regulations to supply a veterinary medicinal product classified as Prescription-only medicine – veterinarian (POM-V) or Prescription-only medicine – veterinarian, pharmacist, suitably qualified person (POM-VPS), who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction that show the following information:
    a. The date
    b. The name of the veterinary medicinal product
    c. The batch number (except that, in the case of a product for a non-food-producing animal, this needs only to be recorded either on the date of receipt of the batch or the date a veterinary medicinal product from the batch is first supplied)
    d. The quantity
    e. The name and address of the supplier or recipient
    f. If there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.

If the client or other records already have this information no additional separate records are needed, as long as the information is accessible on request.

Responsible antibiotic use and the cascade

Responsible antibiotic use under the cascade requires veterinary surgeons to take into consideration not only the most appropriate active substance(s) but also:

- The most appropriate formulation
- The posology
- The current pattern of resistance in their locality
- An awareness of how to reduce selection pressure
- Related factors (e.g. good biosecurity and husbandry/hygiene, avoiding surgical sepsis, etc.).

If a veterinary surgeon can demonstrate that these steps have been taken, then the cascade use of antibiotics is supported. More information about the views of the regulatory authority, the VMD, on the cascade and antibiotics can be accessed on the VMD website ( ).

Informed consent before treatment of animals

It is not a legal requirement under the VMR to obtain informed consent from the owner of an animal to be treated under the cascade. This requirement is part of the RCVS Code of Professional Conduct, which states the following:

'A decision to use a medicine which is not authorized for the condition in the species being treated, where one is available should not be taken lightly or without justification. In such cases, clients should be made aware of the intended use of unauthorized medicines and given a clear indication of potential side effects. Their consent should be obtained in writing. In the case of exotic species, most of the medicines used are unlikely to be authorized for use in the UK and owners should be made aware of, and consent to, this from the outset.'

Conclusion

Animals need medicines to help prevent disease and to help treat them if they do fall ill. All species deserve the benefit of medicinal products which have been specifically developed and authorized for their treatment. The cascade ensures this happens wherever possible, but also gives flexibility for veterinary surgeons to use their clinical judgement to prescribe a medicine where no veterinary authorized medicine exists.

Further information

- UK Veterinary Medicines Regulations 2013 ( )
- VMD Guidance: The cascade: prescribing unauthorized medicines ( )
- Apply for a certificate to import a Veterinary Medicine into the UK ( )
- VMD statement: Responsible antibiotic use under the cascade ( )
- RCVS Code of Conduct ( )

QUESTIONS

1. Is it legal to use a human medicine where an authorized VMP exists for the treatment of a condition?
    a. Yes in certain circumstances e.g. if the animal being treated had a previous reaction to the product with a veterinary authorization
    b. No
    c. Yes, but only if it is cheaper
    d. Yes, but only if it has been used to treat the animal on a previous occasion
2. Which of the following statements is correct?
    a. Veterinary surgeons, veterinary nurses and pharmacists are allowed to prescribe under the cascade
    b. Veterinary surgeons, pharmacists and SQPs are permitted to prescribe under the cascade
    c. Only veterinary surgeons are permitted to prescribe under the cascade
    d. Only veterinary surgeons are permitted to prescribe under the cascade and they are also the only professionals who can supply the required product
3. When prescribing under the cascade, the prescribing veterinary surgeon should do the following to fulfil the RCVS requirements:
    a. Explain to the owner of the animal that they are prescribing under the cascade
    b. Explain to the owner of the animal that they are prescribing under the cascade and obtain the owner's written consent to do so
    c. Not mention to the owner of the animal that they intend to prescribe under the cascade
    d. Obtain written consent from the owner of the animal, but only if they are concerned that there may be a suspected adverse reaction to the product
4. Which of the following statements is correct?
    a. A generic veterinary medicine is a human medicine that can be administered to animals under the cascade
    b. A generic veterinary medicine is essentially 'interchangeable' with the pioneer or originally developed product and must undergo the usual assessment for safety, quality and efficacy
    c. A generic veterinary medicine can only be used under the cascade if the pioneer product is unavailable
    d. A generic product is a pioneer product marketed under another name

ANSWERS 1 – a; 2 – c; 3 – b; 4 – b

Informed consent

KEY POINTS

- Consent must be 'informed'. In simple terms, the owner must understand the nature of the procedure or treatment to be undertaken, the estimated costs and the risks and possible side effects which may ensue from the course of action. Ideally, consent should be acknowledged in writing
- Veterinary surgeons (veterinarians) should be satisfied that the person being requested to provide consent is the owner registered in the clinical records or an agent acting on the owner's authority
- Datasheets are not legally binding documents, but veterinary surgeons must have sound clinical reasons to prescribe unauthorized medicines in accordance with the cascade
- Although it is not a legal requirement to obtain written consent to prescribe an unauthorized medicine under the cascade, the Royal College of Veterinary Surgeons (RCVS) Code of Professional Conduct designates that consent for use of an unauthorized medication must be obtained in writing
- If unauthorized medicines are likely to be used as part of an anaesthetic routine or in an emergency situation following hospitalization, a consent form should contain some reference to this fact

What is informed consent?

The concept of informed consent arose in human medicine during the early 20th century, based on the opinion all men owned their own bodies, thus having a legal right to submit, or not, to medical treatment. In veterinary medicine, it is accepted that the legal owner of an animal has a similar right of control over their property (the animal).

Legally, medical informed consent goes beyond completion of a standard consent form, and has been defined in human medicine as 'that consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in a procedure as compared to alternative procedures, or no treatment at all'.

Veterinary informed consent is considered to be the owner's formal agreement to the medical or surgical course of action proposed, based on the principle that the owner or authorized agent has been given adequate information to be able to make the right decision for their animal(s).

Consent must be 'informed'; in simple terms, the owner must understand the nature of the procedure or treatment to be undertaken, the financial implications and the principal risks and possible side effects which may ensue.

Chapter 11 of the Supporting Guidance to the RCVS Code of Professional Conduct (December 2018) ( ) outlines the profession's obligations on consent and advises *inter alia*:

- *'Informed consent, which is an essential part of any contract, can only be given by a client who has had the opportunity* ***to consider a range of reasonable treatment options****, with associated fee estimates, and had the significance and main risks explained to them.'*
- *'Veterinary surgeons and veterinary nurses should seek to ensure that what both they and clients are saying is heard and understood on both sides, and encourage clients to take a full part in any discussion. Veterinary surgeons and veterinary nurses should use language appropriate for the client and explain any clinical or technical terminology that may not be understood. Usually, the veterinary surgeon or veterinary nurse will have to be able to speak the English language to an appropriate standard. If there is any doubt about the client's consent, efforts should be made to resolve this, which are then recorded.'*
- *'Where the client's ability to understand is called into question, veterinary surgeons and veterinary nurses will need to consider whether any practical steps can be taken to assist the client's understanding. For example, consider whether it would be useful for a family member or friend to be present during the consultation. Additional time may be needed to ensure the client has understood everything and had an opportunity to ask questions.'*
- *'If the client's consent is in any way limited, or qualified, or specifically withheld, this should be recorded on the clinical records; veterinary surgeons and veterinary nurses must accept that their own preference for a certain course of action cannot override the client's specific wishes, other than on exceptional welfare grounds.*
- *'Provision should be made for uncertain or unexpected outcomes. Clients should be asked to provide contact telephone numbers to ensure discussions can take place at short notice. Provision for the veterinary surgeon or veterinary nurse to act without the client's consent if necessary in the interests of the animal should also be considered.'*
- *'When an animal is enrolled on a clinical trial, the client should be made aware of the general provisions of Good Clinical Practice and be supplied with any other relevant information, such as ethical guidelines and relevant contact details, so that informed consent can be given.'*

If during a procedure an alternative approach is subsequently deemed appropriate, the veterinary surgeon should attempt to contact the owner by telephone to gain verbal informed consent. The nature of the discussion should be entered into the contemporaneous clinical records, including the fact that consent was obtained.

The RCVS consider it is the veterinary surgeon's responsibility to obtain consent. If this is not practical, it can be delegated to a suitably trained individual, considering registered or student veterinary nurses most appropriate in this situation.

Consent forms

Consent forms should be viewed as an aid to consent, in conjunction with a discussion with the client. Consent does not always have to be written, although it is extremely useful to be able to produce a signed consent form in the event of a dispute.

Consent should ideally include acknowledgement of an estimate of the associated costs. It is wise for any estimate to be put in writing, or on the consent form, and to cover the approximate overall charge for any procedure or treatment including VAT, pre- and postoperative checks, any diagnostic tests, etc. The owner should be warned that additional charges may arise if complications occur. If a quote is given, it may be binding in law (whereas an estimate can still be amended).

Consent forms may be used to record agreement to carry out specific procedures. The RCVS considers consent forms to be part of the clinical records and if any amendments are made subsequently, these should be made in ink, initialled and dated and a note of subsequent conversations recorded in the clinical records.

For consent to be informed, the owner must understand what they are signing. It is no longer considered sufficient to add the catch-all phrase, 'and any such procedures which may be considered necessary' to consent forms, without some explanation as to what they might be. 'Such procedures' will involve additional cost, and possibly additional risk, and the various options should be explained beforehand wherever possible.

For routine procedures, information leaflets can be useful to explain to clients what is involved with a specific procedure and should include expected outcomes, after care and potential postoperative complications. Clients should be given an opportunity to consider this information before being asked to sign a consent form. Use of information sheets should be encouraged, but should not be used as a substitute for discussions with individual clients.

If a client does not want to know about the possible risks and costs of a proposed procedure or treatment, this should be documented on the consent form/clinical records.

The RCVS Code of Professional Conduct advises *a copy of the consent form should be provided to the person signing the form unless the circumstances render this impractical. The RCVS Practice Standards Scheme Manual provides that for 'General Practice', signed consent forms are required for all procedures including diagnostics, medical treatments, surgery, euthanasia and when an animal is admitted to the care of a veterinary surgeon.*

Specimen consent forms for euthanasia and anaesthetic and surgical procedures are available from the RCVS website ( ).

Who can give consent?

The veterinary surgeon should be satisfied that the person being requested to provide consent is the owner registered in the clinical records.

If the individual presenting the animal is not the owner, the veterinary surgeon should be satisfied that the person has the authority to give consent.

If the animal is presented by one half of a couple (i.e. joint owners), the veterinary surgeon should be sure, as far as is practicable, that the wishes of the presenting owner are also those of the one who is not present.

If the animal is presented by the owner of a boarding kennel in the owner's absence, there should ideally be a pre-existing agreement between them, which delegates authority to the kennel or cattery owner.

If the animal is presented by a young person, the veterinary surgeon should be sure that they are legally competent to give consent. Unfortunately, there is no clear legal ruling on this point, but the supporting guidance on consent in the RCVS Code advises:

- *Persons under the age of 18 are generally considered to lack the capacity to make binding contracts and should not be made liable for any veterinary or associated fees. Moreover, persons under the age of 16 should not be asked to sign a consent form. Where they have provided a signature, parents or guardians should be asked to countersign.*

Consent to the use of medicines not authorized for the treatment of species such as some small mammals, birds, reptiles, amphibia, fish and invertebrates, for which there are few, or no, authorized medicines

Description of animal

Species.....

Name.....

Breed.....

Colour..... Age..... Sex M | F | NM | NF

Other identifying features.....

Microchip/tattoo/brand/ring/other.....

Owner details

Name.....

Address.....

Tel nos Home..... Work..... Mobile.....

I am the owner of the above animal(s) (or the owner's agent).
I understand that while the animal(s) is(are) under the care of the veterinary practice named below, there may be occasions when it will be necessary to use medicines which, while not specifically authorized (ie have not passed the regulatory assessments for safety, quality and efficacy) for the treatment of this species, may be used legally[1] when justified clinically.
I have been made aware, and accept, that there may be unknown side-effects associated with the use of such medicines in this species, and I consent to their use. I confirm I am over 18 years of age.

Signature of owner/agent..... Date.....

If agent

Name.....

Address.....

..... Relationship to owner.....

Practice name and address

[1] Note to owners (owners' agents). The relevant legislation in the UK and Republic of Ireland is:
UK: Veterinary Medicines Regulation
RoI: European Communities (Animal Remedies) (No. 2) Regulation

- *Where the person seeking veterinary services is 16 or 17 years of age, veterinary surgeons should, depending on the extent of the treatment, the likely costs involved and the welfare implications for the animal, consider whether consent should be sought from parents or guardians before the work is undertaken.*
- *Particular care should be taken when the treatment involves issues of health and safety, as for supplying Controlled Drugs (within the meaning of the Misuse of Drugs Act 1971) to anyone under the age of 18.*

If the animal is presented on behalf of an owner by a carer, the veterinary surgeon must be sure that the carer has the owner's authority to authorize treatment.

Where it appears a client lacks the mental capacity to consent, the RCVS Code of Professional Conduct *advises veterinary surgeons should try to determine whether someone is legally entitled to act on that person's behalf, such as someone who may act under an enduring power of attorney. If not, veterinary surgeons should act in the best interests of the animal and seek to obtain consent from someone close to the client, such as a family member who is willing to provide consent on behalf of the person.*

If a person who is not the registered owner gives written consent, they should sign the consent form as 'owner's agent' and state their relationship to the owner.

The cascade and unauthorized (off-licence) use of medications

Consent may include reference to the use of unauthorized medicines. Owners should understand why it is sometimes necessary to use an unauthorized medication and give consent for their animal to receive such treatment.

Chapter 4.17 of the RCVS Code of Professional Conduct makes clear the need for informed consent to be obtained, in writing, for the use of any medication outside its product authorization, under the principles of the cascade.

The RCVS Practice Standards Scheme (PSS) inspectors will ask to see examples of signed consent forms for the use of unauthorized medicines.

Use of unauthorized medicines in practice See also **Prescribing cascade**

Product information sheets (datasheets) are not legally binding documents and do not override individual clinical judgement.

If a veterinary surgeon decides to use an unauthorized medicine, they may do so in accordance with the cascade; however, the veterinary surgeon must have a sound clinical reason for taking the decision to invoke the cascade.

If challenged by either a client's solicitor or the Veterinary Medicines Directorate (VMD) inspectorate, a veterinary surgeon should be able to cite some scientific justification for their action, rather than simply base the decision on anecdotal experience.

If a veterinary surgeon intends to use a product by a different route of administration or dose rate than that stated in the Summary of Product Characteristics (SPC) for the product, this is also considered cascade use, even if the product is authorized for the condition in the species.

The prospect of explaining the obligations of the cascade to an owner is a daunting one. On hearing the explanation, the vast majority of pet owners understandably jump to the conclusion that some sort of experimentation is going on, and are immediately sensitized to the possibility of something going wrong. When it does, they may conclude that it was the use of an unauthorized drug(s) which caused the problem. It is, therefore, extremely important that the right message should be given. Specific client information leaflets covering the common unauthorized medications prescribed are available for members to download from the BSAVA website ( ).

Use of information sheets

Practices may consider creating a generic client information sheet on the subject of the need to invoke the cascade in veterinary practice. A practice information sheet could include the following points:

- Medications the practice may wish to use have been in general veterinary use for years, for example those found in the emergency box in most operating theatres (adrenaline, atropine, potassium chloride)
- Specific names of the medications themselves in general use in the practice can usefully be inserted, as this increases the degree of the owner's informed consent
- The reason why these medications do not have a UK marketing authorization.

Consent forms for unauthorized medicine use

It is not a legal requirement to obtain written consent to prescribe a medicine under cascade, but the RCVS Code of Professional Conduct designates that consent for use of a medication outside its market authorization should be obtained in writing, as stated in Chapter 4.17:

A decision to use a medicine which is not authorised for the condition in the species being treated where one is available should not be taken lightly or without justification. In such cases clients should be made aware of the intended use of unauthorised medicines and given a clear indication of potential side effects. Their consent should be obtained in writing.

It is not, however, the signature on the form, but the fact that the owner understands the reason for signing it following a discussion which is paramount to ensure fully informed consent is obtained. Specimen consent forms for unauthorized medicine use are available from the Veterinary Defence Society website (🌐).

Single-use consent form

As the wording implies, this is used in a situation where a specific medication is required, which does not carry a veterinary marketing authorization for the intended use.

If a veterinary surgeon intends to use a product by a different route of administration or dose rate than that stated in the SPC for the product, this is also considered cascade use, even if the medication is authorized for the condition and species. Consent should therefore be obtained.

Single-use consent forms should be used each time a new unauthorized medication is prescribed for an individual animal. If an animal is on a long term repeat prescription for an unauthorized medication, it is sufficient to obtain a new signed consent form at each regular review examination of the patient to ensure the animal is 'under your care', rather than every time the product is dispensed.

Multiple-use lifelong consent form

This is used in situations where there are few or no authorized medicines for use in the species concerned. An increasing variety of non-traditional (exotic) companion animal species are now kept as pets and their owners are usually able to appreciate the reason why veterinary surgeons need to prescribe medicines in accordance with the cascade.

A single consent form can be signed by an owner on registering with the practice, or at the start of treatment, but the giving of 'blanket consent' does not remove the obligation on the veterinary surgeon to ensure that it is informed consent.

Consent forms for general anaesthesia and hospitalization

If unauthorized medications are likely to be used as part of the anaesthetic routine, to provide peri- and postoperative analgesia, or in an emergency situation following hospitalization, a consent form should contain some reference to this fact. The currently recommended RCVS consent form wording is: *'In order to protect the welfare of my animal, in the unlikely event of an emergency, or where additional pain relief or sedation may be required, I understand the veterinary surgeon may decide to use medicines that are not authorized for use in (state species).'*

The fact that the use of these medications is often associated with general anaesthesia, can often raise the owner's level of apprehension unnecessarily. Providing a written explanation for owners to take away with them is helpful, as they will often fail to comprehend information conveyed to them verbally when they are stressed or upset.

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Further information

- BSAVA Client Information leaflets relating to Medicines (🌐)
- Royal College of Veterinary Surgeons (🌐)
  - Code to Professional Conduct: supporting guidance on Communication and Consent (🌐)
  - Consent case study examples (🌐)
- Veterinary Defence Society (🌐)
  - Consent form for unauthorized use of a medicine single use
  - Consent form for unauthorized use of medicines lifetime use
  - Advice call service for members for all medicine-related issues
- Veterinary Medicines Directorate (🌐)
  - Useful guidance notes on all aspects of veterinary medicine usage (🌐)

QUESTIONS

1. If a veterinary surgeon is using an unauthorized medication under the cascade in a dog or cat, when should they obtain consent for use of the unauthorized medication?
    a. Not required for dogs and cats, only for non-traditional companion animals, where it is recognized there are very few authorized medicines available
    b. Each time the medication is prescribed
    c. Only the first time a new medicine is prescribed
    d. At the first time of prescription and at each regular examination of the patient for a repeat prescription
2. What is fully informed consent in practical terms?
    a. The owner should be in a position to understand and acknowledge, preferably in writing, the cost implications, the risks, the benefits and alternative options to the proposed procedure
    b. Informed consent is only required legally for non-routine procedures
    c. Informed consent involves an acknowledgement of the possible risks of a procedure but a discussion regarding the financial implications is not required
    d. The addition of 'any other procedures which may be considered necessary' to a surgical consent form protects the surgeon from the requirement to seek informed consent if intraoperative complications necessitate a different approach during the procedure
3. Who can legally sign a consent form?
    a. Anybody over the age of 16 as long as the treatment does not involve Controlled Drugs
    b. There is no legal ruling but the RCVS advise the veterinary surgeon should be satisfied the person is legally competent to provide consent and over 18 in most cases
    c. Only the owner of the animal
    d. Anybody over the age of 16 if the veterinary surgeon is satisfied that the person has the owner's authority to give consent
4. Which of the following statements is correct regarding datasheets?
    a. Datasheets are legally binding documents and it is illegal for veterinary surgeons to prescribe outside the information provided in them
    b. Datasheets are not legally binding documents and veterinary surgeons can deviate from them without scientific justification
    c. Datasheets are not legally binding documents and a veterinary surgeon can use a medicine outside the protection of the datasheet by invoking the cascade as long as they have a sound clinical reason based on scientific data
    d. The cascade is not invoked if a veterinary surgeon used a medicine outside the terms of the datasheet as long as the product is authorized for use in the species involved

ANSWERS 1 – d; 2 – a; 3 – b; 4 – c

Antibacterials

KEY POINTS

- Antibacterials are essential drugs for treating bacterial infections
- Usage of antibacterials selected for resistant strains of bacteria
- Antimicrobial resistance is now a significant public health issue
- Many of the antibacterials we use in veterinary practice are the same as those used in human medicine
- We have a professional duty to use antibacterials responsibly and follow PROTECT ME to preserve their effectiveness for future use

Note: In this Guide the term antibacterial refers to medicines with antibacterial properties and not to disinfectants or antiseptics.

The development of antibacterials has enabled many previously fatal diseases to be successfully treated and led to significant improvements in both human and animal health. However, as the increase in antibacterial resistance has become a significant public health issue, it is important that the veterinary profession uses antibacterials responsibly in order to:

- Minimize the selection of resistant veterinary pathogens (and, therefore, safeguard animal health)
- Minimize possible resistance transfer to human pathogens
- Retain the right to prescribe certain antimicrobials.

Antibacterial resistance

Bacteria have developed various mechanisms to neutralize the action of antibacterial agents. Some bacteria are inherently resistant to certain antibacterials because of structural or functional characteristics, e.g. the medicine cannot cross the cell wall, the bacteria lack the target for the medicine, or they produce enzymes that destroy the medicine. This resistance is generally stable and well recognized (e.g. *Pseudomonas* spp. are inherently resistant to many antibacterials).

Bacteria may also acquire resistance through genetic change in the bacterial genome or by genetic transfer. In these cases, bacteria may acquire the ability to neutralize an antibacterial, or modify or replace the target for the medicine. It should be remembered that, because many currently used antibacterial medicines have been developed from naturally occurring antibiotics, bacteria have had a long time in which to develop these mechanisms. Multi-resistance can occur either when distinct genes confer resistance to different antibacterial classes (co-selection) or when a single gene confers resistance to two or more antibacterial agents (cross-selection).

Phenotypically, resistance may manifest in a wide variety of ways, including:

- Production of enzymes that destroy the antibacterial agent
- Production of efflux pumps, which prevent adequate accumulation of the antibacterial agent inside the bacterial cell
- Mutation of the target site so that it is no longer recognized by the antibacterial agent.

With few exceptions, antibacterials do not induce resistance. Instead, resistance arises following random genetic mutations that change the cell structure, target molecule or metabolism of the antibacterial. Exposure to antibacterials favours survival

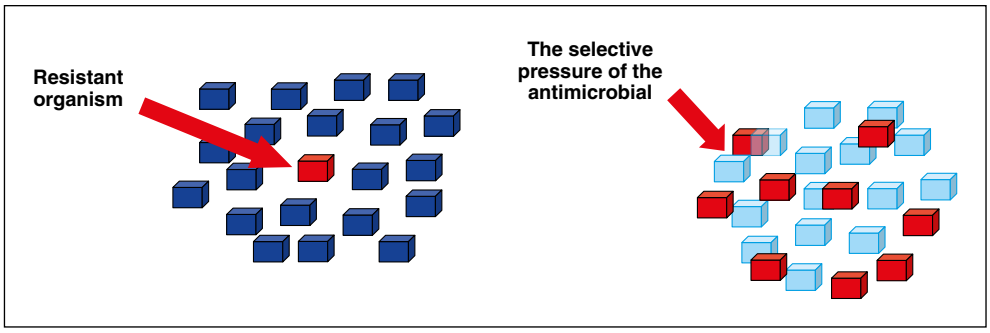
of organisms carrying the resistance genes, so that antibacterials exert selection pressure that allows the resistance genes to spread within the population. Selection pressure for antibacterial resistance is exerted on both pathogenic and commensal bacteria whenever an antibacterial is used.

Inherent resistance

This is the innate ability of a bacterial organism to resist the activity of a particular antibacterial agent through its inherent structural or functional characteristics.

Chromosomal resistance

It is estimated that 1 in 10,000,000 bacterial cells gives rise to a daughter cell with a mutation. If this change confers antibacterial resistance on the organism through a change in the cell structure, target molecule or metabolism of the medicine, it may provide a survival advantage in the face of antibacterial treatment.



Plasmid mediated

Once the genes for antibacterial resistance have appeared, they can be passed on to other bacteria, not only by cell division but also by genetic transfer.

Further details and examples of different types of resistance can be found here ( ).

Guidance and regulations

Resistance has become a significant One Health issue as the antibacterials used in human medicine are, in many cases, the same as or closely related to antibacterials used in veterinary medicine.

UK antimicrobial resistance 5-year strategy

The Department of Health (DoH) and the Department for the Environment, Food and Rural Affairs (Defra) produced a joint 5-year strategy document in 2013, which aimed to slow the development and spread of antimicrobial resistance by focusing activities around 3 strategic aims:

- To improve the knowledge and understanding of antimicrobial resistance,
- To conserve and steward the effectiveness of existing treatments,
- To stimulate the development of new antibiotics, diagnostics and novel therapies.

The strategy document indicates key areas for future action which include:

- Improving infection prevention and control practices
- Optimizing prescribing practice
- Improving professional education and training in order to improve clinical practice and promote wider understanding of the need for more sustainable use of antibiotics
- Better access to and use of surveillance data.

The strategy document also states that veterinary surgeons (veterinarians) and nurses and their professional bodies, need to take action to improve the knowledge and understanding of antimicrobial resistance (AMR) and conserve the effectiveness of existing treatments by developing sector-specific prescribing guidelines and promoting responsible use practices. The full document can be viewed on the Government's website ( ).

UK regulations and guidance on antibacterial prescribing

The Veterinary Medicines Directorate (VMD) is responsible for promoting the prudent and optimal use of antimicrobials in animals.

In order to maximize the efficacy of an antibacterial product, a veterinary surgeon should follow the manufacturer's recommendations for dose and duration of treatment, as detailed in the Summary of Product Characteristics (SPC) on the VMD website ( ).

Cascade prescribing

Where there is no suitable authorized veterinary medicinal product in the United Kingdom for a condition in a particular species, a veterinary surgeon may, in particular to avoid unacceptable suffering, treat the animal in accordance with the cascade ( ).

However, in the light of concerns regarding balancing the responsible use of antibacterials with the legislative requirement to use a UK authorized veterinary medicinal product, the VMD has produced guidance which states that *it is justified, on a case-by-case basis, to prescribe an antibiotic on the cascade in the interests of minimising the development of resistance, particularly where culture and sensitivity data indicate that a particular antibiotic active substance is effective against a bacterial pathogen and where knowledge of pharmacokinetics indicates that the selected product is likely to be safe and effective for the animal species and condition being treated; i.e. prescription of a narrow spectrum antibiotic on the cascade over a broad spectrum antibiotic that has a specific indication for that condition* ( ).

However, as with all prescribing decisions made under the cascade legislation, when selecting a veterinary medicinal product for a condition or species for which it is not authorized, ultimately the responsibility for that decision belongs to the veterinary surgeon, who should ensure that they are able to fully justify their decision-making process using appropriate evidence from reliable sources.

See also **Prescribing cascade**.

For drugs that are not authorized for the particular use in the particular species, the information provided with the product may not be adequate. In this case, the veterinary surgeon is responsible for providing the owner with information regarding potential side effects, risks to the owner and environmental safety, for example by the provision of one of the BSAVA client information leaflets ( ).

Adverse event reporting

Adverse reactions are harmful and unintended reactions to a medicine when administered to an animal. Adverse reactions are normally considered in respect of the individual animal under treatment and include toxicity and treatment failure. In the case of an antibacterial agent, this would include treatment failure despite culture and sensitivity results indicating that an appropriate antibacterial class had been used, or where a particular antibacterial product is authorized for the specific condition and species, and where the clinician's experience would suggest that a positive response should have occurred.

Reports of suspected adverse events should be made to the VMD by using the online reporting site ( ), or by using the report form, which can be downloaded from the VMD website ( ).

The Royal College of Veterinary Surgeons Guidance on antibacterial prescribing

The RCVS has said that *'The development and spread of antimicrobial resistance is a global public health problem that has affected by both human and animal use of these medicinal products. Veterinary surgeons must be seen to ensure that when using antimicrobials, they do so responsibly, and be accountable for the choices made in such use'* ( ).

In the UK, all veterinary antimicrobials are classified as 'prescription-only medicines – veterinarian' (POM-V), therefore the responsibility for and control of antibacterial use rests with the prescribing veterinary surgeon, who must first carry out a clinical assessment of the animal(s) under his or her care. However, as the Veterinary Medicines Regulations (VMR) do not define the phrase 'under his care', the RCVS has interpreted it as meaning that:

a. *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*
b. *Responsibility must be real and not nominal*
c. *The animal or herd must have been seen immediately before the prescription or*
d. *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*
e. *The veterinary surgeon must maintain clinical records of that herd/flock/individual.*

The RCVS guidance goes on to say that what amounts to 'recent enough' must be a matter for the professional judgement of the vet in the individual case. Currently, a veterinary surgeon cannot usually have an animal under his or her care, if there has been no physical examination; consequently, a veterinary surgeon should not treat an animal or prescribe POM-V medicines via the internet alone ( ).

Veterinary access to critically important antimicrobials

There is significant overlap between the classes of antibacterials, and often actual compounds, used in companion animal veterinary medicine and in human medicine. The World Health Organization (WHO) has developed a list of antimicrobial agents used in human medicine classified by importance.

Antimicrobials were assigned to these categories based on two criteria:

1. Where the drug is the sole therapy or one of few alternatives to treat serious human disease.
2. The drug is used to treat disease caused by organisms that may be transmitted via non-human sources, or diseases caused by organisms that may acquire resistance genes from non-human sources.

Antimicrobial drugs that meet both these criteria are classified as critically important while those that only meet one of the criteria are classified as highly important.

Antimicrobials within the critically important category are also assessed against three prioritization criteria:

1. High absolute number of people, or high proportion of use in patients, with serious infections in health care settings affected by bacterial diseases for which the antimicrobial class is the sole or one of few alternatives to treat serious infections in humans.
2. High frequency of use of the antimicrobial class for any indication in human medicine, or else high proportion of use in patients with serious infections in health care settings, since use may favour selection of resistance in both settings.
3. The antimicrobial class is used to treat infections in people for which there is evidence of transmission of resistant bacteria (e.g. non-typhoidal *Salmonella* and *Campylobacter* spp.) or resistance genes (high for *Escherichia coli* and *Enterococcus* spp.) from non-human sources.

Those classes of antibacterials that meet all three criteria are classified as 'Highest Priority Critically Important Antimicrobials' which, in the latest version, includes the quinolones, third and higher generation cephalosporins, macrolides and ketolides, glycopeptides, and polymyxins. The current list can be accessed on the WHO website ( ).

The World Organization for Animal Health (OIE) has produced a similar list of the antimicrobials considered important in veterinary medicine ( ), which used the same classification, although the criteria used were slightly different:

- Criterion 1 was met when a majority of respondents (more than 50%) identified the importance of the antimicrobial class in their response to a questionnaire
- Criterion 2 was met when compounds within the class were identified as essential against specific infections and there was a lack of sufficient therapeutic alternatives.

Although these lists have been compiled in different ways, there is significant overlap with many antibacterials considered critically important in human medicine, also being considered critically important in veterinary medicine.

Responsible antibacterial prescribing

The responsible use of antimicrobials does not simply mean using fewer antibacterials, but using them appropriately. The rationale for the responsible use of antibacterial agents is to maximize therapeutic success and at the same time minimize the development of antibacterial resistance, thereby safeguarding antibacterials for future veterinary and human use. This can be achieved by reducing the unnecessary use of antibacterial agents and optimizing drug choice, drug dose and dosing regimens. However, it should be remembered that unless there is a strong justification for doing so, an authorized veterinary medicine should be administered in accordance with the Summary of Product Characteristics (SPC). This requires that we integrate our knowledge of clinical disease with our knowledge of the pharmacology of antibacterial agents in order to inform our clinical decision making.

The first decision to be made is whether antibacterial treatment is appropriate in a particular case. In addition to decisions regarding the treatment of the bacterial infection in the individual animal, the veterinary surgeon should consider the possible adverse effects on commensal flora and the potential for promoting antibacterial resistance.

Factors that may need to be taken into consideration are:

1. Does the condition necessitate antibacterial treatment?
2. Are there other options besides antibacterial treatment?
3. Will the potential risk of inducing resistance outweigh the benefit of treatment?
4. Is the proposed treatment likely to work against the pathogen involved?
5. Are there any risks to public health when this is done?

The veterinary surgeon should also consider the wider implications of antibacterial use. In order to preserve their effectiveness in serious infections in humans and animals, the use of certain antibacterials should be minimized. In all species, fluoroquinolones and third- and fourth-generation cephalosporins should be used judiciously. This means that their use as first line agents should be avoided and they should only be used when other agents are ineffective (ideally determined by culture and sensitivity testing).

Rational antibacterial selection

Once it has been decided that the use of antibacterials in a particular case is justified, the veterinary surgeon can maximize the likelihood of therapeutic success and minimize the likelihood of selecting resistant bacteria by making rational clinical decisions regarding the choice of antibacterial product or combinations of products, the route of administration and the dose and duration of treatment. There are several criteria that need to be considered in the rational selection of antibacterial drugs:

1. Individual animal factors, including the species, life-stage, immune status and any co-morbidity or current medication
2. The type and severity of infection and the bacterial organisms likely to be involved
3. A sample for culture should be collected before starting antibacterial therapy wherever possible
4. The spectrum of activity of the antibacterial agent and its ability to reach the site of infection at an appropriate concentration
5. The availability of licensed products for the treatment of this condition in this species
6. The appropriate dose of antibacterial including route of administration, frequency and duration of treatment
7. The ability of the owner to carry out the proposed treatment.

Further information on the responsible use of antibacterials can be found here ( ).

There are very strong arguments that antimicrobials with restricted use in human medicine (e.g. imipenem and vancomycin) should not be used in animals under any circumstances.

Categorization of antibacterials

While it is not a legal requirement, it may be helpful to start thinking about antibacterials in a similar way to how we think about Controlled Drugs (CDs), with increasing requirements for justification and recording depending on the category of the product.

Development of practice guidelines

Antibacterial prescribing is a common part of practice and many, though not all, of the conditions that we treat are common. It may also be appropriate to consider guidelines about when antimicrobials should, or should not, be prescribed, when it is appropriate to make empirical decisions (e.g. the first presentation of pyoderma or uncomplicated urinary tract infections) and when cytology or culture and sensitivity should be undertaken. It may be appropriate to consider the duration of treatment and frequency of checks that would be expected in uncomplicated cases. The practice may also agree guidelines on the use of antibacterials in surgical prophylaxis.

Category	Authorization	Justification	Recording
1	Human authorized products which can never be used in veterinary medicine	N/A	N/A
2	Human authorized products	Evidence that no suitable veterinary product is available (e.g. culture and sensitivity test results) plus recommendation from independent veterinary surgeon (e.g. recognized specialist or microbiologist)	Evidence (e.g. culture and sensitivity test). Permanent record in separate book detailing the client, animal, justification, dose, response and veterinary surgeon authorizing the treatment. Non-authorized medicines consent form.
3	Veterinary authorized products of highest importance in human medicine (fluoroquinolones, third-/fourth-generation cephalosporins)	Evidence that other veterinary authorized products are unlikely to be effective (e.g. culture and sensitivity test results)	Evidence (e.g. culture and sensitivity test results). Permanent record in separate book detailing the client, animal, justification, dose, response and veterinary surgeon authorizing the treatment
4	Veterinary authorized product being used in a species, for an indication or at a dose not covered in the Summary of Product Characteristics (SPC)	Reason for use in this way should be recorded	Permanent record in patient record justifying use Non authorized medicines consent form
5	Veterinary products used in accordance with SPC		Normal patient record

Proposed schedules of antibiotics. (Reproduced from the *BSAVA PROTECT poster for rabbits*)

Taking time to institute practice-based guidelines for antibacterial use should be considered. These guidelines should take account of:

- The animals that are commonly treated in the practice
- The conditions that are commonly encountered
- The causal organisms that are likely to be involved in particular conditions, with cytology or culture being used to provide confirmation where appropriate
- The antibacterials to which they are most likely to be sensitive.

PROTECT ME poster

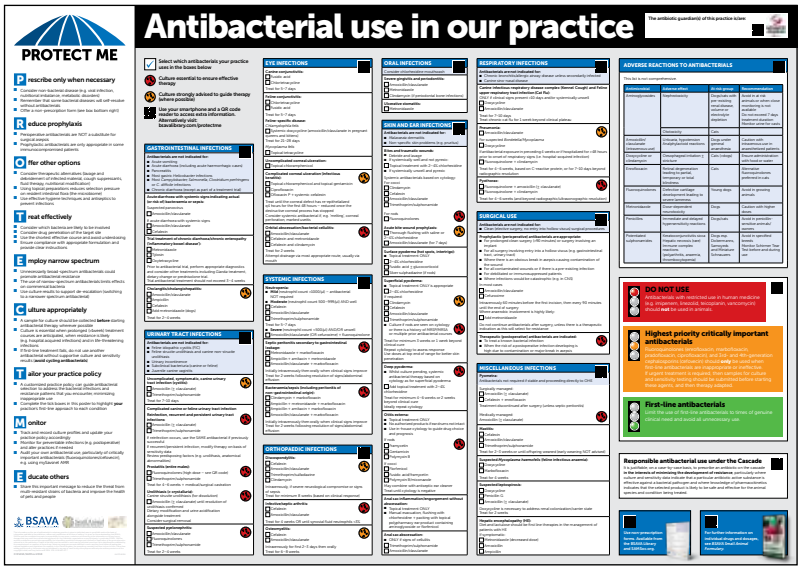
The PROTECT ME poster produced by BSAVA and SAMSoc can provide a useful method of recording the agreed practice policy.

Further information on prescribing for specific infections can be found in the BSAVA/SAMSoc Guide to Responsible Use of Antibacterials:

- Gastrointestinal infections (🌐)
- Oral infections (🌐)
- Orthopaedic infections (🌐)
- Respiratory infections (🌐)
- Skin and ear infection (🌐)
- Surgical use (🌐)
- Systemic infections (🌐)
- Urinary tract infections (🌐)
- Miscellaneous infections (🌐)

The PROTECT ME message developed out of an initiative of the Small Animal Medicine Society (SAMSoc) to review and promote responsible antibacterial prescribing. This led to the PROTECT ME poster, produced by BSAVA and SAMSoc. The original poster was revised in 2018 and expanded to include monitoring and evaluation.

The PROTECT ME message is that we need to use antibacterials responsibly.



Prescribe only when necessary

- Consider non-bacterial disease (e.g. viral infection, nutritional imbalance, metabolic disorders) where antibacterial therapy would be redundant
- Remember that some bacterial diseases will self-resolve without antibacterials
- Offer a non-prescription form to support a decision not to prescribe antibacterial therapy

Reduce prophylaxis

- Antibacterials are not a substitute for surgical asepsis and the need for prophylactic antibacterials in surgery should be carefully considered
- Prophylactic antibacterials are only appropriate in a few medical cases (e.g. immune-compromised patients)

Offer other options

- Consider therapeutic alternatives (lavage and debridement of infected material, cough suppressants, fluid therapy, nutritional modification)
- Using topical preparations reduces selection pressure on resident intestinal flora (the microbiome)
- Use effective hygiene techniques and antiseptics to prevent infections

Treat effectively

- Before prescribing antibacterials, consider which bacteria are likely to be involved and how effectively the chosen drug will penetrate the target site
- Use the shortest effective course and avoid under dosing
- Ensure compliance with appropriate formulation and provide clear instructions

Employ narrow spectrum

- The unnecessary use of broad-spectrum antibacterials could promote antibacterial resistance
- The use of narrow-spectrum antibacterials limits effects on commensal bacteria
- Use culture results to support de-escalation (switching to a narrower spectrum antibacterial)

The VMD says *'that it is justified, on a case-by-case basis, to prescribe an antibiotic on the cascade in the interests of minimising the development of resistance, particularly where culture and sensitivity data indicate that a particular antibiotic active substance is effective against a bacterial pathogen and where knowledge of pharmacokinetics indicates that the selected product is likely to be safe and effective for the animal species and condition being treated; i.e. prescription of a narrow spectrum antibiotic on the cascade over a broad spectrum antibiotic that has a specific indication for that condition'.*

Culture appropriately

- A sample for culture should be collected before starting antibacterial therapy wherever possible
- Culture is essential when prolonged (>1week) treatment courses are anticipated, when resistance is likely (e.g. hospital acquired infections) and in life-threatening infections
- If first line treatment fails, do not use another antibacterial without supportive culture and sensitivity results (avoid cycling antibacterials)

Tailor your practice policy

- A customized practice policy can guide antibacterial selection to address the bacterial infections and resistance patterns that you encounter, minimizing inappropriate use
- Complete the tick boxes in the PROTECT ME poster to highlight your practice's first-line approach to each condition

Monitor

- Track and record culture profiles and update your practice policy accordingly
- Monitor for preventable infections (e.g. postoperative) and alter practices if needed
- Audit your own antibacterial use, particularly of critically important antibacterials (fluoroquinolones/cefovecin), e.g. using mySavsnet AMR

Educate others

- Share this important message to reduce the threat from multi-resistant strains of bacteria and improve the health of pets and people

Alongside the PROTECT ME poster, a non-prescription pad has also been launched this year. This form can be presented to the client at the end of the consultation to support a decision not to provide antibacterial medication. The form will also help inform owners as to the importance of appropriate use and improve AMR literacy.

QUESTIONS

1. Which type of resistance describes the innate ability of a bacterial organism to resist the activity of a particular antimicrobial agent?
    a. Chromosomal resistance
    b. Plasmid-mediated resistance
    c. Inherent resistance
    d. Induced resistance
2. Which of the following adverse reactions should be reported to the VMD?
    a. Apparent toxicity of a veterinary authorized product
    b. Antibacterial treatment failure
    c. Human reaction to a veterinary product
    d. All of the above
3. In developing a practice policy on antibacterial use, which of the following should be taken into consideration?
    a. The animals that are commonly treated, and the conditions commonly encountered, in the practice
    b. The causal organisms that are likely to be involved in particular conditions, with cytology or culture being used to provide confirmation where appropriate
    c. The antibacterials to which they are most likely to be sensitive
    d. All of the above
4. In the PROTECT ME poster what do the initials M and E stand for?
    a. Monitor and Evaluate
    b. Monitor and Educate
    c. Manage and Educate
    d. Minimise and Evaluate

ANSWERS 1 – c; 2 – d; 3 – d; 4 – b

14 Importing medicines

KEY POINTS

- It should always be remembered that it is illegal to import unauthorized medicines without the correct licence
- Where there is no suitable UK authorized veterinary medicinal product (VMP), a veterinary surgeon (veterinarian) may seek to obtain a Special Import Certificate (SIC)
- SICs may be obtained from the Veterinary Medicines Directorate (VMD) Special Import Scheme webpage ( )

Importation restrictions

No one may import or be concerned in the importation of an unauthorized VMP except in the following circumstances:

- A holder of a marketing authorization (MA) may import an unauthorized VMP if it is for the purpose of the manufacture of a VMP for which the importer holds the MA
- A holder of an MA may import an unauthorized VMP if it is for the manufacture of a VMP that the importer is permitted to manufacture
- A holder of a wholesale dealer's authorization (WDA) may import an unauthorized VMP for the purposes of re-export
- A veterinary surgeon may import an unauthorized VMP in accordance with a valid SIC. The product may be imported by the veterinary surgeon or by using a wholesale dealer or pharmacist as an agent
- A wholesale dealer or a pharmacist may import an unauthorized VMP for the purpose of storing it in accordance with a valid Wholesale Dealers' Import Certificate (WDIC), pending administration by a veterinary surgeon who is in possession of a valid SIC
- The holder of an animal test certificate (ATC) may import anything specified in the ATC in accordance with the conditions in that certificate
- The holder of a valid Research Import Certificate (RIC) may import a product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986.

No one may be in possession of an unauthorized VMP with the intention of supplying the product to another person. This does not apply in the following circumstances:

- A VMP imported in accordance with an import certificate
- A product prescribed by a veterinary surgeon under the cascade
- A holder of an MA if the possession is for export
- A holder of a WDA if the possession is for export or re-export
- A holder of a manufacturer's authorization or MA if the intention is to manufacture a VMP
- A veterinary surgeon who practises in both the UK and another Member State may hold VMP authorized in the other Member State provided that the amount held does not exceed the amount expected to be used in that Member State
- The product is for the purposes of research or development of a VMP and the appropriate authorizations have been obtained
- A veterinary surgeon may have possession of an authorized human medicinal product intended for administration to animals under the cascade, provided that the amount held does not exceed the amount expected to be used under the cascade.

However, on certain occasions there will be medications that are available abroad, but not in the UK, and it is possible to import these for use with animals under the care of a veterinary surgeon. An example of this would include certain immunotherapeutics for allergen desensitization (in these cases special dispensations apply in terms of ease of import as they are classed as low-risk products). It is the importing veterinary surgeon's responsibility to:

- Obtain data about the product and clinically justify the use of such a product, and to keep full records of its use
- Establish a source – this may be the medicine manufacturer or it may be a special medicine importer
- Apply for permission from the VMD to import the medicine.

In general, this will be on a named patient basis only; however, where a medicine is in regular use within a clinic (e.g. depot doxycycline injection for psittacosis therapy in avian practices), it may be possible to apply for a licence to hold stock (though generally no more than 1 month's stock should be held and in any case less than the lifetime of the certificate (1 year)). In these cases, it is essential that the VMD is supplied monthly with a list showing medicine use, the name and address of each client, and details of each animal for which the medicine has been supplied. Applications can be made online and proformas downloaded from the VMD website (🌐). Otherwise, stock should not be held and any excess (e.g. following death of the patient before the end of therapy) should be disposed of in a suitable manner (see also **Medicine waste disposal**), or the amount should be transferred on to a new SIC if the VMD permits this. Stock should not be supplied to other veterinary practices unless they apply for a separate SIC citing the original veterinary surgeon as source (and that original SIC). Alternative arrangements may be in place for importation of honeybee medications.

See also **Responsible prescribing and dispensing for exotic pets, zoo and wildlife species**

If the product to be imported falls within the scope of the Misuse of Drugs Regulations 2001, in addition to complying with VMD requirements, it is also necessary to fulfil Home Office requirements. If the veterinary surgeon has in place a Home Office licence to supply Schedule 4 Part I medicines, in addition to a WDIC from the VMD, they will need to apply to the Home Office (🌐) for an import licence to bring the Controlled Drug into the UK for onward supply. In these circumstances, the veterinary surgeon may find it easier and quicker to obtain the product from a company or wholesaler who has applied for and received a WDIC for the product in question, and has in place the necessary licences from the Home Office.

Proforma for submission of retrospective records

Special import certificate number	
Practice name	
Special import certificate issue date	
Period of use covered by this record	
Species	
Number of animals treated	
Quantity of product used	
Quantity of product remaining	
Quantity of produce wasted (if any)	
Comments (including to record use in more than one species)	

Special Import Certificates

Applications for SICs, to import medicines from outside the UK, must be submitted electronically via the VMD website (https://www.vmd.defra.gov.uk/sis/default.aspx (🌐))

Applications for SICs

SICs applied for electronically are currently free-of-charge. However, a WDIC, where more than 100 SICs naming the wholesale dealer as the importer were supplied in the 12-month period before the application was made, costs £760.00.

In the case of new medicines, data in the form of Word, Excel or PDF documents may be uploaded to the VMD website. In each case details must be given of:

- The veterinary surgeon applying for the medicine importation (the applicant's Royal College of Veterinary Surgeons (RCVS) membership number must always be provided). This does not have to be the person administering the medicine as long as administration is performed under instruction from the applicant
- The premises where the medicine is to be used
- The patient for which the medicine is to be used (including pet name, species and weight, owner's name and address)
- The medicine and importer. The authorization number of the medicine in the country of production will also be required
- Amount of the medicine, including dose rate, route of administration, calculations of dose required, frequency of doses and number of doses. Combined, this should give the total amount needed (extra 'just in case' doses should not be included)
- Justification for importation. This is not a means for avoiding the cascade – this should always be followed and medicines only imported where there is no alternative. It is the veterinary surgeon's responsibility to perform a risk:benefit analysis in each case. Even though the VMD may add additional warnings to any certificate, the risk:benefit analysis is still the responsibility of the applicant.

Records must be available for inspection for 5 years after application. All adverse events must also be recorded and sent to the VMD within 15 days of the event.

Applying the cascade

Importation is not a means of avoiding the cascade. For example, mitotane (Lysodren®) was commonly imported for treatment of canine hyperadrenocorticism. Now that trilostane (Vetoryl®) is available as an authorized medicine for this condition, mitotane can only be imported to continue an existing course of medication, if changing to trilostane is not justifiable or if use of mitotane is justifiable for medical reasons. Cost is not a justifiable reason.

Where there is an authorized alternative, full justification must be given before an importation licence will be issued. For example, importation of doxycycline (Vibravenös®) for the treatment of psittacosis in a grey parrot despite there being an

alternative form available in the UK (Ornicure®) is justifiable as the alternative form of doxycycline is authorized for use in water, and larger parrots rarely drink consistently. Therefore, it is hard to treat psittacosis effectively by this route of administration. Justification for importing Vibravenös® for this reason can be made, especially where birds may be additionally stressed and handlers exposed to a zoonotic disease if the birds are handled for direct oral medication (as opposed to weekly injections of Vibravenös®). The dose rate is 100 mg/kg weekly by intramuscular injection on seven occasions, and the medicine is supplied in 5 ml vials of 20 mg/ml. Once opened, the medicine quickly deteriorates. A 400 g grey parrot will require 40 mg of the medicine weekly, so justification can be made for importation of 7 x 100 mg vials.

Additional notes

- It is always important to remember that the medicine must be given directly to the patient either by the named veterinary surgeon on the certificate, or by a specific person as directed by that veterinary surgeon.
- Special arrangements apply for immunological products ( ).
- The certificate will usually be emailed direct immediately after application.
- The VMD website provides full instructions on how to apply for a SIC. It is also vital that all adverse reactions are recorded and reported. This can be done online ( ).
- For food producing animals, if used within the summary of product characteristics (SPC), the EU specific withdrawal period should be used. If used outside of these terms, UK standard withdrawal times should be used ( ).
- For veterinary surgeons practising in a Member State of the European Economic Area and providing services in the UK, it is acceptable to import and use small quantities of non-immunological compounds without an import certificate. However:
  - The quantities brought in must not exceed those generally required for the daily needs of good veterinary practice. The veterinary surgeon may hold stock of such products provided such quantities do not exceed that which is expected to be used
  - The product must be authorized in the Member State in which the veterinary surgeon is established
  - The product must be transported into the UK by a veterinary surgeon in the original manufacturer's packaging
  - Products for food producing animals must have the same composition of active substances as a UK authorized product
  - The veterinary surgeon must be familiar with good veterinary practices applied in the UK
  - The veterinary surgeon must ensure that withdrawal periods specified on labels are complied with, unless longer periods are appropriate
  - Only sufficient product to complete the course of treatment may be supplied to animal owners/keepers
  - The veterinary surgeon must keep records of animals treated, diagnosis, products administered, dosage, duration of treatment and withdrawal periods
  - The veterinary surgeon must make such records available to a duly authorized person in the UK for at least 3 years.

QUESTIONS

1. Who may import animal medication without authorization?
   a. A veterinary surgeon
   b. The owner
   c. No one
   d. Anyone
2. Human medicinal compounds may be imported using a:
   a. Special import certificate (SIC)
   b. Written script posted to manufacturer
   c. Email
3. The maximum length of time imported stock may be held on a single certificate is:
   a. Stock may not be held. It is a named patient basis only
   b. 3 months
   c. 6 months
   d. 12 months

ANSWERS 1 – c; 2 – a; 3 – d

Backyard poultry

KEY POINTS

- Backyard poultry are technically food producing animals
- Where medicines are prescribed under the cascade, only medicines containing substances listed in the Table of Allowed Substances should be used
- Withdrawal periods for the cascade use of medicines should take into account the withdrawal periods for the species in which the product is authorized, along with the fact that a chicken or duck's ovary contains approximately 14 egg yolks, all at various stages of development

Over the past decade, small scale poultry keeping has increased dramatically. Many of these new keepers view their poultry as pets rather than farmyard animals. However, **irrespective of the purpose for which poultry are kept, they are technically 'farm animals' and 'food producing animals'**. Unlike in horses, there is no current provision allowing for poultry to be classed as non-food producing animals. This has implications for medicating such birds and for their disposal after death.

Poultry

There does not appear to be a definition of poultry in the Veterinary Medicines Regulations (VMR), but there is under other UK legislation.

The Avian Influenza (Preventative Measures) (England) Regulations 2006 defines poultry as: *all birds that are reared or kept in captivity for the production of meat or eggs for consumption, the production of other commercial products, for restocking supplies of game or for the purposes of any breeding programme for the production of these categories of birds.*

The Diseases of Poultry (England) Order 2003 defines poultry as: *domestic fowls, turkeys, geese, ducks, guinea fowls, quails, pigeons, ratites and pheasants and partridges reared or kept in captivity for breeding, the production of meat or eggs for consumption or for restocking supplies of game.*

There are a great number of medicines (antimicrobials) authorized for use in poultry, all of which have meat withdrawal periods that can be easily followed. For male birds and turkeys, the use of any of these medicines is straightforward. However, for egg-laying chickens or ducks, the majority of authorized products state that they 'should not be given to birds producing eggs for human consumption'.

For commercial laying flocks, products with a zero-day egg withdrawal are almost exclusively used. These products are licensed for a small number of diseases, and any birds failing to respond are humanely euthanased. For general practitioners dealing with pet chickens, such an approach would be unthinkable.

When treating backyard poultry, before any medication is prescribed under the cascade, the veterinary surgeon (veterinarian) must ensure that the ingredient(s) are listed in the Table of Allowed Substances in Commission Regulation (EU) No 37/2010 ( ).

Defining birds as producing eggs for human consumption

Classifying whether or not birds are producing eggs for human consumption is difficult. Prepubescent chickens are allowed to be treated with products not licensed for birds producing eggs for human consumption up to 14 days prior to the point of lay. Should a bird come into lay prior to the 14-day period elapsing, then any eggs laid within this period should not be eaten.

For owners using their eggs for hatching rather than eating, these birds are not considered to be producing eggs for human consumption. Furthermore, owners could potentially argue that they will never eat eggs from a treated bird. However, if the poultry are re-homed or sold (as frequently happens with breeding birds), their new owners may not be aware that any eggs from their new birds should not be eaten.

Antimicrobials

The majority of antimicrobials authorized for use in poultry do not have established Maximum Residue Limits (MRLs) for eggs. Furthermore, many of these antimicrobials have explicit notes in the Table of Allowed Substances to explain that they are not to be used in birds producing eggs for human consumption.

Before the cascade use of any product, the prescribing veterinary surgeon must ensure that there is no authorized product to treat the patient's condition. For non-egg producing birds, there are a sufficient number of products available with meat withdrawal periods. For laying birds, the prescribing veterinary surgeon must then use a product under the cascade. There is no preference for using a product with an MRL for eggs *versus* one without an MRL.

See also **Antibacterials**

Antimicrobials with a defined MRL for eggs

Products with a defined MRL in eggs	*MRL*	*Spectrum of activity*
Chlortetracycline	200 µg/kg	*Mycoplasma*, *Salmonella*, *Escherichia coli*, *Pasteurella* and *Clostridium perfringens*
Colistin*	300 µg/kg	*E. coli* (poor intestinal absorption)
Erythromycin	150 µg/kg	*Mycoplasma*, *Pasteurella* and *E. coli*
Lincomycin	50 µg/kg	*Staphylococcus*, *Erysipelothrix*, *Mycoplasma* and *Clostridium perfringens* (poor intestinal absorption)
Neomycin*	500 µg/kg	*E. coli* (poor intestinal absorption)
Oxytetracycline	200 µg/kg	*Mycoplasma*, *Salmonella*, *E. coli*, *Pasteurella* and *Staphylococcus*
Phenoxymethylpenicillin*	25 µg/kg	*Clostridium perfringens* (poor intestinal absorption)
Tiamulin*	1000 µg/kg	*Mycoplasma* and *Brachyspira*
Tylosin*	200 µg/kg	*Mycoplasma* and *Clostridium perfringens*
Tylvalosin*	200 µg/kg	*Mycoplasma gallisepticum* and *Orthinobacterium rhinotrachealae*

*Antimicrobials currently authorized in the UK with zero-day egg withdrawal preparations available

If none of the products in this table are suitable, then the prescribing veterinary surgeon must use the cascade to prescribe either a product authorized to treat another condition in the same species or a product authorized to treat the same condition in another food producing species.

See also the **Prescribing cascade**.

The following table details antimicrobials in the Table of Allowed Substances that have no MRLs for eggs but that do not specifically indicate that they are not to be used in birds producing eggs for human consumption. Only currently available antimicrobials in the UK have been listed.

Antimicrobials allowed in food producing animals in the UK with no specific prohibition for use in birds producing eggs for human consumption

Products with no MRL for eggs but that do not indicate 'not for use in birds producing eggs for human consumption'	Spectrum of activity
Marbofloxacin	*Mycoplasma*, *Salmonella*, *E. coli*, *Pasteurella* and *Staphylococcus*
Cefquinome*	*Mycoplasma*, *E. coli*, *Pasteurella* and *Staphylococcus*
Ceftiofur*	*E. coli* and *Pasteurella* (poor intestinal absorption)
Gamithromycin	*Pasteurella*
Tulathromycin	*Pasteurella* and *Mycoplasma*

*Although these products could be technically allowed, due to the risk posed to humans from AMR, their use in poultry is contraindicated.

There are some products for which an MRL cannot be established and, therefore, must not be used in any food-producing animals, as listed in the following table:

Prohibited substances

Chloramphenicol
Chlorpromazine
Colchicine
Dapsone
Dimetridazole
Metronidazole
Nitrofurans (including furazolidone)
Ronidazole

Anticoccidials

There are two currently authorized anticoccidial agents in the UK: toltrazuril and amprolium. Toltrazuril has no MRLs for eggs and states that it should not be used for birds producing eggs for human consumption, but is licensed in birds 4 weeks prior to the onset of lay. As coccidiosis normally affects prepubescent birds, toltrazuril can usually be used in cases of coccidiosis.

Amprolium does not require an MRL and can be used in laying chickens with a zero-day egg withdrawal.

Anthelmintics

Currently, fenbendazole and flubendazole are authorized in the UK with an established MRL for eggs. There are preparations of both with zero-day egg withdrawal.

See also **Antiparasitic resistance**.

Ectoparasite treatments

There are a number of ectoparasite treatments listed in the Table of Allowed Substances with no MRLs for eggs. Most of these do not prohibit their use in birds producing eggs for human consumption. However, it must be ensured that any treatments considered are listed in the Table of Allowed Substances, as a number of products authorized for small animals, such as fipronil, are not.

Other veterinary products

For other veterinary medicines, such as analgesics, there are no currently authorized products for poultry in the UK. Almost all such products have no MRLs for eggs, but also do not prohibit their use in birds producing eggs for human consumption.

Setting an egg withdrawal period

When setting withdrawal periods under the prescribing cascade, the **minimum** withdrawal period for eggs is 7 days and for meat is 28 days. However, the Veterinary Medicines Directorate (VMD) guidelines also state that consideration must be given to the withdrawal periods set for other species. For example, a meat withdrawal period may be used as a guide when setting an egg withdrawal period. Additionally, consideration must be given to avian physiology; laying hens and ducks tend to have at least 14 days' worth of eggs developing in their ovary.

In practice, the meat withdrawal period set for products used under the cascade should either be 28 days or identical to the meat withdrawal period for the authorized (food-producing) species (whichever is longer).

With regard to egg withdrawal periods, they should be a minimum of 7 days, but if there is a meat withdrawal period, this should be used as a guide, with 15 days added on to take into account the developing egg yolks.

Where a product is being used 'off-label', it is advisable to have the owner sign an informed consent form.

See also **Informed consent**.

Note: Owners selling eggs must keep a veterinary medicines record book. Records need to be kept for at least 5 years.

QUESTIONS

1. Which of the following best describes the status of backyard poultry as food-producing animals?
    a. Poultry, when kept as pets, are not counted as food-producing animals and can, therefore, be treated as any cat or dog would
    b. Poultry are classed as food-producing animals unless the owner signs a disclaimer
    c. All poultry, whether pets or commercial livestock, are classed as food-producing animals
    d. Poultry can be classed in the same way as horses and classified as food producing or non-food producing
2. Which one of the following statements is true?
    a. Most antimicrobials have an MRL set for eggs
    b. A veterinary medicine cannot be used in poultry without an MRL set for poultry meat and eggs
    c. Many products that have no MRL for eggs state in their literature that they are not to be used in birds producing eggs for human consumption
    d. Any antimicrobial can be used in egg-producing poultry if the owner agrees not to eat the eggs
3. A client presents a pet chicken with lice and the veterinary surgeon wants to use a spot-on treatment. What should they do next?
    a. Treat the bird and advise that any eggs laid are discarded for the next 7 days
    b. Check in the Table of Allowed Substances that the active ingredient in the spot-on is listed in the table
    c. Treat the bird and as the medication is a spot-on, no egg withdrawal needs to be applied
    d. Advise the owner that no treatment is permitted and the bird must be euthanased
4. A client presents an 8-week-old pullet with bloody droppings. Faecal oocyst counts confirm the suspicion of coccidiosis. What treatment options can be considered?
    a. Toltrazuril
    b. Amprolium
    c. Both toltrazuril and amprolium could be used
    d. Neither product

ANSWERS 1 – c; 2 – c (if the bird is in lay, then the product must not be used; 3 – b (some products authorized for small animals are not listed in the table and, as such, cannot be used; if they are listed, then an appropriate egg withdrawal period can be set); 4 – c Amprolium is licensed for use in poultry and has a zero-egg withdrawal period. Although toltrazuril is not licensed for use in laying hens, there is provision in datasheet for its use in birds 4 weeks prior to the onset of lay. Most chickens will not come into lay at least until 16 weeks, therefore toltrazuril is an equally valid treatment to amprolium.

Remote supply

KEY POINTS

- The requirements for remote supply of veterinary medicines are the same as for face to face supply
- Prescribers and dispensers must be aware of prescription misuse and the ways of mitigating it
- Care must be taken when dispatching medications by post or courier to ensure that they reach the correct recipient without damage
- Returned veterinary medicines may not be returned to stock for resale, but protocols must be in place to avoid a legal obligation to refund clients if purchases are returned under distance selling laws
- Advertising of prescription-only medicines to the general public is an offence
- Internet retailers can apply for accreditation under the Veterinary Medicines Directorate (VMD)'s Accredited Internet Retailer Scheme (AIRS), which provides reassurance to customers

UK law permits the remote supply of all categories of veterinary medicinal products (VMP), provided the legal requirements regarding prescription and supply are met. The requirements are the same regardless of whether a transaction is online or face to face.

Remote supply is commonly associated with internet sites (). Although these are often informally described as 'internet pharmacies', this usage should be discouraged by staff if the business is not a retail pharmacy registered with the General Pharmaceutical Council (GPhC) in Great Britain or the Pharmaceutical Society of Northern Ireland (PSNI), as the term 'pharmacy' is a restricted title. Inappropriate use in connection to a business may result in legal action from the GPhC or PSNI. Some internet sites are true pharmacies controlled by pharmacists, and a number of sites are under the control of suitably qualified persons (SQPs), but many are hosted by veterinary practices or other organizations under the professional control of veterinary surgeons (veterinarians) and are therefore best referred to as internet or online retailers.

As well as online ordering, some businesses also promote mail order supply of VMP through more traditional printed price lists and advertisements, and others (including many veterinary practices with clients in more remote areas) may wish to supply medicines by post or courier on an *ad hoc* basis as an occasional customer service.

Legislative requirements

The general requirements of UK legislation apply to the prescription and supply of medicines, irrespective of whether a client physically visits the premises and meets the veterinary surgeon (or pharmacist/SQP) face to face. A veterinary surgeon supplying medicines remotely must be able to demonstrate that they comply with the Veterinary Medicines Regulations (VMR), including the supply, registration, storage and inspection requirements. The same regulation applies to SQPs overseeing remote supply of appropriate products to clients (as many veterinary practices employ SQPs for dispensary duties).

As a result, although the supply of VMP ordered online or via direct mail can be carried out legally, veterinary medicines (other than those classified as 'authorized veterinary medicine – general sales list' (AVM-GSL) and Exemption for Small Pet Animals (ESPA) medicines) should not be offered or supplied via auctions (such as eBay or Gumtree), since legal and professional obligations cannot be met satisfactorily.

Veterinary premises that supply medicines ordered online or via direct mail under the professional control of a veterinary surgeon must be registered as veterinary practice premises and inspected either by the VMD or a Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (PSS) inspector.

The VMD publishes guidance, including the supply of medicines remotely, on the retail of veterinary medicines webpage ().

Prescriptions

The requirements for the prescribing and supplying of VMP are the same for remote supply as for face to face. However, key points to bear in mind include:

- Veterinary surgeons must ensure that they have sufficient information to make a clinical judgement about the animal and the correct medicine to prescribe
- Prescription-only medicine – veterinarian (POM-V) medicines may only be prescribed for animals under the veterinary surgeon's care

- Prescription-only medicine – veterinarian, pharmacist, SQP (POM-VPS) and Non-food animal – veterinarian, pharmacist, SQP (NFA-VPS) medicines may be prescribed or supplied for animals not under the veterinary surgeon's care, but the other professional and legal obligations must be met
- Where POM-VPS or NFA-VPS medicines are being prescribed or supplied by a pharmacist or SQP, the prescriber's professional and legal obligations likewise remain unchanged in terms of selecting a medication that is suitable for the animal(s) and the client.

See also **Prescribing, supplying, dispensing and labelling procedures**.

Dispensing against prescriptions

Prescriptions may be faxed or emailed to an internet or mail order supplier. Electronic transmission of prescriptions for Controlled Drugs (CDs) in Schedules 2 and 3 of the Misuse of Drugs Regulations is not allowed. Note that the drugs present in these Schedules do change periodically (for example, the inclusion of gabapentin and pregabalin in Schedule 3 from April 2019) and so up-to-date knowledge of drug classifications, especially for human medicines prescribed under the cascade, must be maintained. It is incumbent upon the dispensing professional (in this case, almost invariably the veterinary surgeon) to ensure that they are operating in accordance with the law as it stands when the drug is dispensed, which may in rare cases have changed since the medication was prescribed. A suitable source of reference should therefore be sought in situations where the dispensing professional is unfamiliar with the drug prescribed ( ).

Prescriptions for VMP must contain all of the information required by law in order to be valid. There are additional requirements for prescriptions for Schedules 2 and 3 CDs.

See also **Controlled Drugs**.

Suppliers have a legal obligation to take all reasonable steps to ensure that a prescription is genuine, is issued by a person entitled to prescribe and is only fulfilled once (unless it is repeatable, in which case the number of repeats must be stated on the prescription). Whatever method is used to ensure the validity of received prescriptions, it is important to be able to demonstrate that these steps have been taken, in case of audit or investigation by the VMD.

Prescription misuse is a growing concern and veterinary surgeons should take care when writing and dispensing against written prescriptions. Common examples include the same prescription being used simultaneously at multiple retailers or counterfeiting the prescriber's authorization (considered to be fraud), and amendments to the date or quantity specified on a prescription (considered a lesser offence by the VMD if for a non-food animal, but still illegal). If it is unclear whether prescription fraud or misuse has occurred, it is good practice for the dispensing professional to contact the prescriber directly to confirm the validity of the prescription and any alterations or amendments. If a veterinary surgeon suspects that a prescription has been misused, it should be reported to the VMD via its prescription misuse reporting form available on the VMD's website ( ). Guidance on how to mitigate prescription misuse is also available on the Retail of veterinary medicines page ( ).

Veterinary surgeons providing a written prescription should seek to ensure that it will be legally filled. The VMD encourages prescribers to include text on their prescriptions raising awareness of its Accredited Internet Retailer Scheme (AIRS) and the importance of sourcing medicines from responsible sources. The VMD will provide suitable text and a copy of its AIRS logo to include on prescriptions upon request.

You may only buy these prescribed medicines from another veterinary practice or a pharmacy. If you buy them online, we recommend that you use a Veterinary Medicines Directorate (VMD) accredited internet retailer. VMD accredited internet retailers will display their AIRS logo containing their unique accreditation number on their website. Clicking on the logo will confirm their accreditation details on the VMD's website ( ).	VMD ACCREDITED RETAILER ID: 0000000

Supply by post

Veterinary surgeons may legally supply medicines by post or courier, whether operating from a traditional veterinary practice, an internet site or a mail order service.

Veterinary surgeons should take account of whether the VMP are potentially harmful to the general public. Medicines not in the manufacturer's packaging should be supplied in child-resistant containers. Appropriate safeguards should be taken to protect the medicine in transit; for example, medicines that are in liquid form will require different safeguards from those that must be kept refrigerated. The Royal Mail ( ) provides guidance on what can and cannot be sent in the post. Be aware that the regulations for business use are not necessarily identical to those for personal mailings. Note also that some topical preparations may contain a flammable liquid base, in which case it is necessary to comply with the requirements for flammable liquids. If a courier is to be used, it is necessary to confirm that they will accept medicines and/or flammable liquids, as some may refuse to carry such products. In many cases, products sent that are in breach of the company's terms and conditions will be destroyed if detected.

If packages are reported lost in transit, with no evidence as to whether this is in fact the case, it is difficult for the dispensing professional to refuse to re-dispense, even though this would (if the client was misleading them) strictly amount to prescription fraud by the client. Some mechanism should be in place to minimize this risk, for example, by dispatching any POM-V products by a recorded and signed-for delivery route. By doing so, it is possible to demonstrate, if needed, whether the product has been delivered or genuinely lost in transit. This would also assist the supplier in meeting their legal requirement under the VMR to 'take all reasonable steps to ensure that it is supplied to the person named in the prescription' and is therefore suggested as best practice.

If cold-chain medications are to be dispatched, it is necessary to ensure that cold chain will be maintained throughout the dispatch, processing and delivery process. It is considered good practice to be able to demonstrate that the chosen packing, insulation or system will maintain products at +2–+8 degrees throughout by, for example, dispatching a sample package containing a data logger or max-min thermometer, and recording the results on receipt.

In general, CDs should not be sent via post, but if this is essential then they should be sent at least by recorded delivery to ensure an audit trail, and preferably via a service that ensures the CDs are only handed over to a competent adult.

The standard legal obligations on suppliers apply, including:

- Being satisfied that the person who will use the VMP is competent to do so safely, and intends to use it for its authorized purpose
- Advising on safe administration and on any necessary warnings or contraindications on the label or package leaflet
- Supplying only the VMP named on the prescription; unlike in human pharmacy, generic substitution is not permitted. Where the prescription specifies a generic name rather than an identified VMP, only authorized products (not human medications, 'specials' or products imported under an SIC) can be supplied, unless the prescription states otherwise.

Returns

See also **Correct storage of medicines, dispensary management and standard operating procedures**.

Medicines that have been dispensed and dispatched may not be returned to stock for resale if the storage conditions cannot be guaranteed. This is likely to be the case for all remotely supplied medicines dispatched by post or courier (with the possible exception of cold-chain products returned to the dispatcher undelivered). However, under UK law (The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 ( ), clients are entitled to an automatic refund on return of undamaged products sold unseen ('distance selling').

This does not apply to prescription medicines (POM-V and POM-VPS), which have a specific exemption from the Part 3 Right to Cancel (para. 27 (2)). However, NFA-VPS and AVM-GSL medications are not strictly covered by this exemption, as they are not prescription medicines. In some situations, this could result in retailers being forced to refund the customer and destroy the product as pharmaceutical waste.

Other exemptions which could be held to apply would include orders under £42 (para. 27 (3)); 'the supply of goods which are liable to deteriorate or expire rapidly' (para. 28 (1) c); or the 'spoilage' clause at 34 (9). However, for either of these latter to be considered a defence, the customer should be made aware that the retailer takes this interpretation before purchase.

Where products are to be dispensed, supplied or dispatched remotely, it is advisable to ensure that your terms of business with your clients specify what exemptions to returns are being used, and that the right of cancellation and return does not apply to these products. Note that where other, non-medicinal, products are also being sold, the right to cancel still applies to that component of any order.

Examples

The following examples demonstrate some of the ways in which the requirements at the time of supply of VMP can be met, with particular reference for internet and mail order retailers.

- It is considered good practice for all businesses supplying VMP to clearly display the authorization details (e.g. name and registered number) of the veterinary surgeon, pharmacist or SQP responsible. This person should be available to advise clients directly.
- It must be possible for a client to be given direct advice so that the most appropriate medicine is prescribed/supplied to them, regardless of the medicines that the supplier has in stock (or any special offers).
- Even if a client asks for a specific POM-VPS or NFA-VPS medicine, there must be an interaction between the client and supplier to ensure that it is the appropriate medicine for the animal and circumstances (including husbandry and condition). The use of customer disclaimers (such as 'yes'/'no' tick boxes) and simple 'add to basket' with no customer interaction is not acceptable.
- For clients who wish to order POM-VPS or NFA-VPS medicines over the internet, an online registration system should be set up so that details of the client and of the type, number, weight, age and other details of their animals are recorded, up to date and can be used to enable a supplier to make the necessary checks on suitability of the medicine ordered before any are supplied. The batch number and expiry date of products dispensed should be recorded to enable a batch recall to be enacted quickly and accurately from the end user. This would also enable returning customers to log in without having to provide this information again, unless it has changed, and there should be a confirmatory declaration with each order to this effect.
- Internet suppliers may also set up an online questionnaire for clients to confirm whether they have administered the VMP previously, if they are aware of the relevant safety precautions and to confirm that they will read the packaging and product literature before using the medicine. This does not, however, absolve the dispensing professional of their legal responsibilities to prescribe or supply the most appropriate product for the animal(s) in question and should be considered an adjunct to collecting the data above rather than a replacement for it.
- An email or telephone call may be made to the client following order placement, to enable the supplier to discuss any problems before supplying the medicine. This approach would be considered good practice and must happen if there is any missing or conflicting information, or if the dispensing professional believes the product selected by the client is unsuitable.
- All information provided must be carefully checked by the dispensing professional before any supply is made.
- Records of communication with clients should be made and retained.
- All records relating to the client may comprise or contain personal data, and therefore the General Data Protection Regulation (GDPR) applies. In an online retail environment, additional security protocols must be instituted to protect client data, which is relatively easily accessible compared with that stored on a hardened Practice Management System (PMS). For more information, see the Information Commissioner's Office guidance ( ).

Advertising

Advertising of POM-V and POM-VPS medicines is only permitted to defined groups, which do not include pet owners, clients or the general public. Following a change in law in 2013, antimicrobial VMP cannot be advertised to professional keepers of animals. In addition, POM-VPS medicines cannot be advertised to non-professional horse owners or keepers.

The VMD define advertising as 'any activity that is aimed or designed to promote the sale, supply or use of a veterinary medicine, including electronic advertising (for example website banners, emails), but not including price lists'. The home page of a website is deemed to be a public space, and therefore, no POM-VPS or POM-V products should be presented there; likewise, price promotions (such as 'special offer' or 'buy one get one free') and social promotions ('people who bought X commonly buy Y') are considered advertising and should not be applied to these classes of drugs.

However, price lists (printed or online) of POM-V or POM-VPS medicines may be supplied to the general public, provided certain conditions are met:

- All products within a particular category must be included (e.g. all 'flea treatments' or all 'anti-inflammatory drugs' stocked by the retailer)
- Text and images displayed must all be of the same size and type; it is unacceptable for a single medicine on a price list to feature more prominently than the rest
- The name of each medicine, its image and a description may be shown within a price list, providing that the wording is in accordance with the VMP's published summary of product characteristics (SPC). The name of the medicine should be exactly as its full authorized name. This is important, as different medicines within the same brand should be clearly distinguished
- A description may be given (e.g. 'dog flea treatment') as long as it is in accordance with the SPC
- Any image of the packaging used must show the UK authorized packaging
- Pay-per-click advertising (paid for advertisements on search engines) is deemed to be a price list as long as the main keyword used is the brand name of the medication, as under these circumstances the VMD's interpretation is that clients will not see a product unless they have specifically searched for it.

There are no specific restrictions placed upon NFA-VPS and AVM-GSL medications, provided that any advertising contains no misleading information, and that the claims that are made for the VMP are in accordance with its SPC.

It is not lawful to advertise, or even to include in price lists, products whose only legal use is under the cascade (i.e. human authorized medications, 'specials', and imported medicines). These can legally be sold by retail supply, if in receipt of a suitable prescription, but not displayed openly on a website or price list. A statement to the effect that: 'If you have a prescription from your vet for a medication that is not listed, please contact us' is legal, and is a useful adjunct to a website or mail order price list if these products are stocked.

The VMD publishes guidance on the advertising of VMP ( ).

Non-UK websites

UK law requires that (save for the exemptions provided to veterinary surgeons under the cascade) only authorized VMP should be used.

It is an offence for an animal owner to:

- Be in possession of a VMP not lawfully supplied in the UK
- Administer a VMP unless it has a marketing authorization valid in the UK or comes under the ESPA
- Import a VMP into the UK, even if authorized for use in the UK (except for AVM-GSL and ESPA medicines)
- Supply a VMP to another person, other than as legally required.

It may be helpful for veterinary surgeons to ensure that animal owners requesting a written prescription, or otherwise intending to source medicines via the internet, are aware of the importance of a UK-based and legal supplier. Only by doing so can owners be sure that their animals will receive safe and effective medicines – and avoid breaking the law themselves. Illegally sourced medicine may be counterfeit, ineffective or unsafe for the client's animals.

Internet retailers

VMD Accredited Internet Retailer Scheme

Internet retailers of VMP can apply for accreditation under the VMD's Accredited Internet Retailer Scheme (AIRS). Retailers who meet the accreditation criteria will be able to display a logo on their website.

This logo includes the retailer's unique accreditation number. Clicking on the number will take the customer to the retailer's entry in the register of accredited retailers on the VMD website, allowing them to check the accreditation status.

The VMD's AIRS is a means of facilitating self-regulation by UK-based internet retailers supplying VMP. Following accreditation, onsite inspections of the internet retailer's premises (if they have not been inspected already) will be carried out, to check compliance with the VMR. It is a voluntary scheme and is free of charge.

Further information about the scheme may be found on the VMD website ( ).

The VMD have also produced detailed guidance as to the operation of an internet retailer which is available here ( ).

Illegal sales of VMP via the internet

The VMD's Enforcement Team acts on complaints it receives about internet retailers. When appropriate, the VMD's inspectors or the Department for Environment, Food and Rural Affairs (Defra) Investigation Services will investigate allegations of illegal activities relating to the importation, supply and administration of VMP. If practices are concerned that a client may have been supplied illegal products, they can discreetly report incidences to the enforcement team (see Legal controls on veterinary medicines ()) or contact the enforcement team for more details on enforcement@vmd.gov.uk.

Useful links

Royal Pharmaceutical Society ()
Veterinary Medicines Directorate ()
Prescription misuse reporting ()
Veterinary Medicines Guidance ()
VMD's Accredited Internet Retailer Scheme ()
VMD Model Retailer Guidelines ()
The Veterinary Medicines Regulations 2013 ()
The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 ()

QUESTIONS

1. What prescriptions can be sent electronically to be fulfilled?
    a. All
    b. Only prescriptions for non-Controlled Drugs
    c. Prescriptions for non-Controlled Drugs and Schedule 4 and 5 Controlled Drugs
    d. None
2. To whom can you report a suspected prescription misuse?
    a. VMD
    b. Police
    c. VMD and Police
    d. The Suspected Adverse Reaction Reporting Scheme
3. How can an internet retailer comply with the requirements to prescribe/supply a POM-VPS medicine?
    a. Display a disclaimer saying the customer is responsible for purchasing the correct product
    b. Add to basket with a tick box asking the customer to confirm they have read the Terms and Conditions
    c. Have a detailed questionnaire that the customer has to complete and which is then assessed by the registered qualified person
    d. Require a face-to-face consultation
4. What does the VMD's AIRS scheme do?
    a. Provides a means for customers to check they are buying from a reputable and appropriate UK supplier of VMP
    b. Check the registered website systems and processes ensure compliance with the law
    c. Confirm that the retailer's premises have been inspected
    d. All of the above

ANSWERS 1 – c; 2 – c; 3 – c; 4 – d

Racing Greyhounds

KEY POINTS

- Welfare is paramount – every patient must be treated according to its needs regardless of whether it is a racing Greyhound or other patient – **but remember doping control**
- Veterinary surgeons (veterinarians) should consider the racing scene and whether the patient is racing licensed or unlicensed
- Possible pitfalls:
  - Lack of specific knowledge
  - '7 day Rule'
  - Depot injections
  - Sustained release medicines
  - Topical treatments
  - Unknown previous treatments
  - Greyhound Board of Great Britain (GBGB) elective testing
- Medicines storage, record keeping requirements and the Trainer's Treatment Book: what the treating veterinary surgeon is required to do; what the trainer is required to do; what it is prudent to do
- Oestrus suppressants – to suppress or not is a controversial issue. Veterinary surgeons need to consider what the Veterinary Medicines Directorate (VMD) and GBGB say, which products have a UK marketing authorization, the evidence for norethisterone, and the owner's declaration

Greyhound welfare

All welfare legislation applies equally to Greyhounds as other dogs; in addition there are the Welfare of Racing Greyhounds Regulations 2010 under the Animal Welfare Act 2006.

The veterinary surgeon's welfare duties to the Greyhound are recognized by the GBGB:

'It is essential that any racing greyhound requiring veterinary attention receives it promptly. It is against the law to deny a greyhound access to veterinary treatment if needed. Therefore treatment for an illness must take priority over racing or trialling.'

Trainers Guide to Medication Control in Greyhounds ( )

Veterinary surgeons treating racing Greyhounds should also refer to the Rules of Racing ( ). Most of the comments in this article relate to the regulated sector, but it is important to recognize that analgesia facilitating trialling or racing can conceal injury and make it worse, so unintended consequences of treatment should be part of all treatment considerations for racing Greyhounds, whether in the independent or licensed sectors.

Consideration must always be given to the best interests of the Greyhound, how long a rest from racing has been recommended to allow treatment and recovery, and if treatment raises the possibility of a prescribed medication remaining detectable after the Greyhound's return to racing. It could be argued that if a Greyhound requires treatment, it may not be fit to race.

The Greyhound racing scene

Greyhound racing in the UK consists of 2 sectors:

1. The majority of racing takes place under **the licensing and regulation of the GBGB**. Licensed racing is an important gambling medium, worth about £1.3 billion per year. It is therefore attractive to fraud, sometimes by doping of Greyhounds, in an attempt to alter race outcomes. To try to prevent this, there are strict drug detection rules and protocols, and all personnel and Greyhounds in the industry are registered/licensed by GBGB. There is a comprehensive GBGB Rule Book ( ), and access to it online will give the most recent information, particularly about permitted minor treatments and rule changes.
2. The small 'independent' sector, which has a loose structure, no generally agreed rules and no drug testing. There is no official betting at these tracks.

GBGB doping control

GBGB's medicines control protocol is on a par with human sport drug testing. However, there is no general dispensation to allow Greyhounds to race with medications required to maintain health or treat disease. The Rules are clearly stated in respect of a positive sample result, explaining the trainer's strict liability for Greyhounds in their care: Rule 217 (GBGB Rules of Racing 2017 ( )) states (referring to any person under its jurisdiction):

A Greyhound when taking part in a Race or Trial must at that time be free of any substance that could affect its performance or well being, the origin of which could not be traced to normal and ordinary feeding. The only permitted exceptions to this Rule are:

i. *medicinal products which have been authorised by the Veterinary Medicines Directorate for the suppression of a bitch's season, prescribed by a Veterinary Surgeon.*
ii. *medicinal products which have been authorised by the Veterinary Medicines Directorate as anti-parasitic drugs (for internal/external) parasites or as vaccines, authorized for use in canines.*
iii. *substances included in the GBGB published list of permitted treatments.*

There is, in addition, a list of permitted substances, mainly topical, which do not affect racing but may be used according to manufacturers' instructions for minor first aid:

- Ferric chloride
- Hibitane
- Potassium permanganate
- Savlon™
- Sudocrem™
- Petroleum jelly
- Wound powders without antibiotics or insecticides.

Traditionally, most medicines were considered to be undetectable or excreted within 7 days of administration, but longer-acting preparations and more sensitive testing mean that can no longer be relied upon and 7 days should be considered an absolute minimum.

Drug testing is both random and targeted, and usually by collection of free flow urine samples; on occasion blood or other samples are used.

With all this in mind, it does matter whether the Greyhound is racing on a licensed or unlicensed track!

Possible pitfalls

Lack of specific knowledge

The Royal College of Veterinary Surgeons (RCVS), in their Code of Conduct ( ) state: *'Veterinary surgeons must keep within their own area of competence and refer cases responsibly.'*

It is necessary to balance the immediate needs of the patient with the above; most experienced Greyhound veterinary surgeons are happy to advise less experienced colleagues upon request; this advice is most easily accessed via the Society of Greyhound Veterinarians website ( ). It may not be possible for all Greyhounds to be treated at all times by experienced Greyhound veterinary surgeons as those are few in number, but it should be remembered that Greyhounds are fundamentally dogs, albeit specialized athletes.

The treatment of racing Greyhounds is in most respects the same as for non-racing Greyhounds, both of which have special characteristics shared by many other sight hounds. There are, however, a few possible problem areas associated with the management practices and doping control of racing Greyhounds of which veterinary surgeons should be aware.

It is unsafe to assume that all topical treatments are safe to use in relation to drug testing, as some may be absorbed in sufficient quantities to result in a positive test, for which the trainer has sole responsibility under GBGB Rules. The prescribing veterinary surgeon also has professional responsibility.

'7 day Rule'

Historically, the so-called '7 day rule' indicated that 7 days post-treatment would be sufficient time to be assured of a negative sample result. However, the development both of more sensitive drug testing and of prolonged action pharmaceuticals (e.g. mavacoxib) means that every medication should be considered in the light of its pharmacokinetics. It is prudent to use the shortest-acting medicine to meet the clinical needs of the patient, to give the handler written recommendations regarding possible withdrawal times, and to record all the medications and advice provided. Often there will be insufficient information available from any public source for any given medicine about the duration of effect or its possible detection. Medicine manufacturers may have unpublished information about their product, which may be helpful.

Depot injections

Residues and metabolites can be excreted for prolonged and unpredictable periods, especially if given by less common routes, such as intra-articular injection. Anabolic steroids and depot corticosteroid preparations can persist for many months.

Sustained release medicines

Caution should be exercised when prescribing sustained release medicines. Consideration of whether any combination of medicines could lead to a delay in their metabolism or excretion is also important. It is prudent to use short-acting preparations whenever equally efficacious. Meloxicam has recently been found to test positive 25 days after administration. GBGB advice states: *'Meloxicam should not be used as an anti-inflammatory within 30 days of a race or trial'*.

Topical treatments

Many topical medications can be absorbed in sufficient quantities to give a positive sample result. Corticosteroid creams and ointments will normally be absorbed systemically.

Unknown previous treatments

A Greyhound may be treated within a short space of time at a number of centres, either because it has emergency treatment at a track followed by continuing treatment at a local practice, or because it has changed owner or trainer. It is not yet general practice for a Greyhound's complete clinical record to transfer with it. To avoid adverse medicine combinations, to prevent repetition of ineffective treatment, or duplication of treatment, it is good practice for the treating veterinary surgeon to get as much information as possible from the owner/trainer/handler, and to ask if the Trainer's Treatment Book, which is designed to travel with the Greyhound, has been actively used to record all dates, conditions and treatments, as well as contact information for the previous veterinary practice.

GBGB elective testing

Elective testing may be available via the GBGB's forensic laboratory to give guidance to a trainer about whether a sustained action product has been excreted and is no longer likely to result in a positive dope test. This is only available in certain circumstances, and for specified medicines, in particular long-acting corticosteroids which have been used as a legitimate treatment by a veterinary surgeon. A subsequent negative dope test cannot be guaranteed if the sample levels are close to the threshold of detection, especially if the substance has been administered by a route such as intra-articular, which may result in inconsistent distribution into the circulation.

Storage and record keeping

Veterinary surgeon responsibilities

Use of the treatment room at Greyhound race tracks, whether GBGB licensed or not, is subject to regulation by both the RCVS ( ) and the Veterinary Medicines Directorate (VMD) ( ). All medicine storage, prescribing, dispensing and recording must be in accordance with current legislation and professional guidance.

A treatment room must be registered with the RCVS as a **Veterinary Practice Premises** (VPP), if Veterinary Medicinal Products (VMP) are delivered to it directly from a wholesale dealer and/or the VMP are stored there overnight. However, if VMP are transferred to the treatment room from a registered VPP only for the duration of the race/meeting (i.e. they are returned to that VPP the same day) the treatment room does not have to be registered.

Medicine use must be responsible and records kept where mandatory or good practice. Consideration should be given to:

- Storage of medicines within the temperature range specified in the summary of product characteristics (SPC)
- Labelling of medicines dispensed into smaller containers
- Controlled Drugs
- Batch numbers as required for non-food producing animals
- Broach dates
- Prescriptions
- Disposals
- Cytotoxic, cytostatic and certain hormonal medicines
- Spill kit
- Antimicrobial resistance.

See also **Record keeping and audits**.
See also **Antiparasitic resistance**.

Trainer responsibilities

All GBGB trainers are issued with a Trainer's Treatment Book for each Greyhound. It is the trainer's responsibility to present the book, to provide details of previous medicines used and to enable the treating veterinary surgeon to record the administration or prescription of any medicines to the Greyhound. Should the book not be available, a written record with the same details required in the book may be, in practice, acceptable to GBGB.

Additional requirements

It is prudent to recognize that many Greyhounds are treated at more than one practice or track, and that the provision of written treatment details to the handler can assist other treating veterinary surgeons and promote better treatment and welfare.

Oestrus suppression

Oestrus suppression and, more recently, surgical spaying are widely used in Greyhound racing to permit regular racing without the required withdrawal from racing during oestrus or dioestrus. Careful consideration needs to be given to the method of medical oestrus suppression to comply with the requirements of both the VMD and GBGB.

Regulations

Oestrus suppression is permitted under GBGB Rules under certain conditions, including a written declaration of the treatment by the trainer.

Current VMD authorized products for oestrus suppression in dogs

The following products have a marketing authorization from the VMD for oestrus suppression in bitches:

- Delvosteron (delmadinone)
- Ovarid (megoestrol acetate).

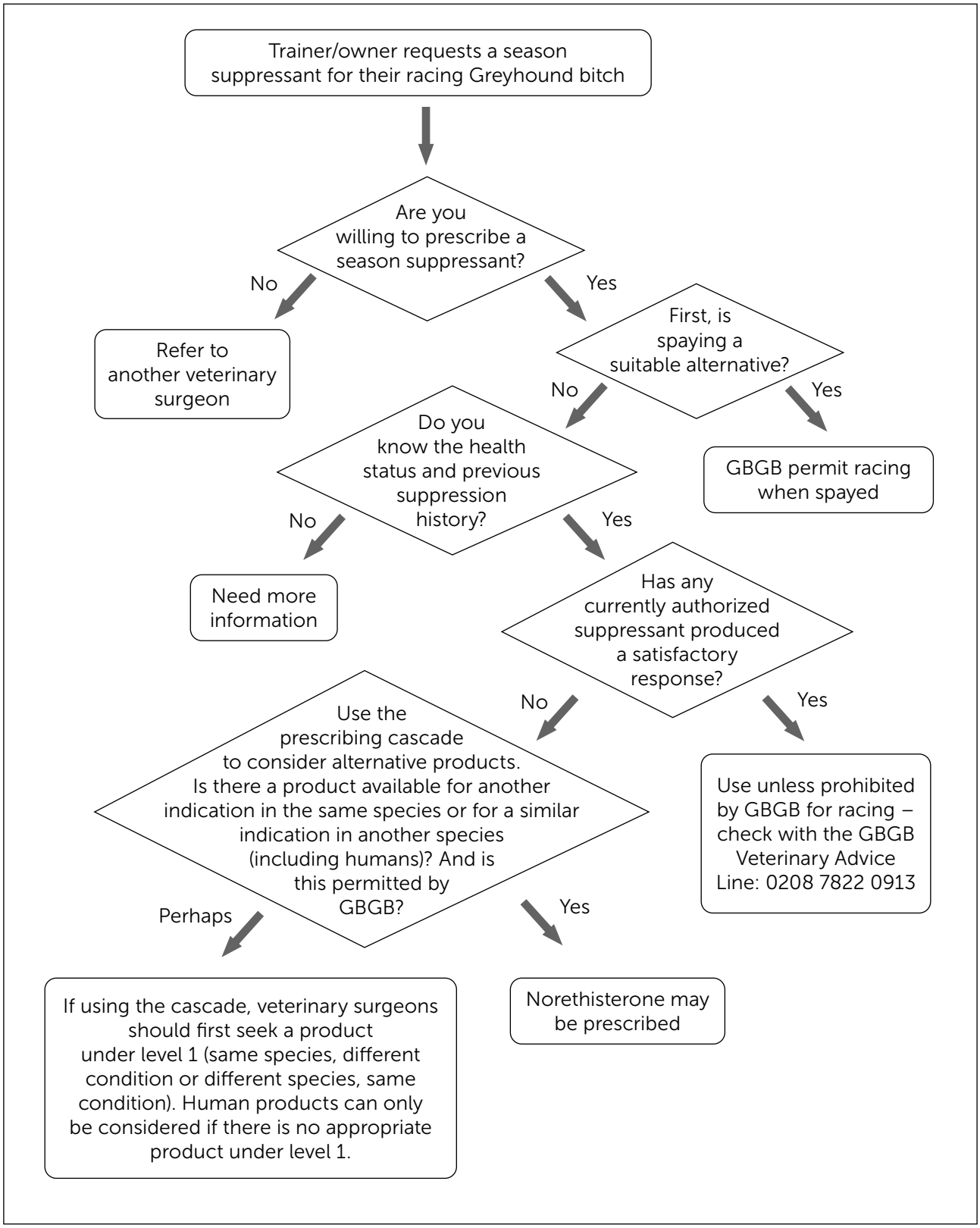
Norethisterone

GBGB rules also permit the use of norethisterone, a human oral contraceptive as a possible alternative, if the conditions required under the prescribing cascade are satisified.

Conclusion

If a Greyhound requires medical oestrus suppression, the VMD permits use of a veterinary surgeon's clinical judgement to use the cascade provisions on a case-by-case basis if an authorized product has proven unsuitable. RCVS Code guidance ( ) states:

4.17 *A decision to use a medicine which is not authorised for the condition in the species being treated where one is available should not be taken lightly or without justification. In such cases clients should be made aware of the intended use of unauthorised medicines and given a clear indication of potential side effects.*



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QUESTIONS

1. Who is formally responsible for the welfare of a racing Greyhound?
    a. The trainer/owner
    b. The treating veterinary surgeon
    c. Track management
    d. All of the above
2. Which of the following are permitted for racing?
    a. Progestagen oestrus suppressants
    b. Intra-articular corticosteroid injections
    c. Local anaesthetics
    d. Wound powders
3. After treatment for an infected toe wound requiring minor surgery under sedation with medetomidine and local anaesthetic, clavamox and mavacoxib, how long should the veterinary surgeon advise the trainer the Greyhound should not race?
    a. 7 days
    b. Until the wound is healed and the medication course has all been administered
    c. 6 weeks
    d. Not possible to say with any certainty
4. You are asked to cover for a colleague as track veterinary surgeon for an evening race meeting. Your mobile phone has no reception. A Greyhound has a serious injury requiring analgesia and further assessment at the local practice, which provides the track veterinary service. You decide to administer some methadone so that it can travel without too much distress. What *must* you record?
    a. Any product supplied on prescription to an animal
    b. Controlled Drugs Register
    c. Date, name and address of person supplied
    d. All of the above
5. A Greyhound bitch is presented as a new patient with a request for you to prescribe norethisterone for oestrus suppression. You know this is not an authorized product for oestrus suppression in dogs, but is a human contraceptive tablet. Which of the following should you not consider?
    a. Whether spaying might be an appropriate alternative
    b. Whether she is currently training or racing
    c. What response there has been to any other previously used season suppressant
    d. The cost of the medicine

ANSWERS 1 – d; 2 – d; 3 – d Any advice about excretion times should be tempered by uncertainty, and it would be unwise to be dogmatic. The half-life of mavacoxib in dogs is up to >80 days, so it would be prudent when dealing with racing Greyhounds to use short-acting medications whenever clinically appropriate; 4 – d; 5 – d

Dart guns

KEY POINTS

- Dart guns are also commonly referred to as dart projectors, remote delivery systems (RDS) or remote chemical injection (RCI) and are used to remotely deliver liquid anaesthetic or medical agents to animals that cannot be routinely handled such as wild, dangerous or escaped animals
- Consideration should be given as to whether darting is suitable in a given situation and whether more benign methods (e.g. oral medication, hand injection, pole syringe (jab sticks), physical restraint, animal training) could be deployed safely. Dart guns are a projectile weapon and as such carry risk of injury to operators, bystanders and the animals themselves, independent of the pharmaceutical agents they are delivering. Dart systems are a firearm and should be respected like any other gun or rifle
- A variety of different dart guns are available on the market and consideration should be given to the requirements of the operator prior to purchase. This should include: the species darting may be required for; effective range, accuracy and consistency; dart volume required; dart velocity and impact energy; operator familiarity and ease of use; availability of parts, budget and long-term disposable costs
- Dart guns, including blowpipes, are considered as Section 5 prohibited firearms under the Firearms Act 1968, with an exemption available if they are to be used for tranquilizing or treating animals. Even with the exemption from a suitable firearm certificate, appropriate secure storage facilities, and in some cases Secretary of State authority, are both required before a dart gun can be purchased
- Knowledge of the dart system's function, including how to accurately sight a rifle or pistol and how to respond in different environments, is essential to effective use. Experience combined with regular practice is vital and demonstrable training is often required before a firearms licence is given

Legal controls

Dart guns are classified as Section 5 prohibited firearms under the Firearms Act 1968, and its subsequent amendments. Such prohibited weapons include stun guns, rocket launchers, mini-guns and 'any weapon of whatever description designed or adapted for the discharge of any noxious liquids, gas or other thing' (Section 5(1)(b)), which includes dart guns (and blowpipes). Under Section 8 of the Firearms (Amendment) Act 1997, a Secretary of State's authority is not required for the possession of a dart rifle, gun or blowpipe if it is designed or adapted for tranquilizing or otherwise treating an animal, and if the professional has a firearm certificate subject to a condition restricting its use to the treatment of animals.

As such, a suitable firearm licence must be obtained before purchase or handling of a prohibited weapon. Currently, a Section 5 firearm offence carries a 6-month summary prison sentence or fine or both, and on indictment 10 years or a fine or both. A person commits an offence if they do not have a licence for, and they have in their possession, or purchase, acquire, manufacture, sell or transfer any of the prohibited weapons and ammunition listed in Section 5(1) of the 1968 Act. In simple terms, if a person does not have a licence for a specific weapon, they are committing an offence by handling or firing any type of darting equipment. In certain cases, there are exemptions to this (e.g. licensed firearms dealers at specified sites as part of training programmes).

Firearms law and licensing is in place to allow the legitimate possession and use of firearms by those judged safe to do so. A firearm certificate is granted following application to the local police force under the Firearms Acts 1968 to 1997. In general, the licence needs to be renewed every 5 years. Before being granted, the chief officer of police must be satisfied that the applicant can be permitted to have the firearm and ammunition in their possession without danger to public safety or to the peace. As such, the local police force will be able to provide veterinary surgeons (veterinarians) with the specific details required to be met, which usually consist of:

- Formal application for a firearm licence, which includes all types of firearm and their ammunition proposed to be held along with personal details, signed photographs of proposed licence holders, medical statements, personal references and statements of intent. This is followed by an interview with the local firearms officer before a licence can be issued
- Demonstration of secure storage for the proposed dart gun (and any other firearms). Legislation does not specify the level of security; however, there may be stipulated levels required by the local police authority depending on the weapon and the local environment. It is usual to have a commercially available gun cabinet of sufficient size and space (BS7558 standard). In some cases, additional security such as barred windows, metal access doors, a separate armoury, alarms or CCTV may be requested prior to acquisition, depending on the individual's situation

- A specified maximum amount of ammunition may be held, all of which must be locked in a secure gun cabinet, preferably separate to where the dart gun itself is held. All components of the darts (e.g. needles, darts) must also be secure. Ammunition is also considered Section 5 prohibited and the number of darts that can be held is specified on the individual's firearm licence
- Specified conditions on the firearm licence may stipulate limited use of a weapon (e.g. 'the rifle may only be used within zoo grounds' or 'the rifle may be used anywhere following logged communication with the local police authority'). It is prudent to discuss with the issuing police authority any limitations that may be enforced by proposed conditions as they may be prohibitive to a general practitioner's needs. There is variation within each county police force's requirements in the UK and it is down to the practitioner to discuss any additional conditions prior to the licence being issued. In some instances derogations can be provided from conditions whereby each movement of a dart system is communicated and logged with the police.

Separate to the firearm licensing requirements and the duty of care that comes with holding the dart projector, the veterinary surgeon must comply with the relevant legislation for dispensing, storage and use of any anaesthetic or other veterinary medicinal products (VMP) utilized within the dart itself – namely the Veterinary Medicines Regulations (VMR) and the Misuse of Drugs Regulations ( ). Often this is simple if the veterinary surgeon is also the person delivering the dart. However, it should be noted that there are several lay capture teams that utilize darting systems and these may request VMP or anaesthetic agents to be delivered using dart guns, often without the presence of a veterinary surgeon: in such cases advice should be sought from the Veterinary Medicines Directorate (VMD) or the Professional Conduct Team at the Royal College of Veterinary Surgeons (RCVS) as to the legality or appropriateness of supplying medicines in these situations. Examples include the police with respect to dangerous dogs or specialist capture teams for the translocation of deer.

Types of device

Dart delivery systems can be classified as falling into one of three groups based on the methodology utilized to project the dart:

- Manual (lung-powered) systems
- Pressurized gas systems
- Powder-charged systems.

Manual dart systems are limited to blowpipes and pole syringes. Whilst not a dart system in itself, consideration should be given to **pole syringes** (also known as jab sticks), which may be a suitable alternative to a darting system and do not require the practitioner to have a firearm licence. Pole syringes are effectively an extension of the clinician's arm and can be used over very short distances, usually 1–2 m (determined by pole length). They are useful in crush cages, over animal boards or in places where hand injection is inappropriate. Pole syringes are available as gas-driven or hand-driven at the time of injection.

Blowpipes require considerable practice and user skill. They have an effective range of 10–15 m, and are a cheap and effective tool in the hands of a competent operator, but they still require the level of security of any of the high-end rifles and firearms on the market. The advantages of blowpipes should not be overlooked when considering purchasing a darting system. In addition to being cheap and effective they are quiet, can be used for any size of animal and come in to their own for smaller animals were there may be a risk of injury from some of the higher pressured systems. However, they require operator skill and experience to a level not required with some of the more advanced systems, therefore they are used less frequently.

Pressurized gas systems mostly use carbon dioxide to deploy the dart, although there are foot-pump air-driven systems available that are equally effective. These are the most common systems used by capture teams and zoos as they have an effective working range of up to 75 m, which meets the needs of most professionals. Pressurized systems are available as pistols, rifles or hybrids that have interchangeable barrels allowing a variety of different dart sizes to be used and greater flexibility in their use. There are even double-barrelled systems that can deploy a second dart without having to reload. In all of the commercially available pressurized systems, a release valve allows the user to directly fill a compression chamber to a designated pressure determined by the size of the dart and the distance required for the dart to travel. As the trigger is depressed, the gas is released and propels the dart through the barrel, towards the target. This effectively replaces the lungs and any variability seen in the manual systems. If sighted and utilized properly, these systems should be consistent with each shot.

Powder-charged systems are similar to pressurized systems except that they typically use a .22 calibre blank charge to propel the dart. Various charges are used for different distances and these can be further dampened using venting ports that allow the operator to dial down a distance from the maximum setting for that charge. Powder-charged systems have the longest range, from 40–100 m depending on the system, but are often limited in their flexibility.

Selecting a device

There is a range of options available when selecting a darting system and it is important that consideration is given to the situations where a dart system will be used in practice. Primary considerations should include:

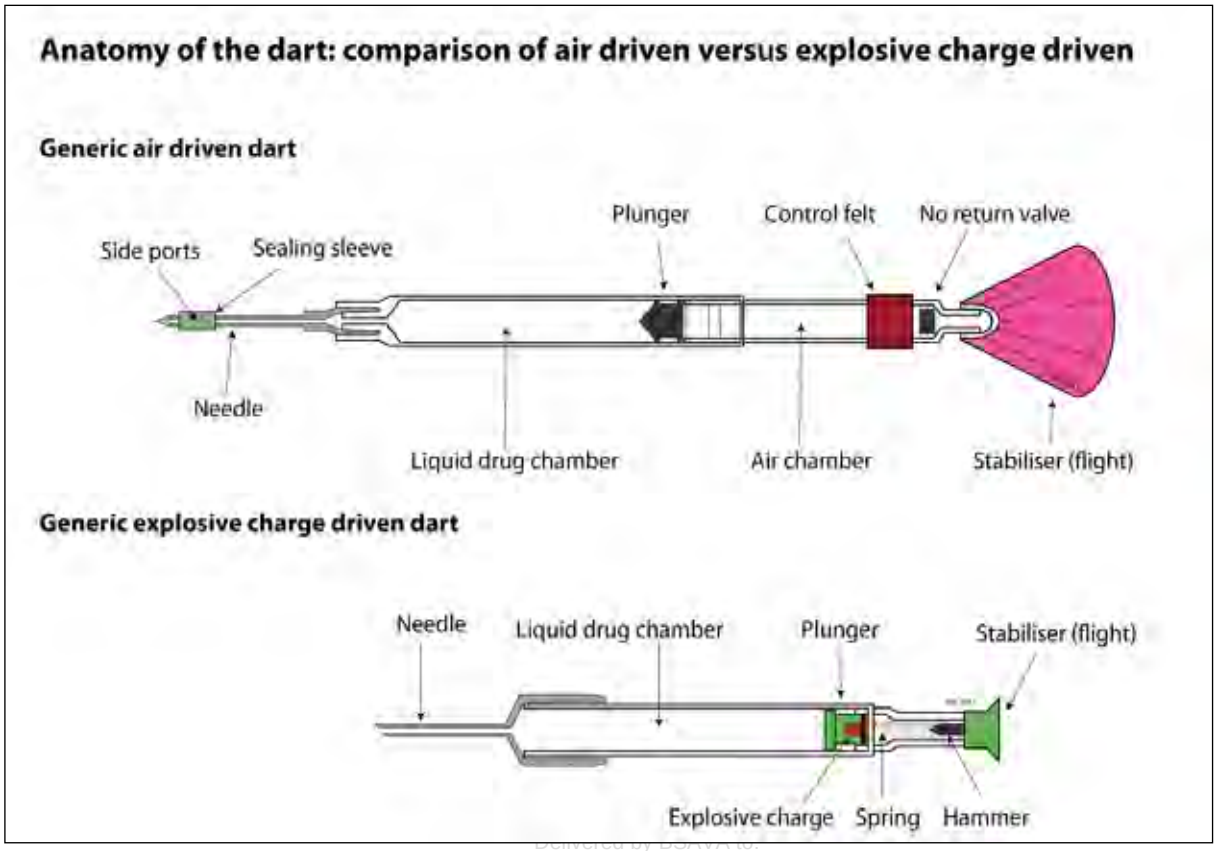
- Effective range
- Accuracy
- Consistency
- Dart volume required (determined by the range of species and medicines to be used)
- Dart velocity
- Impact energy
- Flexibility
- Operator skill and knowledge required for safe use
- Ease of use
- Frequency of use (to some degree this influences operator skill and experience required to operate the system, e.g. if infrequent then a system that requires low operator skills supported by laser sights should be used)
- Availability of parts and disposables (especially if the system is to be used overseas)
- Cost and financial return for practice
- Willingness to meet legislative requirements.

Dart type

The type of dart that can be used with the system should also be considered in the selection process. Specific brands have little crossover and once committed to a dart system often only specifically associated darts can be used with that firearm. The biggest limitation is the maximum volume that a dart can hold and this selection criterion is essential when considering the purchase of a darting system. For instance, one dart projector has a range of over 100 m yet can only hold a maximum volume of 1 ml, which limits the range of applications.

There are two main types of dart available. These are classified by the method utilized to drive the plunger on impact. Like the dart delivery systems, the darts can either have **pressurized gas** or **explosive charge driven plungers**, the former being recyclable and the latter disposable in most commonly available systems. The darts vary between brands in the level of complexity to build them, from simple active straight out of the packet to complex darts that have up to eight components to put together.

The generic anatomy of a dart comprises a liquid medicine chamber that contains the agent to be delivered, a plunger delivery system, a stabilizer and a needle (with or without a sleeve depending on the plunger delivery mechanism). Needles vary depending on species requirement and consideration must be given to needle length and width to ensure that the medicine delivered is injected, usually, intramuscularly. Needles can have a variety of barbs or collars. They may be smooth or, with some systems, have gelatine collars that melt after a period of time, facilitating removal. Compressed gas-driven plungers have needles with side ports that must be covered with a sealing sleeve; on impact, the sleeve slides backwards exposing the ports and the medicine is injected. Typically, the explosive charge darts are open ended, although some have side ports as well (triports), with no active pressure until the explosive charge activates as the dart hits the animal (or the dart is dropped).



Some manufacturers offer alternative dart types, such as biopsy darts or bear scare darts, which simply make a noise. These have specialist roles and are not capable of delivering medicines. Blowpipe darts are often lighter than other systems and, as such, cause the least impact injury. Some dart brands can be reused. In such cases it is imperative that the dart is cleaned and maintained to the manufacturer's recommendations to avoid dart plunger failure.

Additional equipment

Range finders are an extremely useful addition to any dart box. They are used to accurately estimate the distance between the dart system operator and the target animal. With all of the non-manual dart systems, a control system will allow a deployment pressure for the dart to be set which corresponds to the distance the dart is to travel. The pressure, be it explosive or gas pressure, needs to take into consideration the volume of the dart (weight) and the distance. All darts are designed to be fired full and so must be topped up with water for injection if required and, as such, the only variable is distance. Inaccurate estimation of distance, and hence failure to select the correct pressure, is the most common cause of unsuccessful darting. The use of a range finder addresses this potential error in the darting process.

Sights are commonly supplied with darting systems, except blowpipes. They are only useful if they are accurately aligned and it is therefore important that sights are regularly assessed. Some rifles have both a laser and telescopic sight – in this case it can be useful to have one scope set at a long distance and the other for closer work. If more than one person uses the dart system it is important to write on the rifle the distances that the scopes are set at to ensure accuracy when darting.

Equipment maintenance, for both dart projectors and darts, is essential to ensure accurate darting, guaranteed delivery on impact, safety for both animal and operator, and improved welfare from reduced darting failure and decreased darting times. Manufacturer's guidelines should be followed at all times.

For more information regarding dart guns, equipment and animal capture, see the following website ( ).

Health and safety

Darting should be considered a relatively traumatic event – even with the correct pressure, a dart can cause considerable bruising, a fractured limb or in worst case scenarios the death of the target animal either from darting trauma or from poor management of the darting environment.

All dart systems are firearms and it is imperative that gun safety is followed at all times and the systems are treated with the utmost respect. Only suitably licensed firearm licence holders must handle and use the firearm, and sensible precautions must be taken during the darting process. These include, but are not limited to:

- The dart projector must be secure until imminent use is expected
- The dart projector should be carried in a secure gun bag or case to the site where it is to be used
- When out of the case, if not in use, the safety catch must be on, any firing pins or bolts open or removed and the barrel must always point directly at the floor or sky so it is clearly obvious to bystanders that the firearm is not in a 'ready to fire' state
- The dart projector should never be pointed at an individual or anything that is not intended to be shot
- The darting area must be considered – safe lines of sight, darting techniques that take into account the species of animal being darted, accurate dart placement, area to be targeted, any risks of either ricochet or animal behaviour once darted that may compromise the animal or capture team's safety
- The dart projector should not be loaded until ready to fire.

In addition to gun safety, consideration must be given to the agents placed into the dart. Many of the anaesthetic agents used are either opioids (e.g. etorphine or carfentanil) or highly concentrated agents (e.g. ketamine 200 mg/ml or medetomidine 40 mg/ml), both which are extremely dangerous if inappropriately exposed to the operator or any bystanders. In addition, other VMP such as vaccines and antibiotics are not benign and large doses, injected or inhaled in an aerosolized form, can be extremely dangerous. Written standard operating procedures (SOPs) and emergency procedures must be available and discussed prior to every darting activity with all stakeholders. Where anaesthetic agents are used, it is essential that a buddy system is utilized where a second trained member of the team is available to administer antagonists or provide life support until the emergency services arrive for any accidental exposure of the primary operator to the dart system. Sufficient in date doses of antagonists are an essential part of the emergency response. Advice from your local hospital or doctor is advised prior to offering darting services to your clients to ensure both parties are adequately prepared to manage emergency events.

The high risk areas that need consideration are:

- Loading of darts and the pressurization process
- Removal of the dart from the animal, especially if there still remains agent in a partially discharged dart
- Storage of used darts prior to disposal or cleaning
- Cleaning of the darts where there will be residual anaesthetic agents or similar in the darts.

Risk assessments and suitable personal protective equipment (PPE) should be available and used for all of these areas, in addition to the actual darting event itself. For air pressurized darting systems, all darts should be assessed and, if required, depressurized (de-vented) prior to removal from the animal to prevent any risk of spray. Some brands offer commercial solutions to these problems, others require diligence on the part of the operator.

Another area for consideration is the safety of the operator and bystanders during the induction and recovery period. Both the safety of the animal and the capture team is of paramount importance, and assessment of the darting environment must take into consideration any common and avoidable eventualities. If considered unsafe, all attempts must be made to move the animal to a safer environment that facilitates darting, safe induction and mitigates any risk to bystanders.

Standard operating procedures

General darting system use safety

- Complete, practicable and written risk assessments in a format consistent with current Health and Safety Executive requirements should be carried out for the following areas:
  - Firearm storage
  - Firearm transportation
  - Dart system use (specific to each system, if more than one is used)
  - Dart loading
  - Dart cleaning/disposal
  - Risk assessments for particular medicines used (e.g. potent opioids)
  - Emergency procedure in the event of accidental injection or exposure to agents to be used in the system.
- The use of the darting system (and all firearms) is restricted to people who have been approved and licensed to use them by the Firearms Officer at the local police force. No one else is allowed access to or to use the darting system unless they hold a current firearms licence with the darting system listed on the licence.
- All staff should be briefed on the appropriate risk assessments and the potential agents used in the system, especially if the operator is not cleaning the darts and potent opioids or high concentration anaesthetic agents are to be used.
- Suitable PPE should be available as part of the basic kit. This should include nitrile gloves and suitable eye protection when building, removing or cleaning darts.

Dart management and safety

Explosive discharge darts are typically single-use only darts and must be disposed of in a suitable fashion following use. Extreme care must be taken in handling these darts as, if dropped, they can discharge. Some of the older brands can be reloaded with a charge; this type of dart may still be seen in zoos. These are less reliable compared with some of the newer systems, but are still effective with experienced use. Newer brands are typically clear plastic darts in which the liquid chamber can be seen. A blob of silicone gel can be placed in the nib of the needle to prevent loss of injectable agent, but is not necessary for effective deployment.

The pressurized gas type darts utilize either compressed gas from a can or, more commonly, air injected with a syringe. In both cases, a no-return valve retains this compressed gas. The dart should be held with the needle pointing upwards to enable the no-return valve to drop into place and allow effective filling. A needle sleeve, if available, should be put over the needle to prevent accidental exposure if, during building, the dart has been incorrectly assembled. Once the gas is injected, the dart is armed and must be de-vented to make safe. This can easily be assessed by inverting the dart – with the needle down, the no-return valve drops away from the dart if not pressurized or remains where it is if pressurized. An alternative method to allow quick visual assessment of armed status is to leave a very small air bubble in the liquid chamber. Once armed, this becomes compressed allowing confirmation that the dart is pressurized and ready to be fired. The volume of air to be injected is determined by the size of the dart and the brand requirements as set out by the manufacturer. This should only be done immediately prior to the dart being loaded into the firearm. Darts can lose pressure over time, but this also minimizes the risk of exposure from accidental discharge if armed darts are to be transported.

Following induction, and once the target animal has been assessed and safely approached, the dart must be removed from the animal. To do this the dart should be reviewed carefully. The liquid chamber should be checked visually to ensure that all of the contents have been injected and, in the case of pressurized gas darts, the no-return valve position should also be checked. If any medicine remains extreme care must be taken to prevent exposure to the residual agent on removal. Often, darts fail to discharge due to poor dart cleaning technique or inadequate pressure within the air chamber; however, in some species tissue pressure can be greater than that of the air chamber and on removal the dart effectively discharges any residual agent. To avoid this risk the dart should be de-vented using the supplied pin, which is simply pushed through the no-return valve. Explosive darts should not discharge, but care must still be taken. In some cases the liquid agent may leak out from the needle entry wound and the area should be liberally washed and marked in the case of some of the more potent anaesthetic agents to avoid accidental contamination, especially if the animal is to be physically handled or moved.

Darts should be immediately placed into a designated dart storage receptacle or sharps bin, depending on the choice of the veterinary surgeon. If recycling gas pressurized darts these should be cleaned on the day of use to prevent drying and crystallization of the medicine impairing plunger movement. All manufacturers' guidelines must be followed as to safe and effective cleaning. If using potent anaesthetic agents, cleaning darts is as dangerous as loading and equal care must be taken at this time. Needles should also be assessed at cleaning and injection ports checked for patency – dried blood or tissue cores can block side ports and prevent injection if not suitably cleaned. It is useful to have cleaning protocols with written instructions on safety and expected levels of maintenance.

BSAVA members have online access to Jonathan Cracknell's Darting Manual ( ).

Summary

Dart systems are extremely effective when deployed safely and in an appropriate fashion. There is considerable variation between the different commercial systems and each must be assessed following internal audit for the needs of the practice and the range of uses where such a system may be required. In all cases safe firearm use must be practiced and the manufacturers' guidelines for safe use, maintenance and cleaning must be followed.

References and further reading

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- Home Office (2016) Guide on firearms licensing law ( )
- Kock MD and Burroughs R (2012) *Chemical and physical restraint of wild animals: a training and field manual for African species, second edition.* International Wildlife Veterinary Services, South Africa

QUESTIONS

1. Section 5 prohibited firearms include which of the following weapons?
    a. Pea shooter
    b. Blowpipe
    c. Dart rifle
    d. All of the above
2. What type of licence or accreditation is required prior to the purchase of a dart system, and does that include simple or homemade blowpipes?
    a. Membership of the RCVS
    b. Accredited darting or live capture course qualification
    c. Firearm licence
    d. None
3. What factors should be considered by the practice prior to purchase to ensure the dart system meets their needs?
    a. Effective range, consistency, ease of use, flexibility
    b. Accuracy, dart volume required, dart velocity, impact energy
    c. Frequency of use, operator skill, availability of consumables, cost and financial return for the practice
    d. All of the above
4. Darting should be risk assessed, but what other areas of darting require full risk assessment to ensure safety?
    a. Firearm storage
    b. Handling of darts (e.g. loading, cleaning, disposal)
    c. Risk assessments for particular medicines used (e.g. potent opioids)
    d. All of the above

ANSWERS 1 – d: even a pea shooter with the correct type of ammunition can be classed a section 5 firearm if it is designed to release a noxious substance; 2 – c: shotgun licences are separate to firearm licences and do not allow purchase of a darting system, including blowpipes; 3 – d; 4 – d.

Pharmacovigilance

KEY POINTS

- Adverse events following use of veterinary medicinal products (VMP) include adverse reactions in animals or humans, lack of efficacy, environmental incidents or maximum residue limit (MRL) violations
- All suspected adverse events following the use of VMP in animals can be reported to the Veterinary Medicines Directorate (VMD) or the marketing authorization holder (MAH). MAHs are legally obliged to share all reports they receive for their products with the VMD, and VMD sends all reports they receive to the relevant MAHs. Therefore, there is no need to report to both the VMD and the MAH, and doing so could potentially create duplicate reports in the system
- Reports to the VMD can be submitted online ( )
- The VMD monitors all reports to ensure that the benefit:risk balance of all products is positive

Pharmacovigilance

During the authorization process for VMP, the safety and efficacy of a product may only have been demonstrated in a few hundred animals. Therefore, it is only once a product is commercialized and used in many thousands or even millions of animals that its true safety profile can be properly evaluated. This is achieved through a process called pharmacovigilance.

Pharmacovigilance is 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem' (World Health Organization definition).

The aims of pharmacovigilance are:

- To identify any previously unknown risks associated with the use of medicines
- To evaluate how the newly identified risks affect the overall benefit:risk balance of the product
- To propose suitable mitigation measures to reduce the risks to an acceptable level
- If any risk is too large to be mitigated, to eliminate it by stopping sale of the product
- To communicate the outcome of investigations.

However, none of the above is possible unless adverse events following the use of VMP are reported via the appropriate channels.

Adverse events

An adverse event is 'any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of a veterinary medicinal product (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy or noxious reactions in humans after being exposed to a veterinary medicinal product' (Veterinary International Conference on Harmonization definition).

Adverse events that may occur following use of VMP include:

- Lack of expected efficacy (e.g. vaccine failures and antimicrobial or anthelmintic resistance)
- Adverse reactions in treated animal(s) (e.g. vaccine reactions, injection site sarcomas, anaphylaxis)
- Adverse reactions in untreated animal(s) that have inadvertently been exposed to the product or treated animal(s) (e.g. cats grooming dogs treated with permethrin products)
- Adverse reactions in the person administering the product or other people who have been exposed to the product or the treated animal(s) (e.g. needle stick injuries or stroking pets treated with a topical product)
- Cases where substances above the MRL are detected in food products derived from treated animals despite the withdrawal period being correctly observed (e.g. bulk milk tank failures)
- Environmental incidents where wildlife or plants are affected (e.g. cypermethrin killing fish).

Which adverse events should be reported?

Ideally, **all** adverse events should be reported, even if:

- The veterinary surgeon (veterinarian) is not sure if the product is responsible; they only need to *suspect* that it could be
- The signs already appear on the summary of product characteristics (SPC) or datasheet; if certain signs are reported more frequently than is described, the VMD will request the SPC to be updated
- A VMP has not been used fully in accordance with the SPC (off-label or 'cascade' use). The VMD is interested in understanding what has happened, not questioning why a certain treatment was used
- A human medicine has been used in an animal under the cascade. However, since there is no legal obligation for the MAH of a human medicine to forward details to the VMD, such cases are best reported to the VMD directly
- The medicine has been imported or is currently under investigation as part of an Animal Test Certificate.

Who can report an adverse event?

In the UK, **anyone** (including veterinary surgeons, veterinary nurses, farmers and pet owners) can report adverse events. Although it is not a legal obligation, the Royal College of Veterinary Surgeons (RCVS) guidance (🌐) accompanying the Codes of Professional Conduct states that veterinary surgeons and veterinary nurses should report adverse events.

Reporting of adverse events

Adverse events occurring in the UK can be reported to either the VMD or the MAH, or distributor of the product(s) who are *legally obliged* to pass these on to the VMD. Therefore, there is no need to report adverse events twice, but if this happens by accident (e.g. both the veterinary surgeon and the animal owner submit reports) the VMD and MAH will liaise with each other to ensure that reports are not duplicated in their systems.

The vast majority of adverse events are reported directly to MAHs as they:

- Will take all the information over the phone; there are no forms to fill out
- Can often provide immediate advice on their products and what to do next
- May offer to cover the cost of further investigations (e.g. blood tests or post mortems), which often need to be carried out immediately and, since the VMD cannot fund any investigations, the sooner the MAH is informed about the case the better.

To report to the MAH or distributor of the product(s), veterinary surgeons should either speak to their sales representative or contact the telephone number that appears on the packaging or in the National Office of Animal Health (NOAH) Compendium (🌐). If several products are involved, they can all be reported at the same time (even if they are from different MAHs) as the VMD will pass details of the report to all relevant companies.

The simplest way to report most adverse events to the VMD is online (🌐). There are two separate forms, one for adverse events in animals, and another for humans, which can be found by using the web address above or searching **gov.uk** for 'report animal medicine'. All fields should be filled with as much information as possible about the products involved, the signs observed and when they occurred (compulsory fields are marked with a red asterisk). An email address is required so that the VMD can contact the reporter if they need further information, but personal details will not be passed on without permission.

Any problems with reporting should be forwarded to the Pharmacovigilance Unit by email (adverse.events@vmd.gov.uk) or by calling 01932 338427. Alternatively, paper forms (MLA 252) can be downloaded from **gov.uk** (🌐).

A specific paper exists to report environmental incidents (MLA 1), as well as a paper to report residues of antibiotic in milk (MLA 2), both can be requested directly from the Pharmacovigilance Unit.

What happens to the report?

Whoever receives the report first (VMD or MAH) will classify whether the adverse event is serious. A serious report is one which:

- Results in death
- Is life-threatening
- Results in significant disability or incapacity
- Is a congenital anomaly or birth defect
- Results in permanent or prolonged signs in the animals treated.

The VMD sends all reports to the MAHs involved and, by law, MAHs must send all serious adverse events to the VMD within 15 days of receiving the report. Non-serious reports are submitted at intervals of between 6 months and 3 years, depending on how long the product has been authorized, in periodic safety update reports (PSURs). PSURs also detail the amount of product sold so that the incidence of adverse events can be calculated to ensure that the SPC accurately reflects the frequency of adverse events.

The frequency at which adverse events are reported appears in section 4.6 of the SPC using the following terminology:

- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- Common (more than 1 but less than 10 animals in 100 animals)

- Uncommon (more than 1 but less than 10 animals in 1000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animal in 10,000 including isolated reports).

All reports received by the VMD are assessed by a veterinary surgeon to determine whether the product is likely to be responsible for the reported signs. This is called a causality assessment.

The VMD also analyses all reports in its database using a statistical technique called the proportional reporting ratio (PRR) and currently sends all reports to the central European pharmacovigilance database so that a much larger pool of data can be used for analysis to allow emerging signals to be identified more rapidly (this may change after Brexit).

Outputs of pharmacovigilance

When a potential signal is confirmed, the VMD and MAH will agree on what risk mitigation measures are necessary. This is normally achieved by modifications to the warnings on the SPC, but if the problem is so serious that such warnings would not be sufficient, the product may be suspended whilst the MAH performs additional studies to confirm the safety or efficacy of the product, or the product may be removed from the market altogether.

As well as the SPC being updated (which will be reflected in the product labelling), all variations, suspensions or withdrawals are detailed in the monthly update in the Veterinary Record. The VMD also publishes letters to highlight current concerns to the veterinary profession as well as an annual summary report and articles on issues of more general interest, based on adverse event reports received. The annual summary reports are published on **gov.uk** ( ).

Useful websites

NOAH – Pharmacovigilance ( )
Veterinary Record ( )

QUESTIONS

1. Who can report an adverse event?
   a. Only a veterinary surgeon
   b. Only the owner or keeper of the animal affected
   c. Only the manufacturer of the product
   d. Anyone can report an adverse event
2. Who has a legal obligation to report an adverse event to the VMD?
   a. The attending veterinary surgeon
   b. The suitably qualified person (SQP) who dispensed the product
   c. The qualified person responsible for pharmacovigilance (QPPV) of the medicine company that made the product
   d. The owner or keeper of the animal
3. Which of the following should be reported as an adverse event?
   a. A sarcoma in a cat >1 year since the last injection at the site
   b. Severe diarrhoea after use of a non-steroidal anti-inflammatory medicine in a dog
   c. Failure of a homeopath nosode to protect a dog with canine parvovirus
   d. All of the above

ANSWERS 1 – d; 2 – c; 3 – d

Antiparasitic resistance

KEY POINTS

- Practitioners should regularly review the current status of resistance to companion animal antiparasitics
- Control of parasites should be practiced through responsible product use
- There should be a planned approach to apparent efficacy failure
- Any suspected resistance should be reported under the Suspected Adverse Reaction Reporting Scheme (SARRS)

In theory, any of the ectoparasites (fleas, ticks, lice, flies, sandflies and mites) or the gastrointestinal helminths (including roundworms and tapeworms) challenging domestic pets could develop resistance to the antiparasitic medicines used to control them, although there is a consensus that resistance at present is less likely in tapeworms with their more complex two-host lifecycle.

A current definition of antiparasitic resistance states: 'the selection of a specific heritable trait (or traits) in a population of parasites due to that population's contact with a chemical that results in a significant increase in the percentage of the population that will survive a standard dose of that chemical' (Coles and Dryden, 2014). It should be noted that, within parasite populations, there may be considerable natural variation in susceptibility.

Evidence of resistance to companion animal antiparasitics

To date, treatment failure of authorized antiparasitic preparations used according to product-approved label directions caused by resistant parasitic arthropods has not been proven in the UK or EU. However, flea *Ctenocephalides felis* gene mutations associated with resistance to dieldrin (rdl) and knock down resistance (kdr) and super knock down resistance (skdr) have been identified in UK flea populations. The implications of these mutations for insecticide efficacy remain unclear. Reports exist from the USA of fleas developing resistance to many older classes of insecticide. Reduced efficacy against fleas recently seen with a fipronil-methoprene combination may be the result of resistance, innately tolerant flea strains or other unknown factors (Dryden *et al.*, 2013). There are a few reports of individual tick populations, particularly the brown tick *Rhipicephalus sanguineus* developing acaricidal resistance on the American continent (Coles and Dryden, 2014).

There have been few proven cases of anthelmintic resistance (AR) in worms from cats and dogs. Resistance to pyrantel and to benzimidazoles has been reported in the dog hookworm, *Ancylostoma caninum*, in Australia and Brazil, respectively (Kopp *et al.*, 2007; Furtado *et al.*, 2014). Macrocyclic lactone heartworm preventives in both the USA and Europe aim to achieve 100% prevention of the development of adult *Dirofilaria immitis* heartworms. In the USA (but not Europe) there have been a number of protection failures where the worms have characteristic genotypic changes that differentiate them from susceptible isolates (Bourguinat *et al.*, 2017).

Development of resistance to a variety of anti-protozoals, including metronidazole, can occur with *Giardia* spp., which has to be distinguished from other causes of treatment failure including reinfection (Fiechter *et al.*, 2012).

Parasite control and efficacy monitoring

Whilst helminth control in horses includes leaving some animals with low level infections untreated *in refugia* to reduce selection pressure on the whole population, this concept does not translate readily into companion animal parasite control, where there exists a public expectation for zero tolerance of parasites, particularly where there is a zoonotic risk. Therefore, alternative strategies must be sought.

Parasiticide mixes (a range of possible scenarios, including fixed combinations and sequential administration of licensed products over a period of time) and rotation potentially have value in delaying or preventing resistance, particularly in combination with management strategies. Whilst these principles have been developed for crop pests, and Control of Worms Sustainably (COWS) and Sustainable Control of Parasites (SCOPS) have developed guidance for anthelmintic use in cattle and sheep respectively, more work is needed on their applicability to pet parasites.

Monitoring is important, especially in kennels and catteries, where selection pressure may be particularly high if the same parasiticide is used repeatedly over time. The special considerations associated with rescue kennels have recently been considered in detail by Raza *et al.*, 2018.

Timely and effective control of parasite infections, thereby preventing them from becoming an ongoing problem, is important. Ectoparasiticides aim to eliminate existing pet parasite infestations and, with fleas, their environmental stages.

Control of flea environmental stages can include not only chemical treatment of the pet's bedding and household carpets, but also areas the pet frequents (e.g. the shed or family car). Vacuuming home carpets plus washing pets' bedding are important components in flea management. Success of the strategy also relies on all household pets being treated simultaneously; identifying and eliminating flea infestation 'hot spots'; ensuring that the family pet is not exposed to other parasite infested animals or contaminated environments outside the household; and recognizing that shampooing or swimming may decrease the effectiveness of topical products.

All major worms (excluding heartworm) are transmitted by the passage of eggs or larvae in faeces, hence hygiene measures, especially cleaning up pet faeces regularly, will reduce environmental contamination with infective parasite stages and assist in control alongside parasiticide use.

In the case of heartworm, it is important to check that the pet does not already have adult heartworms prior to commencing preventive treatment, as it is suspected that exposure of adult worms and microfilariae to preventives may be implicated in resistance development in the USA (Bowman, 2012). In addition, there are also concerns regarding target animal safety with inadvertently administering certain preventative products to animals with circulating microfilaria.

Investigation and management of suspected resistance

When treatment failure may be associated with parasite resistance, it is important to carry out a systemic investigation to rule out non-compliance and high environmental challenge. Initial checks to confirm that the prescribed control strategy was applied as directed should be carried out. A 2012 survey of dog owners using monthly spot-on tick treatments found that these products were not used as recommended in 56% of dogs (Beck *et al.*, 2013) and when control measures were properly and consistently applied 92% of households that had experienced a flea control problem were cleared of fleas. Conducting a successful investigation relies on the relationship between clinician and client. An open relaxed relationship built on trust and respect goes a long way to understanding the client's compliance behaviour in relation to parasite control.

Questions to be asked of the client when suspecting product failure relating to flea control

Did the pet owner:

1. Comply with the product treatment regimen?
2. Use commercial chemical treatments for pet bedding, household carpets, the family car and garden shed?
3. Vacuum the household carpet?
4. Maintain environmental hygiene relative to the pet?
5. Wash the pet bedding?
6. Restrict pet access only to other treated animals?
7. Restrict pet access to contaminated environments outside the household including catteries and kennels?
8. Ensure that a pet treated with a topical parasiticide is not inappropriately shampooed or permitted near waterholes or to swim?
9. Maintain a record of the travel history of the pet including an up to date pet passport?

In vitro tests exist for insect and tick strains to establish their susceptibility to parasiticides. At present, there is no way of detecting AR in dogs and cats other than by the faecal egg count reduction test, which is time-consuming and labour intensive, requiring the pet owner's cooperation. When investigations lead to suspect product failure related to AR in worms, issues such as compliance with the product treatment regime, environmental hygiene, feeding of non-commercial diets, contact with other animals, exposure to kennel/cattery environments and access to rodents and slugs, along with the travel history of the pet, need to be considered.

When unmet expectations and non-compliance have been eliminated and resistance remains a concern, then it is important to report the suspected lack of efficacy to the Veterinary Medicines Directorate (VMD) or to the marketing authorization holder (MAH) so that they can investigate the problem quickly. Unfortunately, as has been documented, owners may be keen to eliminate the problem, thus destroying material for any future investigation.

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- Raza A, Rand J, Ghaffar Qamar A, Jabbar A and Kopp S (2018) Gastrointestinal Parasites in Shelter Dogs: Occurrence, Pathology, Treatment and Risk to Shelter Workers. *Animals* **8**, 108

Useful websites

Control of Worms Sustainably (COWS) ()
Sustainable Control of Parasites (SCOPS) ()

QUESTIONS

1. It is generally considered that the following pet parasites are least likely to develop resistance:
    a. Tapeworms
    b. Heartworms
    c. Fleas
    d. Ticks
2. Resistance prevention and control strategies have been well developed for:
    a. Veterinary parasiticides
    b. Crop protection products
    c. Human parasiticides
    d. Tapeworms
3. Fleas in the UK have been identified with which gene mutations?
    a. Rdl, kdr and skdr
    b. Mdr, kdr and skdr
    c. Kdr, skdr and rdr
    d. Rdl, kdl and sdl
4. Which one of the following options is most likely to cause apparent flea treatment failure?
    a. Treating only some of the animals in the household
    b. Treating with an adulticide
    c. Treating with an environmental treatment
    d. Hoovering daily
5. In the USA heartworm reduced preventive efficacy has been reported to:
    a. Macrocyclic lactones
    b. Pyrantel
    c. Diethylcarbamazine
    d. Benzimidazoles

ANSWERS 1 – a; 2 – b; 3 – a; 4 – a; 5 – a

Responsible prescribing and dispensing for exotic pets, zoo and wildlife species

KEY POINTS

- Prescribing and dispensing for exotic pet, zoo and wildlife patients presents unique challenges to be addressed
- In certain circumstances, wildlife centres and zoos can be considered to have a similar relationship with their veterinary surgeon as exists between farmer and veterinary surgeon treating animals under their care on a herd/flock basis using carefully worded Standard Operating Procedures (SOPs)
- There is a lack of authorized medicinal products available for the species to be treated
- Zoos and wildlife centres often have limited veterinary input on site
- Native wildlife are not 'owned' in the traditional sense

Prescribing and dispensing for zoo and wildlife rescue centres

Only a veterinary surgeon (veterinarian) can prescribe a Prescription-Only Medicine – Veterinarian (POM-V) for the treatment of animals, including zoo and wildlife species. Under the Veterinary Medicine Regulations (VMR), a veterinary surgeon must ensure they have met two criteria prior to prescribing a POM-V product, namely having:

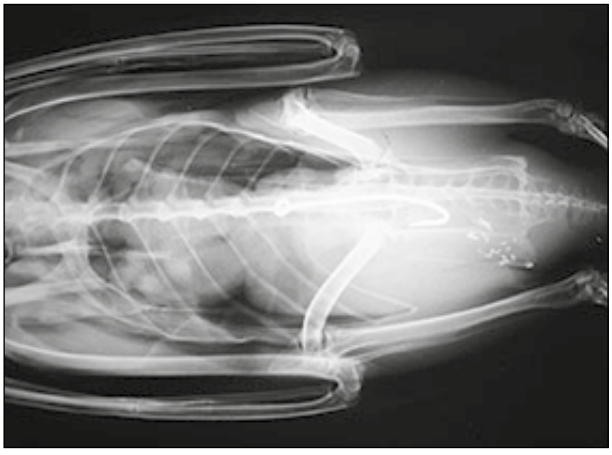
- Carried out a clinical assessment of the animal
- Ensured the animal is under the veterinary surgeon's care.

Neither of these phrases is defined in the VMR, but Chapter 4 of the supporting guidance to the Royal College of Veterinary Surgeons (RCVS) Code interprets 'clinical assessment' as *'an assessment of relevant clinical information, which may* (author's emphasis) *include an examination of the animal'*.

However, the RVCS guidance considers that a veterinary surgeon cannot usually have an animal *'under his or her care'* if there has been no physical examination. Chapter 4 interprets 'under a veterinary surgeon's 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*
- *The 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. What amounts to 'recent enough' must be a matter for the professional judgement of the veterinary surgeon in the individual case*
- *The veterinary surgeon must maintain clinical records of that herd/flock/individual.'*

Wildlife casualties, such as groups of hedgehogs or collections of waterfowl, and zoo collections may be considered to be a 'herd or flock' and, therefore, treated as such with respect to the Code of Professional Conduct supporting guidance on 'under your care'. In other words, wildlife centres and zoos can be considered, in certain circumstances, to have a similar relationship with their veterinary surgeon as exists between farmer and veterinary surgeon. In such circumstances, it is generally accepted that a small stock of drugs is kept on site and may be prescribed by the attending veterinary surgeon either via carefully worded SOPs or remotely via email, telephone or video. The written SOPs need to be robust and include details such as: the specific drug, dose, route of administration, frequency, who can administer the medication, how soon a veterinary surgeon should see the case'. In other words, not every wildlife or zoo casualty necessarily needs to be examined by a veterinary surgeon, if it is considered the animals are under the veterinary surgeon's care and a clinical assessment can be made by interpreting the clinical information provided by the 'owner' via, for example, a telephone call, image or email.



Radiograph showing a fish hook

The level of veterinary facilities at zoos and wildlife rescue centres vary from permanent onsite staff to regular or even occasional visits from a veterinary surgeon. In the latter situation, over and above emergency calls, there should be sufficiently regular site visits to be able to demonstrate that, for the ongoing purpose of the prescribing and supply of medicines to the centre, the veterinary surgeon has the animals both '*under their care*' and considered to have received a '*clinical assessment*'. The frequency of visits should be appropriate to the number of animals on site at any time and may vary with time of year. For example, in a busy wildlife centre, visits might be once or twice a week in the spring and summer, but drop to fortnightly or less frequently in the winter. It is expected that new arrivals to the centre may well need to be seen at the veterinary surgery between visits, to carry out treatment and to enable medicines to be prescribed legally.

Storage of medications at zoos and wildlife rescue centres

Since April 2009, veterinary surgeons have only been permitted to supply veterinary medicinal products from a 'Veterinary Practice Premises' (VPP) registered with the RCVS, and must maintain a record of all premises where medicines are stored. Where veterinary medicines have already been prescribed and dispensed to wildlife centres or zoos from RCVS registered practices for animals under their care, it is unlikely that further registration of the receiving premises would be required.

RCVS guidance also allows for a veterinary surgeon to keep a small stock of their own medications at a wildlife centre or zoo for them to prescribe or use at a later date. The veterinary surgeon does not need to be permanently based at the premises, which also do not have to be registered as a VPP, but the veterinary surgeon should maintain a record of premises where medicines are kept, including stock levels for auditing purposes.

Alternatively, if a wildlife centre or zoo employs their own veterinary surgeon(s) and drugs are delivered directly from a wholesaler to be stored at the premises, they may well need to be registered as a VPP. However, each case is treated on its merits and advice should always be sought from the Veterinary Medicines Directorate (VMD) or RCVS in the first instance.

The stored medications should be kept securely to prevent access by unauthorized personnel, with the veterinary surgeon retaining absolute control and responsibility for both the storage and use of POM-V and POM-VPS (prescription-only medicine – veterinarian, pharmacist, SQP) medicines, irrespective of who now owns them. In order to do so, it is advisable that only a very limited number of staff are authorized to access the medicines left at a wildlife centre or zoo, and the prescribing veterinary surgeon must satisfy themselves these staff are adequately trained and understand the limits of their authority. Written SOPs are invaluable in this respect.

Full records of drug stock, usage and disposal should be maintained and regular inspections carried out by the veterinary surgeon to remove out-of-date drugs. Drug vials must be marked with the date they were initially breached, and discarded within the legally determined time for that product. Maximum/minimum thermometers or temperature loggers should be used in both ambient temperature areas and refrigerators where drugs are kept; the results should be recorded and retained for inspection.

Cascade

There are few authorized veterinary medicines for wildlife or zoo species and so, to safeguard animal welfare, veterinary surgeons may use the provisions set out in the cascade. It is prudent to ensure zoo and wildlife centre owners or a nominated responsible staff member have acknowledged that unauthorized medicines will be used at the facility, perhaps within annually updated terms and conditions contracts between the parties.

When treating an animal of a species '*traditionally farmed for its meat or other produce*', veterinary surgeons must only prescribe a medicinal product whose active ingredients appear in Table 1 of EU 37/2010 (), irrespective of whether the animal is housed in a wildlife centre or zoo, apart from deer where a 'no eat' tag can be applied. Zebras (and other Equidae) are required under UK legislation to have an equine passport, and the obligations regarding 'signing out' of the human food chain in Section IX apply to this species ().

Controlled Drugs

For the avoidance of doubt, Controlled Drugs do not differ from other POM-V medications, insomuch as they can be prescribed and supplied only by veterinary surgeons to animals under their care following a clinical assessment, in just the same circumstances as other POM-Vs, although they have additional prescription, storage and recording requirements.

See also **Controlled Drugs**.

The supporting guidance to the RCVS Code of Professional Conduct states that *'veterinary surgeons should take extra care when prescribing Controlled Drugs, to ensure that the medicines are used only for the animals under treatment.'* Any Controlled Drug left at a wildlife facility or zoo will 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. The illegal use and supply of Controlled Drugs attracts severe penalties.

Etorphine (Immobilon/M99)

See also **Dart guns**.

Etorphine, a Class A, Schedule 2 Controlled Drug, is still the drug of choice for the chemical restraint of some wildlife, especially hoofstock and other large zoo species. Etorphine is a powerful opiate, 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. Veterinary surgeons are legally permitted to prescribe etorphine for use by others in dart guns, assuming they can fulfil the requirement that the animals are under their care. It should be noted that although others may use a dart and dart gun with the appropriate licence, they are not permitted to keep etorphine. The product should only be supplied in the original bottle, encased in the thick polystyrene in which it is packaged, and only be drawn up immediately before use.

Naloxone is a safe, efficacious drug for reversing the effects of etorphine, but no currently licensed veterinary products contain this active ingredient, and those available for humans are POMs. As such, naloxone can normally only be supplied to named individuals at risk of opioid overdose, via a medical prescription. A veterinary surgeon cannot legally prescribe naloxone for a person. However, a veterinary surgeon can legally order/purchase/possess a human POM, although it can only be used to treat an animal. For the treatment of another person, the Medicines Act (1968) usually requires that it is administered by a medical practitioner.

There is, however, an important exception. The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order indicates naloxone can be legally administered by anyone for the purpose of saving a life in an emergency. In practice, if a veterinary surgeon is using Immobilon/M99, he/she can legally possess naloxone and anyone can then use that drug in an emergency in order to save a life. If Immobilon/M99 is to be used in the absence of a veterinary surgeon, then probably the only legal route for a non-veterinary surgeon to possess the drug would be for an individual to get a prescription from their doctor. Nevertheless, in an emergency situation this drug could then be administered by anyone in order to save life.

Treatment of zoo and wildlife patients by lay personnel

With a few notable exceptions, the Veterinary Surgeons Act 1966 makes it an offence for anyone other than a veterinary surgeon to perform an act of veterinary surgery, which includes, but is not limited to, the diagnosis of disease and the medical and surgical treatment of animals. One such exemption is for the owner of the animal, members of the owner's household or the employee of the owner, 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.

Wildlife, by its nature, is wild and as such can only be 'owned' in exceptional circumstances. In the case of a wildlife casualty found by a member of the public and taken to a sanctuary or veterinary practice for treatment, the Wildlife and Countryside Act 1981 allows people to take temporary 'ownership' of a wild animal that is disabled (or injured) for the purposes of tending to it until it is fit to be released. Although it may be assumed that 'ownership' passes with the animal from the person presenting the animal to the wildlife centre or veterinary practice once it is handed over, best practice would be to have the animal signed over to the practice and/or centre. A formal sign over minimises any arguments over management of the case and ensures that wildlife centre staff 'own' the animal and can therefore legally perform minor medical procedures under the Veterinary Surgeons Act.

A suitable form of words would be:

> I, [*name and address*], relinquish all rights of ownership of [*description of animal*] and transfer them to [*veterinary practice and/or wildlife centre name and address*]. If at all possible, the animal will be rehabilitated with the aim of return to the wild, but should this not prove possible then I understand that it will be humanely destroyed.
>
> Signed.....Date .....

An oiled seabird being washed

A swan with lead poisoning being weighed

A cygnet with a fishing line injury

Zoo animals are owned by the zoo, so the exemption permitting the owner and relatives/household, members of their household or their employees, to perform minor medical procedures stands.

Euthanasia and pentobarbital supply to zoos and wildlife rescue centres

The main reason for euthanasia in wildlife centres is to prevent unnecessary suffering in animals that are not considered to have a reasonable chance of survival upon release. Long-term captivity of wild animals is rarely, if ever, an acceptable alternative to euthanasia. This decision to euthanase may be made at admission or at any stage up to the point of release. Where it is deemed necessary, euthanasia should be carried out as early in the assessment process as possible, ideally within the first 24 hours of admission to either a wildlife centre or veterinary practice.

All legislation protecting wild animals includes a defence that allows anyone to kill a protected animal *'if he shows that the (animal) had been so seriously disabled otherwise than by his own unlawful act that there was no reasonable chance of it recovering.'* A protected animal is defined in Section 2 (🌐) of the Animal Welfare Act 2006 as follows:

a. It is of a kind which is commonly domesticated in the British Islands or
b. It is under the control of man whether on a permanent or temporary basis or
c. It is not living in a wild state.

Consequently, any individual, regardless of qualifications, is able to kill a protected wild animal to relieve immediate suffering where no 'veterinary diagnosis' is strictly necessary. A wildlife centre or zoo should have written veterinary SOPs covering such eventualities, which should be discussed and agreed with the consulting veterinary surgeon. Although performing euthanasia is not an act of veterinary surgery, within the meaning of the Veterinary Surgeons Act 1966, the prescription of drugs and their route of administration for performing euthanasia may be, and therefore the animal needs to be under the care of a veterinary surgeon.

There may be circumstances, where a veterinary surgeon with animals under their care within a wildlife facility or zoo might be able to set out clearly defined parameters, in carefully written SOPs, or via telephone or video consultation, allowing authorization of named individual(s) to perform euthanasia with a POM-V that has been prescribed and dispensed in small amounts in advance.

Pentobarbital (Controlled Drug Schedule 3) and quinalbarbitone (Controlled Drug Schedule 2, but with exemption from the Schedule 2 safe custody requirements) are both Controlled Drugs, but they can be legally prescribed and dispensed by veterinary surgeons, following a clinical assessment, for use in animals 'under their care', as defined above. Whilst these barbiturates are legally exempt from safe custody requirements, the RCVS Practice Standard Scheme (PSS) advises they are kept securely, and this is recommended in all zoos and wildlife centres. There is no requirement to keep a register of pentobarbital use (but there is for quinalbarbitone); it is, nevertheless, good practice to keep a record at zoos and wildlife facilities, which is regularly checked to monitor use.

See also **Controlled Drugs**.

Non-traditional companion animals (exotic pets)

An increasing variety of non-traditional (exotic) companion animal species are now kept as pets and may be presented to the veterinary practice. Practically, the guidelines for prescribing for these species are no different than for more traditional companion animals, although there are few or no authorized medicines for use in many of the species concerned. Veterinary surgeons, therefore, regularly need to prescribe medicines for exotic pets in accordance with the cascade (see also **Prescribing cascade**) and need to obtain informed consent.

A single lifetime unauthorized medicine consent form can be signed by an owner on registering with the practice, or at the start of treatment, but the giving of 'blanket consent' does not remove the obligation on the veterinary surgeon to ensure that it is *informed* consent (see also **Informed consent**).

In addition, authorized medicines may be administered via a different route, such as nebulization, or at a different dose rate from that stated in the Summary of Product Characteristics (SPC) and veterinary surgeons should remember that this is also considered cascade use, so informed consent is also required in these cases.

References

- British Veterinary Zoological Society (BVZS)
  - Guidelines for the prescription, supply and control of prescription-only veterinary medicines (POMs) in zoological collections and wildlife rescue centres
  - BVZS Good Practice Guidelines for Wildlife centres
- Royal College of Veterinary Surgeons (RCVS)
  - Veterinary medicines
- Veterinary Medicines Directorate (VMD)
- The cascade: prescribing unauthorized medicines
- Medicines Act 1968
- The Medicines for Human Use (prescribing) (Miscellaneous Amendments) Order 2005
- Veterinary Surgeons Act 1966

QUESTIONS

1. Which of the following is correct about obtaining consent to treat native wildlife presented to the practice?
    a. As native wildlife are not owned in the traditional sense, a veterinary surgeon can act autonomously without consent when presented with a wild animal by a member of the public.
    b. The finder of any injured animal technically becomes the legal owner, so either consent should be obtained in the usual manner, or better still ownership transferred to the practice at point of admittance.
    c. No native wildlife can be released back into the wild after medical treatment so euthanasia is always mandatory and consent from the finder is not required.
    d. Consent only needs to be obtained from the finder if they have agreed to pay the fees incurred to treat the wild animal.
2. When prescribing medicines for use for exotic companion animals which of the following is true?
    a. No written or oral consent is required for treating exotic companion animals with unauthorized medicines, as it is accepted there are limited products authorized for use.
    b. A lifetime consent form for unauthorized medicine administration can be obtained at point of registration of the animal, but owners should still be made aware when unauthorized medicines are used.
    c. Only oral, not written, consent is required for exotic animals, as it is accepted there are limited products authorized for use.
    d. The rules on consent for unauthorized use are exactly the same as for domestic companion animals. A consent form for unauthorized medicine administration must be obtained each time an unauthorized product is used.
3. Which of the following is true about storing medicines at zoos or wildlife centres with no permanent veterinary presence?
    a. RCVS guidance allows for a veterinary surgeon to keep a small stock of their own medications at a wildlife centre or zoo for him/her to prescribe or use at a later date.
    b. All zoos and wildlife centres must be registered as a Veterinary Practice Premises (VPP) without exception.
    c. Wildlife centres are exempt from the VPP scheme as a special exclusion, but most zoos must be registered as a VPP.
    d. If medicines are delivered directly from the wholesalers to a zoo or wildlife centre, the facility does not have to be a registered VPP.
4. Which of the following is true regarding prescription of POM-V products for wildlife and zoo animals?
    a. A veterinary surgeon must ensure they have carried out a clinical assessment of the animal and ensured the animal is under their care before prescribing a POM-V to wildlife or zoo species. Although a clinical assessment would normally involve a physical examination, it can be made by interpreting the clinical information provided through other means for example, a telephone call, image or email.
    b. Zoo or waterfowl collections cannot be considered to be treated as a flock or herd on a farm with respect to the prescription of POM-V products.
    c. A veterinary surgeon can always prescribe POM-V products to treat wildlife in charitable facilities without examining the animals first.
    d. Pentobarbitone cannot be prescribed by veterinary surgeons in any circumstances for use in zoos and wildlife centres as it is a Controlled Drug.

ANSWERS 1 – b; 2 – b; 3 – a; 4 – a